Patient Safety in Surgery

Philip F. Stahel
Cyril Mauffrey
Editors

Springer

Patient Safety in Surgery

Philip F. Stahel • Cyril Mauffrey
Editors

Patient Safety in Surgery

Springer

Editors
Philip F. Stahel, MD, FACS
Department of Orthopaedics
Denver Health Medical Center
Denver, CO
USA

Cyril Mauffrey, MD, FACS, FRCS
Department of Orthopaedics
Denver Health Medical Center
Denver, CO
USA

ISBN 978-1-4471-4368-0 ISBN 978-1-4471-4369-7 (eBook)
DOI 10.1007/978-1-4471-4369-7
Springer London Heidelberg New York Dordrecht

Library of Congress Control Number: 2014946728

We dedicate this book to all our patients and patient families.
The book is furthermore devoted to our hard working residents and enthusiastic medical students who represent the future generation of surgeons.
Finally, we dedicate our patient safety work to the loving memory of Eleta Martinez (09/17/1983–03/01/2014) and to the hope that her death due to medical error and negligent care was not in vain. May Eleta's legacy and shining star contribute to foster an eternal culture of patient-centered and family-centered health care in this world.

"The best interest of the patient is the only interest to be considered!"

William J. Mayo (1910)

Preface

As surgeons, we are arguably practitioners of one of the most entitled, rewarded and rewarding occupations in the world. We are privileged to meet and interact with previously unknown individuals on a most intimate and personal level, and to make a positive difference at some of the worst times in their lives. We eventually know these people in ways they cannot know themselves, and we are able help them in ways they cannot help themselves. We are empowered to the completely legal action of putting a knife to work in a human body. With proper indication and distinguished technical skills, our surgical blade can provide a cure for acute and chronic ailments in the most vulnerable population of human beings. In return, our patients reward us with their unlimited trust in our knowledge, skills, and ability to deliver them to restored health and an improved quality of life. Unfortunately, we fail to restore our patients' health and quality of life more often than we appreciate. While all physicians take the Hippocratic Oath to abstain from doing harm ("Primum non nocere"), our patients are frequently caught in the 'friendly fire' of surgical care—health care providers causing unintentional harm when their only intent was to help.

Interestingly, adverse events resulting from surgical interventions are actually more frequently related to errors occurring before or after the procedure than by technical mistakes by a surgical blade 'gone wrong'. These include (1) breakdown in communication within and amongst the surgical team, care providers, patients and their families; (2) delay in diagnosis or failure to diagnose; and (3) delay in treatment or failure to treat. On a daily basis, surgeons must adjudicate challenges that reach far beyond pure technical aspects—the decision of initiating appropriate and timely surgical care, weighed against the risk of providing delayed or negligent care by rather choosing observation and/or non-operative treatment. This narrow margin represents the foundation of a surgeon's eternal 'moment of truth' ("to cut or not to cut") which could be a crucial turning point in the long-term future of our patients.

How can patients be sure that their surgeon is competent, knowledgeable, and well trained? How can patients be sure that the proposed treatment modality or surgical procedure represents the optimal treatment of choice? How can patients be sure that surgeons are singularly incentivized to provide only high quality and safe surgical care, independent of other metrics of success, including entrenched financial interests? How can patients be sure that the surgical team is dominated by an immutable 'culture of patient safety' with full buy-in by all members of the team?

How can patients be sure that they will not be exposed to the 'learning curve' of a new procedure or a surgeon in training, as the prerequisite of the learning dogma 'Good judgment comes from experience which comes from poor judgment'?

Ironically, the high standard of regulatory compliance-mandated patient safety protocols in the United States emanates from decades of work by lawyers and patient advocacy groups, not from physician-driven initiative. It is time to end this historic negligence. It is time for surgeons to direct and own patient safety as a 'surgical responsibility'.

Patient Safety in Surgery is a first-edition textbook designed to provide a 360° view of all aspects related to safe surgical care. The book is organized into four distinct sections: general aspects of patient safety; the surgeon's perspective; other stakeholders' perspectives (including anesthetists, nurses and patients' families); and specific case scenarios for illustration and emotional learning. Each chapter is designed in uniform structure and includes bullet point-style insights on strengths and limitations in the respective field ('pitfalls and pearls'), in conjunction with a concise take-home message aimed at providing practical relevance.

Beyond a doubt, the 'worst-case scenario' presented by the Skolnik family on the dramatic story of their only son, Michael Skolnik, who died after 3 years of agony following unnecessary brain surgery and a subsequent cascade of horrendous complications, sets an unprecedented imperative for transparent communication and 'shared decision making' for surgical care (see Chap. 33). Clearly, there is no compromise or alternative to open and transparent communication with our patients, who remain the ultimate stakeholders.

This book strives to cover all aspects related to patient safety in surgery, including pertinent issues of interest for: surgeons; medical trainees (students, residents, and fellows); nurses; anaesthesiologists; patients; patient families; advocacy groups; and medicolegal experts, including lawyers and lawmakers. The scope of the new textbook is to increase the safety and quality of care for patients undergoing surgical procedures in all fields of surgery. This work aims to complement traditional surgical textbooks by filling an essential void, and to serve as a future work of reference in this important field.

We hope *Patient Safety in Surgery* will set the precedent for a new physician-driven initiative aimed at creating and sustaining a global 'culture of patient safety'.

Denver, CO, USA — Philip F. Stahel, MD, FACS
Denver, CO, USA — Cyril Mauffrey, MD, FACS, FRCS

Contents

Contributors

Peggy Alder Department of Patient Safety and Quality, Denver Health Medical Center, Denver, CO, USA

Hagen Andruszkow Department of Orthopaedic Trauma, University Hospital Aachen, Aachen, Germany

Timothy Barlow, MD, BSc, MBChB(Hons), MRCS(Glas) Department of Trauma and Orthopaedics, University of Warwick, Coventry, UK

Susan E. Biffl Department of Physical Medicine and Rehabilitation, Children's Hospital Colorado, Denver Health Medical Center, Denver, CO, USA

Walter L. Biffl, MD Department of Surgery, Denver Health Medical Center, Denver, CO, USA

Marja A. Boermeester Professor of Surgery, Department of Surgery (Suite G4–132.1), Academic Medical Center, Amsterdam, The Netherlands

Dennis J. Boyle, MD Risk Manager, Colorado Physician Insurance Companies (COPIC), Denver, CO, USA

Associate Professor of Medicine and Rheumatology, Denver Health Medical Center and University of Colorado School of Medicine**,** Denver, CO, USA

Nathan Butler West Virginia School of Osteopathic Medicine, Lewisburg, WV, USA

Emily P. Caldes, MA Office of Research and Sponsored Programs, University of Denver, Denver, CO, USA

Seleem R. Choudhury, MSN, MBA, RN, CEN Chief Nursing Officer, Northeastern Vermont Regional Hospital, St. Johnsbury, VT, USA

Ted J. Clarke, MD Chief Executive Officer, Colorado Physician Insurance Companies (COPIC), Denver, CO, USA

Pierre-Alain Clavien Department of Surgery, University Hospital Zurich, Zurich, Switzerland

Michael B. Cross Department of Orthopaedic Surgery, Hospital for Special Surgery, New York, NY, USA

J. Paul Curry, MD Department of Anesthesia and Perioperative Medicine, Hoag Memorial Hospital Presbyterian, Newport Beach, CA, USA

Daniel Dindo, MD Department of Visceral, Vascular and Thoracic Surgery, Zurich City Hospital Triemli, Zurich, Switzerland

Nicholas A. Ferran, MBBS, MSc, FRCS Department of Trauma and Orthopaedic Surgery, University Hospitals of Leicester NHS Trust, Leicester, UK

Tom J. Grundy Department of Trauma and Orthopaedic Surgery, University Hospitals of Leicester NHS Trust, Leicester, UK

David J. Hak, MD, MBA, FACS Department of Orthopaedics, Denver Health Medical Center, Denver, CO, USA

E. Mark Hammerberg, MD Department of Orthopaedics, Denver Health Medical Center, Denver, CO, USA

Frank Hildebrand Department of Orthopaedic Trauma, University Hospital Aachen, Aachen, Germany

Kirk J. Hogan, MD, JD Department of Anaesthesiology, University of Wisconsin School of Medicine, Madison, WI, USA

Klemens Horst Department of Orthopaedic Trauma, University Hospital Aachen, Aachen, Germany

Markus S. Huber-Lang, MD Department of Orthopaedic Surgery, Center of Musculoskeletal Research, University of Ulm, Ulm, Germany

Scott N. Hurlbert, MD Department of Surgery, Memorial Health System, Colorado Springs, CO, USA

Ashok N. Johari, MS, MCh, FRCS, FAMS, FCPS, DNB Department of Paediatric Orthopaedics, Children's Orthopaedic Centre, Mumbai, Maharashtra, India

Gregory J. Jurkovich, MD, FACS Department of Surgery, Denver Health Medical Center, Denver, CO, USA

Alan Lembitz, MD Department of Patient Safety and Risk Management, Colorado Physician Insurance Companies (COPIC), Denver, CO, USA

Jeremy A. Long, MD, MPM Department of Medicine, Community Health Services, Denver Health Medical Center, Denver, CO, USA

Ratna S. Maheshwari, MBBS, Dip(SICOT), M.S(Ortho) Department of Paediatric Orthopaedics, Children's Orthopaedic Centre, Mumbai, Maharashtra, India

Shalin K. Maheshwari, MBBS, Dip(SICOT), M.S(Ortho) Department of Paediatric Orthopaedics, Children's Orthopaedic Centre, Mumbai, Maharashtra, India

Cyril Mauffrey, MD, FACS, FRCS Department of Orthopaedics, Denver Health Medical Center, Denver, CO, USA

Philip S. Mehler, MD Department of Medicine, Denver Health Medical Center, Denver, CO, USA

Kendra L. Moldenhauer Department of Patient Safety and Quality, Denver Health Medical Center, Denver, CO, USA

Hans-Christoph Pape, MD, FACS Department of Orthopaedic Trauma, University Hospital Aachen, Aachen, Germany

Roman Pfeifer Department of Orthopaedic Trauma, University Hospital Aachen, Aachen, Germany

Hari Prabhakar, MD, MSc Department of Anaesthesiology, Harvard Medical School, Massachusetts General Hospital, Boston, MA, USA

David M. Skolnik Citizens for Patient Safety, Denver, CO, USA

Patty J. Skolnik, BASW Citizens for Patient Safety, Denver, CO, USA

Philip F. Stahel, MD, FACS Department of Orthopaedics, Denver Health Medical Center, University of Colorado, School of Medicine, Denver, CO, USA

Jeffrey L. Varnell, MD, FACS Department of Patient Safety and Risk Management, COPIC Insurance Cos, Denver, CO, USA

Department of Surgery, University of Colorado School of Medicine, Denver, CO, USA

Michael S. Victoroff, MD Department of Patient Safety and Risk Management, COPIC Insurance Cos, Denver, CO, USA

George G. Youngson, CBE, MBChB, PhD, FRCPEdin, FRCS Department of Paediatric Surgery, Royal Aberdeen Children's Hospital, University of Aberdeen, Aberdeen, Scotland, UK

Part I

General Aspects

Quality Assessment in Surgery: Mission Impossible?

1

Daniel Dindo and Pierre-Alain Clavien

Pitfalls and Pearls

- Quality assessment in surgery represents the prerequisite for providing safe surgical care.
- Surgical complications are globally underreported due to surgeons' reluctance of reporting their own complications for fear of loss of prestige and medicolegal implications.
- The open reporting and root-cause analysis of surgical complications and medical errors, including 'no-harm' and 'near-miss' events, represents a basic tenet to improve safety and quality in surgery.
- Classification of surgical complications, prospective data collection, uniform scoring systems and standardized quality assurance processes represent the 'tools' needed to improve the quality of surgical care provided to our patients.

Outline of the Problem

Definitions for quality assessment are numerous and the concept is challenging to implement in healthcare, particularly in surgical disciplines.

D. Dindo, MD
Department of Visceral, Thoracic and Vascular Surgery, Zurich City Hospital Triemli, Birmensdorferstr. 497, Zurich 8063, Switzerland
e-mail: daniel.dindo@triemli.zuerich.ch

P.-A. Clavien
Department of Visceral and Transplant Surgery, UniversitätsSpital Zürich, Rämistr. 100, Zurich 8091, Switzerland

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_1,

Quality assessment in surgery has gained global attention in recent years. Rising costs, constrained resources and evidence of substantial variations in clinical practice have triggered growing interest in measuring surgical quality. By collecting, reporting and comparing surgical outcome, deficiencies in surgical care can be understood and corrected to improve safety and quality in surgery. Hospitals and physicians are increasingly asked for evidence addressing these areas. Such demands arise from patients and payers. Outcome data are starting to be publicly reported in different countries such as the USA and the UK and this is believed to constitute a powerful market force towards a higher standard of care. This development is driven by patients and by health policy makers. Patients have started to use such reports to select the site for their care and payers are seeking to use such data to direct selected patient population to particular providers trying to lower the exaggerating medical costs. Therefore, health service policy makers want to develop and implement quality indicators that can be appropriately applied to medical practice. However, for the time being, such endeavors have failed.

Limitations of the Current Practice

There is still a dramatic worldwide shortage of quality assessment programs in surgery. In the United States, large databases such as the National Surgical Quality Improvement Program (NSQIP) were established in 1991 so as to record risk-adjusted surgical outcome, rate hospital quality, and benchmark surgical performance. By tracking hospital's performance using NSQIP data, surgical morbidity and mortality would theoretically decrease [1]. However, only a minority of US hospitals joined this program. The annual costs for data collection and the fear of medico legal consequences have hampered the introduction of this or similar programs beyond selected medical centers [2]. Instead, administrative databases are being increasingly used in outcome research [3, 4]. Nonetheless, such administrative quality databases are often unreliable [4, 5] as they have shown significant variations when compared to clinical databases [4–7]. Conversely, clinical databases, that is, those databases designed and controlled by physicians, may underreport complications [8] and their validity is unknown. However, such clinical databases are currently used for benchmarking and marketing in many hospitals.

How to Define Good Quality Surgery?

The term ‘quality’ is poorly defined in surgery. In 1980, Donabedian defined quality care as “that kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts” [9]. This definition leads to another problem: Quality has to be seen from different angles—not only the patient has its demands on the health care system but governments and insurances must have a say too. Therefore, the definition of quality may widely differ between patients, the society, administrators, and health care policy makers. Today, the

incidence of postoperative complications is still the most frequently used surrogate marker of surgical quality. However, the definition of complications in surgery still lacks standardization, hampering the interpretation of surgical performance and quality assessment.

The definition of surgical complications is a challenging task. Many surgeons would argue that the surgeon's intuition is an appropriate guide to define what a complication might be. The appropriateness of the surgeon's intuition for risk assessment has been emphasized [10]. However, the value of the surgeon's intuition is unreliable in many situations because it lacks objective criteria and is strongly dependent on the experience of the individual clinician [11]. More sophisticated definition of complications include "an undesirable, unintended, and direct result of an operation affecting the patient which would not have occurred had the operation gone as well as could reasonably be hoped" [12]. However, the direct cause–effect relationship between surgery and complications is often difficult to assess. This uncertainty carries a risk of underreporting surgical complications, with substantial consequences. Moreover, failure to cure and sequelae should be distinguished from complications [13, 14]. In 1992, "negative outcome" by differentiating among complications, failure to cure, and sequelae has been defined [13, 14]. Complications were defined as "any deviation from the normal postoperative course" and a classification of complications by severity was proposed [13]. Complications were differentiated from sequelae, which cover conditions that are inherent in the procedure, and that thus will inevitably occur (such as scar formation or the incapacity to walk after an amputation). Similarly, diseases or conditions that remain unchanged after surgery should not be seen as complications, but rather as a failure to cure. For example, the early recurrence of an inguinal hernia or an incomplete resection of a malignant tumor reflects a negative outcome and should be classified as 'failure to cure' and not be seen as a complication.

Where Is the "Golden Bullet"?

Classification of Surgical Complications

To classify complications and to grade them in an objective manner, a five-scale classification has been defined in 2004 [15]. An initial attempt has already been published in 1992 [13] but that classification never gained wide acceptance. The classification of 2004 was validated through a large cohort of patients and an international survey. The basic principle of the classification is based on the therapy needed to correct the complication. In this classification, complications are stratified by seriousness and classified into five grades (Table 1.1) [15]. Briefly, grade I complications include complications without need for specific therapy, such as a small hematoma in the skin. Grade II complications need pharmacological treatment (e.g., pneumonia requiring antibiotics). Complications requiring endoscopic, radiologic, or surgical intervention are classified as grade III complications, either IIIa without or IIIb with the need for general anesthesia. Grade IV complications are life-threatening complications requiring treatment in an intermediate or

Table 1.1 Clavien-Dindo classification of surgical complications

Grades	Definition
I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside
II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included
III	Requiring surgical, endoscopic or radiological intervention
III-a	Intervention not under general anesthesia
III-b	Intervention under general anesthesia
IV	Life-threatening complication requiring IC/ICU-management
IV-a	Single organ dysfunction
IV-b	Multi organ dysfunction
V	Death of a patient
Suffix 'd'	*If the patients suffers from a complication at the time of discharge, the suffix "d" (for 'disability') is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication*

intensive care unit; one organ dysfunctions (e.g. pulmonary insufficiency) are classified as IVa, whereas multiorgan dysfunction (e.g. cardio-pulmonary instability) comprise grade IVb complications. Death of the patient is considered to be a grade V complication.

The 'Clavien-Dindo classification' has gained wide acceptance in the surgical community and is extensively used in clinical practice and surgical literature with more than 2,000 citations until now since its introduction in 2004.

Prospective Data Collection

As mentioned above, quality assessment programs are mostly based on clinical databases. However, the reliability of such clinical databases is largely unknown. Hence, a study was designed to audit such a clinical outcome database using a specially trained study nurse [16]. The main purpose of this study was to assess the reliability of residents in tracking complications after surgery. The study was divided into two periods of 3 months duration each. In the first period, a specially trained study nurse, not being involved in the primary care process of the patients, audited all outcome data as recorded by residents in an undisclosed manner. All complications were recorded and graded according to the Clavien–Dindo classification [15] as well as all comorbidities using the Charlson Risk Index. Inconsistencies between recorded and audited data were evaluated.

A total of 305 patients were included during the first period and 447 patients during the second period. The study population of each period was homogenous in terms of types of operation, age, gender, ASA, body mass index, and length of hospitalization. During this period, a total of 206 complications occurred and 80 %

of these complications were not recorded. Of grade I complications (without need for further treatment), 94 % were not recorded, of grade II complications (requiring drugs) 54 %, and of grade III complications (requiring surgical, endoscopic, or radiologic intervention) 71 %. Grade IV (requiring intensive care; n = 1) and grade V complications (death of the patient, n = 1) were both not documented in the database. In the second period, 347 complications occurred. Surprisingly, quality recording did not significantly improve. Of the complications, 79 % were still not or not correctly assessed; 89 % of grade I complications were not or not properly recorded, 59 % of grade II complications, 47 % of grade III complications, and one-fourth of the grade IV complications. All grade V complications were recorded. Focusing on clinically relevant complications (grade II and higher), there was a marginal improvement in the second period with 52 % of the complications that were missed compared with 61 % in the first period. However, this difference did not reach statistical significance.

This study has highlighted that data collection by residents is not suitable for quality control [16]. Strikingly, the reliability of the collected data did not improve despite of teaching, and despite of the disclosure of the audit. The reason for this enormous underreporting of complications is multifactorial. First, recording of outcome data is time-consuming and might therefore be disregarded by the residents. The restriction of the weekly working hours may also significantly impede reliable data collection: Restriction of working time leads to many transitions of care causing loss of information. Second, lack of incentives may also explain insufficient data collection by residents; comprehensive data collection is not rewarded and, unreliable data collection has no negative consequences. This lack of motivation also holds for the hospital as a whole, because there is no apparent monetary benefit for the institution to collect such data. In contrast, payers do not reimburse the additional workload for the data collection in most health care systems. And thirdly, surgeons in general are keener on focusing on their core business, the work in the operating room, than on administrative duties, which may unveil data possibly pointing out poor quality.

Scoring Systems

The assessment of crude morbidity and mortality rates as done in most of the surgical studies do not reflect a surgical performance as the population treated may differ widely in terms of its preoperative risk [17]. Therefore, an appropriate adjustment for the case mix is required for valid comparisons. But risk- adjusted outcome data alone are of little relevance unless there is a consensus on how to report surgical outcome. Additionally, the severity of postoperative complications must be taken into account for quality control since the severity of a complication has been shown to correlate with prolonged hospital stay [18], higher costs [19], and patient dissatisfaction [20].

The risk of a patient to develop postoperative complications may be assessed on an intuitive basis (e.g., expressed by grades as proposed by the American Society of Anesthesiologists [ASA] or with assistance of a Visual Analogue Scale [VAS])

or by objective scoring systems. The value of subjective prediction of postoperative complications has been recognized since the introduction of the ASA grading system. This subjective interpretation of the patients' health and risk status has gained wide acceptance despite the lack of objective evaluation criteria. The disadvantage of this classification is that the intrinsic risk of the planned surgical intervention is not taken into account since the risk profile of a patient is highly reliant on the procedure. It is quite obvious that we may not expect the same risk to develop postoperative complications for a patient after cholecystectomy and after gastric resection. Woodfield et al. published a risk scoring system based on a VAS [10]. Using such an approach, the planned procedure of a patient is intuitively taken into account, thus correcting the limitation of the ASA scoring system. However, such an approach has different weaknesses. First, intuitive risk assessment relies on experience limiting intuition as a good risk predictor for less experienced surgeons. Secondly, there is the danger of an inflated risk assessment since the higher the estimated risk the better the risk-adjusted outcome will look like [21]. Taking these issues into account, a more objective strategy to predict the risk of a patient is necessary such as risk-scores.

Risk scores in surgery are used to estimate the risk for complications of one individual patient or a selected patient population after surgery in a standardized way. Several risk scores have been defined for surgery over the past years. These scores may be classed into three categories: First, there are general scoring systems assessing the operative risk such as the Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) [22]. Then, there are scores that cover a specific kind of morbidity such as the Goldman and Detsky indices for cardiac complications [23, 24]. And finally, there are scoring systems being related to a specific condition or disease such as the Acute Physiology And Chronic Health Evaluation II score (APACHE II score) [25] or the Ranson criteria for acute pancreatitis [26]. Despite of these different scoring systems, surgical performance is generally evaluated without such classifications. This circumstance might be explained by the complexity of such scores or by its specificity for a given patient population hampering the broad introduction of such systems in clinical practice.

Only few risk-scoring systems have gained wide acceptance in surgery. The POSSUM [22] has probably reached the widest recognition. Though the POSSUM has been validated in different surgical subspecialties and showed to be a helpful tool for surgical quality control, pre-operative investigations such as chest radiograph, electrocardiogram, or blood test are required to evaluate the risk for surgery in the patients. Nonetheless, such preoperative examinations are not routinely required for all procedures and all patients. Furthermore, POSSUM is not based on preoperative parameters only. This is open to discussion since the patients' risk might be influenced by the quality of surgery itself. Then, the identification of the patient's risk at the preoperative stage is central to obtain an informed consent of the patient and to consider alternative treatment modalities. Third, POSSUM has been used successfully as a tool especially for the prediction of operative mortality. However, mortality is low after most surgical procedures and is therefore its use as

an instrument for quality assessment in a general surgical population might be challenged [27]. Finally, the mnemonic of the PDCA cycle ("**P**lan-**D**o-**C**heck-**A**ct") enables a constant improvement of the environment and ease of implementation of new processes. The strength of the concept which is firmly established in industry and science lies in its apparent simplicity [28].

Take-Home Message

Taken as a whole, quality assessment remains challenging, as we still lack a standardized, convincing, uniformly used tool to assess surgical quality in many areas. In recent years, a plethora of papers have been published on the topic of quality assessment in surgery. But, have these publications changed anything in daily surgical practice? Did all these endeavors improve the way of quality assessment and the quality of care substantially? Let's face the truth: The answer must be „no". There is still no consensus on how to adjust for the case mix and on how to define surgical outcome and complications, respectively. The Clavien-Dindo classification of complications, however, increasingly gains acceptance in many surgical fields but most of the hospitals do not even record their outcome data on a routine basis. And if they are recorded, data recording relies on self-reporting. The reliability of self-reported data, however, is very doubtful and professional data collectors are not affordable in most places. Furthermore, we still lack of benchmarks hampering the interpretation of surgical outcome data. So, we have to be honest: Quality assessment in surgery is still a neglected subject, and we do not care. We as clinicians should learn from the industry where quality improvement programs are widely implemented for many decades in order to constantly improve quality and processes. We have to define quality and we have to measure it in a standardized and comprehensive manner. Otherwise, others—such as insurance companies, hospital administrators or politicians—will come up such definitions and rules for us. We have a mission. The onus is on us, as surgeons, to make that mission possible.

References

1. Rowell KS, Turrentine FE, Hutter MM, et al. Use of national surgical quality improvement program data as a catalyst for quality improvement. J Am Coll Surg. 2007;204:1293–300.
2. Miller DC, Filson CP, Wallner LP, et al. Comparing performance of morbidity and mortality conference and national surgical quality improvement program for detection of complications after urologic surgery. Urology. 2006;68:931–7.
3. Fiscella K, Franks P, Meldrum S, et al. Racial disparity in surgical complications in New York state. Ann Surg. 2005;242:151–5.
4. Bertges DJ, Shackford SR, Cloud AK, et al. Toward optimal recording of surgical complications: concurrent tracking compared to the discharge data set. Surgery. 2007;141:19–31.
5. Best WR, Khuri SF, Phelan M, et al. Identifying patient preoperative risk factors and postoperative adverse events in administrative databases: results from the Department of Veterans Affairs National Surgical Quality improvement program. J Am Coll Surg. 2002;194:257–66.

6. Mack MJ, Herbert M, Prince S, et al. Does reporting of coronary artery bypass grafting from administrative databases accurately reflect actual clinical outcomes? J Thorac Cardiovasc Surg. 2005;129:1309–17.
7. Shahian DM, Silverstein T, Lovett AF, et al. Comparison of clinical and administrative data sources for hospital coronary artery bypass graft surgery report cards. Circulation. 2007; 115:1518–27.
8. Gunnarsson U, Seligsohn E, Jestin P, et al. Registration and validity of surgical complications in colorectal cancer surgery. Br J Surg. 2003;90:454–9.
9. Donabedian A. The definition of quality and approaches to its assessment. Explorations in quality assessment and monitoring. Ann Arbor: Health Administration Press; 1980.
10. Woodfield JC, Pettigrew RA, Plank LD, et al. Accuracy of the surgeons' clinical prediction of perioperative complications using a visual analog scale. World J Surg. 2007;31(10):1912–20.
11. Clavien PA, Dindo D. Surgeon's intuition: is it enough to assess patients' surgical risk? World J Surg. 2007;31:1909–11.
12. Sokol DK, Wilson J. What is a surgical complication? World J Surg. 2008;32:942–4.
13. Clavien PA, Sanabria JR, Strasberg SM. Proposed classification of complications of surgery with examples of utility in cholecystectomy. Surgery. 1992;111:518–26.
14. Clavien PA, Sanabria JR, Mentha G, et al. Recent results of elective open cholecystectomy in a North American and a European center. Comparison of complications and risk factors. Ann Surg. 1992;216:618–26.
15. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg. 2004;240:205–13.
16. Dindo D, Hahnloser D, Clavien PA. Quality assessment in surgery—rising a lame horse. Ann Surg. 2010;251:766–71.
17. Daley J, Henderson W, Khuri S. Risk-adjusted surgical outcomes. Annu Rev Med. 2001;52:275–87.
18. Collins T, Daley J, Henderson W, Khuri S. Risk factors for prolonged length of stay after major elective surgery. Ann Surg. 1999;230:251–9.
19. Lang M, Niskanen M, Miettinen P, Alhava E, Takala J. Outcome and resource utilization in gastrointestinal surgery. Br J Surg. 2001;88:1006–14.
20. Kjerulff K, Rhodes J, Langenberg P, Harvey L. Patient satisfaction with results of hysterectomy. Am J Obstet Gynecol. 2000;183:1440–7.
21. Galland RB. Severity scores in surgery: what for and who needs them? Langenbecks Arch Surg. 2002;387:59–62.
22. Copeland G, Jones D, Walters M. POSSUM: a scoring system for surgical audit. Br J Surg. 1991;78:356–60.
23. Goldmann L, Caldera DL, Nussbaum SR, Southwick FS, Krogstad D, Murray B, et al. Multifactorial risk index of cardiac risk in noncardiac surgical procedures. N Engl J Med. 1977;297:845–50.
24. Detsky AS, Abrams HB, Forbath N, Scott JG, Hilliard JR. Cardiac assessment for patients undergoing noncardiac surgery. A multifactorial clinical risk index. Arch Intern Med. 1986;146:2131–4.
25. Knaus W, Draper E, Wagner D, Zimmermann J. APACHE II: a severity of disease classification system. Crit Care Med. 1985;13:818–27.
26. Ranson JH, Rifkind KM, Roses DF, Fink SD, Eng K, Localio SA. Objective early identification of severe acute pancreatitis. Am J Gastroenterol. 1974;61:443–51.
27. Birkmeyer JD, Hamby LS, Birkmeyer CM, Decker MV, Karon NM, Dow RW. Is unplanned return to the operating room a useful quality indicator in general surgery? Arch Surg. 2001;136:405–11.
28. Dindo D, Clavien PA. Quality assessment in surgery: mission impossible? Patient Saf Surg. 2010;4:18.

Incidence of 'Never Events' and Common Complications

2

Michael B. Cross and Cyril Mauffrey

Pitfalls and Pearls

- The concept of 'never events' is being utilized and defined differently by the National Quality Forum (NQF) and the Center for Medicare and Medicaid Services (CMS).
- 'Never events' according to the NQF definition are patient safety driven while the definition and types of CMS never events are financially driven.
- The public may be confused and utilize the occurrence of a so-called post operative never event as defined by CMS against a surgeon or an institution.
- NQF 'never events' such as wrong side surgery, medication errors and unintentionally retained foreign materials are still unacceptably high in our hospitals.
- CMS 'never events' such as venous thromboembolic disease and or infections can be difficult to prevent and their occurrence may impact the financial viability of some institutions.
- This latter point may put pressure on institutions and surgeons to carefully select their elective surgical candidate and exclude obese patients, uncontrolled diabetics and patients with poor dental hygiene (for Orthopaedic cases).

M.B. Cross
Department of Orthopaedic Surgery, Hospital for Special Surgery,
535 East 70th St, New York, NY 10021, USA

C. Mauffrey, MD, FACS, FRCS (✉)
Department of Orthopaedics, Denver Health Medical Center,
777 Bannock Street, Denver, CO 80204, USA
e-mail: cyril.mauffrey@dhha.org

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_2, © Springer-Verlag London 2014

Outline of the Problem

Confusion persists with the definition of 'never events'.

Historically, medical errors in surgery have been synonymous with and often are referred to as human errors. Although it was traditionally believed that human errors occur when a health care provider chooses an inappropriate method of care or improperly executes an appropriate procedure, medical errors have more recently, been attributed to communication, cognitive and affective aspects [1, 2]. Such errors are common and can contribute to a substantial number of adverse surgical outcomes.

The challenges lie in the definitions. Confusion persists in relation to the terminology of 'never events'. In fact, two separate entities have utilized these same words in two different contexts. The National Quality Forum (NQF) defines never events as serious reportable events in healthcare. Out of a list of 28 events, the 5 first listed are surgically related and include Surgery performed on the wrong body part, the wrong patient, wrong surgery performed, unintended retention of foreign object and intraoperative or immediate postoperative death in an ASA class I patient. While these represent unacceptable errors, not all of the 28 listed events are preventable at all times. Centers for Medicare and Medicaid Services (CMS) utilized the identical terminology to define their "non reimbursable serious hospital-acquired conditions". The list of these conditions includes deep-vein thrombosis (DVT) following a total knee or hip replacement and a surgical site infection following an orthopaedic procedure amongst others. As pointed out by Lembitz et al. [3] having two lists based on the distinct definitions by the NQF and CMS may create confusion in the public and possible future compensation seeking for events listed in the CMS as 'never events' (such as a DVT following a total knee replacement). While it is true that some surgical complications stem from poor planning, carelessness, or distracted medical professionals, others such as infection and thromboembolic disease can occur despite all precautions that surgical and medical professionals take to avoid them. This chapter will focus on the incidence of some of the surgically related 'never events' as defined by the NQF as well as the incidence of some of the common complications in surgery defined as 'never events' by CMS.

In-Hospital Mortality

During the 10 years period between 1999 and 2009 rates of death in surgery have declined among all age groups. Although comprehensive patient safety programs have been used with success to reduce in-hospital mortality [4], patient death following surgery still occurs. It is a known fact that any surgical procedure carries the

risk of mortality; however more invasive procedures and higher risk patient populations (e.g. elderly, multiple comorbidities) carry a higher risk than others [5]. Mortality can occur secondary to a medical complication after surgery, a result of medication errors or overdoses, reactions to anesthesia, or procedural errors during the surgical procedure itself.

Medication Errors

Medication errors in general are common and affect an estimated 1.5 million Americans per year. In the UK, a recent study suggested that following the review of 688 medical charts, almost 50 % had medication errors [6]. Despite efforts to reduce the incidence of medication errors, adverse drug events (ADEs) continue to be costly for society and cause harm to out patients [7]. The multidisciplinary team approach to surgical care (including the pharmacist), together with the use of physician computer order entry systems (CPOE) has been an accepted strategy to limit ADEs; however, medication errors in surgery still persist. A recent survey quoted that only 50 % of the 160 health care professionals surveyed believed the CPOE reduced drug errors [7]. The ease of using computer systems is essential to reducing adverse drug events through a CPOE [8, 9]; health information technology (HIT) systems that are not user friendly may actually lead to technology induced medical errors [9]. Integrating pharmacists into the multidisciplinary team is beneficial in the reduction of medication errors; however, physicians in general and especially surgeons seldom listen to pharmacists' recommendations [10]. In a recent study, of the 301 recommendations made by the pharmacist in the ER, less than 60 % were followed by the doctors; in addition, surgeons were significantly less likely to accept the pharmacist recommendation (51 %), compared to medical physicians (69 %) [10]. It seems that in order to reduce medication orders, a combined approach of a multidisciplinary team that includes a pharmacist, a user friendly computer physician order entry system, and surgeon's willingness to hear suggestions on medication orders from the team is essential to reduce the incidence of medication errors.

NQF Surgical 'Never Events'

Wrong Site Surgery

The 'horror' of wrong site surgery is far from over, despite a decade of global implementation of surgical safety checklists [11]. This type of 'never event' is far from being isolated to poor quality hospital or surgeons [12]. Using a systematic checklist, universal protocol, or "time-out" procedure reduces the chance of wrong site surgery; however, barriers to their implementation still exist [1, 13]. From the time a patient is indicated for surgery, there are many

steps that occur prior to skin incision, and errors in each or any of these steps may lead to a wrong site surgery. Examples where errors can occur include booking of the procedure by the office staff, an error on the consent, error in reporting the correct site by radiology, poor communication between the surgeon and patient in the holding area, time pressures, changes in nursing staff shifts, time pressures of a surgeon using multiple rooms, improper marking of the patient in the holding area, not performing an adequate "time-out", amongst others [1]. Even in the best of hands, wrong site surgery can occur because of cognitive, administrative, or procedural errors [1]. It is crucial that multiple checkpoints or "systems" be in place to prevent or recognize errors at each point of care.

Unintentionally Retained Foreign Objects

It is estimated that the incidence of retained foreign objects is around 1:5,500 surgeries [14]. Known risk factors for having a retained foreign object include multiple major surgical procedures performed at the same time, multiple surgical teams, and an incorrect sponge/needle count [15]. Surgical counts are used to decrease the incidence of leaving foreign objects in a patient; however, miss counts can occur, and have been reported to occur up to 12.8 % of all operations at a major medical institution in the US [14, 16]. Intraoperative imaging is also used if a retained object is suspected; however, intraoperative imaging has only been able to detect approximately two-thirds of all retained foreign objects [14]. Surgical equipment is now being designed to improve patient safety and decrease the exclusive dependency upon complex and time-consuming counting procedures that are prone to human error by using radiopaque materials that would be seen on an intraoperative radiograph or using a radio-frequency identification system. This technology may help reduce the incidence of retained foreign objects. With the routine involvement of a multidisciplinary team that includes nurses, surgeons and hospital administrators, the incidence of retained foreign objects can be successfully reduced [17].

CMS Surgical 'Never Events'

Venous Thromboembolic Complications

Venous thromboembolic events (VTE) encompass two interrelated conditions that are part of the same disease spectrum: deep venous thrombosis (DVT) and pulmonary embolism (PE). Virchow's triad includes venous stasis, endothelial damage, and hypercoagulability; situations that result in one or multiple of these factors will

increase a patient's likelihood of developing a thromboembolic event. Thus, venous thrombi most often develop in persons who have prolonged immobilization or bedrest (i.e. venous stasis), hypercoagulable states (e.g. cancer, inherited hypercoagulable disorders, etc), or tissue injury that causes endothelial damage and/or hypercoagulable state. The overall annual incidence of venous thromboembolism is estimated to be 1–2 cases per 1,000, and the incidence increases with age [18, 19]. Ninety-five percent (95 %) of all clinically significant pulmonary emboli originate from clots in deep veins of the lower extremity, especially the proximal thigh and pelvis [20]. Although most DVTs are occult and resolve spontaneously with anticoagulation without complication, a massive pulmonary embolism (PE) causes as many as 300,000 deaths annually in the United States. In the hospital setting, VTE prophylaxis is achieved by both mechanical (early mobilization and pneumatic compression devices) and pharmacologic means, with the main goal to prevent fatal pulmonary embolus.

Surgical Site Infections

Surgical site infection (SSI) is one of the most common postoperative complications. Although protocols will vary in different institutions, the accepted current recommendations to prevent postoperative infection include maintenance of operative sterility, preoperative antibiotic prophylaxis within 60 min of incision time (as recommended by the World Health Organization), and continuation of intravenous antibiotic prophylaxis for 24 h after surgery. Risk factors for developing SSI include but are not limited to high body mass index, chronic liver disease, malnutrition, uncontrolled diabetes, and contaminated wounds [21, 22].

Hospital-Acquired Infections

Current regulatory boards have worked to decrease the incidence of other health care-associated infections (HAIs) such as urinary tract infections (UTIs), central-line associated bloodstream infections, and ventilator assisted pneumonia by establishing set protocols for such indwelling devices on a daily basis and nurse education on removal and changing of lines [23].

Limitations of the Current Practice

Our attention and efforts must focus on risk reduction of events that are preventable. However, the financial health of our hospitals is about to be affected by the occurrence of events that are often non preventable. Strategies to improve defensibility of such cases include [3]:

- Pretreatment or pre-hospital documentation of underlying pre-existing conditions (pressure sores, patients with a high risk of VTE, infections)
- Understanding and utilization of clear language to avoid confusion between 'never events' defined by NQF and CMS so as to prevent claims of negligence.
- Implementation of systematic, universal patient safety culture in the institution with creation of a hospital based task force to improve patient safety and quality that incorporates individuals from all disciplines, including trainees, to improve current systems designed to improve patient safety
- Care pathways to prevent hospital acquired infections.
- Involve patients in their own care and encourage patients to "speak up" if they have concerns about their care or the clinical decision-making process.

Take-Home Message

Hospitals and providers are under a tremendous amount of pressure to perform.

Hospitals reimbursements will soon be affected by events that are in some cases non preventable.

The concept of never events and non-reimbursable adverse events are 'negative'. Instead, our attention should focus on positive behaviors with the introduction of the concept of 'always events' [3].

Such events would include:

- Focus on quality of medical handovers between physicians.
- Focus on communication skills and professionalism between providers and between providers and patients.
- Focus on identification of patients and time outs in surgery.
- Disclosure of complications and transparency with patients and families.
- Early involvement of families in the decision making and treatment plan.
- Thorough and clear documentation in patients charts and progress notes.

Health care providers must drive the current healthcare reforms and be part of the inevitable and long awaited universal implementation of a culture of patient safety. This culture should remain a process driven by positive attitudes, behaviors and rewards with the standardization and validation of 'always events'.

References

1. Hadjipavlou AG, Marshall RW. Wrong site surgery: the maze of potential errors. Bone Joint J. 2013;95-B(4):434–5. doi:10.1302/0301-620X.95B4.31235.
2. Cima RR, Kollengode A, Garnatz J, Storsveen A, Weisbrod C, Deschamps C, Institute of Medicine. To err is human: building a safer health system. Washington, DC: The National Academies Press; 2000. ISBN-13: 978-0-309-26174-6 (800-624-6242).
3. Lembitz A, Clarke T. Clarifying "never events" and introducing "always events". Patient Saf Surg. 2009;3:26.
4. Brilli RJ, McClead RE Jr, Crandall WV, Stoverock L, Berry JC, Wheeler TA, Davis JT. A comprehensive patient safety program can significantly reduce preventable harm, associated costs, and hospital mortality. J Pediatr. 2013;163(6):1638–45.

5. Schoenfeld AJ, Ochoa LM, Bader JO, Belmont PJ. Risk factors for immediate post-operative complications and mortality following spine surgery: a study of 3475 patients from the national surgical quality improvement program. J Bone Joint Surg. 2011;2011:1577. doi:10.2106/JBJS.J.01048.
6. Basey AJ, Krska J, Kennedy TD, Mackridge AJ. Prescribing errors on admission to hospital and their potential impact: a mixed-methods study. BMJ Qual Saf. 2014;23(1):17–25. doi:10.1136/bmjqs-2013-001978.
7. Bates DW, Lucian LL, Cullen DJ, et al. Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. JAMA. 1998;280(15):1311–16. doi:10.1001/jama.280.15.1311.
8. Peikari HR, Zakaria MS, Yasin NM, Shah MH, Elhissi A. Role of computerized physician order entry usability in the reduction of prescribing errors. Healthc Inform Res. 2013;19(2):93–101. doi:10.4258/hir.2013.19.2.93.
9. Borycki E. Trends in health information technology safety: from technology-induced errors to current approaches for ensuring technology safety. Healthc Inform Res. 2013;19(2):69–78. doi:10.4258/hir.2013.19.2.69.
10. Mogensen CB, Olsen I, Thisted AR. Pharmacist advice is accepted more for medical than surgical patient in an emergency department. Dan Med J. 2013;60(8):A4682.
11. Cobb TK. Wrong site surgery – where are we and what is the next step? Hand (NY). 2012;7:229–32. doi:10.1007/s11552-012-9405-5.
12. Ring DC, Herndon JH, Meyer GS. Case records of The Massachusetts General Hospital: Case 34-2010: a 65-year-old woman with an incorrect operation of the left hand. N Engl J Med. 2010;363(20):1950–7.
13. Treadwell JR, Lucas S, Tsou AY. Surgical checklists: a systematic review of impacts and implementation. BMJ Qual Saf. 2014;23(4):299–318.
14. Cima RR, et al. Incidence and characteristics of potential and actual retained foreign object events in surgical patients. J Am Coll Surg. 2008;207(1):80–7. doi:10.1016/j.jamcollsurg.2007.12.047.
15. Lincourt AE, Harrell A, Cristiano J, Sechrist C, Kercher K, Heniford BT. Retained foreign bodies after surgery. J Surg Res. 2007;138(2):170–4.
16. Greenberg CC, Regenbogen SE, Lipsitz SR, Diaz-Flores R, Gawande AA. The frequency and significance of discrepancies in the surgical count. Ann Surg. 2008;248(2):337–41. doi:10.1097/SLA.0b013e318181c9a3.
17. Cima RR, Kollengode A, Storsveen AS, Weisbrod CA, Deschamps C, Koch MB, Moore D, Pool SR. A multidisciplinary team approach to retained foreign objects. Jt Comm J Qual Patient Saf. 2009;35(3):123–32.
18. Cross MB, Boettner F. Pathophysiology of venous thromboembolic disease. Semin Arthro. 2009;20:210–16. doi:10.1053/j.sart.2009.10.002.
19. Gilmore R, Doyle M, Holden F, White B, O'Donnell J. Activated protein C resistance, factor V Leiden and assessment of thrombotic risk. Ir Med J. 2008;101(8):256–7.
20. Morris CD, Creevy WS, Einhorn TA. Chapter 12: Pulmonary distress and thromboembolic conditions affecting orthopaedic practice. In: Buckwalter JA, Einhorn TA, Simon SR, editors. Orthopaedic basic science: biology and the biomechanics of the musculoskeletal system. 2nd ed. American Academy of Orthopaedic Surgeons, Chicago, IL. 2000.
21. Itatsu K, Sugawara G, Kaneoka Y, Kato T, Takeuchi E, Kanai M, Hasegawa H, Arai T, Yokoyama Y, Nagino M. Risk factors for incisional surgical site infections in elective surgery for colorectal cancer: focus on intraoperative meticulous wound management. Surg Today. 2013. Epub ahead of print.
22. Pruzansky JS, Bronson MJ, Grelsamer RP, Strauss E, Moucha CS. Prevalence of modifiable surgical site infection risk factors in hip and knee joint arthroplasty patients at an urban academic hospital. J Arthroplasty. 2014;29(2):272–6.
23. Fakih MG, Heavens M, Ratcliffe CJ, Hendrich A. First step to reducing infection risk as a system: evaluation of infection prevention processes for 71 hospitals. Am J Infect Control. 2013;41(11):950–4.

Cognitive Errors

3

Dennis J. Boyle

Pitfalls and Pearls

- There is a "dual system" of diagnostic reasoning: System 1, instinctual thinking; System 2, logical hypothetico-deductive reasoning.
- Clinicians tend to rely extensively on System 1 heuristics for speedy diagnosis.
- Understand the underlying bias in human thinking.
- System 2 helps avoid uncertainty in establishing a diagnosis.
- "Anchoring bias" is the most common reasoning error. When in doubt, reconsider the diagnosis and avoid "favoritism" to the original diagnosis.
- Uncertainty is best addressed by creating a problem list and developing a complete differential diagnosis.
- Analyze your errors in decision making and their underlying root causes and preventability.

Outline of the Problem

Physicians rely on instinctual thinking which leads to errors in judgment and decision-making. Metacognition will help us understand and resolve the root cause of preventable cognitive errors in medicine.

The Institute of Medicine [1] has reported that 44,000–98,000 deaths a year result from iatrogenic injury and error. This exceeds the number of those who die in auto

D.J. Boyle, MD
Risk Manager, Colorado Physician Insurance Companies (COPIC),
7351 Lowry Blvd, Denver, CO 80230, USA

Associate Professor of Medicine and Rheumatology, Denver Health Medical Center and University of Colorado School of Medicine, 777 Bannock St, Denver, CO 80204, USA
e-mail: dboyle@copic.com

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_3, © Springer-Verlag London 2014

accidents in the United States. Autopsy series have suggested a 15 % error rate in the practice of medicine. Diagnostic error occurs in every specialty. A review in 2008 [2] showed an error rate of less than 5 % in the specialties of radiology, pathology and dermatology, which are the visual interpretive fields. In most other fields where history is culled from the patient and diagnoses are inferred before all the data is obtained, the error rate is higher at 10–15 %. An explosion of interest has occurred in the arena of patient safety over the last decade. Huddles, safety checklists and attention to the filing of reports have all been part of our focus on safer health care. The elimination of wrong-side surgery through a presurgical timeout is a classic example of such "low hanging fruit." Another example is the filing away of an elevated PSA level or abnormal mammogram in the chart without being seen by the physician. The one area that has received little attention so far is diagnostic or cognitive errors, and this area may turn out to be the Holy Grail in improving patient safety.

A commentary by Newman-Toker et al. [3] has called attention to this underpublicized issue. A striking example is that up to 9 % of cerebrovascular events are missed initially, usually when the symptoms are more subtle. Diagnostic errors are more likely than drug errors to result in litigation (14 % vs. 9 %) and are more likely to be considered negligent (75 % vs. 53 %). As a result, tort claims are twice as likely to result from diagnostic errors as compared to medication errors. Graber et al. [4] created a taxonomy that can help us understand the issue of medical error. He and his fellow investigators evaluated 100 internal medicine misses and concluded that approximately half were diagnostic in nature and related to poor data gathering and faulty synthesis of information. The other half of the errors were systems issues, which were defined as technical failures, organization and policy flaws such as abnormal tests not being communicated to the patient. There were six errors for each case reviewed; often both cognition and systems issues were involved. Diagnostic errors are associated with higher morbidity than other medical errors. Groopman [5] in his book states "research shows that technical errors account for a small fraction of incorrect diagnoses and treatment. Most errors are mistakes in thinking." In a different paper Graber et al. [6] categorized cognitive errors as follows: (1) Inadequate knowledge; (2) Faulty data gathering, for example, a missed breast cancer because an exam was not done; (3) Faulty information processing such as a missed lung cancer on a misread x-ray; (4) Faulty thinking. The latter is the area of cognitive issues we will be addressing.

These findings are concerning and raise important questions about medical practice. What is known about cognition? How does it apply to doctoring? What kind of mental errors do providers make? What does the literature of medical reasoning tell us? Are there any patterns that occur in our cognitive mishaps? And finally, how can we reduce the incidence of such occurrences?

Outline of the Problem: How Humans Think

The nature of how we think and decide is fascinating and an understanding of this science is still evolving. As far back as Plato, the mind was thought to be divided into two components: a rational reasoning part and an emotional sphere with

primitive desires. The soul is torn between these two components. Plato had the image of a charioteer driving two horses, one horse calm and behaved and the other wild and bucking. The driver was ultimately in charge. In this view we are all wild animals with a reason and rationality that can be imposed by our mind. This epic image has been engrained in our culture.

In the computer age there came a new image, that of the brain as a computer. The brain is the hard drive and our learning is the software. This cognitive psychology concept misleads us as it ignores the importance of feelings and instinct. In all of these images there is conflict between the two types of reasoning and ultimately the rational part has the job of controlling thoughts and decisions.

In the 1970s two psychologists, Daniel Kahneman and Amos Tversky, revolutionized the understanding of the brain's function [7]. They were working at the Hebrew University in Jerusalem and Kahneman ultimately won the Noble Prize for this work. They described two systems that worked together to make decisions in what is termed dual process theory.

The first system, System I, involves pattern recognition and originates in the deeper part of the brain in dopamine-rich neurons. This part of the brain is an instinctual area that integrates life experiences, senses, emotions and feelings and comes to an intuitive conclusion. It is effortless and leads to decisions via associations. It is primitive and is the decision-making organ in the vertebrate creatures that preceded us in evolution. Everyday life is full of such responses. The color of the car we purchase, the dinner we order or even the person we marry are usually gut-level decisions. A trip down the grocery aisle is a classic area for System I thinking. Driving is another. Have you ever arrived home and forgot what route you took? Decisions a driver makes during a time of crisis are a result of experience and practice. Athletic events are replete with the same instinctual responses. Consider Peyton Manning's Sunday passes or Serena Williams' backhand returns. These skills have grown with the evolution of cerebral cortex and the ascent of Homo sapiens from lower animals. System 1 is automatic, quick and influenced by past experiences and can be described as "go with the gut." The technique that helps System 1 work so efficiently is the use of heuristics. These are shortcuts that are simple, hard coded and explain how we solve problems rapidly, make snap judgments and even decide about complex problems. They serve us well but may lead to cognitive biases that will be discussed later. Pattern recognition is another form of System 1 thinking. Often one can tell the make and model of an automobile or the breed of a dog without being able to identify what features lead to that identification.

The other system of diagnostic reasoning is, of course, System 2. It is the systematic and analytical style that is evolutionarily recent and seen only in humans. It is slow and sequential and relies on rational reasoning and the ability to imagine abstract concepts. It is capable of making judgments but requires time. It allows you to think of various reasons, to ponder the evidence and to weigh their benefit and risk. It is described as truth seeking and puts weight on intellectual honesty. It is best when processing complex and challenging problems. It is what your brain is doing when you hear "multiply 18 times 24" or when you prepare to do your income taxes. This is the hallmark of the Homo sapiens and is the feature that separates us from other creatures in the course of evolution.

What is recent in our understanding is how these two systems work together. They have evolved in unison and we often move between the two styles. In general people operate in System 1. When necessary System 2 will kick in but this is actually rare. Kahneman states [7] "What we have is a storytelling system, and the coherence of the stories determines how much faith we have in them. The coherence is associative and emotional. It involves concrete events. You have to assume that System 1 is largely indifferent to the quality and amount of evidence; it is bound more by the coherence of the story than by the evidence behind it."

One fascinating study showed what happens if you are given an assignment involving a cognitive task and then given two food choices. The choice is between chocolate cake and a fruit salad. If the task is challenging and the brain is busy with calculations then you are much more likely to choose the rich desert. When system 2 is busy, System 1 makes the choices.

Let's examine the events of January 15, 2009. Captain Sully Sullenberger was piloting an Airbus A320. The plane was leaving New York and struck a large a flock of birds, losing power in both engines. No commercial airliner had successfully survived such a disastrous engine failure. Captain Sully went through options with air traffic control and deemed he was too far away for a return to the airport. Although no one had ever successfully landed a commercial plane on a body of water, he chose to put down on the Hudson River. He glided the 80 ton on jet onto the water with no loss of life. What part of his brain was involved in this decision? Sully had a lifetime experience of gliding. Certainly there was some rational System 2 thinking involved in the decision to glide the jet. And then years of gliding experience and instinct took over. Speaking with news anchor Katie Couric, Sullenberger said: "One way of looking at this might be that for 42 years, I've been making small, regular deposits in this bank of experience, education and training. And on January 15 the balance was sufficient so that I could make a very large withdrawal." Sounds like system 1 "in action."

Limitations of the Current Practice

How Doctors Think

The diagnosis of medical problems requires a combination of the clinician's experience, knowledge and acumen. Critical thinking is at the core of this process and requires us to collect information, work through a problem and reach a reasonable conclusion. The advances in cognitive psychology outlined above have provided a theoretical framework to understand decision making and how we diagnose [8, 9].

In our professional lives, many of our day-to-day diagnoses or therapeutic decisions are instinctual and made by System 1. Early in training we learn about illness scripts. These scripts are a combination of the signs and symptoms of various illness clues. As we grow experienced they become the rich tapestry of patients we've seen, articles we've read and the stories we've heard. This is also called thin slicing. We often take just two or three symptoms and come to the diagnosis. Right lower

quadrant pain and a WBC count of 14,000 in a young man equals appendicitis. Or how about the older woman who presents with flank pain and gross hematuria? Frequently the clinician does not do an extensive workup but simply dips the urine, checks an X-ray and treats the pain. The above are often called heuristics or shortcuts in reasoning. These are fast, intuitive rules of thumb and can be the source of brilliant diagnoses. Perhaps this lower abdominal pain patient is from the Middle East and has recurrent pain. You've seen one patient with Familial Mediterranean Fever and they look the same. You send the appendix to pathology and ask them to look for vasculitis which is identified.

I'm reminded of the time my partner diagnosed a patient with Ehlers-Danlos syndrome. When I asked him how he even thought of it he said simply "he looked like the last Ehlers-Danlos patient I saw." This is pattern recognition at work. Thin slicing, pattern recognition and heuristics are often simple and allow us to move through a busy day of 30 patients and still practice caring, competent orthopaedics. For example, "Post op total knee there is no infection. Let's push harder in therapy." "A football player had a knee injury, felt a pop. The knee is too swollen for a reliable drawer sign but it's an ACL tear. Let's get an MRI." The 'post-op hip patient' asks you to look at a rash. "I'm not an internist but it certainly looks like shingles to me." Heuristics can be flawed and lead to cognitive errors as they are by nature quick and not rich with all the data.

System 2 is the systematic and analytical style that we associate with great diagnosticians [10]. Experienced physicians use this method when they are faced with a complex or puzzling illness. In these situations this system is knowledge-based and allows us to come up with the complete differential diagnosis. The scientific description of this style is "Hypothetico-deductive" and the thinking occurs in the prefrontal and frontal cortex and the memory area of the brain. System 2 is rational decision making at its best, thorough, a detailed and the hallmark of being a physician. The consult could be "please see this patient in the unit. I can't figure it out. They have abdominal pain and the CT is not diagnostic. Anything in the differential I'm missing?" It involves a thorough problem list of all complaints and organs affected and a robust differential diagnosis. The expert will be continually considering and refining new diagnostic considerations. The exam is focused in this situation. Is the liver or spleen enlarged? Are there any nodes? How about bruits? Every finding generates a hypothesis, changes the differential and leads you to new tests. If the liver is large, then what are the LFTs and hepatitis tests? If the LFTs are normal is there a vascular cause? "That ICU patient could have Budd Chiari so let's repeat the ultrasound." This is a hypothesis-driven style. System 2 is much slower, requires high cognitive awareness and scientific rigor. It may lead to more diagnostic testing but when diagnostic uncertainty exists, the analytic approach is the most reliable. Of interest is how the relationship between the two systems changes with time. Initially medical students rely more on System 2 to make a diagnosis [11]. When a third year medical student is faced with a hospitalized patient with abdominal pain, they might do a two hour history and physical. They don't have clinical experience with which to rely on so they go through as complete a differential as possible. As they progress in training they develop the experience that allows them to rely on

System 1. Finally as providers' progress in their careers they may rely exclusively on System 1 reasoning.

In our day-to-day clinical worlds, clinicians move between the two styles. Efficient doctoring requires frequent use of heuristics and occasional reliance on System 2 reasoning. Often we need to invoke a combination of both styles. Just as in everyday life, most clinicians spend most of their time in System 1 thinking and only occasionally invoke System 2.

Cognitive Errors in Medicine

Problem solving is quite complex and we have learned that errors are a result of human cognition. Cognitive errors are thought process mistakes that lead to the wrong diagnosis or plans. They are usually the result of some of the 30 cognitive biases that have been identified and affect our clinical thinking (see Table 3.1). Identification of these biases creates a framework to classify physicians' mental errors. Cognitive errors are complex and less able to be analyzed via root cause analysis as opposed to procedural issues such as wrong-side surgery. They are often low visibility to the doctor who commits them and to those who are evaluating them after an event [12]. Groopman states "while heuristics serve as the foundation of mature medical decision making, they lead to grave errors. The doctor must be aware of which heuristics he is using, and how his inner feeling may influence them" [5].

Availability bias is related to the diagnosing of a disease that easily comes to mind. We tend to diagnose what we've seen in the most recent past. An example would be diagnosing a recent gall bladder surgery patient with a DVT because several months ago while on call you had a patient with that same complication.

Table 3.1 Examples of cognitive bias

Confirmation bias	Tendency to seek confirmatory evidence
Availability bias	The diagnosing of a disease that easily comes to mind
Framing bias	Occurs when a diagnostician is misled or influenced by the way a problem or patient is presented
Attribution bias	An interpretive judgment that is made by some behavior that is observed
Search satisficing	The physician calls off the search for a problem when they have found an abnormality
Hindsight bias	The knowledge of the outcome influences a true appraisal of what actually happened
Authority bias	Accepting a diagnosis without question that had been made by an esteemed colleague
Ying yang bias	When the patient has worked up the ying yang and we shouldn't repeat the workup
Anchoring bias	A shortcut in thinking where a person doesn't consider multiple possibilities but latches on to a single one, sure that he has thrown his anchor down just where he needs to be
Premature closure	Accepting a diagnosis early and not paying attention to further vetting that would allow an alternative diagnosis

Another example would be diagnosing a patient with influenza at the height of the flu season, and as a result, missing the patient's pulmonary embolism.

Confirmation bias is when you "see only the landmarks you expect to see and neglect those that should tell you that in fact you're still at sea [5]. Your skewed reading of the map 'confirms' your mistaken assumption that you have reached your destination." It is the tendency to seek confirming evidence rather than looking for other findings that would disprove the diagnosis. In the above flu case, you might latch on to the temperature as proof of an infection and gloss over a normal chest X-ray. In the anesthesia world an example would be the repeating of arterial measurements and changing of cuff sizes in an effort to get a reassuring reading rather than recognizing the hypotension is real [12].

A *framing bias* occurs when a diagnostician is misled or influenced by the way a problem or patient is presented. It can occur when you get a consult: "Can you see the drunk who's in the ER and rule out an acute abdomen?" This consult might lead us to a less than thorough evaluation. This also comes into play when you are presenting a patient with a difficult choice. The statements "this surgery has a 90 % failure rate" will result in fewer patients choosing surgery than a frame of "this surgery has a 10 % cure rate.

An *attribution bias* is an interpretive judgment that is made by some behavior that is observed. This might occur when one is taking care of an addicted patient with somatic complaints. The physician might be influenced by his emotional bias and miss the infection because of the attribution to a withdrawal syndrome. Emotion can affect how you reason in a variety of ways. The amygdala controls the deep emotional responses and works directly with the decision areas of the frontal cortex [13]. Many of these biases are tied to our emotional state.

Search satisficing occurs when the physician calls off the search for a problem when they have found an abnormality. Crosskerry asks the teaching question [14] "what is the most common missed fracture?" The answer is, of course, "the second fracture." Every year several fractures are missed by orthopaedists or ER doctors because they call off the search for a fracture after finding the first one.

Hindsight bias is when the knowledge of the outcome influences a true appraisal of what actually happened. This is informally known as the retrospectroscope. One may overestimate what they did at the time of an event, what they knew and what they thought. Or one may be devastated when they present and are criticized in a morbidity and mortality conference.

An *authority bias* would be accepting a diagnosis without question that had been made by a senior, more esteemed colleague. Perhaps the patient has had extensive evaluation at the university for their abdominal pain. In this situation a clinician might assume further evaluation would be of no benefit. This is also related to the *ying yang bias*, as in "the patient has been worked up the ying yang and we shouldn't repeat the workup."

Finally, there is the most common and troublesome pair of all biases, *anchoring bias* and its close relative *premature closure*. Anchoring is "a shortcut in thinking where a person doesn't consider multiple possibilities but quickly and firmly latches

on to a single one, sure that he has thrown his anchor down just where he needs to be" [5]. Premature closure is where you accept a diagnosis early and do not pay attention to further vetting that would allow an alternative diagnosis. An example might be an orthopaedist who sees a post op total knee replacement and assumes the swelling is typical of what he sees post op and misses a DVT. The fact that the patient is on anticoagulation is the confounding issue that leads him away from a DVT diagnosis. The data on anticoagulation is clear that even with best practice, anticoagulation DVTs will occur in post op orthopaedic settings. Another example would be in the renal colic patient who is writhing in pain as did the last three renal colic patients you've encountered and you miss the aortic aneurysm dissecting into the renal artery. You anchored or prematurely closed on your first impression. These are the bane of System 1 thinking. Heuristics serve a clinician well as they race through the day and are part of the economy of thought that lead to a smooth practice, but anchoring on your first impression leads to misses that are the price of cognitively cutting corners.

Case Studies

Case 1

This case involves an alleged wrongful death resulting from the failure to recognize and treat post surgical internal bleeding. The 38 year old Caucasian female patient with a significant history of obesity and heavy irregular bleeding, pain, and anemia presented to Doctor X (OB/GYN) for a laparoscopic assisted total vaginal hysterectomy with fulguration of pelvic endometriosis. The surgery was conducted in early December 2007 and thought to be uneventful.

Post surgery the patient was transferred to the PACU in stable condition. Over the next 3–4 hours, the patient experienced changes in blood pressure and became pale and diaphoretic. A CBC revealed HGB of 4.4 and HCT of 13.1. She was given Packed RBCs and monitored throughout the late afternoon. At approximately 6:30 p.m., Dr. X was contacted to asked to return to the hospital as it was believed that the patient might be taken back to surgery. A different physician was also contacted as an intensivist to evaluate the patient. At 7 p.m. both physicians evaluated the patient and determined that she should be stabilized prior to being taken back to surgery. Additional Packed RBC and fluids were administered. The patient was complaining of abdominal pain and Dr. X ordered 50 mg IV fentanyl for the pain. He also suggested to consider dopamine to protect the liver. Dr. X left the hospital at that time. The patient's blood pressure continued to deteriorate and she was pronounced dead at approximately 11 p.m. Cause of death per autopsy is hemoperitoneum due to laparoscopic hysterectomy with delayed surgery to repair internal bleeding.

Case Analysis

In the recent past, the gynecology surgeon had been through a painful and protracted lawsuit for a post op complication. Likely he was hoping that the patients' deterioration was not the result of the surgical bleeding. Looking at this on paper it is obvious that the patient should have been brought back to the OR urgently. There are probably a variety of cognitive biases that occurred in this case. There was certainly a component of confirmation bias in the physician's actions. He was hoping that the patient had nothing serious and anchored on the hope that the patient could be stabilized with fluids and vasopressors. Perhaps the two years out of training intensive medicine physician had an *authority bias*, deferring to the gynecologist who had much more experience in the care of post op patients. Certainly they both appeared to be using pure instinct and System 1 thinking as they cared for this patient.

Case 2

Dr. Y performed an L4-5, L5-S1 anterior lumbar diskectomy and anterior interbody arthrodesis with interbody cage on a 49-year-old Hispanic male. The surgery was thought to be without complication. The patient was given a prescription for subcutaneous anticoagulation and discharged three days post op. The patient did not fill his Lovenox® prescription.

Six days postoperatively, the patient presented to the Emergency Department (ED) complaining of numbness in his right leg below the knee. He also related pain in his right thigh. He complained that he was unable to ambulate or fully bear weight. The ED flowchart shows "positive pedal pulses and positive movement." The patient was seen by ED physician who was unable to determine the source of his pain but noted "good pulses." The patient was given morphine for the pain. The ED physician consulted the surgeon, and it was determined that an MRI of the lower back was warranted to rule out a post op complication. The patient required sedation for the MRI and it was noted that he was very difficult to sedate requiring multiple doses of Ativan®. He eventually needed conscious sedation. Dr. Y arrived at the hospital at approximately 10:00 p.m. and noted that the MRI showed normal post-operative changes. Because of the patient's pain and motion Dr. Y was unable to assess pedal pulses. He did note that the nursing staff had documented lower extremity pulses. Dr. Y palpated the patient's leg compartments, noted that the leg was warm, had good color, and the patient was able to move it.

Dr. Y was unable to determine the source of the patient's pain and admitted him to the floor for close monitoring. Nursing notes document pedal pulses, color, and warmth in the RL throughout the night. Early the next morning staff noted that pedal pulses were not present. Dr. Y was called and the patient was taken to the OR within 30 min where the consultant vascular surgeon noted an acute and critical ischemia of the right lower extremity, thought to be related to surgical retraction resulting in arterial thrombosis. The patient went on to have an above the knee amputation.

Case Analysis

This case represents an anecdotal example of the *availability heuristic*. In a post-operative patient the diagnosis is most likely some sort of operative complication (not unreasonable especially if the pulses are normal). However once the MRI was noted to be unremarkable, the surgeon should have moved to System 2 thinking and come up with the differential of what was causing the pain. In this case the patient had critical limb ischemia and the true diagnosis was missed.

Case 3

A patient presented with a history of recurrent diverticulitis and a right benign adrenal mass with complaints of left lower quadrant abdominal and lower back pain. He had a history of drug addiction. He was admitted for an elective right adrenal resection and hand assisted laparoscopic sigmoid colectomy performed by Dr. A. He appeared to be doing well in the first several days after surgery. On the second post op day the patient developed delirium and agitation. Dr. A decreased the PCA narcotics concluding the patient was receiving too much pain medication.

Dr. A was off the next week. He signed the patient over to his partner Dr. B. The patient's prior addiction was emphasized in the handoff and Dr. A described that he found the patient to be cranky and not likable. Dr. B saw the patient for the next three days. The patient was confused and agitated. He ran a temperature of 100.5 maximum. He had increasing abdominal pain. Dr. B felt this was all compatible with withdrawal, wrote in the chart the patient was improved and treated the patient with light pain medication and Torodal®. On the fifth post op visit the patient worsened with increased pain. His abdominal examination revealed hypo active bowel sounds and there was mild left upper quadrant tenderness. No gas, no BM, and some left-sided abdominal pain were noted. At noon on the fifth day according to nurse's notes, the patient jerked himself out of bed and stated he had excruciating pain. Dr. B evaluated the patient and the plan included: "Consider CT scan if it does not settle down. Continue gas drugs." Orders were written for fentanyl, valium, heating pad to abdomen, lidoderm® patch to incision, and robaxin was discontinued as was the ativan®. That afternoon a CT of the abdomen showed a small amount of fluid/air near the anastomosis a little more than was expected five days postop. Dr. B indicated this was a possible anastomotic leak with no clear perforation noted on CT. On day six, Dr. B again examined the patient and reported he was calm with no acute distress. The abdomen was distended and non tender. Pain was described as improved. Early on the sixth post op day, Dr. B ordered a Gastrografin® enema for that morning since the CT was unclear. The Gastrografin® enema showed a leak. He then ordered the patient to be NPO, and ordered IV antibiotics and a type and cross, with a plan for surgery that afternoon. At approximately 3:00 p.m., the patient had a very large watery bowel movement, became diaphoretic and was having a significant increase in abdominal pain. He was moved to ICU, and was intubated at approximately 4:00 p.m. due to his diminished

respiratory status. He was taken to surgery urgently at this point and the patient expired on the table. An autopsy was performed and the final anatomic diagnosis was severe acute peritonitis secondary to anastomotic leak, post sigmoid colon resection for diverticulitis.

Case Analysis

This is a representative case of *framing bias* and *attribution bias.* At deposition, Dr. B stated that he did not like the patient. The plaintiffs' attorney pointed out that Dr. B had never actually talked to the patient when the patient was not in pain or distress. The history of narcotic abuse turned out to be an addiction to prescribed medication 15 years ago and the patient had been clean and sober since that time. This would be an example of *framing bias* in the manner in which the patient was originally described during the handover. The patient was described as a drug abuser when in fact that was a distant issue and really not related to his increasing pain. This is also an example of *attribution bias* as Dr. B assumed the increasing abdominal pain was related to drug seeking behavior.

Where is the "Golden Bullet"?

The solutions to reducing cognitive errors and improving safety are not as apparent as in other areas of patient safety.

Let's start with a few simple strategies…

Feedback and follow-up: Quick, specific feedback is vital to improvement of patient care. It cannot be in the form of statistics about misses. That would be like telling your favorite basketball team to "play better." If mistakes are made the clinician needs to learn about these rapidly and honestly and participate in a breakdown of how the error occurred and how to keep it from happening.

Increase perception: This starts with the highlighting of abnormal laboratory tests with a different, more noticeable color. This computer assisted feature matching has the potential to improve readings of abnormalities. This has already been shown to improve sensitivity and specificity of X-ray reading reports.

Make expertise more available: This may occur in several ways. The introduction of nighthawks has improved X-ray reads in the ED setting. An automatic second read might also decrease roetenographic or pathological perceptual errors. In the ICU world virtual rounding has occurred where an offsite Tele-ICU specialist can make video rounds even in rural community hospital settings. Using technology to increase our expert involvement seems an obvious way to improve patient safety.

The "time out" to decrease reliance on memory: A decade ago engineers observed patient care in ICUs for 24-hour stretches. They found that the average patient required a 178 individual actions per day, ranging from administering a drug to suctioning the lungs, and every one of them posed risks. Remarkably, the nurses and doctors were observed to make an error in just 1 % of these actions—but that still amounted to an average of two errors a day with every patient [15]. Algorithms, checklist and timeouts all improve how we perform and prevents errors.

Guidelines: There is wide variability in how clinicians act and guidelines might be able to reduce cognitive mishaps. Consider the institution of guidelines around MIs and the standard use of aspirin and beta blockers at patient discharge, or perioperative antibiotic use, which has now become standardized.

Beware of fatigue and stress: Fatigue and sleep deprivation have a clear impact on motor skills [16] and cognitive reasoning. In a fascinating study by Kahol et al the effect of fatigue and being post call had a dramatic effect on surgical proficiency. There was a 47 % increase in cognitive errors related to sleep deprivation with memory errors being most significantly increased.

There are more advanced strategies to be attempted and evaluated in the future…

Be aware of biases: Another simple approach is to be aware of the gestalt of a diagnosis or your own heuristic. These instincts usually can be trusted and relied upon. These are the skills that make a clinician an expert diagnostician. After registering your impression though, one needs to pause and ask "what diagnosis might I be missing?" This combats the most common cognitive error we see, premature closure or anchoring bias. We need to analyze how we make System 1 errors and avoid them in the care of the patients.

Computer based decision support system: These promise to improve diagnostic accuracy by being a fresh set of eyes and a quick second opinion. This approach started in the 1970s at the University of Pittsburgh where they developed the commercially available Quick Medical Reference. Massachusetts General Hospital later developed DXplain. Today IBM is in the process of developing Watson for healthcare. These, along with other similar programs, need to be integrated into the everyday patient flow to be of best use. They have the major advantage of identifying low frequency diagnoses that few would be aware of. This allows us to always ask oneself "is there a chance I am missing one of these?" When one is confronted with an unusual symptom such as "I hear my eyes move," one might presume a psych consult is in order, whereas an internet search would identify superior canal dehiscence syndrome.

Simulation or gaming training: Cognitive training in a high tech simulation center allows a rehearsal or walkthrough of potential high stress situations such as cardiac arrest, crash tracheotomy or trauma situation. This training allows an obstetrics team to practice delivery scenarios such as shoulder dystocia and HELLP syndrome. Those are rare events in the obstetric setting and practice in a simulation setting allows for work on both communication and cognitive awareness. In addition, if it takes 50 knee arthroscopies to achieve some clinical expertise in knee arthroscopy why not have those done in a simulation rather than a real setting?

Metacognition and cognitive forcing strategy: These are two strategies that flow together. Metacognition is thinking about thinking. When an error or near miss occurs, step back and reflect on the thinking issues that might have occurred. Gleitman, years ago, described this as the hallmark of human intelligence [17]. Cognitive forcing strategy [18] occurs when one self monitors error risk and bias before and during decision making. If you previously have made a search satisficing error, when a fracture is discovered, always commit yourself to a search for a second fracture.

The "Golden Bullet" is summarized in Table 3.2.

Table 3.2 The "Golden Bullet"

Basic strategies	Feedback and follow-up
	Increase perception
	Make expertise more available
	The timeout- decrease reliance on memory
	Guidelines
	Beware of fatigue and stress
Advanced strategies	Be aware of biases
	Computer based decision support system
	Simulation or gaming training
	Metacognition and cognitive forcing strategy

Take-Home Message

Each of us, as clinicians, need to understand how we approach medical decision making and we need to be aware of our blind spots that lead to cognitive errors. I would urge all of us to analyze our own errors as that will most likely be where we will err again.

Groopman [5] understands much of what is at the heart of medicine. For example, that "the core reality of the practice of medicine [is] where – in the absence of certitude – decisions must be made" and that "among many other wrong beliefs about primary care, the concept that doctors take care of diseases [is] … Wrong. Doctors take care of people, some of whom have diseases and all of whom have some problem." He understands many of the external pressures on doctors: time constraints, the temptations posed by lucrative procedures, and the pharmaceutical companies' and manufacturers' pressure to use their products.

It will always be impossible to completely eliminate diagnostic errors and we need to consider what an acceptable error rate is. Much of what we are talking about lies beyond the control of the clinician. Medical diagnosis is really a black box as we often try to make sense and a diagnosis out of a nonspecific story and incomplete workup [5]. It will be rare for us to have time and energy to make sure all the mental reasoning is correct. Hopefully educational awareness, interest and new funding will lead to more research and understanding of the world of diagnostic and cognitive errors.

We need to be cognizant of the dual process model of cognition that weaves throughout our day. We need to push ourselves to use rigorous, System 2 thinking when the answer is not clear. When your patient, recently returned from surgery, suffers from a falling blood pressure and is transferred to the ICU, we need to step back. Certainly internal bleeding may be the most obvious answer but have we considered a PE, MI, or a medication reaction as the diagnosis. "What else could this be? What other examination or tests do I need to do to sort out this problem?" Critical thinking occurs when we are aware of our biases, especially the anchoring bias, and force ourselves to reconsider the diagnosis when new information surfaces. Understanding cognition will lead us to safer, more effective care.

References

1. Kohn LT, Corrigan JM, Donaldson MS, editors. To err is human: building a safer health system. Washington, DC: The National Academies Press; 2000.
2. Berner ES, Graber ML. Overconfidence as a cause of diagnostic error in medicine. Am J Med. 2008;121(5 Suppl):S2–23.
3. Newman-Toker DE, Pronovost PJ. Diagnostic errors—the next frontier for patient safety. JAMA. 2009;301(10):1060–2. doi:10.1001/jama.2009.249.
4. Graber ML, Franklin N, Gordon R. Diagnostic error in internal medicine. Arch Intern Med. 2005;165(13):1493–9.
5. Groopman J. How doctors think. New York: Houghton Mifflin; 2007.
6. Graber ML, Gordon R, Franklin N. Reducing diagnostic error – what's the goal? Acad Med. 2002;77:981–92.
7. Kahneman D. Thinking, fast and slow. New York: Farrar, Straus and Giroux; 2011.
8. Sloman S. The empirical case for two systems of reasoning. Psychol Bull. 1996;119(1):3–22.
9. Lehrer J. How we decide. Boston: Houghton Mifflin Harcourt; 2009.
10. Croskerry P. Clinical cognition and diagnostic error: applications of a dual process model of reasoning. Adv Health Sci Educ Theory Pract. 2009;14 Suppl 1:27–35. doi:10.1007/s10459-009-9182-2.
11. Coderre S, Mandin H, Harasym PH, Fick GH. Diagnostic reasoning strategies and diagnostic success. Med Educ. 2003;37(8):695–703.
12. Stiegler MP, Neelankavil JP, Canales C, Dhillon A. Cognitive errors detected in anaesthesiology: a literature review and pilot study. Br J Anaesth. 2012;108(2):229–35. doi:10.1093/bja/aer387.
13. Croskerry P, Abbass A, Wu AW. Emotional influences in patient safety. J Patient Saf. 2010;6(4):199–205.
14. Croskerry P. The cognitive imperative: thinking about how we think. Acad Emerg Med. 2000;7:1223–31.
15. Gawande A. The checklist manifesto – how to get things right. New York: Metropolitan Books; 2009.
16. Kahol K, Smith M, Brandenberger J, Ashby A, Ferrara JJ. Impact of fatigue on neurophysiologic measures of surgical residents. J Am Coll Surg. 2011;213(1):29–34.
17. Gleitman H. Some trends in the study of cognition. In: Koch S, Leary DE, editors. A century of psychology as science. New York: McGraw-Hill; 1985. p. 420–36.
18. Crosskerry P. The importance of cognitive errors in diagnosis and strategies to minimize them. Acad Med. 2003;78(8):775–80.

Diagnostic Errors

4

E. Mark Hammerberg

Pitfalls and Pearls

- Diagnostic error occurs at a rate of 10–15 %.
- Diagnostic error is the most common reason for malpractice litigation, and it represents the most costly malpractice category.
- Diagnostic error results in a significant rate of preventable mortality.
- Most diagnostic error is attributable to a cognitive lapse on the part of the physician.
- The most common error is "premature closure," the decision to accept a diagnosis without considering other appropriate diagnoses.
- Most errors occur with "familiar" diagnoses.
- Appropriate follow-up allows for correction of diagnostic error.
- Diagnostic errors will remain undiscovered if physicians fail to consider alternatives.
- Diagnostic errors will remain undiscovered if there is no follow-up.
- Alert physicians can learn from their mistakes.
- A diagnostic "time-out" can be a routine prompt to ask whether the diagnosis in question makes sense or whether other diagnoses should be considered.

E.M. Hammerberg, MD
Department of Orthopaedics, Denver Health Medical Center,
777 Bannock Street, Denver, CO 80204, USA
e-mail: e.mark.hammerberg@dhha.org

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_4, © Springer-Verlag London 2014

Outline of the Problem

Diagnostic errors in medicine represent the next frontier for patient safety.

While the true rate of misdiagnosis in modern medicine remains uncertain, our best estimates suggest that the rate of diagnostic error has remained constant over time. When misdiagnosis results in obvious patient harm, prolonged hospital stay, multiple diagnostic tests, or overutilization of health care resources, then we are prompted to detect the cause and to attribute responsibility for diagnostic error appropriately. When a patient complains, or when a diagnosis results in a course of expensive treatment and/or testing, then the diagnosis in question seems to receive additional scrutiny by default. It is likely that many cases of diagnostic error do not result in permanent patient harm, and certainly many patients get better despite their physicians' lack of diagnostic skill. In such cases, it is likely that misdiagnosis will remain undetected. However, it is quite possible that many diagnostic errors remain undetected even when such errors contribute to real patient harm. This may happen, for example, when a patient is lost to follow-up. In the worst case scenario, diagnostic error will remain permanently concealed when a patient's death is explained by the wrong diagnosis.

It is difficult for any given physician to estimate his or her own rate of diagnostic error. When diagnostic error occurs, the physician in question is, by definition, unaware of it. So, it should come as no surprise that physicians are poor judges of their own performance. In fact, physicians' certainty regarding their own diagnoses has a poor correlation with diagnostic accuracy. Friedman et al. performed a study comparing the concordance between diagnostic certainty and diagnostic accuracy among faculty internists, senior residents, and medical students [1]. All participants generated a list of differential diagnoses from a standard set of clinical case scenarios, and they were questioned about their certainty regarding each diagnosis. Students tended to have a higher rate of agreement between confidence and accuracy, reflecting their general tendency for underconfidence to match their higher rate of diagnostic error. On the other hand, faculty internists demonstrated the highest rate of correct diagnoses, but the alignment between confidence and accuracy was relatively poor: 64 % [1].

Davis et al. performed a comprehensive meta-analysis of studies evaluating the accuracy of physician self-assessment [2]. While there is wide variation in study design and quality, most studies demonstrate that physicians have an inaccurate understanding of their own performance. In general, there tends to be a poor correlation between physician self-assessment and external objective measures of performance. Furthermore, those physicians who demonstrate poor performance scores tend to have the least accurate assessment of their own ability. It may come as no surprise that those physicians most in need of improvement are the least likely to recognize their own errors.

The baseline rate of diagnostic error tends to vary according to specialty. The rate of error for the so-called "perceptive fields" of radiology and pathology can be measured directly with over-reads of initial diagnoses and with chart review. With these specialties, it is easier to isolate the diagnostic episode (interpretation of an xray, reading of a histologic specimen, etc.) and to determine whether the original

diagnosis was correct. The rate of diagnostic error in these specialties tends to be around 5 % [3]. Clinical specialties, such as internal medicine, family practice, or emergency medicine tend to demonstrate a higher rate of diagnostic error. In these specialties, the process of diagnosis is not a self-contained discrete episode. Rather, the process of diagnosis runs concurrently with other processes of patient care, including data acquisition, ordering of tests, communication with patients, and provision of treatment. The rate of delayed diagnosis and misdiagnosis in clinical specialties as measured by chart review is approximately 10–15 % [3]. It is possible that a number of misdiagnoses remain undetected, such as when a patient is lost to follow-up or when an illness resolves spontaneously despite the wrong diagnosis.

In the worst case, when a diagnostic error results in a patient's death, the ultimate measure of this is autopsy. In a meta-analysis of multiple autopsy series spanning four decades, Shojania et al. demonstrate that the diagnostic error rate as reported in the English literature has tended to decrease over time [4]. This may reflect improvement in diagnostic accuracy, or it may reflect selection bias. In the United States, the autopsy rate has decreased considerably over the last half the twentieth century, from 40 % in the 1960s to less than 6 % in the 1990s [4]. So, it is possible that a number of lethal misdiagnoses remain undetected. Even so, modern autopsy series demonstrate a significant rate of diagnostic error. Shojania et al. estimate that major diagnoses remain undetected at least 8.4 % of the time, and nearly half of these misdiagnoses may represent class I error [4]. Class I error is defined as a major diagnostic error that results in or contributes to a preventable patient death.

Diagnostic error has obvious practical consequences for patients, and may result in irrevocable harm. Two recent reviews of the United States National Practitioner Data Bank demonstrate that diagnostic error is responsible for a significant proportion of medical malpractice claims [5, 6]. Compared to claims associated with other allegation categories, claims alleging errors in diagnosis are most common, and these claims account for the highest proportion of payments [6]. While claims originating in the outpatient setting are more frequent, claims originating in the inpatient setting are most likely to be related to more serious harm [6]. As diagnostic error tends to occur upstream in the delivery of healthcare, prior to any surgical or medical intervention, it tends to represent a common root cause of patient harm. Clearly, diagnostic error can be dangerous and expensive. To the degree that it can be prevented, diagnostic error it serves as an appropriate focus for those who seek to improve patient safety.

Limitations of the Current Practice

When diagnostic errors occur, the correct diagnosis is missed or delayed, or a decision is made to accept an incorrect diagnosis. When diagnostic errors are discovered, it is the responsibility of the physician not only to disclose the error to the patient and the patient's family, but the physician should make every effort to examine what went wrong. By reviewing each case, it may be possible to identify certain root causes that contribute to a diagnostic delay and misdiagnosis, and to prevent similar errors in the future. It is one thing to take responsibility for an error, but it is another thing to learn from an error and to identify regular lapses in the diagnostic

process that can be corrected. This is the goal of regular morbidity and mortality conferences and the aim of every quality assurance committee. Each case of diagnostic error may represent an opportunity for improvement, but this improvement is possible only if we take the time to dissect our errors.

In a landmark study, Graber et al. evaluated a series of 100 diagnostic errors collected from five tertiary medical centers [7]. They proposed a regular taxonomy whereby each case of diagnostic error could be described as belonging to one of three categories: no-fault errors, system related errors, or cognitive errors. No fault errors are errors that cannot be corrected, and these include cases of masked or atypical presentation of disease, or cases in which the patient is uncooperative or deliberately deceptive. System related errors are either technical or organizational. An example of a technical error would be a faulty laboratory reading due to faulty instrument calibration. An example of an organizational error would be an error in communication such that consultations are not completed as expected or laboratory results or not provided in a timely fashion. Cognitive errors are divided into three types: faulty knowledge, faulty data gathering, or faulty synthesis. Using this taxonomy, diagnostic errors can be classified according to etiology, and common or recurring problems can be identified.

From this study, it appears that most cases of diagnostic error have a multifactorial etiology, including a combination of systemic and cognitive errors. While system-related error occurs in a majority of cases, cognitive error is most often present. When a system error is identified, it is most often a form of organizational error, such as poor communication between providers or poor communication of test results. Cognitive error was identified in 74 % of cases, often combined with system errors, and sometimes found in isolation. Further analysis of cognitive errors demonstrates that most errors do not result from poor data gathering or knowledge deficits. Rather, most cognitive error is described as an error in synthesis of data, or an error in clinical reasoning. The most common flaw identified is described as "premature closure," or the decision to accept a diagnosis too early, without giving sufficient attention to other competing diagnoses [7].

Another study evaluating the occurrence of diagnostic error provides slightly different results. Schiff et al. evaluated the causes of diagnostic error for a series of 669 self-reported cases [8]. These authors used a different taxonomy system, classifying errors in a somewhat chronological fashion, according to the time they occur in the diagnostic process. Errors can occur at any point along the diagnostic timeline: presentation, history, physical exam, testing (laboratory or radiological), assessment, referral/consultation, and follow-up. Using this methodology, Schiff et al. conclude that most errors (44 %) occur during the testing phase of the diagnostic work-up, while errors in clinician assessment (32 %) are the second most-common cause of diagnostic error [8]. These results tend to downplay the role of cognitive error, such as failure to synthesize data, or failure to consider the correct diagnosis. But it is clear that much of the testing phase requires appropriate physician assessment skills. Indeed, of all the failures in the testing phase recorded by Schiff et al., many are attributable to some cognitive error on the part of the physician: from failure to order the correct tests to failure to interpret tests correctly. From this, it is clear that testing and assessment errors are difficult to separate. In clinical practice, testing and assessment occur simultaneously, with each process informed by the other. So, it is likely that an error in one process will contribute to an error in the other.

In a study of adverse events resulting from misdiagnosis, Zwaan et al. evaluated the causes of diagnostic error according to the Eindhoven classification: human, organizational, technical, patient related, or other. In nearly all cases (96.3 %), human error was identified as the chief cause of the adverse event [9]. Specifically, lack of knowledge was identified as the predominant cause of diagnostic error, and several knowledge-based lapses were identified. Physicians either lacked appropriate knowledge to form the right diagnosis, or they failed to use their knowledge correctly.

In a separate study, the same authors evaluated the rate of cognitive error as determined by so-called "suboptimal cognitive acts" or SCAs, using a retrospective chart review [10]. They found that not all cognitive errors result in an adverse event, but errors do occur at a surprising rate. SCAs were present in 66 % of all patient records, with an average of 2.3 SCAs per record. Not all error results in patient harm, but each "suboptimal cognitive act" appears to have a cumulative effect. Not surprisingly, adverse events can be predicted by a higher SCA count [10]. Like Schiff et al., Zwaan et al. found that most cognitive lapses tend to occur during the data gathering stage of the diagnostic process. This stage includes history taking and the ordering of laboratory and radiological studies. As data gathering occurs early in the diagnostic process, errors at this stage may delay the correct diagnosis. If they remain undetected, errors in data gathering may be compounded by other errors of clinical reasoning, and misdiagnosis will be the result.

In order to clarify the cognitive processes underlying diagnostic error, a fair amount of consideration has been given to the mechanics of the general clinical reasoning process. In particular, the "dual process" model of cognition has been used to describe the typical elements of thought that characterize the act of making a diagnosis [11, 12]. According to this model, there are two processes at work during every diagnostic decision. Type 1 processes are fast, intuitive, and instinctual. Type 1 decisions are based on pattern recognition and previous experience. Such decisions are made instantaneously, unconsciously, without deliberation. Immediate perception and intuition dominate over reasoned thought. An example of a Type 1 decision would be slamming on the brake to avoid running over a toddler that has run in front of one's car. This is not so much a decision as a reflex. Type 2 processes, on the other hand, are slow, deliberate, and informed by rational thought. Type 2 decisions allow for reflection and consideration of multiple data elements. An example of a Type 2 decision would be the decision one makes regarding how best to get from point A to point B. This decision can be determined after reading a map, considering the time of day, and consulting an expert on typical traffic patterns during rush-hour. Most decisions involve a combination of Type 1 and Type 2 processes, but certain decisions are dominated by one process or the other.

Depending on the clinical scenario, it is easy to imagine how one type of thought process may tend to dominate diagnostic decisions. To the degree that a case presents a classic combination of signs and symptoms, and to the degree that a physician is familiar with the disease in question, a successful diagnosis may result from simple pattern recognition, without the need for further testing or consultation. In this scenario, Type 1 processes appear to dominate. On the other hand, if a case presents an unfamiliar collection of signs and symptoms, or if a physician has little experience with the disease in question, then the correct diagnosis is not easily recognized.

Further deliberation, including additional testing, and consultation with other physicians may be required before the correct diagnosis can be identified. In this scenario, the diagnostic work up is shaped mainly by Type 2 thought processes. It has been suggested that Type 2 processes tend to be engaged whenever a physician is unfamiliar or uncomfortable with the disease process at hand. But if the same disease is encountered multiple times, repetition of similar Type 2 processes should result in increased familiarity with the disease, such that the disease is more easily recognized upon subsequent encounters. In this way, Type 2 processes seem to be replaced by Type 1 processes as physicians become more expert with a particular diagnosis [11].

A successful clinical practice depends upon a physician's ability to recognize routine cases and to make diagnoses efficiently, without undue delay or unnecessary testing. As physicians are called upon to evaluate more and more patients, they will have less time to deliberate and less time to consider multiple competing diagnoses. Now as ever, a physician's intuition is essential for success. Insofar as the diagnostic endeavor tends to become more of a Type 1 thought process, a physician will tend to rely on mental shortcuts and rules of thumb in order to make successful diagnoses. These rules of thumb are alternately described as heuristics or biases [12–14]. A heuristic is understood as a mental shortcut that allows one to arrive at a plausible answer quickly without an extended search for all possible alternatives. A bias indicates a tendency to favor a preferred answer over other potential but less familiar alternatives. While clinical rules of thumb are used frequently to provide accurate diagnoses, their efficiency comes with a potential price. Each rule of thumb cannot consider every possible alternative, so they are prone to error if they are used unwittingly.

Most of the time, when heuristics are used successfully, physicians are likely unaware of the particular mental shortcut they are using (Box 4.1). But if physicians are to be aware of the potential error associated with these tools, then they should be familiar with a number of common diagnostic heuristics and biases [12–14].

Box 4.1. Common Heuristic Pitfalls Leading to Diagnostic Errors

- *Availability:* The tendency for physicians to favor a diagnosis if it comes readily to mind.
- *Representativeness:* The tendency to promote a diagnosis based on the prototypical manifestation of a disease, disregarding the potential for atypical presentations.
- *Base rate neglect:* The tendency of physicians to ignore the true prevalence of a disease in order to support or entertain a rare or exotic diagnosis.
- *Anchoring:* The tendency of physicians to prefer their initial hypotheses despite contradictory information that appears later in the diagnostic process.
- *Premature closure:* The tendency of physicians to accept a diagnosis before other possibilities have been considered.
- *Confirmation bias:* This describes the tendency of physicians to seek and accept evidence that confirms rather than refutes the initial hypothesis.
- *Search satisfying:* This describes the universal tendency to call off a diagnostic search as soon as a single positive finding has been obtained.

Errors are more likely to occur when the diagnostic process is shaped more by intuition than by careful analytic thought [11, 13]. It seems plausible that most misdiagnoses represent a hasty decision made without adequate deliberation. This type of error appears to result when physicians have an unwarranted confidence in their diagnostic abilities [3, 11]. An overconfident physician is more likely to accept an initial incorrect diagnosis and to ignore important contradictory evidence. The problem is a lack of familiarity with the diagnosis in question. If this type of error is to be avoided, physicians should be encouraged to consider multiple alternate diagnoses rather than accepting the first diagnosis that comes to mind. In other words, error is reduced when Type 1 processes are replaced by Type 2 processes [11].

Still, it should be recognized that Type 2 processes are not necessarily free from error [12]. Heuristics have a proven efficacy in the clinical setting because they produce a correct diagnosis most of the time. When the initial intuitive hypothesis leads to the correct diagnosis, there is a danger that continued deliberation will lead away from it [3]. Furthermore, if the correct diagnosis has been reached, continued diagnostic testing for the purposes of diagnostic confirmation might be unnecessary and expensive. In the worst case scenario, an additional test may expose the patient to an unnecessary procedure and potential harm. In order to minimize diagnostic error, therefore, physicians must learn when they should trust their intuition. At the same time, physicians need to be aware of the mental shortcuts they may be taking. With continued experience, physicians should develop an awareness of potential errors and flaws associated with each diagnosis, and they should learn when additional analysis is required.

Where Is the "Golden Bullet"?

Perhaps the first step in reducing error is the recognition that the possibility for diagnostic error exists. With each new diagnosis, a physician should be encouraged to pause and reflect, asking whether the diagnosis is correct or whether other diagnoses deserve further consideration. This process is described as metacognition, or "thinking about thinking" [3, 13]. If physicians are encouraged to cultivate a heightened awareness of their thought processes, if they are aware of common biases and when they are most likely to be present, then they might be in a better position to detect and prevent errors in diagnosis [14]. If physicians perform this form of diagnostic introspection on a regular basis, it should become a habit rather than an exception to the rule. This process need not contribute to unnecessary diagnostic delay. If practiced regularly, this type of quality control can be performed quickly in real-time, preventing misdiagnosis before it occurs.

Croskerry has developed a process to reduce common diagnostic errors through the application of what he has termed "cognitive forcing strategies" [15]. For each diagnosis or set of symptoms, a diagnostic forcing strategy prompts the physician to look for alternative or additional diagnostic possibilities. In this way, every conclusion prompts an appropriate set of questions. Depending on a physician's particular practice, a familiar set of pitfalls could be generated to accompany each frequently encountered diagnosis. As an example, Croskerry cites the potential for sepsis

developing unexpectedly after an animal bite. This could happen if a physician had failed to obtain the history of a previous splenectomy. With this pitfall in mind, a cognitive forcing strategy could be designed to prompt physicians to rule out a history of immunocompromise whenever an animal bite is encountered.

An example of a general cognitive forcing strategy is the practice of "prospective hindsight" [3]. Using this method, clinicians are encouraged to imagine that their diagnosis is proven to be wrong at some point in the future, thus prompting the consideration of other diagnostic possibilities. The common advice to "always consider the opposite," is another example of a cognitive forcing strategy, reminding physicians that tests to rule out competing diagnoses may be more useful than tests intended to confirm the working diagnosis. Similarly, it may be useful for physicians to consider and rule-out the most dangerous potential diagnosis for any given set of signs and symptoms. This exercise is intended to prevent a physician from accepting a more benign, but incorrect, diagnosis [3]. If general cognitive forcing strategies are used routinely, physicians should become more comfortable with the notion that their initial diagnostic impressions may be wrong. If physicians can train themselves to avoid overconfidence, then alternate diagnoses may be more readily accepted when appropriate.

Even if physicians can be convinced to challenge their original hypotheses with every clinical case, no amount of deliberation will matter if physicians fail to consider the correct diagnosis as one of the many possible diagnoses under consideration. In the case of a rare diagnosis or in the case of an atypical presentation, even experienced physicians may fail to include the correct diagnosis in their differential. According to Zwaan et al., knowledge-based lapses represent the most common root cause behind diagnostic failure [9]. With this in mind, a number of computerized diagnostic support tools have been developed to help physicians generate an appropriate list of differential diagnoses, according to presenting signs, symptoms, and clinical history. These software programs have been available for nearly two decades, but they have not become a part of routine clinical practice [3].

In a busy clinical setting, physicians may experience pressure to consider the first two or three diagnoses that come to mind, and they may feel that there is insufficient time to pause and generate an expanded list of alternative hypotheses. If a computerized diagnostic aid is to be of value, it must be practical in a busy setting. It is unlikely that busy physicians will embrace a tool that requires a significant amount of time for data entry. Physicians may not find these differential diagnosis generators helpful if they suggest too many possible alternatives without ranking their relative probability. Or, physicians may feel that they do not need this type of support. Whatever the reason, physicians have not embraced this technology.

A recent review demonstrates that several modern diagnostic support systems are available, and they may be helpful in the clinical setting [16]. While most systems require manual data entry, some systems are available that can integrate with electronic medical record systems. As this type of software continues to evolve, and as electronic medical record keeping becomes more prevalent, is possible that physicians will grow to accept computerized diagnostic support as a standard part of the diagnostic process. For the time being, the success of failure of these systems to reduce diagnostic error in the clinical arena remains untested.

If physicians remain unaware of their own diagnostic errors, they cannot correct them. If a patient is lost to follow-up, then there is no way for a physician to know whether the diagnosis is correct. Arranging a timely follow-up visit is a powerful mechanism to reduce the rate of diagnostic error and to correct it when it occurs [17]. Timely follow-up allows the physician to monitor the progress of treatment and to re-evaluate the accuracy of the original diagnosis. Standard follow-up visits can be seen as automatic reminders for physicians to reconsider all the elements of the diagnostic work-up. Since the time of the previous visit, have new elements of the history come to light? If tests have been ordered, have they been completed, and what are the results? If consultation with a specialist has been requested, do recommendations agree with the original hypothesis, or is further work-up required? If treatment has been started, how has the patient responded? Does the patient's response, or lack thereof, fit within the expected pattern of the working diagnosis, or should another diagnosis be considered? If timely follow-up is successful, physicians can optimize the treatment for a correct diagnosis, or they can alter or change the diagnosis when appropriate.

During follow-up, if the original hypothesis is determined to be wrong, this need not threaten the doctor-patient relationship. When a physician determines that an original diagnosis should be modified or changed entirely, it should be understood as an example of diagnostic success, not as evidence of failure. Much of the perception of diagnostic accuracy can be shaped by the expectations that patients are given at the time of the initial clinical encounter. A confident physician should have no difficulty expressing diagnostic uncertainly. If a presumptive diagnosis is explained as a hypothesis that needs testing, then patients will not be surprised if the diagnosis changes over time during the course of follow-up. Original treatment recommendations can be seen as a form of diagnostic test that either corroborates or challenges the initial hypothesis. Understood in this way, a missed or delayed diagnosis becomes a diagnosis that takes time to figure out [18]. But this process cannot occur if follow-up does not happen. And follow-up cannot be successful if a physician blindly accepts the original diagnosis and fails to challenge it regularly.

Obviously, some diagnoses do not allow for lengthy follow-up: stroke, myocardial infarction, etc. And many given scenarios will suggest pathology that needs be ruled-out or treated in real time. But, as clinicians progress from the most dangerous diagnosis (myocardial infarction) to the least dangerous (heartburn), they will do well to consider the formation of a diagnosis not as an isolated act but as a process in time. Even when pressed for time, a physician should be prepared to suggest a diagnosis and almost instantaneously challenge it. If "premature closure" is one of the most common biases leading to diagnostic error, then physicians might be challenged to "never close a case." With this in mind, any given diagnosis might be understood not as answer but as a set of questions.

Given the success of checklists to improve the safety in other areas of healthcare delivery, for example in the operating room, it is not surprising that checklists have been suggested as a potential tool to reduce the rate of errors in diagnosis. Ely et al. have suggested a comprehensive set of checklists that should serve to reduce diagnostic error if they are used in a regular fashion [19]. They have

proposed a set of three different types of checklist. One set of checklists is used to generate a stratified list of differential diagnoses according to the chief complaint. Another set of checklists is used to direct case-specific cognitive forcing strategies, with sets of "must not miss" questions for each diagnosis under consideration. Even in a busy clinical setting, these checklists can be used to organize the work-up such that all relevant diagnoses are considered, including rare variants or atypical cases.

The most important checklist, the so-called "general checklist," helps to organize the diagnostic work-up such that important steps are not missed [19]. This general checklist includes apparently mundane instructions, such as "perform your own history and physical" that may seem obvious to most practitioners. While it might not seem necessary to consult a checklist to ensure completion of the most basic steps of the diagnostic process, the authors are quick to point out that checklists are most useful in routine settings. When a case poses a difficult and conspicuous diagnostic challenge, physicians may be trusted to pay particular attention and to make sure that all appropriate measures are taken to reach a workable diagnosis. However, it is when a diagnosis seems simple or familiar that physicians are most likely to make a diagnostic error. This is when a diagnostic checklist will be of most value.

Regardless of presentation, the generic checklist includes two additional instructions that remind physician to give the diagnosis additional scrutiny. One instruction reminds the physician to take a "diagnostic time out" before settling on a final diagnosis. This prompts the physician to start the metacognitive process of challenging the diagnosis in question. Treatment is not initiated immediately, but only after sufficient consideration has been given to alternative competing hypotheses. The last instruction of the generic checklist reminds the physician to arrange appropriate and timely follow-up. In this way, treatment is not administered in a context blind to outcome. Rather, even as treatment is initiated, a plan is set in place to observe the patient over time, so physicians can ensure that a treatment is completed according to recommendations. Follow-up allows closure of the diagnostic loop, for it is only after appropriate follow-up that we can know whether the diagnosis is correct or not.

If physicians are to reduce their rate of diagnostic error, they must be aware of it when it occurs. The first step is to acknowledge that the possibility of diagnostic error exists, and that there is a risk of error with each new diagnosis. While this serves as a prompt to consider alternate hypothesis at the time of initial presentation, it also serves as a challenge to reconsider the diagnosis at each follow-up visit. If the original diagnosis is found to be erroneous or incomplete, it serves not only to improve the care of the patient, but it also serves as a poignant piece of education for the physician. When discovered, each error is no mere thought experiment considering what might go wrong. Rather, it is a practical example of what has gone wrong. If physicians make an effort to be alert to their own errors, then they will have a chance to learn from them and to prevent them in the future. If follow-up does not occur or if the original diagnosis remains unchallenged, then the rate of diagnostic error may remain unchanged.

Take-Home Message

- Every physician should be aware of his or her own potential for diagnostic error.
- Diagnostic error is most likely to occur in seemingly familiar settings, dealing with "common" diagnoses.
- Always perform a diagnostic "time-out" to step back and scrutinize the diagnostic process.
- Be aware of common pitfalls of diagnostic reasoning, and develop a regular series of "cognitive forcing strategies" to prevent them.
- Always ask: "What else might this be?"
- Always ask: "What diagnoses can I not afford to miss?"
- Checklists are useful, especially with common presentations, and they can be used to make sure that no important element of the diagnostic work-up has been overlooked.
- Always ensure appropriate and timely follow-up.
- Keep an open mind, and never "close" a case prematurely.

References

1. Friedman CP, Gatti GG, Franz TM, Murphy GC, Wolf FW, Heckerling PS, Fine PL, Miller TM, Elstein AS. Do physicians know when their diagnoses are correct? J Gen Intern Med. 2005;20:334–9.
2. Davis DA, Mazmanian PE, Fordis M, Harrison RV, Thorpe KE, Perrier L. Accuracy of physician self-assessment compared with observed measures of competence: a systematic review. JAMA. 2006;296(9):1094–102.
3. Berner ES, Graber ML. Overconfidence as a cause of diagnostic error in medicine. Am J Med. 2008;121 Suppl 5:S2–23.
4. Shojania KG, Burton EC, McDonald KM, Goldman L. Changes in autopsy-detected diagnostic errors over time: a systematic review. JAMA. 2003;289(21):2849–56.
5. Bishop TF, Ryan AM, Casalino LP. Paid malpractice claims for adverse events in inpatient and outpatient settings. JAMA. 2011;305(23):2427–31.
6. Saber Tehrani AS, Lee H, Matthews SC, Shore A, Makery MA, Provnost PJ, Newman-Toker DE. 25-year summary of US malpractice claims for diagnostic errors 1986–2010: an analysis from the National Practitioner Data Bank. BMJ Qual Saf. 2013;22(8):672–80.
7. Graber ML, Franklin N, Gordon R. Diagnostic error in internal medicine. Arch Intern Med. 2005;165(13):1493–9.
8. Schiff GD, Hasan O, Kim S, Abrams R, Cosby K, Lambert BL, Elstein AS, Hasler S, Kabongo ML, Krosnjar N, Odwazny R, Wisniewski MF, McNutt RA. Diagnostic error in medicine: analysis of 583 physician-reported errors. Arch Intern Med. 2009;169(20):1881–7.
9. Zwaan L, de Bruijne M, Wagner C, Thijs A, Smits M, van der Wal G, Timmermans DR. Patient record review of the incidence, consequences, and causes of diagnostic adverse events. Arch Intern Med. 2010;170(12):1015–21.
10. Zwaan L, Thijs A, Wagner C, van der Wal G, Timmermans DR. Relating faults in diagnostic reasoning with diagnostic errors and patient harm. Acad Med. 2012;87(2):149–56.
11. Croskerry P. Clinical cognition and diagnostic error: applications of a dual process model of reasoning. Adv Health Sci Educ Theory Pract. 2009;14:27–35.

12. Norman G. Dual processing and diagnostic errors. Adv Health Sci Educ Theory Pract. 2009;14:37–49.
13. Rajkomar A, Dhaliwal G. Improving diagnostic reasoning to improve patient safety. Perm J. 2011;15(3):68–73.
14. Croskerry P. The importance of cognitive errors in diagnosis and strategies to minimize them. Acad Med. 2003;78(8):775–80.
15. Croskerry P. Cognitive forcing strategies in clinical decision making. Ann Emerg Med. 2003;41(1):110–20.
16. Bond WF, Schwartz LM, Weaver KR, Levick D, Giuliano M, Graber ML. Differential diagnosis generators: an evaluation of currently available computer programs. J Gen Intern Med. 2011;27(2):213–19.
17. Schiff GD. Minimizing diagnostic error: the importance of follow-up and feedback. Am J Med. 2008;121 Suppl 5:S38–42.
18. Redelmeier DA. The cognitive psychology of missed diagnoses. Ann Intern Med. 2005;142:115–20.
19. Ely JW, Graber ML, Croskerry P. Checklists to reduce diagnostic errors. Acad Med. 2011;86(3):307–13.

Technical Errors

5

David J. Hak

Pitfalls and Pearls

- Technical errors are a common cause of surgical adverse events.
- Technical errors include direct manual errors, errors in judgment, and errors due to lack of knowledge.
- Lack of specialization or expertise in a particular procedure, low volume, communication breakdown, and physician fatigue can contribute to technical errors.
- The increasing complexity of advanced technologies may increase the risk for technical error for surgeons who are unfamiliar with the nuances of the new technology.
- Technical errors, which reflect on the surgeons skill and self-concept, may not always be readily disclosed or reported.
- Recommended preventative strategies include designing targeted interventions to improve decision making and performance during routine operations in high-risk situations such as emergencies, reoperations, or patients with unusually difficult anatomy.

Outline of the Problem

A surgeon's level of technical skill is an important part of their persona. Unlike other medical specialties that rely solely on cognitive activities, surgery requires an additional skill set that focuses on manual dexterity and eye-hand coordination.

D.J. Hak, MD, MBA, FACS
Department of Orthopaedics, Denver Health Medical Center,
777 Bannock St., MC 0188, Denver, CO 80204, USA
e-mail: david.hak@dhha.org

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_5, © Springer-Verlag London 2014

Individuals drawn to surgery invariably have a strong sense of technical expertise. They know that they have a "good set of hands." Few surgeons would admit to having average surgical skills, much less lower than average technical skills, yet such universally superior surgical skills can only exist in places such as Garrison Keillor's fictional town of Lake Wobegon, where all the children are above average [1].

Technical errors include direct manual errors, errors in judgment, and errors due to lack of knowledge. Adverse operative outcomes due to technical errors have been commonly defined by traditional morbidity and mortality conferences as, "Technical and therefore preventable." Such errors strike directly upon the surgeon's sense of self-worth and can be particularly difficult and demoralizing for the surgeon to address.

A number of different factors can contribute to technical errors. Some factors include the lack of specialization or expertise in a particular procedure [2, 3], low surgeon volume [3], low hospital volume [4, 5], communication breakdown [6], and physician fatigue [7].

Limitations of the Current Practice

Technical Errors in Surgery

Most surgical errors occur in the operating room and are most commonly technical in nature. The incidence and types of adverse events and negligent care was examined in a study that randomly sampled 5,000 discharges in Utah and 10,000 discharges in Colorado during the calendar year 1992 [8]. Adverse events were defined as an injury caused by medical management that resulted in a prolonged stay or disability at discharge. Technical errors caused by poor surgical techniques accounted for 30 % of the identified surgical adverse events, and were the most common type of surgical adverse event. Negligence was identified in 23.6 % of these technical adverse events.

Regenbogen and colleagues reviewed 444 surgical malpractice claims and identified 140 discrete technical errors that occurred in 133 of the cases [9]. These technical errors occurred in a wide range of specialties, most commonly occurring in general or gastrointestinal surgery (31 %). Other specialties included spine surgery (15 %), gynecologic surgery (12 %), a non-spine orthopedic surgery (9 %), cardiothoracic surgery (8 %), otolaryngology (7 %), plastic surgery (5 %), urology (4 %), non-spine neurosurgery (4 %), ophthalmology (3 %), vascular surgery (2 %), and oral and maxillofacial surgery (1 %). These errors resulted in 22 deaths, 68 cases of permanent disability, 28 cases of temporary major disability, and 22 cases of temporary minor disability.

In their analysis, they examined the patterns of technical errors and identified that a manual error occurred in 91 % of cases. These included incidental injury to viscera or other anatomic structure, breakdown of repair or failure to relieve the condition, hemorrhage, peripheral nerve injury, misplacement or improper choice of prosthesis, and retained surgical equipment. In addition they identified judgment or knowledge errors in 35 % of cases. These included delay or error in intraoperative diagnosis and/or treatment, incorrect procedure or technique, wrong site surgery, and failure to change the operative plan in light of contraindication or

intraoperative findings. Nine percent of cases involved a knowledge/judgment error alone, while 26 % involved both a manual error and a knowledge/judgment error.

Contributing complicating factors were identified in 69 % of these technical errors. A patient related factor was identified in 61 % of cases. These included difficult or unusual anatomy or operative findings, reoperation, urgent/emergent operations, and medical comorbidities. A human or systems factor was identified in 21 % of cases. These included equipment use problems, ambiguity of responsibility, and handoff of care issues.

Case Examples

Intramedullary nails used for fracture repair are commonly interlocked with screws that pass through holes in the nail. These screws maintain the bone length and rotation during healing. An outrigger jig attached to the intramedullary nail insertion handle is used for screw placement at one end of the nail. A series of sleeves inserted into this outrigger jig directs the passage of both the drill bits and screws. This allows simple and efficient screw insertion compared to the more complicated free-hand method used for the opposite end of the nail. While use of the insertion guide in generally accurate, it is possible for the screws to miss the nail anteriorly or posteriorly. Potential causes for this technical error include a outrigger jig that is not fully tightened to the nail, damage to the outrigger jig, or the surgeon may inadvertently lever the drill bit such that he/she causes the drill to be directed anterior or posterior to its intended path. Failure to confirm that the screws are correctly inserted into the nail with intra-operative fluoroscopy can lead to fracture displacement that may require revision surgery (Fig. 5.1).

Technical errors can also result from judgment errors made by the surgeon. Because of the high forces acting on the forearm, relatively rigid dynamic compression plates are required for fracture treatment. More malleable plates, known as reconstruction plates, are available for other purposes where the forces are not as great. They are not indicated for use in treatment of forearm fractures. Using a more malleable plate for fixation of a forearm fracture would be an example of a judgment error leading to a technical complication (Fig. 5.2).

Technical Errors Related to Advanced Technology

Technology used in surgery is becoming increasingly complex. While in some cases these advances may reduce the risk of technical error, in other cases unfamiliarity or confusion with the new and ever expanding technologic devices may increase the risk for technical error.

The introduction of laparoscopic surgery was a revolutionary change in surgical technology [10]. Along with clear advantages, this technology also brought a series of new technical errors [11, 12]. The rate of common bile duct injury increased shortly after the introduction of laparoscopic cholecystectomy. These injuries were also more commonly reported early in the surgeon's laparoscopic experience [13].

Robotic surgical systems are increasingly being used for general surgical, cardiothoracic, and urologic procedures [14]. Since most facilities will only have one

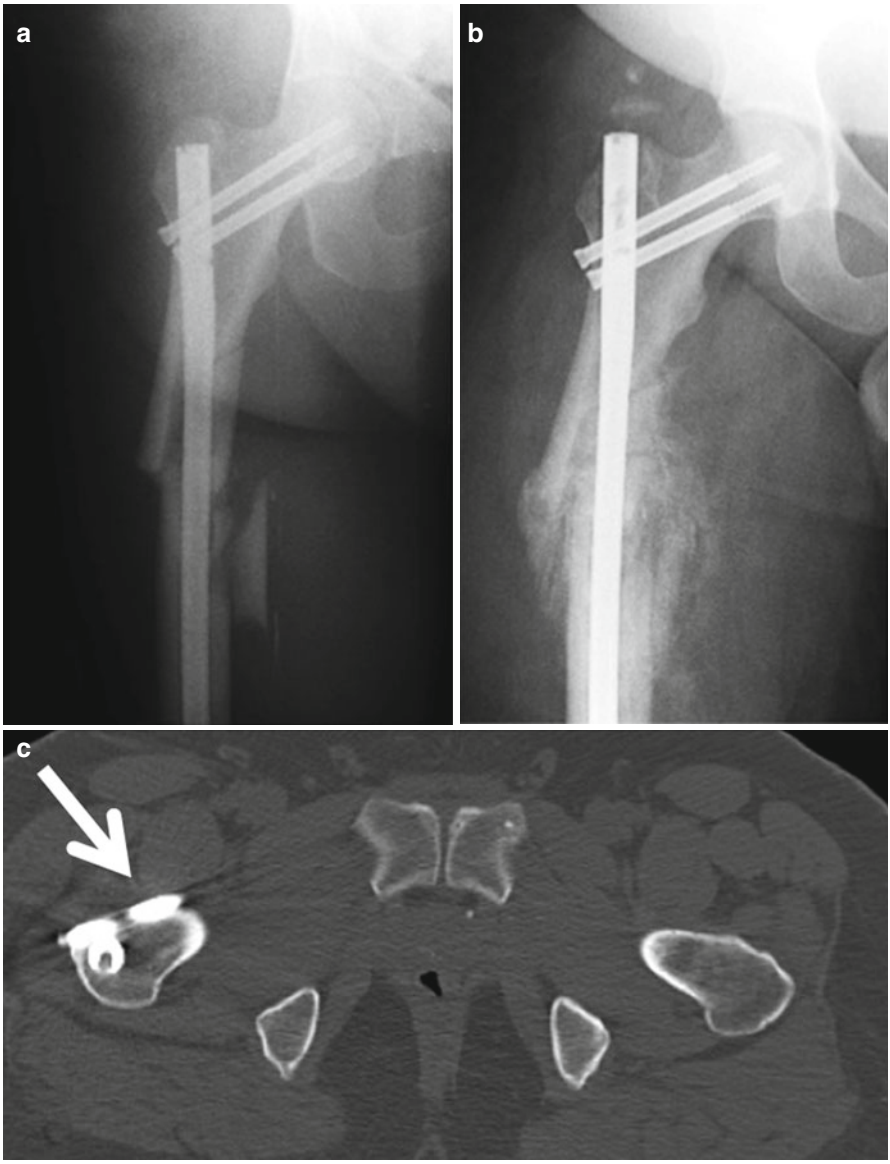


Fig. 5.1 This morbidly obese man sustained a femoral shaft fracture as a result of a motor vehicle accident. He was treated by intramedullary nailing using a cephalomedullary reconstruction nail. Immediate postoperative radiograph shows acceptable fracture reduction in slight varus position (**a**). Radiographs taken at 8 weeks post-operatively show fracture shortening and increased varus angulation (**b**). Not visualized is a clinical increase in rotational deformity. Note the changed position of the two interlocking screws with respect to the proximal end of the nail compared to the immediate post-operative position. Neither screw was correctly placed through the holes in the intramedullary nail leading to fracture shortening, angulation, and malrotation that required additional corrective surgery. Computed tomography scan (**c**) showing the interlocking screw anterior to rather than through the intramedullary nail (*arrow*)

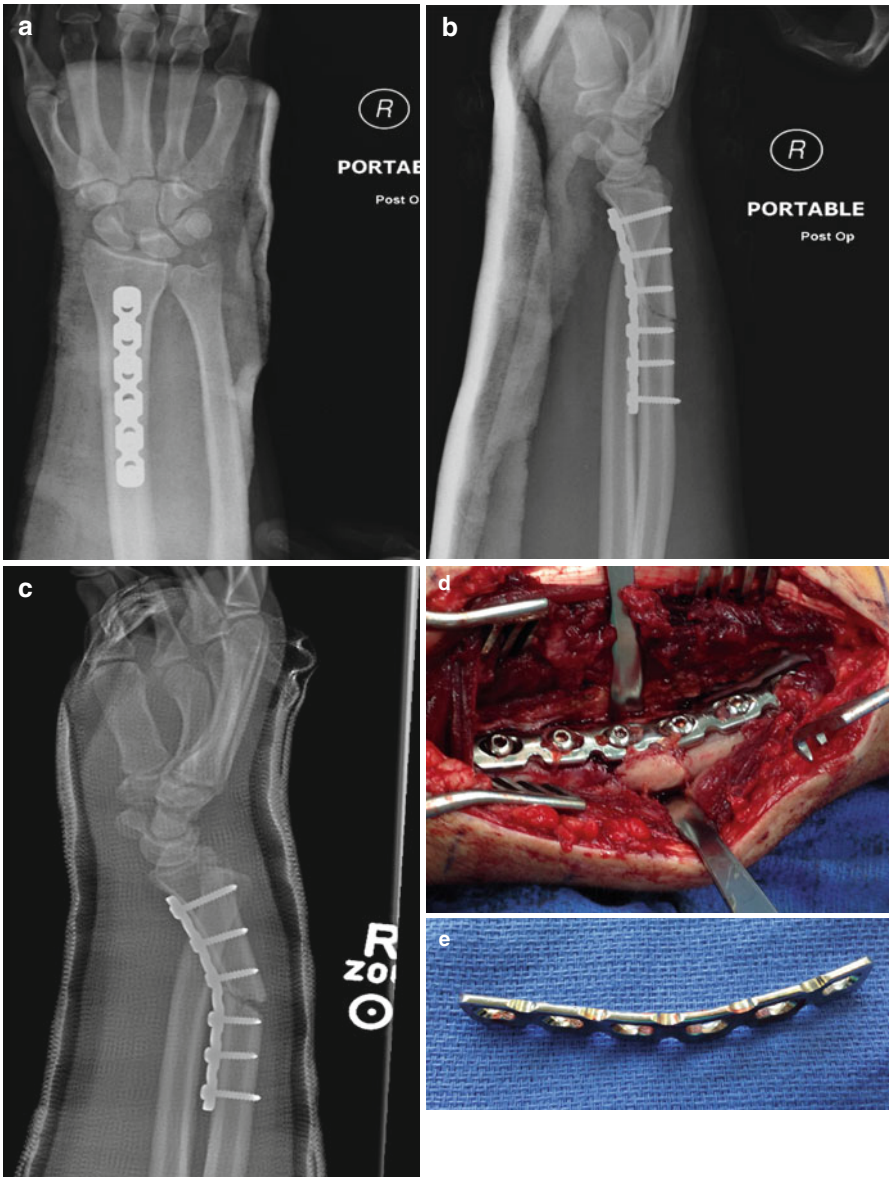


Fig. 5.2 This radial shaft fracture was treated by open reduction and internal fixation, however the surgeon made a judgment error in using a malleable reconstruction plate that was not sufficiently rigid to resist the muscular forces acting on the forearm. (**a**) Anteroposterior post-operative radiograph. (**b**) Lateral postoperative radiograph. (**c**) At 2 weeks post-operatively, the plate has bent and the fracture has angulated despite being protected in a cast. (**d**) The patient had to undergo an unneeded 2nd revision surgery for removal of the reconstruction plate and revision fixation with a more appropriate compression plate. (**e**) Photograph of the deformed reconstruction plate

of these costly systems, system failure may require surgeons to abort the planned surgical procedure. In a review of 725 robot-assisted laparoscopic radical prostatectomies, robotic system failure that lead to case abortion occurred in only four cases (0.5 %), while other reports have cited a 2–5 % system failure rate [15–17]. In order to avoid surgical cancelation and unnecessary anesthesia, the system should be completely set up and its operational status confirmed prior to bringing the patient into the operating room [15, 18].

In another review of the da Vinci S robotic system (Intuitive Surgical Sunnyvale, CA, USA), authors reported a 10.9 % overall device failure rate during 340 consecutive robot-assisted urologic operations [18]. The most frequent technical problems were related to the robotic instruments and included broken tension wires, wires dislodged in the working pulleys, non-recognition of the instruments, locked instruments, and limited range of movement. Most of the problems, 76 %, were successfully corrected or overcome during the course of the surgery but required additional surgical time. Technical problems requiring conversion to standard open or laparoscopic procedure was required in only two cases.

Zorn and colleagues reported only a 0.4 % rate of technical errors resulting in their series of 725 robot-assisted laparoscopic radical prostatectomies [15]. In two cases this was a camera problem that resulted in a loss of 3-D vision and one case in which there was a robotic arm failure. Despite these problems the surgeon was able to complete the operation, although with difficulty.

The introduction of any new technology invariably results in a learning curve as surgeons become increasingly adept with the technology [10, 19]. New technology also creates training and credentialing challenges [10, 20]. Education and training must be offered to ensure that users are proficient in the standard skills and procedural tasks of the new technology. Additional credentialing may be required, either through an independent agency or through the hospital to ensure patient safety.

Technical Errors Related to Time Constraints

The increasing time and cost constraints placed on physicians have been identified as increasing the risk for technical errors. In a report that identified three cases in which angled drill guides were inadvertently retained following locked plating of wrist fractures, the authors indicated that this error could have been prevented by making a postoperative radiograph prior to leaving the operating room. They note that, “This practice has become rare as operating room has become tighter and cost-control pressures on surgeons have increased” [21]. Prior teaching emphasized the importance of obtaining any necessary radiographs in the operating prior to the leaving in order to ensure that the outcome was satisfactory. Radiographs obtained in the recovery room have been referred to as “Discovery Room radiographs,” to emphasize the potential for discovering an unexpected finding which may necessitate returning the patient to the operating room for additional surgical intervention.

Where Is the "Golden Bullet"?

Reporting of Technical Errors

While complication rates are often reported in published studies, there are few detailed reports that describe technical complications in the literature. Most frequently these take the form of a case report that details the subsequent treatment of a patient whose technical complication occurred at the proverbial "Saint Elsewhere Hospital" [22]. Far less frequent are reports written by surgeons at the institution where the technical error occurred [21]. Even the reporting of complications are inconsistently presented in the surgical literature [23].

There are a number of factors that hinder the reporting of complications, including medicolegal concerns, incomplete records, multiple sites of postoperative care, and worry over public disclosure of data [23]. There is also a natural reluctance for surgeons to publicly highlight their technical mistakes for their peers to view.

Strategies for Preventing Technical Errors

Based on their findings that almost 75 % of technical errors involved fully trained and experienced surgeons operating within their area of expertise, and that 84 % occurred in routine operations, Regenbogen and colleagues recommended that future preventative strategies focus on designing targeted interventions to improve decision making and performance during routine operations in high-risk situations such as emergencies, reoperations, or patients with unusually difficult anatomy [9].

A study among senior medical students has shown that instruction that included examples of common errors, when combined with instruction showing the correct technique, enhanced the acquisition of knot tying, albeit a relatively simplistic technical task [24]. Similar methods showing common errors could be used in simulation labs for teaching more complex technical skills.

Take-Home Message

Surgical adverse outcomes are commonly caused by technical errors, including direct manual errors and errors in judgment. Because such errors reflect on the surgeon's skill and self-concept, they may not always be readily disclosed or reported. Innovative strategies need to be developed to address technical errors, especially with the increased complexity of advanced technologies being used in surgery. One preventative strategy recommends designing targeted interventions to improve decision making and performance during routine operations in high-risk situations such as emergencies, reoperations, or patients with unusually difficult anatomy.

References

1. Keillor G. Lake Wobegon days. New York: Viking Press; 1985.
2. Porter GA, Soskolne CL, Yakimets WW, Newman SC. Surgeon-related factors and outcome in rectal cancer. Ann Surg. 1998;227:157–67.
3. Ruby ST, Robinson D, Lynch JT, Mark H. Outcome analysis of carotid endarterectomy in Connecticut: the impact of volume and specialty. Ann Vasc Surg. 1996;10:22–6.
4. Luft HS, Bunker JP, Enthoven AC. Should operations be regionalized? The empirical relation between surgical volume and mortality. N Engl J Med. 1979;301:1364–9.
5. Birkmeyer JD, Siewers AE, Finlayson EV, Stukel TA, Lucas FL, et al. Hospital volume and surgical mortality in the United States. N Engl J Med. 2002;346:1128–37.
6. Lingard L, Espin S, Whyte S, Regehr G, Baker GR, et al. Communication failures in the operating room: an observational classification of recurrent types and effects. Qual Saf Health Care. 2004;13:330–4.
7. Gaba DM, Howard SK. Patient safety: fatigue among clinicians and the safety of patients. N Engl J Med. 2002;347:1249–55.
8. Thomas EJ, Studdert DM, Burstin HR, Orav EJ, Zeena T, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. Med Care. 2000;38(3):261–71.
9. Regenbogen SE, Greenberg CC, Studdert DM, Lipsitz SR, Zinner MJ, et al. Patterns of technical error among surgical malpractice claims: an analysis of strategies to prevent injury to surgical patients. Ann Surg. 2007;246(5):705–11.
10. Ellison EC, Carey LC. Lessons learned from the evolution of the laparoscopic revolution. Surg Clin North Am. 2008;88:927–41.
11. Tang B, Hanna GB, Bax NMA, Cuschieri A. Analysis of technical surgical errors during initial experience of laparoscopic pyloromyotomy by a group of Dutch pediatric surgeons. Surg Endosc. 2004;18:1716–20.
12. Bonrath EM, Dedy NJ, Zevin B, Grantcharov TP. Defining technical errors in laparoscopic surgery: a systematic review. Surg Endosc. 2013;27(8):2678–91.
13. Archer SB, Brown DW, Smith CD, Branum GD, Hunter JG. Bile duct injury during laparoscopic cholecystectomy: results of a national survey. Ann Surg. 2001;234:549–58.
14. Atug F, Castle EP, Woods M, Davis R, Thomas R. Robotics in urologic surgery: an evolving new technology. Int J Urol. 2006;13:857–63.
15. Zorn KC, Gofrit ON, Orvieto MA, Mikhail AA, Galocy RM, et al. Da Vinci robot error and failure rates: single institution experience on a single three-arm robot unit of more than 700 consecutive robot-assisted laparoscopic radical prostatectomies. J Endourol. 2007;21:1341–4.
16. Kozlowski PM, Porter CR, Corman JM. Mechanical failure rate of DaVinci robotic system: implications for pre-op patient counseling [abstract 1159]. J Urol. 2006;175(Suppl):s372–3.
17. Eichel L, Ahlering TE, Clayman RV. Robotics in urologic surgery: risks and benefits. AUA Update Ser. 2005;24(lesson 13):106–11.
18. Nayyar R, Gupta NP. Critical appraisal of technical problems with robotic urologic surgery. BJU Int. 2009;105:1710–13.
19. Kaul S, Shah NL, Menon M. Learning curve using robotic surgery. Curr Urol Rep. 2006;7:125–9.
20. Lee JY, Mucksavage P, Sundaram CP, McDougall EM. Best practices for robotic surgery training and credentialing. J Urol. 2011;185:1191–7.
21. Bhattacharyya T, Wadgaonkar AD. Inadvertent retention of angled drill guides after volar locking plate fixation of distal radius fractures: a report of three case. J Bone Joint Surg Am. 2008;90:401–3.
22. Leggon RE, Meister B, Lindsey RW. Inadvertent sacral bar transfixion of the cauda equina. J Orthop Trauma. 2002;16:127–30.
23. Martin RC, Brennan MF, Jaques DP. Quality of complication reporting in the surgical literature. Ann Surg. 2002;235:803–13.
24. Rogers DA, Regehr G, MacDonald J. A role for error training in surgical technical skill instruction and evaluation. Am J Surg. 2002;183(3):242–5.

The Missed Injury: A 'Preoperative Complication'

6

Roman Pfeifer and Hans-Christoph Pape

Pitfalls and Pearls

- Studies demonstrate that musculoskeletal injuries commonly escape detection.
- Missed injuries may result in modifications of medical or surgical treatments.
- Strict adherence to protocols such as the ATLS may reduce the incidence of missed injuries in the emergency room.
- The role of a tertiary survey to reduce missed injuries, performed by an experienced orthopaedic trauma surgeon must be emphasized.

Outline of the Problem

Minor musculoskeletal injuries commonly escape detection during the early assessment and management phase in multiply injured patients.

The initial assessment of multiply injured patients is challenging. Several factors may contribute to the appearance of medical errors and the presence of missed injuries (Table 6.1). The patient's ability to communicate may be compromised due to a reduced level of consciousness, alcohol or drug intoxication, or a language barrier. All of these can cause diagnostic problems. An unconscious and intubated patient's medical history and medication is usually unknown or incomplete, another factor that facilitates treatment errors. Less experienced personnel may be overwhelmed, especially in the presence of other

R. Pfeifer, MD (✉) • H.-C. Pape
Department of Orthopaedic Trauma, University Hospital Aachen,
30 Pauwels street, Aachen 52074, Germany
e-mail: rpfeifer@ukaachen.de

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_6, © Springer-Verlag London 2014

Table 6.1 Factors contributing to the appearance of undetected injuries in multiply injured patients

Patient related factors
Presence of multiple injuries
Unconsciousness
Intubation
Intoxication/drugs
Language barrier
Examiner related factors
Inexperience
Presence of life-threatening injuries
Time-pressure
Incomplete examination
Technical errors

life-threatening conditions. If time-critical decisions must be made, significant injuries may be neglected or even missed. In some cases diagnostics may be interrupted due to hemodynamic instability. Other examiner related errors include: incomplete physical or clinical examination, misinterpretation of clinical or radiologic signs, technical errors in performing examinations, and radiologic errors (Table 6.1).

The introduction of Advanced Trauma Life Support provide standardized clinical assessment of severely injured patients [1–3]. Mortality rates have been shown to decrease after the implementation of ATLS protocols [4, 5]. However, some reports indicate that relevant injuries are still undetected even after the primary and secondary surveys [6–9]. Enderson et al. [10] described the importance of the tertiary survey in order to minimize the incidence of hidden injuries.

This chapter summarizes the clinical appearance of missed injuries in trauma patients and their typical anatomical locations and clinical consequences. Moreover, strategies are reviewed to minimize the clinical appearance of undetected injuries.

Limitations of the Current Practice

Multiple factors are associated with missed injuries and treatment errors. The majority of errors occur in the Emergency Department [11–13], the Intensive Care Unit [11, 13] and the Operating Room [13]. Typical treatment errors were incorrect haemorrhage control (28 %), airway management (16 %), management of unstable patients (14 %) and prophylaxis (11 %) [11]. In particular, severely injured patients with associated head injury [8, 14, 15], a Glasgow Coma Scale score of 8 or lower [7, 16], and a high Injury Severity Score [6–9, 14, 16–18] are more likely to have missed injuries or delayed diagnoses. Studies demonstrate that musculoskeletal injuries commonly escape detection. A widespread distribution (1.3–39 %) of incidence rates for musculoskeletal missed injuries and delayed diagnoses appears to occur [19]. The incidence of unrecognized injuries in all studies mentioned above is

approximately 9 % in mean [19]. This difference may be a result of inconsistent definitions of what constitutes a missed injury (Table 6.2). Another possibility is that many authors limited their investigations to a particular subset of missed injuries (Table 6.3). Several studies focused on missed injuries in multiple trauma patients [6, 16, 20, 21], others describe unrecognized injuries in patients with abdominal [22] and orthopaedic trauma [23–26]. Study design also affects the incidence rates. Enderson et al. [10] reported that prospective studies show a higher incidence of missed injuries as compared with retrospective reviews.

Anatomic sites that are among the typically missed include the extremities, most commonly wrist and hand fractures, fractures of the foot, elbow fractures, posterior shoulder dislocations and epiphyseal plate injuries (Table 6.4) [19, 21, 29–31]. These injuries do not have a great influence on respiratory or hemodynamic stability of the patients, however, long-term investigations demonstrate the importance of these injuries on long-term outcome and rehabilitation [32, 33]. In the initial stage the identification of life threatening injuries within the thorax, abdomen and pelvis are of immense importance. These injuries are less frequently missed (up to 8 % of all missed injuries), however, these may be responsible for hymodynamic or respiratory instability. Rib fractures are important indicators for the presence of life-threatening thoracic or abdominal injuries [8, 34]. In unconscious and intubated patients extended diagnostics (e.g. CT scans) in addition to plain radiographs are recommended to exclude those injuries.

Table 6.2 List of definitions used in the literature

Definition of the missed injury type
Minor injuries: Hand, wrist, foot, ankle, forearm, uncomplex soft tissue injuries and fractures, rupture of ligaments, muscles and tendons were defined as minor injuries
Major injuries: Skull injuries, neurological and arterial lesions, liver, spleen, and intestinal lacerations, femoral, humeral, pelvic, and spine fractures and dislocations were defined as major injuries
Life threatening injuries: Injuries of main vessels in thorax, Hemothorax and Pneumothorax were defined as life threatening injuries

Table 6.3 Definition of missed injuries

Missed injuries
Injuries that were not identified by primary and secondary survey. All diagnoses made in tertiary survey (24 h). [6 studies]
Injuries detected after the admission to the ICU (24 h). [4 studies]
Injuries found after complete assessment and diagnostics, and are directly related to the injury. [4 studies]
Injuries that were missed within 6–12 h. [2 studies (12 h time point) 1 study (6 h time point)]
Clinically significant missed injuries
Missed injuries that are associated with high morbidity and mortality. [2 studies]
Missed injuries that require additional procedures and alterations of therapy. [1 study]
Missed injuries with significant pain, complications, residul disability and death. [1 study]

Table 6.4 Incidence of missed musculoskeletal injuries in trauma patients

Published Articles	Pat.# In study	Foot/ankle (%)	Leg (%)	Hip/pelvis (%)	Wrist/hand (%)	Arm (%)	Spine (%)
Buduhan et al. [16]	567	Extremities: 33.3		7.9	Extremities: 33.3		7.9
Guly [27]	934	25.8	4.3	4.9	17.2/21.7	15.1	3.4
Houshian et al. [14]	876	12.8	8.1	8.1	8.1	11.6	5.8
Vles et al. [8]	3,879	12.2	6.1	6.1	4.1	12.2	8
Soundappan et al. [28]	76	Lower limb: 31		–	Upper limb: 23		15
Kalemoglu et al. [7]	709	Extremities: 38.2		9.3	Extremities: 38.2		9.3

Table 6.5 Presence of clinically significant missed injuries in trauma patients

Reference	Pat. #	Clinically sign. missed injuries (%)
Buduhan et al. [16]	567	15.2
Houshian et al. [14]	786	15.4
Rozoli et al. [17]	432	20.3
Janjua et al. [9]	206	22.3

Source: Pfeifer and Pape [19]

A comparatively small number of studies have distinguished between clinically significant missed injuries and missed injuries in general (Table 6.5) [9, 14, 16, 17]. Patients with clinically significant missed injuries have been reported to make up 15–22.3 % of the total number of patients with missed injuries. In these studies different definitions were used to determine clinical significance. Some studies focused on those missed injuries that were associated with high morbidity and mortality as a result of a delayed diagnosis [14, 16]. Others defined missed injuries as those that required additional surgical procedures [6].

Unrecognized injuries may be classified as minor, major, and life threatening injuries in order to assess their clinical relevance (Table 6.6) [8, 14, 17, 18, 20, 23, 25]. Most published studies have identified life-threatening missed injuries. Three publications found that only a small percentage (1–4 %) of life threatening injuries was missed. When the classification (minor, major, life threatening injuries) of missed injuries is used, studies have observed that approximately 27–66 % of unrecognized injuries were major injuries [19]. These injuries have the potential to be clinically significant. Several studies have also indicated that trauma patients with missed injuries and delayed diagnoses required significantly longer hospital stays (15.7–42.1 days vs. 7.9–26.7 days) and longer Intensive Care Unit stays (5.4–10.9 days vs. 1.5–5.7 days), than those without missed injuries [7, 16–18]. Some studies also report high rates of mortality [6, 7, 14, 18, 22] among trauma patients with missed injuries.

Undetected injuries may also affect the treatment strategies in trauma patients. Rizoli et al. reported that approximately 40 % of missed injuries resulted in a change of medical therapy and 20 % required additional surgical treatment [17]. Vles et colleaques confirmed and described that in 24.5 % of patients with missed injuries an additional operative treatment was necessary [8]. Consequences for the surgical

Table 6.6 Presence of minor, major, and life threatening missed injuries

	Injuries classified as		
References	Minor (%)	Major (%)	Life threatening (%)
Chan et al. [20]	51.1	48.9	0
Born et al. [23]	66.7	33.3	0
Juhl et al. [24]	72.3	27.7	0
Rizoli et al. [17]	56.8	41.9	1.3
Kremli [25]	33.7	66.3	0
Robertson et al. [18]	35.3	60.3	4.4
Houshian et al. [14]	36.1	61.6	2.3
Vles et al. [8]	47.3	52.7	0

Source: Pfeifer and Pape [19]

outcome have not been studied so far. If diagnosed, missed injuries resulted in delayed surgical treatment [8].

Moreover, undetected injuries may underestimate the burden of trauma. Consequently early total care may be considered with relevant consequences. Hidden bleeding (e.g. in thorax, abdomen, pelvis) may result in circulatory instability and respiratory dysfunctions during surgery. Therefore, undetected injuries may adversely affect patients' outcome and compromize the outcome of the surgery.

Hoyt et al. analyzed the caused of death in the operating room in trauma patients [35]. This study group identified that bleeding was the main cause of death in deceased patients in the OR [35]. Embolism and herniation of the central nervous system were further causes [35]. Authors advocated a staged surgical procedure to allow resuscitation and rewarming.

Where Is the "Golden Bullet"?

Thorough clinical and radiological examinations according to the ATLS protocols represent the main tools for the diagnosis of fractures and injuries. After severe trauma clinical examination of awake and alert patients allows the diagnosis of clinically significant missed injuries. Further diagnostic methods (radiologic imaging) continue to be beneficial in unconscious patients [36–38]. Several studies have identified that lack of admission radiographs of the specific area of injury (46.3–53.8 %) [23, 25] and misinterpreted X-rays (15–34.9 %) [14, 16] as main radiological factors that contributed to missed injuries. Further factors include clinical inexperience (26.5 %) [20] and assessment errors (33.8–60.5 %) [7, 9, 14, 16]. Other investigations found additional contributing factors such as technical errors [9], inadequate x-rays [16, 20, 27], interrupted diagnosis [21], and associated injuries [14]. In addition, patients with missed injuries and delayed diagnoses tend to have a combination of contributing factors [9, 25]. Janjua et al. [9] found that in 50 % of cases, more than one factor was responsible.

The following action should be undertaken to reduce the rate of missed injuries, we must focus on unconscious and intubated patients with severe trauma (ISS↑)

and brain injuries (GCS↓) during the primary and secondary survey [6–9, 14, 16–18]. As previously described, some authors emphasized the role of tertiary trauma survey in patients with multiple injuries, since relevant injuries may be missed during the primary and secondary surveys [6–9]. Approximately 50 % of overall missed injuries and 90 % of clinically significant missed injuries were diagnosed by tertiary trauma survey within 24 h of admission [8, 9]. This survey can also be performed after the patient has gained consciousness and is able to voice complaints [7]. The tertiary trauma survey (TTS) should cover:

1. standardized re-evaluation of blood tests
2. careful review initial x-rays
3. clinical assessment for the effective detection of occult injuries

Furthermore, as musculoskeletal injuries are usually missed during the first and second survey, an experienced orthopaedic surgeon must be involved in the tertiary survey. Awareness of commonly missed anatomic sites focuses the clinical examination. A head-to-toe examination should be performed with a special attention on frequently affected anatomic sites (hand, wrist, foot, shoulder, spine).

Take-Home Message

In order to reduce the rate of missed injuries, tertiary trauma survey has to be performed in unconscious and intubated patients with severe trauma (ISS↑) and brain injuries (GCS↓) during the primary and secondary survey, since relevant injuries may be missed. This survey can also be performed after the patient has gained consciousness and is able to voice complaints. An experienced orthopaedic surgeon must be involved in the tertiary survey and should focus of commonly missed anatomic sites (hand, wrist, foot, shoulder, and spine). In addition, the tertiary trauma survey (TTS) should cover: standardized re-evaluation of blood tests, careful review initial x-rays and clinical assessment for the effective detection of occult injuries.

References

1. Stahel PF, Heyde CE, Wyrwich W, Ertel W. Current concepts of polytrauma management: from ATLS to “damage control”. Orthopade. 2005;34:823–36.
2. Olson CJ, Arthur M, Mullins RJ, Rowland D, Hedges JR, Mann NC. Influence of trauma system implementation on process of care delivered to seriously injured patients in rural trauma centers. Surgery. 2001;130:273–9.
3. Ali J, Adam R, Butler AK, et al. Trauma outcome improves following the advanced trauma life support program in a developing country. J Trauma. 1993;34(6):890–8.
4. Van Olden GDJ, Meeuwis JD, Bolhuis HW, Boxma H, Goris RJ. Advanced trauma life support study: quality of diagnostic and therapeutic procedures. J Trauma. 2004;57:381–4.
5. Van Olden GDJ, Meeuwis JD, Bolhuis HW, Boxma H, Goris RJ. Clinical impact of advanced trauma life support. J Emerg Med. 2004;22:522–5.

6. Brooks A, Holroyd B, Riley B. Missed injury in major trauma patients. Injury. 2004; 35:407–10.
7. Kalemoglu M, Demirbas S, Akin ML, et al. Missed injuries in military patients with major trauma: original study. Mil Med. 2006;171(7):598–602.
8. Vles WJ, Veen EJ, Roukema JA, Meeuwis JD, Leenen LPH. Consequences of delayed diagnoses in trauma patients: a prospective study. J Am Coll Surg. 2003;197:596–602.
9. Janjua KJ, Sugrue M, Deane SA. Prospective evaluation of early missed injuries and the role of tertiary trauma survey. J Trauma. 1998;44(6):1000–7.
10. Enderson BL, Reath DB, Meadors J, Dallas W, Deboo JM, Maull KI. The tertiary trauma survey: a prospective study of missed injury. J Trauma. 1990;30(6):666–9.
11. Gruen RL, Jurkovich GJ, McIntyre LK, Foy HM, Maier RV. Patterns of errors contributing to trauma mortality. Lessons learned from 2594 deaths. Ann Surg. 2006;244(3):371–80.
12. Esposito TJ, Sanddal ND, Hansen JD, Reynolds S. Analysis of preventable trauma death and inappropriate trauma care in rural state. J Trauma. 1995;39(5):955–62.
13. Kreis DJ, Plasencia G, Augenstein D, et al. Preventable trauma death: Dade County, Florida. J Trauma. 1986;26(7):649–54.
14. Houshian S, Larsern MS, Holm C. Missed injuries in a level I trauma center. J Trauma. 2002;52:715–19.
15. Reid DC, Henderson R, Saboe L, Miller JDR. Etiology and clinical course of missed spine fractures. J Trauma. 1987;27(9):980–6.
16. Buduhan G, McRitchie DI. Missed injuries in patients with multiple trauma. J Trauma. 2000;49:600–5.
17. Rizoli SB, Boulanger BR, McLellan BA, Sharkey PW. Injuries missed during initial assessment of blunt trauma patients. Accid Anal Prev. 1994;26(5):681–6.
18. Robertson R, Mattox R, Collins T, Parks-Miller C, Eidt J, Cone J. Missed injuries in a rural area trauma center. Am J Surg. 1996;172:564–8.
19. Pfeifer R, Pape HC. Missed injuries in trauma patients: a literature review. Patient Saf Surg. 2008;2(1):20.
20. Chan RNW, Ainscow D, Sikorski JM. Diagnostic failures in the multiple injured. J Trauma. 1980;20(8):684–7.
21. Pehle B, Kuehne CA, Block J, et al. Die Bedeutung von verzögert diagnostozierten Läsionen bei Polytraumatisierten. Unfallchirurg. 2006;109:964–74.
22. Sung CK, Kim KH. Missed injuries in abdominal trauma. J Trauma. 1996;41(2):276–8.
23. Born CT, Ross SE, Iannacone WM, Schwab CW, DeLong WG. Delayed identification of skeletal injury in multisystem trauma: the "missed" fracture. J Trauma. 1989;29(12):1643–6.
24. Juhl M, Moller-Madsen B, Jensen J. Missed injuries in an orthopaedic department. Injury. 1990;21(2):110–12.
25. Kremli MK. Missed musculoskeletal injuries in a University Hospital in Riyadh: types of missed injuries and responsible factors. Injury. 1996;27(7):503–6.
26. Laasonen EM, Kivioja A. Delayed diagnosis of extremity injuries in patients with multiple injuries. J Trauma. 1991;31(2):257–60.
27. Guly HR. Diagnostic errors in an accident and emergency department. Emerg Med J. 2001;18:263–9.
28. Soundappan SVS, Holland AJA, Cass DT. Role of an extended tertiary survey in detecting missed injuries in children. J Trauma. 2004;57:114–18.
29. Freed HA, Shields NN. Most frequently overlooked radiographically apparent fractures in a teaching hospital emergency department. Ann Emerg Med. 1984;13(10):900–4.
30. Moore MN. Orthopedic pitfalls in emergency medicine. South Med J. 1988;81(3):371–8.
31. Wei CJ, Tsai WC, Tiu CM, Wu HT, Chiou HJ, Chang CY. Systematic analysis of missed extremity fractures in emergency radiology. Acta Radiol. 2006;47:710–17.
32. Zelle B, Brown RS, Panzica M, et al. The impact of injuries below the knee joint on the long-term functional outcome following polytrauma. Injury. 2005;36:169–77.

33. Pfeifer R, Lichte P, Zelle BA, et al. Socio-economic outcome after blunt orthopaedic trauma: implications on injury prevention. Patient Saf Surg. 2011;5(1):9.
34. Al-Hassani A, Abdulrahman H, Afifi I, et al. Rib fracture patterns predict thoracic chest wall and abdominal solid organ injury. Am Surg. 2010;76(8):888–91.
35. Hoyt DB, Bulger EM, Knudson MM, et al. Death in the operating room: an analysis of a multicenter experience. J Trauma. 1994;37(3):426–32.
36. Guillamondegui OD, Pryor JP, Gracias VH, Gupta R, Reilly PM, Schwab CW. Pelvic radiography in blunt tram resuscitation: a diminishing role. J Trauma. 2002;53:1043–7.
37. Pehle B, Nast-Kolb D, Oberbeck R, Waydhas C, Ruchholtz S. Significance of physical examination and radiography of the pelvis during treatment in the shock emergency room. Unfallchirurg. 2003;106:642–8.
38. Hilty MP, Behrendt I, Benneker LM, et al. Pelvic radiography in ATLS algorithms: a diminishing role. World J Emerg Surg. 2008;3:11–5.

Non-technical Aspects of Safe Surgical Performance

7

George G. Youngson

Pitfalls and Pearls

- Errors occur more frequently during "routine" cases when vigilance is reduced and automaticity dominates.
- Distractions require active management. Anticipate demanding phases of the operation and utilise a "sterile cockpit" communications protocol.
- Team briefings open communication channels. Open communication improves patient outcomes.
- Checklists liberate the surgeon's mind from the task of remembering routine but obligate procedures and need to be employed. Checklists are not a panacea however against all forms of individual or team error.
- Rudeness in the workplace will disable the effectiveness of both the recipient and adjacent observers. Other emotions will also impact upon cognitive processes reducing their efficiency and effectiveness.
- Communication masking can be caused by communicating excessive amounts of information in an undirected fashion with a substantial portion of negative commands.
- Hierarchy within the team can be created for the surgeon rather than by the surgeon as a mistaken expression of respect. This requires active management if it is not to constitute an impediment to effective communication.
- The task load of the different members of the surgical team varies substantially throughout the different phases of an operation. Scrub nurses and anaesthetists often have a high task load at the start and finish of the procedure, at the time

G.G. Youngson, CBE, MBChB, PhD, FRCPEdin, FRCS
Department of Paediatric Surgery, Royal Aberdeen Children's Hospital,
University of Aberdeen, Foresterhill Road, Aberdeen AB 25 2ZG, Scotland, UK
e-mail: ggyrach@abdn.ac.uk

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_7, © Springer-Verlag London 2014

when the surgeons' task load reduces. Consideration should be afforded other team members in order to avoid distraction.
- Personal well-being affects performance. Self calibration can be carried out using the *"I'm safe"* checklist.

Outline of the Problem

Definition of non-technical surgical skills:
The cognitive and social skills which underpin optimal surgical performance

Hazards in the operating room (OR) have traditionally been associated with the risks imposed by the physical characteristics of that environment (fires, fluids, sharps, radiation etc.). Errors, however, produced by either the individual surgeon, the surgical team collectively, or the health organisation and its infrastructure, are now appreciated as being equally, – if not more relevant, in producing unintended consequences in healthcare and causing patient harm. At individual level, the nontechnical as opposed to the technical skills contribute significantly to error. Characterising these behaviours and processes of judgement allows analysis of error-prone circumstances and situations, and possibly identification of periods when we find ourselves vulnerable to our environment and to our own human deficiencies. Appropriate and increasing appreciation of these influences has been promoted by the implementation of surgical briefings [1], checklists [2] and protocols [3], which have gone some way to reducing morbidity and improving outcome following operation. However, quite why these effects are achieved without any obvious change in the skill set of the surgical team and its constituent individual members, remains ill-defined. Indeed, in some circumstances, these measures have failed to completely control the more severe form of error, as can be found in the list of never events [4] (see Chap. 15).

Insight into the reasons behind the benefits of the checklist effect and indeed the judgement used by surgeons and their ability to perform under crisis situations, as well as their ability to support others and enhance the performance of their operating team is, in large measure, best understood through recognition of the importance of human factors in the surgical setting in general, and the impact of non-technical skills in particular.

Current Practice

Behavioural Rating Schemes

Non-technical skills (NTS) can be described, classified and utilised for assessment, learning and feedback purposes, by a variety of different methods, all of which employ behavioural rating schemes. These tools either look at the individual surgeon, e.g. NOTSS, – non-technical skill for surgeons [5] or at the behaviour of the

surgical team e.g. OTAS, – observational teamwork assessment for surgery [6], and evaluate cognitive (e.g. judgement and decision-making) or interpersonal behaviours (teamwork, communication, leadership). The NOTSS taxonomy (Table 7.1) will be used for illustrative purposes in this chapter which explores how the different demands, stressors and pressures placed by healthcare organisations, events (invited or otherwise) within the OR environment, the individuals in the operating team, the kit (surgical equipment and instrumentation) and technology,-and indeed our own individual performance-how these all interact to influence what is done and how it is done to our patients [7]. Examples will be chosen to illustrates how our NTS can be affected by such influences and what can be done to control the environment, team and self, in order to optimise the performance of the operating staff.

Non-technical Skills – Content and Classification

The NOTSS taxonomy contains two cognitive categories-situation awareness and decision-making, and two categories of social or interpersonal behaviours,-teamwork and communication, and leadership.

NOTSS Cognitive Categories

The two categories in this part of the taxonomy are:
- Situation awareness
- Decision-making

Situation Awareness

Good awareness of what is happening in and around the operative field is a self evident requisite of the operating surgeon yet a multitude of factors may conspire to

Table 7.1 NOTSS taxonomy (version 1.2)

Category	Element
Situation awareness	Gathering information
	Understanding information
	Projecting and anticipating future state
Decision making	Considering options
	Selecting and communicating option
	Implementing and reviewing decisions
Leadership	Setting and maintaining standards
	Supporting others
	Coping with pressure
Communication and teamwork	Exchanging information
	Establishing a shared understanding
	Co-ordinating team

compromise that vision and perception. Situation awareness,-as defined by Endsley [8], involves collecting the information around you that is needed for the task (noting that at times, some of that desired information may be unavailable), understanding that information and then using it to project forward and deciding on a plan or course of actions. That tripartite, – "what, – so what, – now what" sequence, is fundamentally important to both the tempo of the surgery as well as the choice and course of the procedure; and yet, it is a dynamic subject to various interruptions resulting in potentially adverse decisions or actions. The required information may not be available or indeed it may even be suppressed for fear of provoking an adverse reaction from its recipient (possibly an ill-natured surgeon?) or because of steep hierarchy within the team. Thus it may not be offered or not received (or given in the wrong format, by the "wrong person",– ? given at the wrong time).

Intense concentration on one element of the operative task may inhibit and compromise recognition of other concurrent finding events actually occurring within the field of vision (see "gorilla in our midst" for a fuller explanation of inattentional blindness and compromise produced by undue fixation on tasks) [9]. When information is given that does not "fit" with the expected pattern,-then a tendency can exist to either subconsciously discard it (exclusion bias) or amend it because it does not suit our primary objectives and mental pattern (confirmation bias); we are prone to such error – particularly if we have multiple tasks needing attention concurrently and there is competition for our finite attention. In the presence of increasing stress levels, our cognitive "space" may thus fail to accommodate fresh or conflicting information and consequently our processing facilities diminish. This coping ability is in part dependent on experience of prior similar circumstances, but is also partially dependent on our personal well-being on that day. Calibration of your own "personal status" can be performed using the "I'm safe" mnemonic used in aviation [10] to run a well-being check on your situation awareness and how it is holding up on the day (Box 7.1).

All these affect various aspects of situation awareness and due note should be taken that these effects may also be shared by other team members. In particular rudeness has a scattered effect and the cognitive ability of those observing as well as

Box 7.1. "I'm Safe" Mnemonic

I – illness
M – medication (e.g. antihistamines for a coryzal illness and coping with a "runny nose" behind a surgical mask)
S – stress (personal relationships, time pressures)
A – Abuse, – substance/alcohol (or its after-effects, (an estimated 15 % of doctors abuse alcohol and other pharmacological agents)
F – fatigue
E – Emotion (rudeness, anger, aggression, personal grief) or E for eating (impact of hypoglycaemia)

those who are the primary recipients of the target of rudeness will result in shrinkage of the cognitive space of those involved. An outburst therefore intended to "improve" the performance of the recipient may have quite a contrary effect [11, 12].

Examples of factors which produce disruption to situation awareness therefore are:-

- Distraction
- Fixation/bias
- Personal circumstances on the day
- Rudeness
- Inattentional blindness

Examples of how to militate against disruption of that second phase of comprehension include:-

- Knowledge and Experience
- Pre-task briefing
- Get feedback on your situation assessment
  - Double check assumptions
  - Verbalise reasoning behind decisions
- Stay focused but avoid tunnel vision
- Use open rather than leading questions
- Encourage junior staff to speak up if concerned
- Realize that *even* experts can make errors

Just as intense concentration on a particular task may reduce overall situation awareness, so may undue familiarity with the task potentially result in a loss of vigilance. The potential risk of automaticity needs constant prompting such that recognition of cues which convert automaticity into mindfulness and increasing awareness of difficulty or hazard requires an attention to avoid inappropriate manoeuvres and is a feature of good surgical performance [13]. Similarly, while a number of surgeons will find background music a positive contribution to the ambience of the operating room, that noise,-along with other uninvited noises (e.g. chatter from other OR personnel including medical students) may impact detrimentally upon our consciousness. Similarly the likes of stress and fatigue will all shrink the cognitive capacity of our minds resulting in compromise of situation awareness. The use of the "sterile cockpit" policy and explaining it to the other OR personnel, is a helpful way of managing distraction [14]. The aviation industry is conscious of the demands made of pilot attention to flight related tasks in the first and last 10,000 feet of take-off and landing respectively. Only flight-related information is exchanged on the flight deck and between/to air traffic control during these phases of aviation. Choosing those elements of surgical procedure which represent that first or last 10,000 feet, allows you to deploy a sterile cockpit equivalent in your operating room and control the amount of distraction you are subjected to. It also appears to have an beneficial effect in engaging others in the complexity of your task and promoting better teamwork. It is equally important to terminate the particular phase with a note of appreciation for that engagement.

The third part of situational awareness-the now what-or projecting forward is also a phase subject to error and incorrect anticipation. This is a distressing event for the surgeon if it comes about, because it indicates a mistaken intention. Indeed plan

continuation error – a feature again taken from aviation [15], where ambiguous or incomplete information arising during the course of the procedure, points to the need for a change in direction. However, with an uncertainty surrounding the final destination or outcome, this often results in the operator being faced with incomplete information, options and uncertainty in authenticity of the new information, and hence adhering to the original course or plan (usually incorrectly).

Decision-Making

The hallmark of surgical attitudes and behaviours is the willingness to make and follow through on decisions, sometimes taken as a matter of urgency, with incomplete information and yet a full awareness of the associated level of procedural risk. While the risk usually relates to patient well-being, professional and reputational risks are also new concepts emerging from the recent surgical literature which bear an impact on the choice of decisions made [16]. That "strong but wrong" profile of surgical decision-making of the past, is now less attractive than previously perceived and carries with it numerous consequences. Decision-making is contingent upon accurate situation awareness and frequently acts as a sequitur to that third – "now what" – phase. The course of action to be employed can use one or more of four common methods [17]. These are

- recognition prime decision-making – (RPD, a.k.a. intuitive, pattern recognition)
- rule-based
- analytical
- creative

RPD is used by the expert as opposed to the novice. It is entirely dependent on "having been there before" and being able to match the actions used successfully in the past to the current task or problem. By its nature, it has a high accuracy and success rate and is often used in time-limited, higher risk circumstances; it is known as "fast and frugal" by virtue of the low requirements for cognitive effort [18]. That ability to match actions to circumstances, is dependent on a "store" or "library" of past experience but also creates a cognitive capacity that is liberated by use of this type of decision-making, – allowing mental capacity for other purposes and hence its value is in those urgent, high-risk circumstances when stress has the effect of potentially reducing the available cognitive space but where rapidity of action is also essential.

By contradistinction, the analytical decision-making mode requires time, more cognitive effort, and is an obligate process for those with no access to pattern matching by virtue of lack of previous experience. For the inexperienced/novice surgeon, this level of decision-making requires more effort, leaves less available resource for other tasks, and has a greater stress affect with the potential for overload and freezing. It is in such circumstances, therefore, that slowing down and using time to equilibrate and spread the demands of the situation by producing an intraoperative pause, allows a review of the situation and an

opportunity to spread the load and create time in order to allow consideration of options. The elements in the NOTSS taxonomy on decision-making encourage disclosure and sharing of the options to ensure optimal selection and that again creates time to good effect.

Rule-based decision-making is knowledge – dependent and is algorithmic in its nature. It is therefore accessible to all with the appropriate information base. It is less time-dependent than the analytical decision-making method and should require little discriminating thinking in its implementation other than recognition of the circumstances being appropriate for application of that rule or guideline/protocol.

Finally, and used only very occasionally, is the method of creative decision-making, which requires luxuriant amounts of time to originate solutions which are not stored in either memory or knowledge banks. Nonetheless, this will require a pragmatic solution to often a unique problem and needs both time and attention.

In practice these methods are not mutually exclusive but maybe blended to cope with the challenges of the operative task.

NOTSS – Behavioural Categories

The two categories in this part of the taxonomy are :-

- Communication and teamwork
- Leadership

Communication and Teamwork

There is a strange irony in the fact that when surgical errors occur, as in the case of a Never Event, that the surgeon is commonly working as part of a team and not in isolation. In effect, other team members observe the operating surgeon perpetrate a significant error, but without effective intervention from themselves. These team members are frequently highly experienced. Why that permissive relationship goes unchecked is unclear. A number of potential reasons may exist

- Incomplete or different mental models across the team members
- Steep hierarchy or chain of command suppressing and inhibiting “speak up” policy
- An expectation that “some other person” will make the intervention
- A lack of situation awareness of the rest of the team as to the implications of what is happening
- A lack of confidence to intervene of cultural or linguistic origin

In relation to a lack of confidence to intervene, the “Power Distance Index” expanded by Gladwell in his book “Outliers”, may originate in cultural values which confuse the ability to challenge with some code of good manners, courtesy and politeness. That deference to status may be created for the surgeon rather than by the surgeon and may mistakenly denote a form of respect [19]. This needs active

management. A "speak up" or graded assertiveness policy should be in place for all to use rather than "hoping and hinting" that an incipient error will be diverted. One mnemonic which has found favour is the "CUSS" tool featuring keywords indicative of escalating levels of concern (Box 7.2) [20].

Communication within high-performing teams is an expansive topic with a rich literature on the effect on outcomes following surgery [21]. There are also lessons to be learned from adverse events in other high-risk domains as a consequence of communication failure. In particular the factors that contribute to fratricide-mortality as a consequence of friendly fire in battle situations (see Chap. 24), – points to the fact that low volumes of communication may not themselves result in poor team performance, but, excessive communication, – particularly if indiscriminate and poorly directed, may be ineffective or possibly even hazardous (e.g. distracting for the team, – so-called "communication masking"). Indeed simulation studies of British Army tank commanders found that high levels of communication, if associated with a high proportion of negative commands, produced a higher fratricide rate (so-called "blue on blue" incidents) than the more discriminating and positively communicating commander who did not share the high fratricide rate-perhaps a finding of implication for surgical trainers [22].

Various tools have been developed to promote effective communication. SBAR is one such model that ensures effective transmission of critical information in a time efficient and succinct manner [23]. Again it has its origins in military protocol (nuclear submarines) and is of particular value in urgent or unanticipated communications (e.g. the need to request assistance in the OR), – providing both context and signalling the nature of the problem in hand (Box 7.3).

Just as too much communication can be detrimental, so can too many people involved in that communication and that "social redundancy" can result in inaction when an urgent request is made; e.g. the request "will someone get me the … quickly" may result in no one getting it, – each bystander assuming that another will

Box 7.2. "CUSS" Mnemonic
C – "I am **c**oncerned about what is happening"
U – "I feel **u**ncomfortable about progressing"
S – "I think there is a **s**erious problem here"
S – "I would like us to **s**top and …"

Box 7.3. "SBAR" Mnemonic
S – The **s**ituation is …
B – The **b**ackground to that situation is …
A – My **a**ssessment is that …
R – My **r**ecommendation is that …

respond. So communication needs to be timely, precise, directed, and understood. Those features along with a read/speak- back policy from the intended audience/recipient should ensure accuracy of the message received.

Finally, the third element of the teamwork and communication category in the NOTSS taxonomy, – co-ordinating the team – is best achieved by person-specific briefing when the situation demands it, so that the social redundancy effect outlined above is minimised. Ensure each team member is aware of their specific responsibilities.

There are a number of intrinsic and extrinsic factors prevalent in the operating room which can compromise good communication, just as they can have an effect upon situation awareness. Examples include:

Intrinsic

- Language difference
- Culture
- Motivation
- Expectations
- Past Experience
- Status
- Emotions/Moods

Extrinsic

- Noise
- Low Voice
- Deafness
- Electrical Interference
- Separation in space and time
- Lack of visual cues (body language, eye contact, gestures, facial expressions etc.)

The impact of communication failure is widely accepted as being responsible for a significant number of adverse events occurring in the operating room with 43 % of adverse events being attributed to this element of failure in behaviours [21].

The communication dynamics and relationships that are established in the triad of anaesthetist, surgeon, and scrub nurse have been evaluated and there is significant variation in the perceptions of the value of that dynamic when evaluated by self as opposed to other team members. For example, the status afforded the surgeon anaesthetist relationship is not considered quite as valuable by nursing team members as it is by the surgeon and indeed is also rated less highly by anaesthetists than it is by surgeons. However team training not only improves interprofessional relationships but also enhances surgical outcomes [24]. The benefits of a flat hierarchy therefore mitigate against those differential perceptions of importance. Similarly, the notion that the surgical team represents the ultimate example of team working and elite interprofessional performance within healthcare, is at odds with the daily

tensions experienced in operating departments and disagreement and aggression between team members is not an infrequent occurrence but is one which is poorly represented in surgical literature. The incidence of different team members who have experienced aggression in the recent past are seen in Table 7.2 taken from the study of Coe and Gould [25].

This aspect of team communication failure is ubiquitous but its management is left to the discretion (or otherwise) of those involved rather than being subject to a more policy driven approach. Moreover, it is clear from the above study that the issuing and receipt of aggression is not the preserve of anyone rank or grouping within the surgical team. These factors clearly compromise the potential for producing an expert team in spite of the team possibly being constituted by experts in their field.

The core element of communication failures can be thus classified according to Lingard [26]

- Occasion
- Purpose
- Content
- Audience

In cases of actual harm to patients [21] the contribution of communication failure has been outlined as follows in 60 cases of communication breakdown:

- 49 % information not transmitted
- 44 % info communicated but inaccurately received
- 7 % info communicated but not received

Leadership

Again the subject matter of leadership has a vast literature associated with it but within the operative setting there is a surprising scarcity; the features of leadership outlined in the NOTSS taxonomy (Table 7.1) of setting and maintaining standards is best served by simple measures such as being in a attendance and behaving as though you are the example ("be the lesson"). Supporting other implies a firm and confident personal stance is already established which enhances the performance of a good team and helps restore the performance of a team struggling to cope with a challenge. Surgeons are more likely to exhibit leadership during more complex procedures belying the vulnerable status of the routine and common procedures when errors are proportionally more likely [27].

Table 7.2 Status and number of staff experiencing aggressive behaviours

Staff group	n	%
Register nurses/ODP	256	65.6
Consultant surgeon	209	53.4
Consultant anaesthetist	131	33.5
Surgical registrar	124	31.7
Anaesthetic registrar	55	14.1
Line manager	52	13.3

Source: Coe and Gould [25]

There are a range of opinions to be had in respect of who is leader in the operating room at any one point in time. Recognising that preparation for an operative procedure commences long before attendance of the surgical staff, then there are clearly leadership responsibilities entailed in procedural preparation and planning for which reside with the nursing staff. By the same token, the task load of the nursing staff begins to escalate at the time when the surgical operation is coming to an end. As the surgeons task load diminishes and closure begins, then the scrub nurses' work increases with equipment checks, swap counts, appropriate labelling and disposal of surgical specimens and even planning forward into the next case on the operating list. Similarly induction of anaesthesia and wakening the patient are "task- heavy" phases of the anaesthetists' schedule. At those points in the operating list, leadership is dispersed if not devolved across those subteams. With leadership, so goes responsibility and whilst there is recognition that the surgeon has overall responsibility in both clinical and a medico-legal sense, there are specific elements to an operative procedure where the responsibility is uniquely allocated to an individual (as in the case of airway management during anesthesia), and in those procedure specific phases, the leadership belongs to those with responsibility.

Leadership failure is perhaps more conspicuous than high-quality leadership which is often imperceptible. A range of reasons can lie behind poor quality of surgical leadership

- Unwillingness to exercise authority
- Reluctance to confront problems and conflicts
- Tyrannising subordinates
- Exploiting subordinates
- Over control/managing to closely
- Micro management
- Irritability
- Unwillingness to use discipline

Intraoperative leadership is as much about displaying composure as it is about retaining it, and that display of leadership standards can be assisted through

- Anticipating
- Sharing a plan
- Agreeing a consensus (not necessarily a democratic one)
- Being cool under pressure
- Controlling emotional display
- Appreciating the effect that the way you cope with pressure has on the performance of your team

Where Is the "Golden Bullet"?

Teaching and Assessment of Non-technical Skills

Aviation has provided a credible example to the medical profession on how that industry has implemented non-technical skills, although comparisons are finite.

Cockpit or crew resource management (CRM) is the pilots' equivalent of NOTSS. Whilst the parallels between aviation and surgery have grown somewhat tired with overuse [28], the value placed on judgement, decision-making, and consistent and high standards of behaviour on the flight deck must, as in operative surgery, constitute shared objectives for those faced with the responsibility for the safety and well-being of others. NTS have therefore been integrated into pilots training programme as an obligate process in many (but not all) airlines. The sophistication of simulation enjoyed by the aviation industry is, however, not mirrored in the provision or quality of simulation facilities across all sectors of surgical education. However, in the first instance, an acceptance of the importance of non-technical skills, and integration into the architecture of the surgical syllabus will allow us to teach and perform assessment of NTS in a more rigorous and objective fashion. Within the United Kingdom, early work is underway to integrate non-technical skills into the national curriculum for all surgical specialities – the Intercollegiate Surgical Curriculum Program (ISCP) (www.iscp.ac.uk).

The optimal methods of assessing NTS still remains to be established but early experience with workplace-based assessment, has shown that repeated ratings of surgeons in training, by a faculty with modest training in NOTSS, can produce a reliable evaluation [29]. Approximately 6 or 7 evaluations appear to achieve the requisite reliability and accuracy of assessment.

A number of different options exist for tuition of "trained surgeons". These include simulation-based scenario teaching and taught courses which are currently delivered internationally by a range surgical colleges and educational agencies. Crucially however, all these are entirely dependent on the existence of a vocabulary and a classification that can impart the concepts contained in non-technical skills taxonomies such as NOTSS and allow recognition, rating, and discussion of the skills concerned. Some of that may be done by using recorded surgical scenarios as exemplars or live role-play in simulation suites. In either event, confident use of the taxonomy is a prerequisite.

The NOTSS taxonomy also has the advantage that it can be utilised for feedback and debriefing purposes. This is particularly valuable as a tool for analysis of adverse events since it provides the opportunity for depersonalising thinking and discussions and introducing triangulation into an otherwise potentially challenging discussion.

Implementation of NTS Across Countries and Professions

The Royal Australasian College of Surgeons have integrated NOTSS into their competence and performance frameworks and there is a current research focus on the impact of NTS on care in variety of outcome studies in a wide range of countries including Japan, Denmark, Holland, Australia, USA, Scotland, England, Canada, Spain, and China. Key to the success of this work is recognition that whilst non-technical skills in the NOTSS model relates to individual surgeons, that similar non-technical skills taxonomies are available for utilisation by

anesthetists (ANTS – anaesthetic non-technical skills) [30] and scrub nurses (SPLINTS – scrub practitioners list of intraoperative non-technical skills) [31]. These share a slightly different content to the surgeon's taxonomy and also display differences in emphasis (task management and sequencing are important for anesthetists, and situation awareness – especially predicting the surgeons requirements, as well as the requirement of the patient, being important elements for scrub nurses).

NOTSS has also been amended to cater for different specialties and an early modification has been used by ophthalmic surgeons who, by dint of the fact that much of their surgery is done under local anaesthetic with an awake patient listening to the interactions between staff, who also carry out much of their operative work looking through an operating microscope, and who depend upon cues and surrogate keywords to imply the various commands or to signal an alert to the rest of the operating team. It is important that this is done without alarming the patient in order to maintain a normotensive, anxiety- free patient and ensure optimal reduction of intraocular pressures. Similarly cardiac surgeons have shown interest in the NOTSS taxonomy given the added complexity of their intraoperative communication between the triad of surgeon/anaesthetists/and perfusionist. Thus, in spite of NOTSS being a generic classification, customisation for specific procedures may be an area for future development.

Performance Improvement for 'Intraoperative Crisis'

Whilst retention of composure is an aspiration for all surgeons at all times, the reality is something different and remaining calm during difficult intraoperative crises carries with it the best chance of remaining focused on the task and yet at the same time retaining enough cognitive space for making best choices and exhibiting best judgement. That ability and facility is acquired slowly and the characteristics that determine the extent and rate of acquisition are hazy but repeated exposure and exemplary illustrative behaviour are both valuable and valued. Simulation has the advantage of providing that exposure without harm to patients and is an area fertile for further development in surgical training (see below). What is less clear however, is that once acquired, how is preservation of NTS maintained and indeed what is entirely unclear, is how to pre-empt against degradation and loss of those attributes. Experience itself is no antidote against degradation of non-technical skills and it would appear that experts, perhaps by virtue of the fact that they have better insight as to the potential implications of an intraoperative crisis, are more prone to degradation of their intraoperative non-technical skills than are novices or surgeons of intermediate experience [32]. Skill degradation is an area that has received scant attention in surgical research but data on adverse performance across the medical profession generally points to loss of competence being a function of age amongst other factors. However recent experience with simulation utilising checklists designed for intraoperative crisis appears to improve management by staff across all levels of experience [33].

Anticipation – "To See It Coming"

The category of situation awareness lies at the heart of good non-technical skills and surgeons indulge in anticipatory behaviour on a constant basis. There are however significant time periods, particularly during routine phases of an operation where relaxation of the focus or distraction within the OR may promote performance as a matter of routine and introduces a certain amount automaticity. Coming out of that automatic mode into a purposeful or mindful status requires recognition of cues sufficiently far in advance as to avoid any inappropriate actions or decisions by self or others (e.g. a trainee being taken through the case) [13]. Cue recognition (involving all three phases of situation awareness) is a facet of surgical performance that again is dependent upon experience (often defined as learning from previous mistakes!). Being aware therefore, slowing down and anticipating imminent events, all require a level of vigilance that should never fall below a given level. Similarly when training junior colleagues and acting as a surgical assistant, it is crucial for the surgical trainer to avoid inconsiderate behaviours and distract the trainee with unnecessary chatter by virtue of the fact that the trainer himself/herself, does not have the responsibility of performing what is seen in their view as a perceptibly straightforward task. Surgeons should also remember as stated previously, that at the phases of operative sequence where the operative task load as low (e.g. during wound closure), the task load of the scrub nurses is high and he/she should not be distracted from their final count, labelling of specimens, organisation of the preparation of next case by frivolous or inconsequential discussions. The use of the sterile cockpit by anaesthetic and scrub nurse staff is equally legitimate as is its use by the operating surgeon.

Take-Home Message

It is still far from clear as to whether non-technical skills are traits (and therefore are inherent but subsequently embellished through application and use) or whether they are skills and competencies that are acquired through the journey of surgical training. In the latter instance, the velocity of acquisition in the absence of direct tuition (to date few trainees have had specific training in human factors and non-technical skills and yet they are attributes possessed by most surgeons to different levels of ability), still needs to be characterised. Additionally, there has been no attempt to introduce prioritisation or weighting into the different skills. Intuitively, it would appear that situation awareness is at the heart of all the other categories and elements and that would favour increasing attention being paid on this particular attribute.

Once there is an accumulated experience in rating non-technical skills throughout the surgical community (and the magnitude of that task should not be underestimated) then perhaps translation into use of these important facilities when making selection into surgery can take place in the future. Controversy has surrounded the use of simulation as a mode of selecting the best candidates into surgical training

programs and most of that simulation has focused on basic manual skills. Perhaps a more rigorous approach is required into evaluating non-technical skills such as situation awareness and decision-making, or indeed communication teamwork and leadership- or perhaps the entire suite of non-technical skills would constitute an entirely appropriate rubric on which to base selection into surgical training, – with the acquisition of technical skills being an easier task in that candidate with good awareness and judgement.

One of the major hurdles however over the coming years will be the acceptance of cognitive and social abilities as being as much a feature of the "master surgeon" as is the ability of that surgeon to display the appropriate manual dexterity. Embedding NTS into the curricula of surgical education is a crucial early phenomenon in pursuit of that acceptance.

Another potential use for the NOTSS taxonomy is as a diagnostic tool when a forensic analysis of a major untoward incident is required. The objectivity afforded by the taxonomy provides a useful opportunity for rating of the individuals concerned and makes a contribution that is otherwise difficult to acquire.

Whilst analysis of surgical errors has rightly been the subject of significant attention over the last few years, perhaps the time is right to look beyond errors to enhancing the performance of all – of making the good team better still-as well as strengthening the weakest link. Data from reported underperformance of the medical profession in the United Kingdom identifies that it is in fact the "experienced" doctors who attract most adverse comment and it is the behaviours and attitudes that constitute the commonest criticism. That indicates that skill acquisition of the workforce is but one of the challenges facing provision of high quality care. Maintenance and preservation of those skills is also key and whilst high standards of clinical competence are expected of all surgeons, so is there an expectation of preservation of behaviours attitudes and cognitive ability in the established workforce as much as acquisition for those in training. Being able to react appropriately in a crisis, make sound judgements in the face of complex intraoperative scenarios, encourage the rest of the surgical team through appropriate communication teamwork and leadership will encourage the development of high performing teams. Due recognition of the contribution of non-technical skills lies at the heart of these standards.

References

1. Haynes A, Weiser G, Berry W, Lipsitz S, Breizat S, Dellinger E, Herbosa T, Joseph S, Kibatala P, Lapitan M, Merry A, Moorthy K, Reznick R, Taylor B, Gawande A. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med. 2009;360(5):491–9.
2. de Vries E, Prins H, Crolla R, den Outer J, van Andel G, van Helden S, Schlack H, Wolfgang S, van Puttten A, Gourma D, Dijkgraaf M, Smorenburg S, Boermeester M. Effect of a comprehensive surgical safety system on patient outcomes. N Engl J Med. 2010;363(20):1928–37.
3. Commission J. Universal protocol for preventing wrong site, wrong procedure, wrong person surgery. Oakbrook Terrace: The Joint Commission; 2007.
4. Stahel PF, Sabel A, Victoroff M, Varnell J, Lembitz A, Boyle J, Clarke T, Smith WR, Mehler PS. Wrong-site and wrong-patient procedures in the universal protocol era – analysis of a prospective database of physician self-reported occurrences. Arch Surg. 2010;145:978–84.

5. Yule S, Flin R, Maran N, Rowley D, Youngson G, Paterson-Brown S. Surgeons' non-technical skills in the operating room: reliability testing of the NOTSS behavior rating system. World J Surg. 2008;32:548–56.
6. Sevdalis N, Lyons M, Healey AN, Undre S, Darzi A, Vincent CA. Observational teamwork assessment for surgery: construct validation with expert versus novice raters. Ann Surg. 2009;249:1047–51.
7. Arora S, Sevdalis N, Nestel D, Woloshynowych M, Darzi A, Kneebone RL. The impact of stress on surgical performance: a systematic review of the literature. Surgery. 2010;147:318–30.
8. Endsley M, Garland D. Situation awareness. Analysis and measurement. Mahwah: Lawrence Erlbaum Associates; 2000.
9. Simons DJ, Chabris CF. Gorillas in our midst: sustained inattentional blindness for dynamic events. Perception. 1999;28:1059–74.
10. http://www.faa.gov/regulations_policies/handbooks_manuals/aviation/risk_management_handbook/media/rmh_ch03.pdf. Accessed Jun 2014.
11. Porath CL, Erez A. Does rudeness really matter? The effect of rudeness on task performance and helpfulness. Acad Manage J. 2007;50:1181–97.
12. Flin R. Rudeness at work. BMJ. 2010;340:c2480.
13. Moulton CA, Regehr G, Lingard L, Merritt C, MacRae H. Slowing down to stay out of trouble in the operating room: remaining attentive in automaticity. Acad Med. 2010;85:1571–7.
14. Wadhera R, Henrickson Parker S, Burkhart H, Greason K, Neal J, Levenick K, Wiegmann D, Sundt T. Is the "sterile cockpit" concept applicable to cardiovascular surgery critical intervals or critical events? The impact of protocol-driven communication during cardiopulmonary bypass. J Thorac Cardiovasc Surg. 2010;139:312–19.
15. Bourgeon L, Valot C, Vacher A, Navarro C. Study of perseveration behaviors in military aeronautical accidents and incidents. Analysis of plan continuation errors. In: Proceedings of the Human Factors and Ergonomics Society annual meeting, vol. 55, No. 1. SAGE Publications: Santa Monica; 2011. p. 1730–4.
16. Chunzi J, Martimianakis M, Kitto S, Moulton C. Pressures to "measure up" in surgery. Ann Surg. 2012;256:989–93.
17. Flin R, Yule S, Youngson GG. How do surgeons make intraoperative decisions? Qual Saf Health Care. 2007;16:235–9.
18. Abernathy C, Hamm RM. Surgical intuition: what it is and how to get it. Philadelphia: Hanley & Belfus; 1995. p. 89. ISBN 1560530596.
19. Raghunathan K. Checklists, safety, my culture and me. BMJ Qual Saf. 2012;21:617–20.
20. Campbell RD, Bagshaw M. Human performance and limitations in aviation. 3rd ed. Oxford: Blackwell Science; 2002. p. 86–98.
21. Greenberg C, Regenbogen E, Studdert M. Patterns of communication breakdowns resulting in injury to patients. J Am Coll Surg. 2007;204:533–40.
22. Rafferty L, Stanton N, Walker G. The human factors of fratricide. Ashgate Publishing: Surrey; 2012.
23. Haig K, Sutton S, Whittington J. SBAR: a shared mental model for improving communication between clinicians. Jt Comm J Qual Patient Saf. 2006;32(3):167–75.
24. Neily J, Mills P, Young-Xu Y, Carney B, West P, Berger D, Mazzia L, Paull D, Bagian J. Association between implementation of a medical team training program and surgical mortality. JAMA. 2010;304(15):1693–700.
25. Coe R, Gould D. Disagreement and aggression in the operating theatre. J Adv Nurs. 2008; 61(6):609–18.
26. Lingard L, Espin S, Whyte S, Regehr G, Baker R, Reznick R, Bohnen J, Orser B, Doran D, Grober E. Communication failures in the operating room: an observational classification of recurrent types and effects. Qual Saf Health Care. 2004;13(5):330–4.
27. Edmondson A. Speaking up in the operating room: how team leaders promote learning in interdisciplinary action teams. J Manag Stud. 2003;40(6):1419–52.

28. Ricci M, Panos A, Lincoln J, Salerno T, Warshauer L. Is aviation a good model to study human errors in health care? Am J Surg. 2012;203(6):798–801.
29. Crossley J, Marriott J, Purdie H, Beard J. Prospective observational study to evaluate NOTSS (Non-Technical Skills for Surgeons) for assessing trainees' non-technical performance in the operating theatre. Br J Surg. 2011;98:1010–20.
30. Fletcher G, McGeorge P, Flin R, Glavin R, Maran N. The role of non-technical skills in anaesthesia: a review of current literature. Br J Anaesth. 2002;88:418–29.
31. Mitchell L, Flin R. Non-technical skills of the operating theatre scrub nurse: literature review. J Adv Nurs. 2008;61:15–24.
32. Black SA, Nestel DF, Kneebone R, Wolfe J. Assessment of surgical competence at carotid endarterectomy under local anaesthesia in a simulated operating theatre. Br J Surg. 2010;97:511–16.
33. Arriaga A, Bader A, Wong J, Lipsitz S, Berry W, Ziewacz J, Hepner D, Boorman B, Pozner C, Smink D, Gawande A. Simulation-based trial of surgical-crisis checklist. N Engl J Med. 2013;368:246–53.

Postoperative Monitoring for Clinical Deterioration

8

J. Paul Curry

Pitfalls and Pearls

- When we closely examine bad outcomes associated with rapidly changing clinical conditions in hospitalized postoperative patients, especially while on the general care floors (GCF), lack of knowledge invariably plays a role.
- It is likely that either no one present has the necessary knowledge in these critical moments, or that no one has created an easy path to access this timely knowledge.
- These clinical deteriorations are called Rapidly Evolving Clinical Cascades (RECC), and are unexpected, uniquely differentiated, and often deadly clinical events.
- These events can manifest subtly at first or be totally disguised by sleep with clinical deterioration evolving through progressive, unique types of respiratory dysfunction.
- While not every day occurrences, these events persist in every hospital and are associated with exceptionally high mortality and morbidity because most bedside clinicians aren't properly trained to recognize or manage them early.
- When rapid response teams and in-house intensivist/hospitalist personnel do arrive, recognize, and address these problems today, often the opportunity for achieving an optimal outcome has long passed.
- This chapter defines and explains these types of clinical deterioration while proposing strategies for detecting and acting on the events much earlier, enabling us to achieve better outcomes going forward.

J.P. Curry, MD
Department of Anesthesia and Perioperative Medicine, Hoag Memorial Hospital Presbyterian, One Hoag Drive, Newport Beach, CA 92658, USA
e-mail: jpaul.curry@hoag.org

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_8, © Springer-Verlag London 2014

Overview of the Problem

Lack of knowledge can be found at the core of problems associated with managing Rapidly Evolving Clinical Cascades (RECC).

Rapidly Evolving Clinical Cascades: A Persistent Problem in Hospitals

Much of our impaired ability to detect RECC early stems from our dependence on monitoring strategies that are incapable of providing reliable early warning [1, 2]. Current hospital general care floor (GCF) monitoring is often limited to isolated parametric spot checks that include the patient's heart rate, respiratory rate, temperature, and the brief observations that come from an array of clinical and non clinical visits, all separated by significant time spans where no monitoring occurs. This kind of surveillance is typically done every 4 h, which leaves patients unmonitored 96 % of their total time spent on the GCF [3]. Some facilities provide patients additional protection on their GCF with continuous electronic monitoring (e.g. continuous pulse oximetry), but rarely are all GCF patients simultaneously afforded this level of continuous surveillance, even in institutions with the resources and capability to do so. Most chosen numeric values that must be reached to trigger GCF continuous monitoring alarms, called alarm threshold values (ATV), are physiologically extreme, e.g. heart rates >130/min or <50/min, respiratory rates >30/min or <8/min. This assures high specificity, statistically meaning very few false positives with regard to something significant being wrong. In turn, it assures less direct resource waste that otherwise would be incurred from having to respond to more false alarms. These extreme ATV often define when our bedside clinicians start taking notice and deploying necessary corrective actions. The values are memorialized in written policy with little thought given to the consequences of waiting for these highly specific threshold extremes to be breached.

Unfortunately, the time spent waiting often condemns patients to more advanced stages of clinical deterioration, where corrective attempts, now urgently needed, become much more costly in terms of resource utilization, morbidity and mortality. In years past, the consequences comprising this additional cost were shifted to the traditional payers and fully remunerated. But that has changed, now with the cost of many complications deemed the responsibility of the institution where they've occurred. This can resonate as being excessively stern, but longitudinal studies have clearly demonstrated that any postoperative complication occurring within 30 days of surgery, no matter how trivial, is significantly more important than preoperative patient risk and intraoperative factors in determining reduction in long term survival, regardless initial full recovery [4, 5]. Said another way, the *No Harm, No Foul* attitudes of many clinicians regarding potential long term consequences from postoperative

complications that appear to resolve innocently, have been proven wrong. There is no such thing as an innocent complication, as all contribute significantly to shaving patient survival. We must always bring our 'A' games and plan always to provide optimal care. Most importantly, we must embrace learning from our mistakes.

Threshold science is under more scrutiny now than ever in the past because bright, early adopters are finally coming to realize its inherently flawed premise. We have been applying oversimplified, static threshold values to warn, diagnose, and even define RECC for two decades with mediocre outcomes at best to show for it [6]. RECC are complex dynamic relational processes that evolve over short periods of time, which without aggressive intercession are capable of quickly and lethally distorting our human physiologies. Yet no one had thought to add an aspect of time to the thresholds that define these entities today. Ignoring time allows for the adoption of extreme ATV that indeed are specific, but at the cost of advancing clinical deterioration as discussed earlier.

Static ATV can be misused easily because they discourage critical thinking with their overly simplistic promises of actionable alerts. A host of problems have evolved over the last two decades because clinicians have long abandoned the analytic skills needed to properly address sources of dysfunction when relying on thresholds alone. For example, ATV are often inherited from very different practice environments, where they had been previously used with high rates of success. One would be the 90 % SpO_2 (blood oxygen saturation) ATV commonly found in operating rooms. This ATV makes great sense in ORs and other similar areas where unique conditions exponentially increase the risk for airway loss and immediate respiratory arrest. But in an environment like the GCF, where airways generally remain patent or at most transiently obstruct from sleep apneas, this ATV choice becomes dysfunctional and potentially dangerous. Yet decisions to copy practices like this, regardless the context within which they function well, persist in many healthcare silos. The reasons most often heard are that these unique, context driven successes somehow comprise a pan-contextual 'Standard of Care'. Reasoning like this is not only wrong, but reflects an absence of clinical knowledge and critical thinking that otherwise would allow for better suited ATV adjustments.

There are fixes for these ATV conundrums that involve new technologies on our immediate horizon. These technologies are able to bypass threshold science entirely, but the knowledge and resources needed to actually transform our current monitoring culture are still years away. Patient lives between now and then will continue to be placed at risk if we don't come up with a reliable contingency plan to ease ourselves into a workable transition using current threshold technologies.

Is There an Immediate Answer?

To understand monitoring strategies today that could constitute such a contingency plan, capable of detecting deterioration much earlier than what generally occurs now, it is important to understand the unique patterns of respiratory dysfunction

comprising RECC. In 2011, Lynn and Curry published two papers [1, 2] detailing three such patterns, how they evolve and 'compete' at cross purpose with one another for an optimal ATV. Aside from the ATV issues, the daunting number of individual RECC can now be reduced to just three unique types of respiratory events, each distinguished by its distinctive pattern. While these patterns, named Patterns of Unexpected Hospital Death (PUHD), evolve fully over spans of time lasting minutes to several hours, and are detected by tracking concurrent respiratory parametric change, they can warn us of their presence with early clues. Unfortunately, these clues often go unappreciated, missed because no one has taken the time to make this information about them easy to understand or remember. As you will soon learn, our three PUHD comprise straightforward, understandable physiologic processes that happen to correlate with three simple ways to think about our breathing. We complete the trilogy theme with a third discussion on three ways supplemental oxygen has been associated with patient harm. We hope by offering you our '3 threes' that you will find this information on RECC PUHD not only clear, manageable, and interesting, but easy to recall, especially when actually having to face them.

To use this knowledge well, we have to appreciate how our three RECC Types relate to one another within a perioperative GCF context. Special attention will be given to the prevalence of each PUHD, the emotional impact each has on patient, staff, and family, and how to detect each type early using monitoring strategy that accounts for their distinct differences simultaneously. Focusing exclusively on one clinical problem is our custom today when attempting to define best practice strategies for such problems. But doing so often forces important relationships to be overlooked. Like anything removed from context, it can lead to mistakes, and with RECC the consequences can be devastating. This problem has been ongoing with RECC because we historically learn about medical conditions by focusing on distinct entities in series, not parallel.

In addition, each of our three RECC types are conventionally regarded the 'intellectual property' (IP) of very different medical specialties, each proffering exclusive recommendations for the process it 'owns', while often ignorant of unintended, undesirable consequences involving the other two RECC types. Making matters even more confusing, none of these 'IP' experts have extensive experience actually working within the GCF culture. Diplomatic anticipation of these potential dilemmas often intervenes, and ends up leaving RECC strategic discussion purposely vague so that no definitive guidance is proffered. This shall not be the case here. The substance and form of each RECC pattern will be discussed in detail with equal time spent integrating these processes and their potentials for conflict. Conclusions and recommendations will be clear, logical, straightforward and proven. Learning from context allows for simple, easily remembered adjustments to the way we typically go about our monitoring today. And moving forward with these adjustments can assure all postoperative patients their optimized safety. Let's get started first by exploring some basic respiratory physiology and our first historic example of how supplemental oxygen was thought to cause harm.

The Power of Knowledge

Oxygen Supplementation Can Turn Deadly

Years ago nurses and physicians had been trained to believe that supplemental oxygen was good for everyone except the acutely ill Chronic Obstructive Pulmonary Disease (COPD) patient who retained CO_2. This exception was most often explained by using the fundamentals to respiratory drive. The strongest stimulus for breathing was believed to come from centrally automated pH receptors in the brain. These receptors responded to the acidification of the cerebral spinal fluid (CSF) that occurred when carbon dioxide (CO_2) crossed the blood brain barrier. Additional control came from a variety of peripheral chemoreceptors (carotid bodies on the common carotid arteries and aortic bodies on the transverse aortic arch) connected through cranial nerves IX and X to our brain stems. These peripheral receptors responded to arterial oxygen partial pressures, pH and O_2 content respectively, but accounted for only about 1/10th the total respiratory stimulation to breathe.

Breathing is automatically modulated to maintain arterial partial pressures of CO_2 ($PaCO_2$) close to 40 mmHg. Even higher levels of CO_2 can contribute to sleep apnea arousal (self rescue process seen most commonly with obstructive sleep apnea [OSA]). There are medications [7–10], consequences of medical procedures [11], and ongoing cycling hypoxemia [12] that may increase CO_2 arousal thresholds to levels so high that the further consequential arousal delay (e.g. repeating narcotic administration) can result in profound hypoxemia and failure of the self rescue arousal entirely, i.e. 'lights out' saturation and arousal arrest (RECC Type III PUHD) [13–15]. More to come on this important subject later in the chapter.

Patients diagnosed with COPD often present with an impaired ability to rid themselves of excessive CO_2. Exposure to significantly high levels of retained CO_2 causes respiratory acidosis that normally stimulates compensatory increases in ventilation. But with advanced COPD, there is little ventilatory reserve available. Instead, the kidneys do the work by reinforcing the body's buffer system through the preservation of bicarbonate. This ultimately buffers the acidic cerebral spinal fluid, raising the pH back to more normal levels even in the presence of significantly higher partial pressures of CO_2 working against it. Although debatable, it was generally thought years ago that excessive bicarbonate desensitizes the brain's pH sensors, tricking the brain into believing its high $PaCO_2$ was actually much closer to normal than it really was.

Administrating supplemental oxygen to decompensating COPD patients who retained CO_2 was thought to become lethal by dulling the ability of the oxygen content sensitive peripheral receptors' to sustain ventilatory effort in the presence of already critically high (>60 mmHg), buffer compensated levels of $PaCO_2$. In other words, oxygen deprivation was the only ventilatory stimulus thought to remain functional. Removing this stimulus by providing oxygen would in theory completely turn off the drive to breath in these already exhausted patients. $PaCO_2$ would quickly climb into the 70s, compounding the problem now with 'CO_2 narcosis' that would

then contribute to an accelerated acute respiratory collapse. Its accompanying respiratory acidosis would overwhelm an already overextended buffer system, and crash intubation with rescue maintenance on a ventilator was often the only solution for these patients, stabilizing both the chronic and acute disease processes in the moment. But years ago the frailty and debilitation associated with this disease and primitive ventilator adaptations made it extremely difficult to wean the survivors successfully, essentially condemning them to death once the endotracheal tube had been placed.

An alternative explanation for the frequent respiratory collapses found in this patient population when treated with supplemental oxygen had been derived from a physiologic principle known as Hypoxic Pulmonary Vasoconstriction (HPV). HPV was theorized to induce respiratory decompensation through a reverse ventilation/perfusion mismatching process. Here injured or dysfunctional lung tissue no longer capable of maintaining normal oxygen tensions or diffusion was thought to have had its normally assigned blood supply already shunted away to other, healthier lung segments as HPV serves as an adaptive survival process. When transient oxygen partial pressures in dysfunctional lung tissue are artificially elevated from well intended supplemental oxygen delivery, blood perfusion was thought to return to these dysfunctional areas, upsetting a delicate homeostasis and ultimately worsening ventilation/perfusion mismatching that accelerates the initial respiratory failure.

This discussion on COPD has been somewhat esoteric and removed from our goal to learn about RECC, although it did briefly address OSA. Today, largely because of better technologies and treatment processes, these former concerns and contra-indications in COPD are no longer valid or germane. However, the subject does segue nicely with two very common ways that supplemental oxygen can cause serious patient harm when used thoughtlessly in RECC situations. What's more, we've all been guilty of these thoughtless behaviors because we've all been taught at some time in our training to believe that applying supplemental oxygen is perfectly safe. Remember, no one had taken the trouble or time to explain otherwise, in straightforward, easy to remember terms. Until 2011 our RECC conceptualizations had never been disseminated, nor their nuances fully appreciated. Everyone in healthcare has to some degree been either overtly or covertly influenced by the overly simplistic, reductionist solutions offered from threshold science. You will learn from our coming in-depth discussions why many of our clinical assumption are incorrect and what we can do now to improve care when facing RECC challenges.

But first we need to consider one more, closely related piece of conventional wisdom that has singlehandedly caused more RECC detection delay than all other misinformation combined. It has to do with exactly how critical oxygen delivery occurs and the Oxyhemoglobin Dissociation Curve. (Illustrated in Fig. 8.1 below.)

Conventional Wisdom Can Be Harmful

The Oxyhemoglobin Dissociation Curve (ODC), discovered in 1903 by Christian Bohr, was changed substantially in the mid 1980s because of our scientific infatuation with reductionism and the over simplified methodology of Threshold Science,

also helped along with an 'educational interest' surge in our society to 'go metric' [6]. Because of these influences, the so called 'knee' of the curve was conceptualized and disseminated with the introduction of pulse oximetry into our OR, PACU, and Critical Care environments. Those responsible for propagating the concept, namely the oximetry industry, had really not thought this through very well, as we shall explain.

The gist of the ODC 'knee' construct was that medicine was indeed fortunate to have a precise oximetric SPO_2 (blood oxygen saturation) threshold value that could reliably determine whether or not respiratory function was stable and well. So long as we maintain oxygen saturations at 90 % and above, all is well, but let it slip just a bit below 90 % and *watch out!* … nothing short of a free fall spiral of respiratory dysfunction that must be corrected immediately to avoid grave consequences. This 'knee' threshold, depicted at the green oval that sits on the curve's 90 % SPO_2 mark in Fig. 8.1, and everything leftward of this curve's mark indicates the sharp, potentially lethal drop-off advertised. While it is difficult to quantify how much damage a misleading belief like this may have caused, here are two explanations for why this belief should be abandoned.

Reasons to Dispel Oxyhemoglobin Dissociation Curve 'Knee' Construct

Evolutionary Disconnect

We all have inherited any number of astonishingly efficient compensatory mechanisms, summoned automatically with injury. We've known for a century that an amazing amount of resiliency is packed into all our organ systems, including:

- The ability to increase our oxygen supply 9 fold through coordinated increases in our heart rates, cardiac performance, and ventilatory responses
- Remodeling once organs have been damaged
- Regeneration, as our livers are able to accomplish under certain circumstances

So why might our moment to moment management of oxygen, the most primal of human needs, be so fragile that it could outright fail simply by breaching a metrically friendly (100–10 %) threshold SPO_2 value located at the ODC 'knee'? The correct answer – it's not! We just momentarily got our interpretation of the curve turned backward. Instead of interpreting the curve's steep dive from its knee as being a problem, we should appreciate its immediately narrowed range of O_2 partial pressures (x axis) preserved during this accelerating saturation decline (*The magic lives here in* Fig. 8.1). It's these partial pressures that are responsible for transferring oxygen molecules across the multiple bio-barriers and ultimately into our mitochondria for aerobic processing. In order for this to happen, we need a 42 mmHg PcO_2 pressure head in our capillary beds to ultimately penetrate our intracellular mitochondria and their 26 mmHg P_MO_2 steady states. Seen this way, any falloff from the knee automatically deploys an evolutionary marvel designed to preserve aerobic metabolism at all costs. It's our last wall of defense, protecting us from shock like states that otherwise would arise from even the most insignificant, transient episodes of hypoxemia.

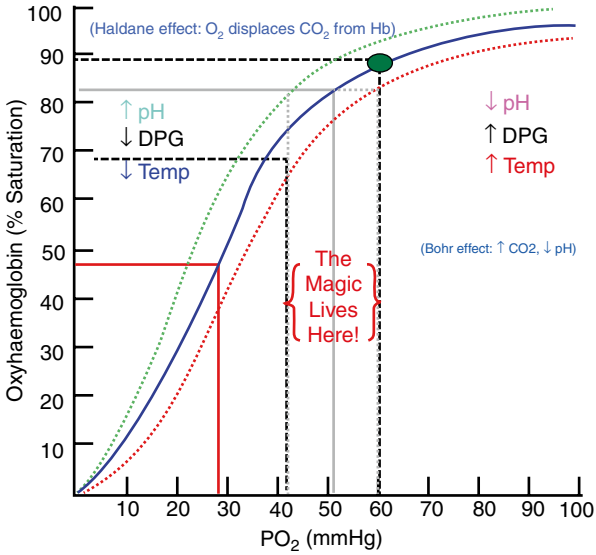


Fig. 8.1 Oxyhemoglobin dissociation curve

Naïve Interpretation of Respiratory Stability

SpO_2 values well above 90 % on continuous pulse oximeters can be deceiving and should never be considered sentinels of respiratory contentment when patients complain they are short of breath. Any patient can maintain a 'good' saturation early while slipping toward the RECC clinical abyss because of compensatory hyperventilation. The patient's actual unfavorably declining PaO_2 changes remain concealed because of this compensatory adaptation. Respiratory alkalosis from hyperventilation and its effect on hemoglobin affinity hold saturations stable almost immediately in early crisis. Our compensatory actions will deliver oxygen first and foremost when the respiratory system is challenged. Only later in the process does hydrogen ion stability, conformational changes of the hemoglobin molecule, and ultimately a precipitous fall in oxygen saturation (SpO_2) combine to produce a resounding state of total respiratory collapse. Unfortunately this is when we most often are just beginning to realize our patients really are in trouble, when it's difficult to miss and much more difficult to reverse, with death likely to follow quickly. We will explore the wonders of the Oxyhemoglobin Dissociation Curve (ODC) more thoroughly with our in depth review of RECC Type II PUHD.

Designing the Solution

Now we're ready to begin explaining our three patterns of unexpected hospital death associated with RECC. These patterns don't account for all the ways people die in hospitals, but they do define those rapidly progressing, unexpected clinical processes persistently taking us by surprise. They're routinely associated with

catastrophic outcomes because of delayed detection, and their prevalence hasn't changed in two decades regardless the 'advances' in monitoring technologies. Don't be overly concerned if you don't immediately grasp the context of our three constructs. All will become clear more quickly than you think.

The Three RECC Pattern Types of Unexpected Hospital Death

TYPE I: Hyperventilation Compensated Respiratory Distress (*e.g. Sepsis, Congestive Heart Failure, Aspiration, Pulmonary Embolism*). Here a stable SpO_2 (blood oxygen saturation) with progressively falling $PaCO_2$ (arterial partial pressure of carbon dioxide) eventually yields to a slow SpO_2 decline (mitigated by compensatory respiratory alkalosis shifting the oxyhemoglobin dissociation curve to the left), then followed by a precipitous SpO_2 decline when metabolic acidosis dominates nearing its terminal stages.

TYPE II: Progressive Unidirectional Hypoventilation (*CO_2 Narcosis, overdose of opioids or sedatives*). Here one finds a progressive rise rather than the usual rise and leveling off of an elevated $PaCO_2$ and $etCO_2$ (end tidal carbon dioxide), and a concurrent fall in SpO_2 over 15 min to many hours once the P_ACO_2 (alveolar partial pressure of CO_2) becomes high enough to begin competing with the P_AO_2 (alveolar partial pressure of oxygen) for alveolar space.

TYPE III: Sentinel Rapid Airflow/SpO2 Reductions Followed by Precipitous Falls in SpO2 (*A state of 'arousal dependent survival' that occurs only during sleep in sleep disordered breathing conditions such as obstructive sleep apnea and some hypoventilation syndromes*). Here one finds a preconditioned degree of arousal failure often partially enabled by a decrease in oxygen reserves that allows for a precipitous hypoxemia event during apnea causing a terminal arousal arrest.

Linking the Patterns to Physiologic Principles (Understanding Lung Capacities and Volumes – Ventilatory Anatomy and Physiology)

Before we begin our deeper looks into each of our three RECC PUHD Types, we'll take a moment to review some basic pulmonary science. This will provide us an easy way to both understand and remember the unique patho-physiologic processes that define each PUHD.

The diagram in Fig. 8.2 illustrates what we mean when we discuss lung capacities and volumes.

Functional Residual Capacity (FRC) depicted above in Fig. 8.2 is an important, albeit virtual anatomic structure whose job is to continually provide our bodies any additionally needed oxygen beyond that being delivered within our moment to moment tidal volumes, so to maintain the stability our arterial oxygen content. It functions largely as an oxygen reservoir, playing a vitally important role as a necessary and persistent contributor to our respiratory physiology, maintaining our

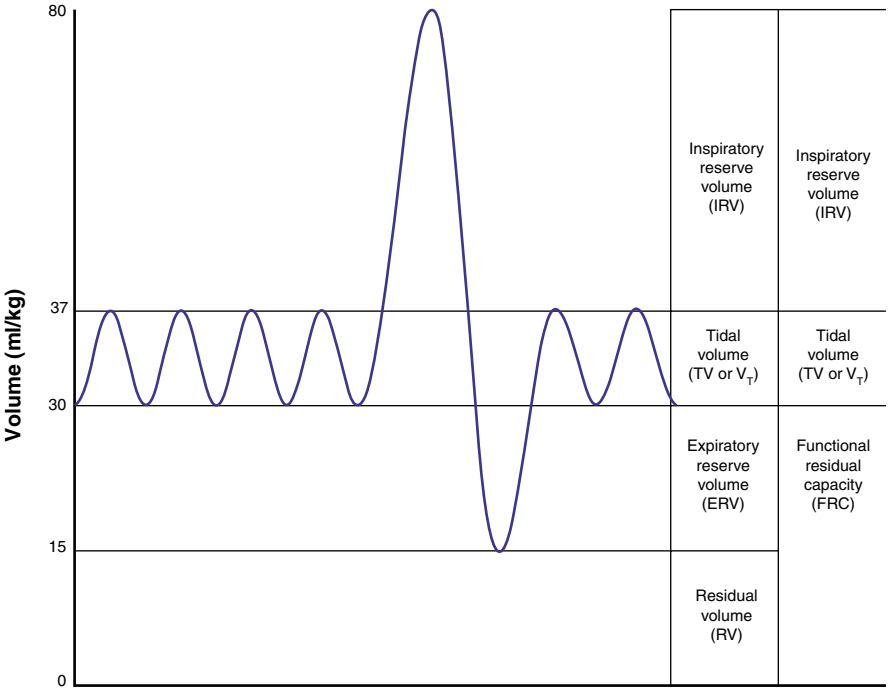


Fig. 8.2 Lung capacities and volumes

generally very stable arterial oxygen saturations. FRC is a combination of two real and separate anatomic volumes called Expiratory Reserve Volume and Residual Volume, but is more easily remembered as the lung air left over after normal exhalation. Our lungs hold approximately 6 L of air for men and less than 5 L for women at full capacity, achieved only during deepest inspiration. But on average our lungs normally operate at rest with our taking in tidal volume (V_T) breaths of 500 ml 'atop' our FRC. Exhalation occurs approximately 16 times a minute leaving on average 2 L of air behind. Without our FRC, the tidal volumes we depend on to 'freshen' our FRC would only be capable of introducing oxygen into our circulations during a small portion of our ventilatory cycles. The FRC adds a comfortable cushion, allowing for continual restocking of oxygen desaturated blood that recurs reliably (to a point) even when lungs are partially damaged or breathing stops over short time intervals, like when holding our breaths, or at the onset of being strangled. Unfortunately, more prolonged apneas can deplete this FRC reservoir regardless how robust it might be under normal circumstances, which is germane to our coming discussion on Obstructive Sleep Apnea and RECC Type III PUHD. But our primary reason for discussing FRC is that all three RECC pattern types can be easily remembered by associating each with a purposefully exaggerated, distinctly separate pathologic influence it inflicts on the FRC.

These three exaggerated pathologic FRC influences are defined with one word each, except for the last (RECC Type III), requiring two words. Exaggerations were purposefully chosen because they have proven to be the most reliable memory cues available. Recall association always works best when using unusual or absurd cues. These memory cues enable bedside clinicians to quickly, easily, and reliably recall how to approach GCF patients regarding each of our three RECC Types. Critical thinking, what constitutes an appropriate response, what doesn't and why, all of this remains fresh and available to any clinician using these cues. The importance of ongoing monitoring and paying attention to trends becomes obvious and engaging as well, even though the cues aren't meant to be precise. Respiratory dysfunction that involves acute progressive hypoxemia is a complex subject, comprising a myriad of supply and demand contributors that include ventilation/perfusion mismatching, shifting closing pressures, hypoventilation, apnea, FRC reductions, atelectasis, diffusion failure, shunting, and low venous saturations to name just a few. But our simplified FRC associated cues make this complexity vanish and appropriate early correction possible, the RECC Types I, II, III now recognizable early and understood. This should translate to providing patients their best chances to avoid needless complications, or if unavoidable, to limit morbidity. And now we shall begin our deep looks into our RECC PUHD Types.

RECC Type I PUHD

A healthy male who had just undergone elective surgery develops shortness of breath that's noticed by his family who express concern to the nurse. The nurse, citing a normal oxygen saturation reading on his oximeter, reassures the family that the monitor indicates he's okay. Eventually his respiratory rate does rise to a critical value, but by this time it's too late to effectively respond to his rapidly deteriorating clinical condition and the patient, with sepsis, dies.

This pattern, defined as Hyperventilation Compensated Respiratory Distress, reflects a clinically evolving process associated with microcirculatory failure induced by such common conditions as sepsis, congestive heart failure (CHF), aspiration, and pulmonary embolism (PE). It's the most common pattern of our three, with incidences reaching as high as 3 % in some postoperative populations. Let's first examine how the onsets of our four RECC examples of Type I PUHD might compromise the FRC and its ability to stabilize oxygen saturation. The word cue to describe this Type I process is '*replacement'*. RECC Type I PUHD involve processes that replace a patient's healthy lung (FRC) acutely and near immediately. With CHF, water does this replacing. In sepsis, it's pus (inflammatory factors). It's gastric and bowel content with eventual pus in cases of aspiration, and with PE, portions of the FRC vanish outright to become dead space. Targeting the correct replacement process early, before a critical mass of lung becomes irreversibly injured, is essential to survival.

Type I patterns generally begin with subtle hyperventilation and a persisting respiratory alkalosis (RA), despite subsequent progressive increases in anion gap

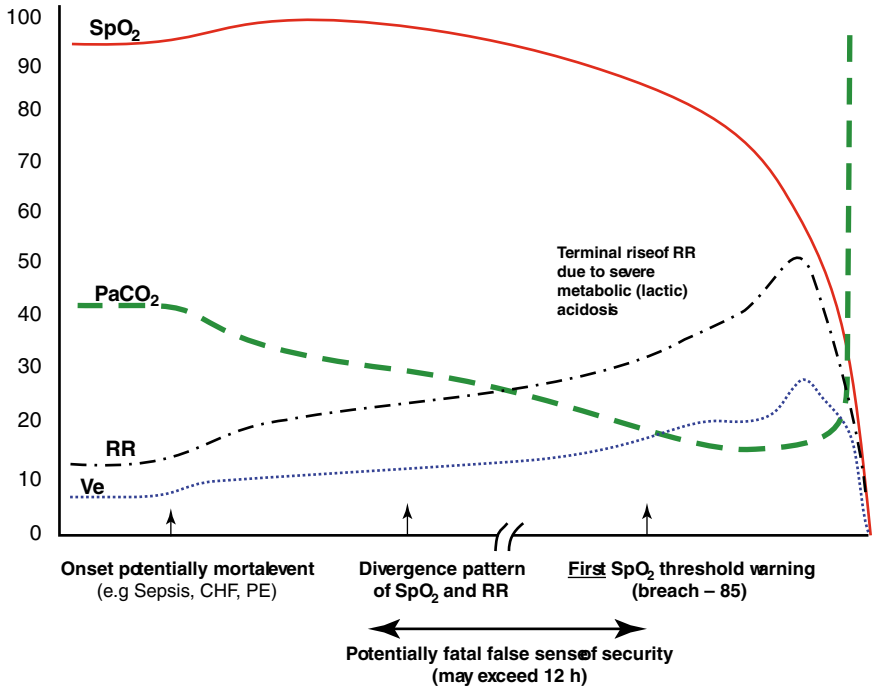


Fig. 8.3 RECC Type I PUHD

and lactic acid levels. This stage occurs well before the development of dominant metabolic acidosis (MA), which is usually associated with its later, and very late terminal stages. These progressive pattern phases (initially isolated RA followed by mixed RA and MA, in turn followed by dominant MA) comprise the typical progression of a Type I PUHD. (Illustrated in Fig. 8.3 below.)

The subtle early signs are easily overlooked, usually accompanied with complaints of mild dyspnea (shortness of breath) if patients are able to articulate their symptoms, and often mistaken for anxiety. Nurses and physicians have been too willing to discount these harbingers, even more so today than back in the pre-oximetry era, because now with oximetry often available patients may begin complaining, but their SpO_2 values are seen as remaining 'normal'. Saturations in the mid-90 % are commonly misinterpreted as indicating respiratory stability when it's really not. What's forgotten is that the subtle hyperventilation accompanying early complaints of dyspnea can easily mask the troubling changes taking place in the patient's blood and lungs by shifting the Oxyhemoglobin Dissociation Curve (ODC) leftward. Here time becomes the patient's most important resource…using it appropriately can be life-saving! FRC *replacement* is actually a progressive injury developing in the lungs where oxygen saturation at first holds steady from the compensatory respiratory alkalosis while PaO_2 begins to diminish. Caregivers walk away falsely reassured because they've forgotten their basic science. Any

complaints or signs of dyspnea need to always be carefully evaluated at their onset! Unfortunately, this frequently isn't the case. Instead, very high respiratory rates (≥30/min) eventually trigger rapid response team activations in most hospitals [16, 17], likewise triggering these patients' first detailed evaluations, both late and sadly most often found in the non survivors when examined retrospectively [18].

Mildly elevated respiratory rates are known to be nonspecific markers for respiratory distress, and are often ignored or unreliably recorded until extreme values are reached. Once reached, like high lactate levels [19], they become specific, but for the much later RECC Type I PUHD manifestations of severe metabolic acidosis. Here they are best considered markers of severity and diagnostic delay [20] rather than useful warnings of early instability. Late Type I PUHD is both sensitive and specific for an irreversible condition, and both the misinterpretation of pulse oximetry and the unreliable recordings of respiratory rate have combined to contribute to, rather than counter Type I events. However, now available is an accurate, continuous non-invasive minute ventilation monitor that could be combined with pulse oximetry to provide the most reliable information needed for early detection of all Type I PUHD events, and Type II and III as well…more to come on this subject later.

Once again, early microcirculatory failure in the lungs begins a progressive fall in PaO_2 and available oxygen content [21] as you might imagine the patient's FRC starting to be replaced. But the accompanying patient hyperventilation perpetuates normal appearing oxygen saturation (SpO_2) values because of its associated respiratory alkalosis and the ODC's leftward shift [22]. These early compensatory changes can fool uninformed clinicians with initial, 'normal' appearing saturations that disguise this RECC. By thinking it through, early detection and intervention is possible. But what more commonly follows makes matters worse. Supplemental oxygen is ordered, starting at 'low' levels, then increased in increments, where it continues to conceal the advancing pathologic *replacement* changes, all the while the patient's condition deteriorating.

The iterative increases in supplemental oxygen mask and delay accurate assessment by matching the dynamically advancing *replacement* (injury) process with its own dynamic concealment process. The oximeter and its SpO_2 values remain falsely reassuring until quite late when the RECC Type I PUHD turns deadly. These routine delays in detection and management are commonplace on our general care floors. When reviewed, these events show both physicians and nurses lulled into early complacency. Then hours go by with the only documented 'management' being incremental increases in the supplemental oxygen that perpetuates this complacency. These passive tactics, rather than workups and aggressive treatments these situations call for, become causative! They are directly associated with the inevitable dismal outcomes, but rarely appreciated as culpable. Patients generally get whisked off to Critical Care Units, considered only victims of expected perioperative risk. And the cavalier misuse of supplemental oxygen continues, mistakenly condoned or ignored from ignorance. Death, when it does come this way, is rarely regarded catastrophic except within those families involved … though it ought to be. Remember, supplemental oxygen should only be used in tandem with an aggressive search for a possible underlying RECC process. Otherwise, it unfortunately becomes the second way supplemental oxygen can harm.

RECC Type II PUHD

A healthy female who is receiving routine post–op nasal oxygen has been up all night complaining of severe post-op pain, but is now finally asleep after yet another dose of IV opioid. The nurse, noticing on rounds the patient's oxygen saturation is 'perfect' on the monitor, decides not to awaken her. She is found dead in bed 4 h later.

This pattern is best defined as Progressive Unidirectional Hypoventilation (CO_2 Narcosis). Since the 1950s [23], nurses and physicians in training have learned that opioids produce death through a singular path involving progressive hypoventilation. The combination of opioids and a rising $PaCO_2$ contributes to central depression of our ventilatory drive, ultimately leading to 'CO_2 Narcosis' severe enough to bring on respiratory arrest. Opioid associated events aren't unusual in hospitals today. Experts speculate that up to a third of all code blue arrests in hospitals could result from opioid induced respiratory depression [24], and naloxone is administered as an antidote for opioid associated events in 0.2–0.7 of patients receiving them postoperatively [25, 26]. One estimate has these representing 20,000 of our nation's patients annually with one tenth suffering significant opioid related injuries that include death [27]. When severe injury and death do result from opioids lawfully administered in hospitals, it's termed 'iatrogenic', arguably a less pejorative way to say we clinicians are responsible. These events are always catastrophic, devastating to patients, patient families, and all clinicians involved. Yet in spite of all this incentive to improve, we have not made meaningful progress in protecting our patients from these events for a host of reasons, one being the increased emphasis on optimal postoperative pain management by centers that govern reimbursement [3].

The RECC Type II Pattern exhibits a significant diminution in both inspiration and expiration airflow that results in significant quantitative changes in the amounts of gases normally occupying lung. Because these gas partial pressure shifts equilibrate near immediately with arterial blood minus a small, generally predictable A-a gradient, once extreme levels are reached, they can cause biochemical dysfunction at all end organ sites, most importantly the brain. Specifically, $PaCO_2$ increases within the blood and $PaCO_2$ in lung, unable to be cleared because of the opioid induced ventilatory depression. When levels of $PaCO_2$ have climbed to 'narcotizing' thresholds in the 70 mmHg range, carbon dioxide's own respiratory depressive effect begins to assert, combining synergistically with the opioid to accelerate a covert respiratory failure, and with it both morbid obtundation and severe respiratory acidosis. On the postoperative GCF, these progressing respiratory failures are often confused with blissful sleep while extraordinarily high $PaCO_2$ levels continue to silently mount. These Type II events are frequently discovered only by accident when unsuccessful attempts are made to arouse these patients. They're the lucky ones!

Some patients are at very high risk for postoperative hypoventilation when given 'normal appearing' doses of sedatives and opioids. Patients with congenital central hypoventilation syndrome [28] can be completely asymptomatic while awake, yet despite their normal daytime $PaCO_2$, exhibit profound hypoventilation responses to sedation and opioids when asleep. Others at risk include patients with obesity hypoventilation syndrome [29], chest wall deformities, polio sequelae, advanced COPD [30], and severe hypothyroidism [31].

Our current practice for detecting opioid induced respiratory depression is to monitor the respiratory rate, and while some studies have shown that respiratory rate reductions provide a useful indication of ventilatory depression in some patients [32, 33], there's ample evidence to suggest that it's not quite that simple. Several studies have shown narcotic and sedative induced respiratory depression frequently associated with reductions in tidal volume and more variable patterns of breathing [34–36]. In fact, hypoventilation produced by some benzodiazepines may primarily reduce tidal volumes with accompanying increases in respiratory rate [37]. In obese patients, or others with narrow, semi-patulous upper airways, tidal volumes may be even further reduced through increases in opioid associated upper airway resistance [7, 8], suggesting that any relative reductions in rate and/or tidal volume are likely to be highly variable depending on both patient and drug-related factors. Because, in so many cases, tidal volume may be reduced to a significantly greater extent than respiratory rate, the application of threshold respiratory rate monitoring as our single surrogate marker for opioid induced respiratory depression can easily provide a false sense of security. The addition of continuous pulse oximetry surveillance to intermittent or continuous respiratory rate monitoring can be just as inadequate when supplemental oxygen is being provided [38].

As hypoventilation progresses, if supplemental oxygen is being provided, it can disguise the CO_2 retention and progressively rising $PaCO_2$ from continuous pulse oximetry monitoring until very late when lethal levels have accumulated [39–41]. This masking effect can result in deadly delays much like it does with Type I PUHD, but for an entirely different reason. Without supplemental O_2, the expected Fraction of Inspired Oxygen (FIO_2) contained in the air we entrain into our lungs is more quickly diluted into much leaner partial pressures through a FRC *'substitution'* process. Where Type I PUHD can be thought of as *'replacing'* the FRC itself, Type II PUHD *'substitutes'* one gas's progressively rising partial pressures (P_ACO_2 and $PaCO_2$) for the partial pressures of those others remaining from the inhaled room air (N_2, H_2O, and O_2), a biologic dilution that when added all together equals the expected atmospheric pressure. This trapped, progressively rising P_ACO_2 competes for the same 'FRC' space as the fixed partial pressure components of air, progressively diminishing the latter, most importantly P_AO_2. The alveolar gas equation:

$$[P_AO_2 = F_IO_2\left(P_{ATM} - PH_2O\right) - PaCO_2 / RQ]$$

can approximate what these expected partial pressure values of the diluted (*substituted*) alveolar oxygen should be in people with lungs that function normally. For example, at sea level breathing room air with a normal $PaCO_2$ of 40 mmHg, we can expect the P_AO_2 to be 99.7 mmHg. If the $PaCO_2$ rises to 50 mmHg, the P_AO_2 falls to 87.2 mmHg, 60 mmHg $PaCO_2$ = 74.7 mmHg P_AO_2, and 70 mmHg $PaCO_2$ (CO_2 Narcosis) = 62.2 mmHg P_AO_2. Assuming normal breathing patterns and pulmonary physiology, it isn't difficult to reasonably estimate from the P_AO_2 what the PaO_2 should be. Generally, the P_AO_2-PaO_2 (A-a gradient) when breathing room air can be calculated simply by taking a patient's age, adding 10 to this value, and dividing the sum by 4. So if a 50 year old patient breathing room air has a P_AO_2 rounded off to

100 mmHg, his PaO_2 would be expected to approximate 85 mmHg (15 mmHg A-a gradient). And once we know the PaO_2, we should be able to estimate his blood oxygen saturation (SPO_2) with reasonable accuracy, but only if we account for the variables that influence hemoglobin saturation. These variables are the parameters capable of shifting the Oxyhemoglobin Dissociation Curve (ODC) to the right or left, such as concurrent arterial blood pH, $PaCO_2$, background 2,3DPG (Diphosphoglycerate), and temperature. There may be hidden variables as well, unique to individual patients that can skew any of these mathematical outcomes unexpectedly. However, generally automated mathematical models like HbO. Severinghaus and HbO.Dash are used today to correlate reliable saturation values off any known PaO_2, provided we accept certain assumed fixed values for some of the less important variables, yet account for the most important ones. The HbO.Dash model offers one large correction advantage by allowing us to factor the patient's concurrent arterial blood pH and $PaCO_2$ into its saturation determination. This provides a significant correction because it accounts for the Bohr effect, a major physiologic modifier that shifts the ODC increasingly rightward or left, the more acidotic or alkalotic a patient's arterial blood might be. Respiratory acidosis (elevated $PaCO_2$) and its rightward curve shifts can significantly decrease the expected saturation values on any given PaO_2. Leftward shifts associated with respiratory alkalosis (diminished $PaCO_2$) raise expected saturation values for any given PaO_2, like that caused by the hyperventilatory respiratory alkalosis seen in early Type I PUHD. The same ODC shifts holds true for metabolic acidosis and alkalosis.

Regarding our RECC Type II PUHD, an immediate mounting respiratory acidosis can be assumed from its definition of rapidly evolving unidirectional hypoventilation that results in progressive CO_2 retention. With immediate onsets of respiratory acidosis, an arterial blood's pH value in an otherwise healthy individual can be predicted directly from knowing the $PaCO_2$ value using a Henderson-Hasselbach equation calculator ($pH = 6.1 + \log(HCO_3/(0.03 \times PaCO_2))$), because the equation's bicarbonate (HCO_3) variable remains fixed at 24 mEq/L. (It generally takes 3–5 days for our kidneys to begin compensating for any acute respiratory acidosis by preserving additional HCO_3) Pulse oximeters measure saturation directly and don't sort out which variables are at work altering the ODC to make that SPO_2 possible. That's left for us to determine.

HbO.Dash simulated computation assumes the following fixed values for two of the less important parameters (background 2,3DPG [4.65 mM] and 37.5 C for temperature). Most often these assumptions are nominally misleading, but usually won't play significant roles in masking oxygenation dysfunction unless massive transfusion is needed or complications arising from surgery and/or anesthesia unexpectedly occur. 2,3DPG is an organophosphate created in red blood cells during glycolysis, and its production increases with diminished peripheral O_2 availability (e.g. hypoxemia, chronic pulmonary disease, anemia, and CHF). High levels shift the ODC rightward, while low levels associated with septic shock and hypophosphatemia can cause a leftward shift, again where the SPO_2 for any given PaO_2 value becomes artificially elevated. Likewise, CO_2 can have a double edged effect on the ODC. We've already discussed its important Bohr effect from arterial blood pH

changes that occur with $PaCO_2$ variability. But CO_2 accumulation also causes carbamino compounds to be generated through chemical interactions that once high enough can shift the ODC leftward, also falsely elevating the SPO_2.

This is a lot of information to keep track of. Why should we be able to do this, or at the very least understand why it's done? The reason 'why' becomes critically important once we acknowledge that a large number of bedside clinicians have allowed themselves to become dependent on monitor alarms (e.g. continuous pulse oximetry) to do their thinking for them. This is Threshold Science fallout! Our threshold alarms, as they are generally used today, are incapable of adequately detecting our RECC Types early. At times they are incapable of detecting our RECC Types at all. We discussed early in this chapter that most pulse oximetry monitors, even those used on GCF, are set to alarm once the SPO_2 value dips below 90 %. This particular GCF practice continues to be associated with both alarm fatigue and poor opioid associated GCF outcomes, nor is it practiced universally across our nation. Dartmouth's Hitchcock Medical Center has been deploying universal GCF pulse oximetry monitoring with alarm thresholds set at 80 %, and boasts no opioid associated deaths since 2007 without any nuisance alarms [42]. Nevertheless, 90 % thresholds account for the majority of GCF practices today because most individual institutions have not thought the practice consequences through properly, still mistakenly believing the SPO_2 90 % threshold represents an unimpeachable standard of care. But if we believe ourselves to be clinicians expertly capable of managing patients receiving parenteral opioids, one of our skill sets should certainly be to reliably detect opioid associated CO_2 narcosis (Type II PUHD) at its earliest ($PaCO_2 = 70$ mmHg) when it can be easily corrected. In order to do this, we need to at minimum be aware of the fundamentals of respiration, including an appreciation for its complexity and potential Boobie Traps. We'll now look again at our healthy 50 year old with normal lungs, but will make him a PACU patient with you in charge. We will also compare him to a healthy 30 year old and 75 year old in order to get you comfortable with the vagaries of respiratory complexity and opioid associated Type II PUHD influences. We will assume that this hypothetical PACU is at sea level for those of you clever enough to insist on this amount of granularity.

All three of your hypothetical patients go through operations where there is minimal blood loss but significant pain. For our first vignette, assume each is about to leave the PACU on room air, all are comfortable from appropriately administered intermediate opioids, all easily aroused with SPO_2 of 92 % and breathing at 10/min. They have all been started on standard, demand only morphine PCAs, and will be monitored with continuous pulse oximetry once on the GCF. What might be your concerns? You certainly have done a nice job managing their pain, and there seems to be physiologic evidence that opioids are producing some respiratory depression along with high quality analgesia. Because these are otherwise healthy individuals, and you feel somewhat confident in the safety profiles of demand only PCAs, you shouldn't feel a need to subject these patients to arterial sticks for obtaining blood gases. What you might want most is reassurance that should these patients become progressively more narcotized to the point of CO_2 narcosis ($PaCO_2 = 70$ mmHg), that this will be reliably detected on the GCF. You also know how busy the GCF can

get and that your GCF oximeters alarm once SPO_2 values breach 90 %, just like yours in the PACU. If you are sensitive to ACLS recommendations, stating severe arterial acidosis comprises pH<7.20 you might also want to keep these patients' arterial pH above 7.25 (which can be done in the face of simple respiratory acidosis by limiting the maximum $PaCO_2$ to 55 mmHg). So given all this, let's have a look under the hood using mathematical models to project just how safe these patients will be on the GCF with continuous pulse oximetry surveillance.

Your 30 year old patient breathing room air will have a P_AO_2-PaO_2 (A-a gradient) of 10 mmHg, your 50 year old a 15 mmHg gradient, and your 75 year old a 21 mmHg gradient. You can't calculate precisely what your P_AO_2 will be because you don't know what your $PaCO_2$ is, but you do know you prefer the $PaCO_2$ to not exceed 55 mmHg. So working backwards with the assumption that your 30 year old's $PaCO_2$ is 55 mmHg, his P_AO_2 calculates out to be 81 mmHg. Subtract his A-a gradient of 10 mmHg and his PaO_2 would be 71 mmHg. This value correlates to a HbO.Dash SPO_2 computation value of 91 %, 1 % beneath his current PACU SPO_2 92 %, indicating at the moment a job well done since his $PaCO_2$ must be somewhere beneath your 55 mmHg limit. But there's not a lot of cushion! The HbO.Dash computation also tells you with appropriate recalibrations of his P_AO_2 that this patient's PaO_2 would need to drop to 67 mmHg to trigger a pulse oximeter's alarm set for a 90 % SPO_2 breach. It further quantifies that any such breach would correlate with a $PaCO_2$ of 58 mmHg that calculates to a pH of 7.24, neither ideal but well beneath a $PaCO_2$ of 70 mmHg where emergent, though relatively simple therapeutic interventions would be needed to bring ventilatory performance back in line.

Your 50 year old has a 15 mmHg A-a gradient, so working with the same assumptions above, his PaO_2 drops to 66 mmHg. This correlates to a HbO.Dash SPO_2 value of 89 %. Clearly, with a SPO_2 value of 92 % on room air, his $PaCO_2$ and pH will be within acceptable ranges. Additional computation shows us that the 90 % threshold pulse oximeter will begin alarming (SPO_2 89 %) if his $PaCO_2$ should climb to 55 mmHg. Your 75 year old has a 21 mmHg A-a gradient that drops his PaO_2 to 60 mmHg at a $PaCO_2$ of 55 mmHg. This correlates to a HbO.Dash SPO_2 value of 87 %, leaving even more margin for safety regarding his pH with his PACU SPO_2 being 92 %. In fact, the opioid respiratory depression I fictitiously assigned him doesn't really align with his calculated clinically near normal $PaCO_2$ of 46 mmHg, and pH of 7.34 that were worked out with multiple simulated HbO.Dash computation runs. But any $PaCO_2$ higher than 50 mmHg would drop his SPO_2 below 90 %, causing the GCF pulse oximeter to alarm needlessly, assuring unwanted nursing distraction should he choose to push his PCA demand button. Unfortunately, it also assures little rest for him and unsafe GCF conditions because of alarm fatigue. One way to circumvent this issue would be to provide supplemental oxygen, as we are accustomed to doing. But as will be demonstrated, this decision comes at a steep price.

Back again to your 30 year old patient. Instead of breathing room air in the PACU, he's given 3 L/min O_2 through nasal cannula. Let's assume that this raises his FIO_2 from .21 to .30, a commonplace assumption ($.21 + (.03 \times O_2$L flow/min)) when using this kind of oxygen delivery system [43]. Now his A-a gradient must be adjusted to accommodate this approximate .1 FIO_2 addition, and the new gradient is

estimated by adding an additional 5–7 mmHg to his original A-a gradient for each added .1 FIO_2 increase. Because the FIO_2 is now .3, his calculated P_AO_2 (assuming a $PaCO_2$ of 55 mmHg) will now be 145 mmHg. So we subtract from this P_AO_2, his (age + 10)/4 + the additional 7 mmHg A-a adjustment, and his PaO_2 approximates 128 mmHg. This PaO_2 correlates to a HbO.Dash SPO_2 above 98 %, meaning that at a pH of 7.26 and $PaCO_2$ of 55 mmHg, the pulse oximeter will not indicate any sign of trouble. At a $PaCO_2$ of 70 mmHg (pH of 7.16) his P_AO_2 calculates to 126.4 mmHg and his PaO_2 with A-a adjustments approximates 109 mmHg. This yields a 95 % SPO_2, a value that rarely earns more than cursory notice, yet now your patient is in serious trouble while probably appearing to be sleeping blissfully in no distress at all! Your 50 year old patient will have a near identical experience because with all the adjustments appropriate for his age, at a $PaCO_2$ of 70 mmHg (pH of 7.16) his PaO_2 calculates to 104 mmHg with a HbO.Dash SPO_2 value again of 95 %! Your 75 year old doesn't fair any better. At a $PaCO_2$ of 70 mmHg (pH of 7.16) his PaO_2 calculates down to 98 mmHg with his A-a adjustments, but the HbO.Dash SPO_2 remains in the 95 % range, just a tad lower by fractions of a decimal point. Knowledge is always good, but can be frightening at times! Let's see how things might improve as we attempt to limit your 'low' flows of supplemental O_2, starting at 1 L/min.

1 L/min O_2 flows though nasal cannula by convention will bring the FIO_2 from .21 up to .24, although we'll share some caveats regarding this in a moment. Assuming a FIO_2 of .24 and a $PaCO_2$ of 55 mmHg, your P_AO_2 calculates to 102.4 mmHg. Adjusting for the A-a gradient, your 30 year old will have a PaO_2 of 89.4 mmHg and a HbO.Dash SPO_2 of 95 %, which as mentioned above will not normally draw a lot of attention unless the bedside clinician is very well informed about these basic science details. Your 50 year old will have a PaO_2 of 84.4 mmHg at a $PaCO_2$ of 55 mmHg, with a HbO.Dash SPO_2 of 94 %, and your 75 year old will have a PaO_2 of 78.4 mmHg with a HbO.Dash SPO_2 of 93 %. Said another way, these patients may be comfortable and will probably not attract much clinical attention based on their SPO_2, even though their respiratory acidoses (pH 7.26) are teetering at moderately severe. What happens if we drive the $PaCO_2$ up to 70 mmHg where CO_2 narcosis comes into play? Here the P_AO_2 calculates at 83.6 mmHg. Adjusting for the A-a gradients, your 30 year old will have a PaO_2 of 70.6 mmHg and a HbO.Dash SPO_2 of 89 %, which guarantees a 90 % threshold oximeter alarm. Your 50 year old will have a PaO_2 of 65.6 mmHg at a $PaCO_2$ of 70 mmHg, with a HbO.Dash SPO_2 of 87 %, and your 75 year old will have a PaO_2 of 59.6 mmHg with a HbO.Dash SPO_2 of 83–84 %.

It would seem that delivering 3 L/min supplemental O_2 flows through nasal cannula leaves little to no clue on continuous pulse oximeters that lethal Type II PUHD patterns might be evolving. Even with alarms set to sound at 90 % SPO_2 breaches, early CO_2 narcosis will be missed. Nor is any significant downward SPO_2 drift evident at this flow rate. On the other hand, if supplemental O_2 must be used, containing it at a 1 L/min flow rate does allow detection of early CO_2 narcosis either with continuous pulse oximetry using 90 % alarm thresholds, or the far more desirable observations of adroit bedside clinicians looking for signs of downward SPO_2 drift. Here, being vigilant and aware of unexpected downward trends of SPO_2 on 'sleeping' patients can give CO_2 narcosis away prior to any alarm and harm.

Unfortunately, there is another fly in the ointment we must address before leaving this heady subject. Unappreciated by many clinicians is the striking variation that can occur with FIO_2 when oxygen is delivered through nasal cannula. A patient's actual FIO_2 gain while receiving 'low flow' oxygen supplementation (traditionally 1–3 L/min), can increase significantly if that patient normally pulling in robust tidal volumes is now narcotized to where the associated respiratory depression reduces tidal volume and minute ventilation to half their normal size. Flow rates and the actual percentage of oxygen entrained into patients' lungs can be unpredictable and independent of one another unless specialized equipment like Venturi systems are used. Calculating accurate FIO_2 with nasal cannula requires knowing the patient's minute ventilation and fraction of oxygen flow actually reaching the lung. Shortcut gimmicks suggesting that for every iterative oxygen liter flow increase, the FIO_2 can be expected to climb .03 [43], are based on assumptions of 'average' tidal volumes and 'guestimates' of the entrained oxygen content. All of this can be wildly disparate from one patient to the next, especially where opioid induced respiratory depression is involved.

We'll close this discussion with one last set of HbO.Dash computations, designed to test if early CO_2 narcosis ($PaCO_2 = 70$ mmHg) can be detected on an oximeter at an FIO_2 of .27 (conventionally associated with 2 L/min O_2 flow rates through nasal cannula). Your expected P_AO_2 at a $PaCO_2$ of 70 mmHg would be 105 mmHg. Your 30 year old patient's A-a gradient adjusts his PaO_2 to 90 mmHg and a HbO.Dash SPO_2 of 93–94 %, your 50 year old adjusts to a PaO_2 of 85 mmHg and a HbO.Dash SPO_2 of 93 %, and your 75 year old adjusts to a PaO_2 of 79 mmHg and a HbO.Dash SPO_2 of 91 %. No alarms sound from a 90 % threshold breach, but the SPO_2 downwardly drifting trend is evident, and can forewarn an astute bedside clinician that CO_2 narcosis should be ruled out. How would we rule this out? Simply go to the patient's room, observe if they are 'sleeping' and if they are, try to arouse them. Remember, these comfortably content 'sleepers' could be comatose. Unless we act to determine that they are arousable, we'll never know for certain this is the case. And if it isn't, this is the third way that supplemental oxygen harms patients. It isn't necessarily a bad practice to deliver small doses of supplemental oxygen to postoperative patients (1 L and perhaps even 2 L/min if clinicians are comfortable with the degree of respiratory depression encountered), just potentially dangerous in environments where no one has the ready knowledge and experience to appreciate these physiologic relationships. Unfortunately, this potential danger is both real and quite commonplace on busy GCF today.

To summarize (as illustrated in Fig. 8.4 below): RECC Type II PUHD comprises first a progressive fall in minute ventilation due to declines in tidal volume and/or respiratory rate, both unpredictably variable. This induces a progressive rise in both $PaCO_2$ and FRC CO_2 partial pressures, (P_ACO_2) that eventually '*substitute*' for other essential gases, e.g. O_2. If breathing room air, this '*substitution*' process can be detected early using continuous pulse oximetry because of its downwardly drifting SPO_2 trends. Providing supplemental oxygen at FIO_2 above .27 can disguise the '*substitution*' process from pulse oximeters, making detection of the impending

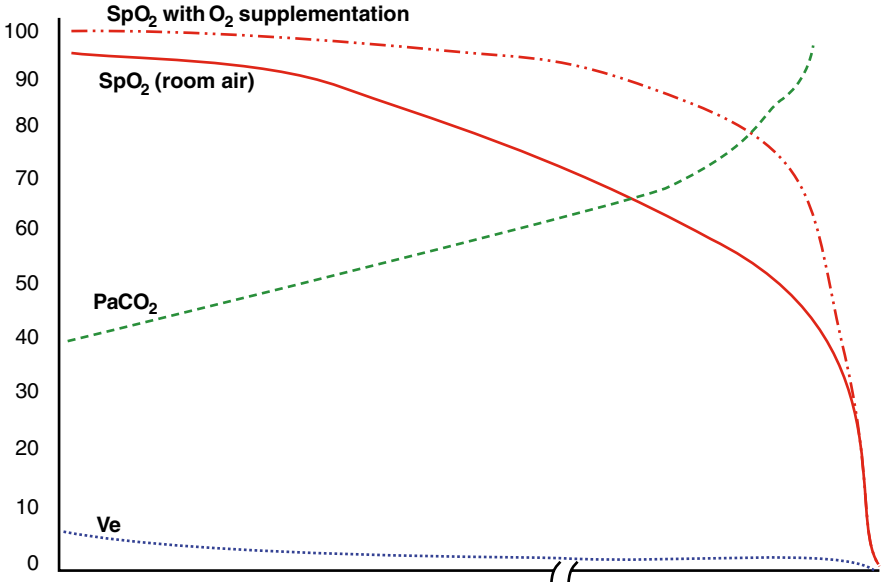


Fig. 8.4 RECC Type II PUHD

'CO_2 Narcosis' exceedingly difficult. These patients exhibit progressively higher sedation scores to the point of stupor and death if unfortunate enough to not have anyone attempt to arouse them.

When provided with even modest amounts of supplemental oxygen (>2 LO_2/min nasal cannula), patients under the influence of opioid induced respiratory depression can maintain oxygen saturations (SPO_2) in 'normal' range until very late. From a surveillance perspective, this is the one RECC Type that can be detected using continuous, real-time CO_2 monitors. However, important issues associated with choosing this strategy, excluding its significant additional cost, center on:

- Agreeing to a value that would define the alarm threshold best representing a legitimate clinical threat
- Patient tolerance for the monitoring and sensors needed
- How best to reverse the respiratory depression once detected, without neutralizing the just as important analgesia that triggered the initial problem.

Optimal treatment today when needed, involves utilizing preemptive ventilatory pressure support, e.g. CPAP and BiPAP. Unfortunately, late detection of RECC Type II PUHD more often than not leads to full naloxone reversal tactics combined with either ventilatory pressure support or crash intubation, depending largely on how advanced the clinical deterioration, the perceived frailness of the patient, and the experience of the rescuer involved. Many patients recovering from painful orthopedic surgeries rest comfortably and are perfectly stable with $PaCO_2$ in the high 40 and even low 50 mmHg, values expert anesthesiologists are cautiously comfortable with, but that would likely make your internal medicine colleagues apoplectic.

Because CO_2 doesn't play a direct role in either RECC Type I or Type III PUHD (as we will soon be learning), this monitoring technique really is of limited use as a continuous, stand-alone first choice surveillance strategy for our GCF, where all three RECC patterns occur. Real-time continuous respiratory rate monitoring can be quite specific, but is known to be unacceptably insensitive with far too many false negatives as already discussed. Reliable continuous non-invasive minute ventilation is now available (Respiratory Motion Inc. ExSpiron™), but currently its sensors are expensive, making mass GCF surveillance at the moment impractical, although it does yield very valuable information on all three RECC Types, especially when combined with continuous pulse oximetry. By providing accurate, real-time quantifications of tidal volume reductions associated with ongoing opioid management, it could make oxygen supplemented FIO_2 estimations far more reliable. In turn this would permit supplemental O_2 delivery to be precisely adjusted to best allow for reliable detection of 'CO_2 Narcosis' using the SPO_2 drifting trend patterns off continuous pulse oximeters. Bedside nurses and hospitalists can be very helpful 'monitors' if knowledgeable, but require a working understanding of all three RECC patterns in order to be able to efficiently adjust their work flows and provide optimal safety. From what we now know about RECC and our coexisting three pattern types, it's difficult to argue that optimal patient safety on GCF can be delivered at all by nurses and physicians rounding intermittently when opioids are involved regardless how enlightened they might be. Again, rounding every 4 h leaves patients unobserved 96 % of their time on GCF [3], much of this time spent 'sleeping'. This does not improve significantly by decreasing the intervals to every 2 h. Many experts now argue soundly that healthcare providers should partner with at least one continuous electronic form of surveillance AND be knowledgeable to make these environments truly safe [44]. An argument for the most appropriate continuous monitoring surveillance will follow once we've mastered all three RECC patterns types, the last pattern, Type III PUHD, coming up next.

RECC Type III PUHD

An otherwise healthy male with unrecognized sleep apnea receives a post-operative opioid. His alarm sounds repeatedly but lasts only for about 30 s before it stops, only to repeat again and again. When the nurse awakens the patient he feels fine and is completely alert, asking for more pain medication, which the nurse gives in a normal dose. The nurse, suffering from alarm fatigue, stops responding to the same alarming. Later that night the patient is found dead in bed.

This final pattern is defined as Sentinel Rapid Airflow/SPO_2 reductions followed by a precipitous SPO_2 fall. Said another way, this is a sleep apnea event with no arousal component intervening (*arousal arrest*). It immediately precipitates a sudden terminal crash due to respiratory arrest. While the actual general population prevalence of Obstructive Sleep Apnea (OSA) in America is estimated at 22 % (approximately 80 million people with up to three-quarters having moderate to severe symptoms and remaining undiagnosed [45], the RECC Type III PUHD is

most likely the rarest of our three pattern types. Its actual prevalence is further muddled with potential crossover from both opioid associated Type II respiratory arrests, and with both Type II and Type III likely wrongly assigned on occasion to unwitnessed cardiac arrest databases as mentioned in our discussion of RECC Type II PUHD. Dead-in-bed prevalence can arise from a number of causes, e.g. those associated with diabetes are estimated at 2–6/100,000 patients [46], while as we already mentioned, parenteral opioids in hospitals have been associated with 20,000 untoward annual events, 1/10th of which are known to involve serious sequelae that include sudden death. Occasionally patients receiving parenteral opioids go on to have unwitnessed cardiac arrests on GCF, and are revived to survive long enough to be transferred to critical care units. Some show surprisingly modest hypercarbia on blood gases drawn during the initial resuscitation efforts. Yet MRI studies ordered to explain their prolonged obtundation following resuscitation occasionally demonstrate severe global anoxic brain injury. These are telling signs that suggest the initial cause is likely from hypoxic respiratory arrest that allows the continued pumping of hypoxic blood to the brain, followed thereafter by an inevitable cardiac arrest, rather than the reverse order with a lethal dysrhythmia initiating the process. Regardless, it's reasonable to assume inaccuracies when assigning cause to many unwitnessed hospital arrests and dead-in-bed occurrences.

The potential for such catastrophic outcomes and the enormous strain Obstructive Sleep Apnea (OSA) places on society with costly co-morbid consequences, have warranted several medical societies and foundations to recommend perioperative detection and management strategies. The Society of Anesthesiology and Sleep Medicine (SASM) has just released its detailed best practice consensus recommendations for managing perioperative OSA, and has provided this chapter with its direct URL link to this information [47]. It can be argued that Type III is the most catastrophic of our three PUHD because it is able to take an otherwise healthy patient's life suddenly (5–10 unobserved minutes) without any visible or audible warning. It disproves an unfortunate misbelief held by some clinicians that patients receiving opioids in hospitals can be assured their GCF safety with routine, intermittent nursing checks, which would leave them unmonitored over 90 % of the time, much of it spent sleeping [3]. It differs from the RECC Type II pattern induced by CO_2 narcosis, being a true sleep dependent hypoxic event associated with arousal dependent sleep breathing disorders, where weak or incomplete arousal components fail completely (arousal arrest). Remember, Type II deaths are directly related to opioid induced respiratory depression and not disordered sleep breathing, although this issue becomes murky in our discussion on opioids in our next section.

Type III PUHD is not associated with elevated, upward trending sedation scores, which many bedside clinicians have placed their absolute faith in regarding detection of opioid associated threats. When awake, these patients can exhibit no pathognomonic symptoms or signs that give Type III away, including evidence of sedation. In other words, patients with arousal failure are orphaned, hidden within our typical perioperative populations. As shown in Fig. 8.5 below, the sentinel instability components of Type III PUHD are the typical recurring cycles of obstructive sleep apneas in the presence of complete arousal failure (arousal arrest).

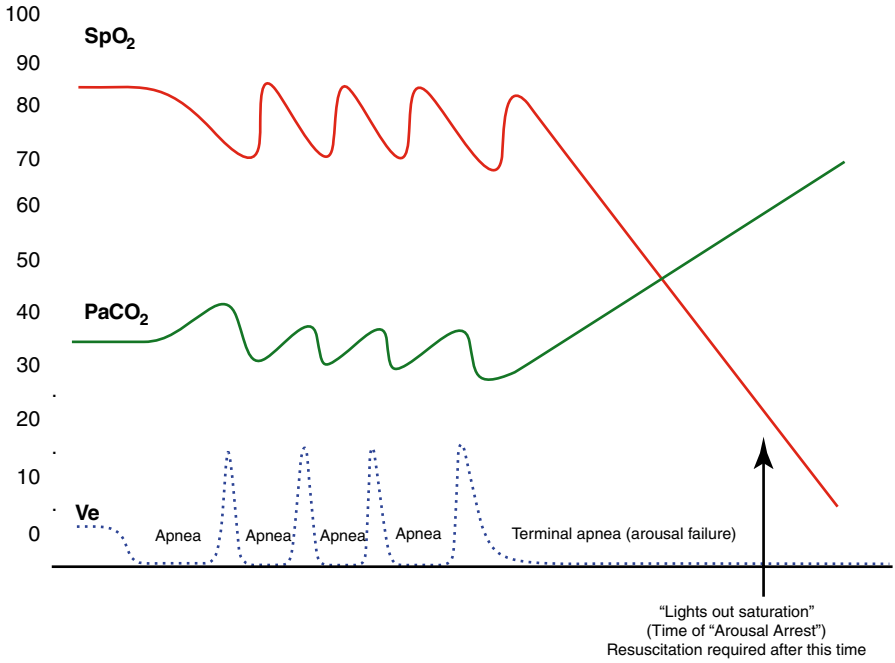


Fig. 8.5 RECC Type III PUHD

These Type III apnea patterns are comprised of repetitive reductions in airflow and SPO_2 from sleep related cycling collapses of the upper airway [48, 49]. This cycling (shown in Fig. 8.6 below) with initial collapsing and then reopening of the upper airway, produces a typical, very distinct pattern of signal clusters that is reliably acquired through high resolution pulse oximetry. Interventions involving pressure support, e.g. CPAP and BiPAP, can diminish or completely resolve this Type III pulse oximetry pattern as they do when used to treat RECC Type II 'substitution' patterns and associated risks.

Obstructive sleep apnea can be best understood as a condition where during sleep, one's upper airway collapses and is held closed by vigorous but ineffective respiratory effort. Each apneic event is generally terminated by a micro-arousal. The arousal then causes brief 'overshoot' hyperventilation that drives the $PaCO_2$ below normal. The drop in $PaCO_2$ triggers a fall in central ventilatory drive and upper airway tone. Since the upper airway is already unstable it collapses again, causing the cycle to reenter and self-propagate, producing its sentinel pattern of repetitive reductions in airflow and SPO_2 [48]. Opioids [7–9] spinal anesthesia [11], sedatives [10] and cycling hypoxemia [12] can increase arousal thresholds causing arousal delays. Then respiratory arrest, though rare, can ultimately result from complete arousal failure (arousal arrest) [13–15]. Once this occurs, if no intervention is provided immediately, a Type III death will follow suddenly during sleep without warning, due to precipitous, extreme hypoxemia…and most often without much progressive $PaCO_2$ elevation because of insufficient time for the hypercarbia to develop.

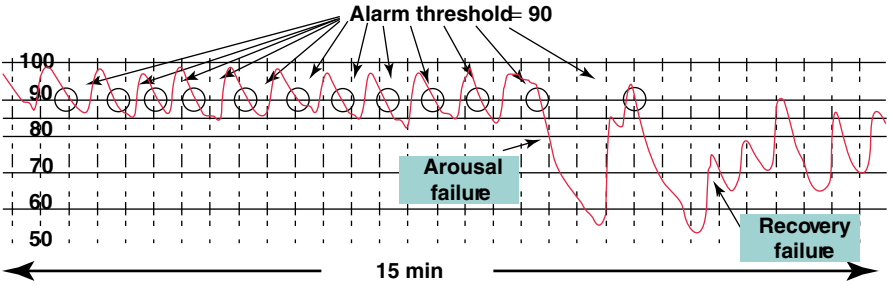


Fig. 8.6 RECC Type III pattern with arousal failure and recoveries

It has been theorized that chronic arousal failure may develop as a function of neural plasticity in response to repetitive exposures to rapid declines in oxygen saturation over many years. By the time these patients arrive for surgery, having been exposed to many years of these repetitive desaturations during sleep, their arousal delays may have unknowingly progressed to now allow extreme levels of intermittent hypoxemia. The reason arousal delays can become so critical is that SPO_2 values are often able to fall at very rapid rates during any given apnea. Many anesthesiologists and surgeons, accustomed to witnessing pre-oxygenated apnea during the induction of anesthesia, lack a full appreciation for the extremely early and very steep desaturation slopes seen in recumbent patients with postoperative sleep apnea. It has long been appreciated that the postoperative functional residual capacity (FRC) does not have definable lower limits, regardless whether surgery is cavitary (abdominal, chest, brain) or peripheral (orthopedic, plastic, and some vascular). This and obesity, commonly associated with sleep apnea and known to further reduce FRC due to its compressive effect from an enlarged panniculus pushing up on diaphragm, assure a reduced oxygen reservoir. Add the intermittent pilfering of oxygen content from this reduced FRC with each recurring apnea episode during sleep, and it's not difficult to picture how oxygen desaturation rates may in some cases exceed 1.5 % per second. This means that oxygen saturations (SPO_2) can dive to critical values with barely enough time for sufficient, contemporaneous hypercarbia to develop in order to marshal the needed rescue arousal [12]. With even the slightest additional delay induced by drugs like opioids, an occasional patient's arterial oxygen saturation will fall to a point where the brain no longer receives sufficient oxygen for central arousal to occur [8, 13–15]. This is called the '*Lights Out Saturation'* (LOS) because the human brain is incapable of generating sufficient anaerobic metabolism, depending solely on a continuous supply of oxygen and aerobic metabolism to support the generation of self-rescuing arousals.

Type III FRC dysfunction is distinctly different from the Type I '*replacement'* and Type II '*substitution'* processes. Because additional oxygen is continuously drawn away from an already reduced FRC with each repeating sleep apnea, these apnea events at times mounting into the hundreds, we choose to call this Type III FRC dysfunction '*bedside larceny*'. Think of the FRC as a living oxygen reserve and imagine its exhaustion, constantly having its oxygen pilfered throughout the night to cover these recurring clusters of cyclical apneas. Combining its reduced

size with this ongoing '*bedside larceny*', and we have a thin reserve at best, marginally capable of keeping pace with oxygen demand. Critical desaturation free falls become more common even with relatively short apneas. These critical nadirs are hidden on traditional pulse oximeters because of their SPO_2 averaging algorithms used to smooth out sampling data. Most often we get away with this, even when opioids are provided generously. We work long stretches in blissful ignorance deluded by our monitors, or that earlier these patients seem to not have any problem self rescuing … until disaster strikes!

These few disasters are always catastrophic, and perplexing as well to those lacking an OSA physiologic perspective. Once SPO_2 values fall below the 'lights out' critical value where the hemoglobin molecule simply cannot release sufficient oxygen, EEG slowing occurs promptly and arousal becomes totally suppressed … the lights go out! When LOS is breached, airway reopening without resuscitation isn't to be expected. The body can remain alive for several minutes and in some instances even longer beyond the arousal arrest, continuing to burn glucose and fat as the heart continues to pump ever mounting CO_2 stores throughout an anoxic body. If the patient is discovered at this later stage and resuscitated, immediately drawn blood gases could show $PaCO_2$ moderately elevated, enough to disguise this Type III incident mistakenly as a Type II event.

The Role of Opioids

The role opioids play regarding the RECC Type III pattern is much more complex than originally thought.

Not only are opioids capable of further delaying arousals in OSA patients already predisposed to having arousal failure [7–9] but they can interfere with normal sleep architecture and have been associated with central apneas during sleep (CNS mediated apneas without any effort to breath) [50, 51]. Furthermore, animal studies have shown opioids to substantially disrupt the medulla's regulation of breathing during sleep but not during wakefulness [52]. Unexpected central apneas have been observed even after opioids have been discontinued days earlier, possibly the result of REM sleep debt accumulated most often within the first 24 h following surgery when opioid effects are most profound. This would argue for continuous monitoring to be extended beyond their discontinuation.

Research has shown in animal models that opioids modulate adenosine levels in two critical areas of the brain that influence arousal states, the pontine reticular formation (PRF) and the substantia innominata within the basal forebrain (BF) [53]. Homeostasis between sleep and wakefulness is maintained through interactions among dozens of disparate nuclei spread along the entire neuroaxis. The neural circuits regulating the arousal state form a flip-flop switch, in which at any given time, only sleep or wake-active neurons are firing. Arousal-promoting nuclei (located predominantly in the pons, midbrain, and basal forebrain) and sleep-promoting nuclei (located predominantly in the preoptic hypothalamus) mutually antagonize each other via reciprocal inhibitory connections. Opioids have been shown to reduce

adenosine levels in these critical areas of the brain [54], and this appears to correlate with the disrupted sleep architecture, blocking access to rapid eye movement (REM) sleep and to the deeper restorative stages of non–rapid eye movement sleep.

More alarming is research published in 2011 demonstrating a critical site within the medulla of rats responsible for mediating opioid induced respiratory depression, called the preBotzinger complex [52]. What's thought provoking is that this complex appears to be the principal respiratory control center within the brain among many other scattered, non dominant control sites, and can appear to function perfectly normally when opioids are directly instilled into it during wakefulness. However, if these animals are then either exposed to anesthesia or allowed to sleep naturally, significant respiratory depression and fatal apneas begin to occur. Likewise, the preBotzinger complex was identified as wholly responsible for respiratory rate suppression following parenteral administration of opioids in these animals. The neurons responsible for this sensitivity express neurokinin-1 receptors that become selectively inhibited by opioids. However, most germane to our clinical interests, this raises an important question. Could awake sedation scales be selectively specific regarding some forms of opioid related respiratory depressions (e.g. very few false positives regarding Type II PUHD), but not adequately sensitive regarding all forms of opioid related respiratory depression because of significant false negatives that only emerge when patients receiving opioids fall asleep, as in Type III PUHD?

Also regarding sleep states, we can all appreciate how the experience of pain might impair sleep. But only recently has it been recognized that impaired sleep itself can directly exacerbate pain by causing hyperalgesia. This in turn, tends to solicit higher doses of opioids [55], again in turn perturbing sleep further and perhaps more importantly the ability of those with preexisting occult arousal failure and disordered sleep breathing to arouse from it. Studies going as far back as 1984 [56, 57] have appreciated a surprisingly high prevalence of postoperative episodic apneas, substantially beyond the expected prevalence attributable to OSA during the time those observations were made.

Essential RECC Type III – Opioid Take-Aways

- There is a 22 % general population prevalence for OSA in America, with three-quarters of those men and women yet to be formally diagnosed despite their moderate to severe conditions [45].
- We are capable of reliably detecting both known and unknown sleep breathing disorders (e.g. obstructive sleep apnea) in immediate postoperative populations using continuous pulse oximetry and/or continuous minute ventilation surveillance.
- The cyclic SPO_2 signals coming from continuous pulse oximetry sampling can provide sentinel markers for both cyclical apneas and arousal failure, though such signals are often purposely attenuated by averaging algorithms.
- Administering opioids unknowingly to patients with OSA and preexisting degrees of arousal failure can induce additional apneas [50, 51], and further delay already failing arousals to the point of arousal arrest [13–15].

- Animal studies support that while awake sedation scales reliably predict increased risk for RECC Type II PUHD, RECC Type III events may occur without any significant awake sedation [52]
- RECC Type III PUHD are hypoxic apnea events that lead to an immediate terminal apnea and arousal arrest. They can be reliably monitored by either continuous pulse oximetry or continuous noninvasive minute ventilation [Respiratory Motion Inc. *ExSpiron 1Xi*], and are capable of producing irreversible brain injury and death within 5–10 min of arousal arrest.
- Standard, intermittent nursing checks on general care floors (GCF) of hospitals leave patients unobserved greater than 90 % of the time [3], much of that time spent sleeping.

One question should now be obvious. Why is it we have not begun to monitor continuously every patient receiving opioids on our general care floors (GCF), especially while asleep? The answer is both complex and revealing. GCF continuous pulse oximetry surveillance has been available and affordable for well over a decade, but the clarity we now have on this subject was earned from years of frustration and discovery while tackling widespread false assumption, conventional wisdom, and disparate cultural beliefs that comprise hospital based healthcare. From this labor eventuated valued hindsight, knowledge, and solutions, but much of it was extracted in teaspoons, painfully slow processes that encouraged failure through attrition. For example, we're all now aware that when we set GCF continuous pulse oximetry alarm thresholds at values near 90 %, problems will follow, e.g. alarm fatigue, monitor abandonment, and patient neglect. But very few have persevered to where sound solutions have been successfully adopted. Early on, those of us responsible for creating GCF oximetric monitoring policies looked appropriately for guidance from the OR, PACU, and Critical Care experiences. In those environments, these thresholds had been spectacularly successful, though few, if any, gave much thought to the reasons for this success. Threshold science was relatively new and highly popular at the time. Simplifying diagnostic definitions of rapidly evolving complex relational processes like sepsis, OSA, and opioid associated hypoventilation into just a few simple thresholds made our work easy. It has taken us a full two decades to realize the weaknesses of threshold science: the inevitability of disappointing outcomes from delays in recognition of RECC, and the shallow knowledge bases encouraged by such strategies that render bedside clinicians incapable of analyzing well any complex relational process once it begins to evolve. This is why we continue to lose lives needlessly in our hospitals and are dealing with the same RECC incidence seen over a decade ago. Yet thresholds still prevail, as Dr. Lawrence Lynn recently wrote in an editorial piece published in Patient Safety in Surgery [6], calcified not through success, but merely because they've been used for years and we've become accustomed.

We have only to observe the overly simplistic understandings found on GCF today of how:

- the Oxyhemoglobin Dissociation Curve (ODC) applies to patients;
- supplemental oxygen is best managed;
- opioids affect respiratory physiology ;
- continuous GCF monitors actually work;

to appreciate, while well intended, just how mediocre we've allowed our GCF practices to become regarding optimal detection of unexpected complications, a competency valued foremost by any rational patient.

These same issues continue to plague GCF continuous oximetry surveillance today, guaranteeing frustration and workflow distraction on many GCF units across the nation, while rendering either the GCF environment unsafe from alarm fatigue, or patients unsafe from lack of appropriate monitoring. Ninety percent SPO_2 threshold settings assure a multitude of alarm breaches from self-correcting sleep apneas. The more truculent nursing departments have felt compelled to design complex GCF patient selection policies based on 'fuzzy' logic in order to reduce these distractions through patient exclusion. Who can blame them? They have a right to preserve their sanity and efficiency. No one has stepped forward with a compelling plan, better explanations, or a path to get us to where we can begin correcting these faulty customs and nuisances that persist in stealing our patients' lives. Most physician leaders responsible for the delivery of optimal clinical care in their regional institutions know little about this and have had even less experience with continuous GCF bedside surveillance. Unfortunately, today these faulty customs have now calcified within a GCF cultural fabric that's become saturated with risk for RECC. When patients invariably suffer opioid associated deaths today, it's rare for policy or GCF culture to be questioned or substantially changed. The blame either falls to a breach in policy, or when none can be found, to an 'unavoidable' act of god.

Useful knowledge emerging from sleep medicine continues to be somewhat removed from those who deliver clinical care on the GCF, although the Society of Anesthesia and Sleep Medicine (SASM) has now begun making inroads with consensus recommendations for best practices [47]. Despite consensus recommendations from the Anesthesia Patient Safety Foundation (APSF) advocating twice in the last 8 years (2006 and 2011) for all perioperative GCF patients receiving opioids to be monitored with some form of continuous electronic surveillance, only two institutions have trialed and published their success, with only one using a single monitor to accomplish this. The APSF has provided this chapter with its direct URL link to its consensus recommendations for best practices regarding continuous electronic monitoring [58]. Challenging us is how to best monitor for the Type III arousal arrest possibility, while optimizing our ability to detect our more common, but just as deadly RECC Type I and Type II events. Our final section will speak to this last issue.

Monitoring – The 'Big Picture' Put Together

We should now realize in order to properly detect the most prevalent (Type I) of our three RECC patterns early, a knowledgeable caregiver must be willing to listen and respond to each and every complaint of shortness of breath. If such patients aren't able to verbally communicate, then observed changes in respiratory effort and restlessness imply the same message. Any downward SPO_2 changes coincidentally discovered with continuous pulse oximetry surveillance reflect Type I RECC processes

no longer in their early stages. Here the benefits of compensatory respiratory alkalosis through hyperventilation (leftward shift of the ODC) can no longer mask the advancing PaO_2 reductions (FRC *replacement*). Continuous Noninvasive Minute Ventilation surveillance would be ideal for objectively detecting this expected early compensatory hyperventilation response to Type I RECC processes, but alert clinicians with good critical thinking skills can intervene appropriately regardless.

Early detection of the less common, but more catastrophic RECC Type II PUHD likewise requires a knowledgeable, observant nurse with excellent critical thinking skills. GCF nurses can provide a safe environment without continuous electronic monitoring for Type II events only if they:

- remain constantly vigilant regarding the potential for CO_2 narcosis
- are able to perform frequent awake sedation checks (made even more frequently once moderate awake sedation is identified)
- stay aware of trending changes in ventilatory effort and awake sedation levels
- are able to deploy a Rapid Response Rescue with critical care backup at the first sign of opioid related respiratory failure

These criteria may sound reasonable, but are very difficult if not impossible to meet on the GCF due to a plethora of competing responsibilities encroaching on nursing time. The optimal mindset for preempting the unexpected (e.g. detecting early RECC) is to believe everything is wrong until proven otherwise. Maintaining that mindset on busy hospital GCF is not only difficult, it's culturally foreign. Caregivers predisposed to assuming things are wrong until proven otherwise (known as *sense-makers* [59]), gravitate toward jobs in hospital EDs, ICUs, PACUs, and ORs. The general care floors have always had to contend with an underlying assumption that their patients are stable. GCF culture is referred to as *decision-making* [59], where all is assumed to be right until proven otherwise. Even in hospital environments where sense-making is expected to predominate (e.g. PACU), Type II events have snuck up on skilled clinicians standing at the bedside giving one-on-one care, so convincingly it's able to mimic 'restorative sleep'.

When continuous pulse oximetry is used for surveillance on these patients breathing either room air or air supplemented with low flows of O_2 that deliver FIO_2 less than .28 (1–2 L/min NC with caveats mentioned in RECC Type II PUHD), a declining drift in the SPO_2 values over time can warn astute clinical nurses to the early, evolving Type II patterns of 'CO_2 Narcosis' in their 'sleeping' patients before a 90 % SPO_2 threshold alarm sounds. Nurses should never hesitate to attempt to arouse these 'sleeping' patients, but first should observe their respiratory rates and depths of breathing to gain experience in realizing how misleading these observations can be.

RECC Type III PUHD is a very different story. Any knowledgeable caregiver will attest that there is no possible way to reliably detect Type III events that include arousal arrest on the GCF without some continuous electronic surveillance. It's just common sense! With OSA so highly prevalent and under-diagnosed [45], and the prescribing of apnea inducing opioids increasing [50, 51], clinicians must become aware of this increased risk and advocate proactively for safe care. Surveillance with either or both continuous noninvasive minute ventilation and continuous pulse oximetry are capable of detecting apneas and arousal arrests, but continuous pulse oximetry on

its own has been proven in one institution to prevent all opioid associated deaths on the GCF. Improving monitoring practices and vigilance at the bedside through well designed education, while coupling these improvements with appropriate continuous electronic monitoring, can prevent all adverse RECC opioid related events (Type II and III), and also allow for much earlier detection of RECC Type I. Experience has shown that the initial cost to provide this inclusive surveillance is likely to be less than any award for which an institution is held responsible, should such an event occur and be adjudicated. Any investment in a transitional safety strategy today using continuous pulse oximetry surveillance either alone or with continuous noninvasive minute ventilation becomes an investment in the transformational pattern recognition surveillance of the future, with a high likelihood of excellent return. Regardless, the only reason required to make this transition imperative today is that we know for certain what we currently are providing is unsafe! Ask any family member who has lost a loved one to our industry's tarnished Standard of Care.

A Success Story from Dartmouth

In 2007 Dartmouth-Hitchcock Medical Center initiated a program called the Patient Surveillance System (PSS) on a 36 bed postoperative orthopedic unit. PSS required all its patients to be electronically monitored with continuous pulse oximetry, and all threshold breaches to be transmitted electronically through pager devices to the caregivers in charge. The program was tightly aligned with their Hitchcock Early Response Team (HERT), a Rapid Response program that brings critical care expertise to the bedside once RECC are detected [42, 60]. Results from the PSS showed significant reductions in morbidity, no opioid associated deaths, and cost benefit to the institution. This PSS program has grown to include all Hitchcock postoperative patients today and has yet to have a single opioid associated mortality.

Although education for all Hitchcock bedside clinical providers increased awareness regarding RECC like events, there were two other important elements contributing to the substantial safety gains found in this Dartmouth research study: (1) the choice of electronic surveillance and (2) the elimination of 'false' alarms. Continuous pulse oximetry surveillance was not an arbitrary choice, but rather based on patient tolerance. Patient comfort and acceptance are extremely important when discussing inclusive monitoring strategies. But perhaps more key to this effort's success was the minimizing of 'false' alarms. Nurses insisted at the inception of this trial that any more than two oximetric alarm per patient per shift would be regarded as unsatisfactory. In order to comply, Dr. Andreas Taenzer, Associate Professor of Anesthesiology and Pediatrics at Dartmouth College Geisel School of Medicine, increased the SPO_2 alarm threshold from 90 % SPO_2 to 80 %, and added a 15 s alarm delay to silence any true breaches or electrical artifacts expected to self correct within the additional 15 s interval once initial breach occurred.

While this strategy has been uniquely successful, its potential pitfalls should now be obvious to you if appropriate education isn't embedded within such a process. Simply waiting on a Dartmouth PSS oximeter alarm to take action will certainly

catch every RECC Type III PUHD, but will also significantly delay detections of both the more common RECC Type I and Type II events with likely disastrous consequences. This is why education and training must be coupled to such monitoring strategies, as it has been, to achieve the exemplary results reported.

Summary of the Vulnerabilities of Threshold Monitoring

- Threshold monitoring alone is effective for detecting RECC events only late in their evolution.
- RECC Type I events (i.e. *FRC replacement*) have no optimal SPO_2 alarm threshold.
- RECC Type II events (i.e. *FRC substitution*) have a SPO_2 alarm threshold that is arguably optimal when set at SPO_2 90 % if patients are breathing room air, but this threshold steadily retracts toward no threshold once supplemental oxygen is added and steadily advanced. Type II death is iatrogenic and by definition catastrophic.
- RECC Type III events (i.e. *FRC bedside larceny*) have been proven to have a SPO_2 alarm threshold optimally set at 80 % (with an additional 15 s alarm delay) that allows for reliable detection of *late* Type III arousal arrest. Although reliable in reducing alarm fatigue and preventing catastrophic Type III deaths, it would be better to pre-empt the events entirely through the perioperative use of sensitive OSA screening tools combined with proper airway management and anesthesia/analgesia adjustments. These detailed recommendations can be accessed through the SASM URL link provided [47].

The Future of Monitoring

The physiologic patterns of three Rapidly Evolving Clinical Cascades provide a framework for clinicians to use in developing critical thinking skills, as well as safe and effective preventative monitoring policies for general care floor postoperative patients. Combining this framework with the evidence provided in the Dartmouth study can both improve patient outcomes and end catastrophic opioid associated deaths. This allows for a safe transitional period in the present while we prepare for the future's transformation from threshold diagnostic science to a science based on motion images using much more of the same data available today including time. This new science comprises automated pattern recognition with machine learning and is fully capable of detecting, identifying, quantifying, and tracking the timed patterns of clinical failure. Its technologies will work in outputs which are intuitive, relational, dynamic and comprehensive, also generating real time outputs of probabilities of specific disease conditions and protocolized treatments based on the motion images that allow for much earlier interventions than ever thought possible. They will generate first level outputs which are recognizable to all clinicians, but that allow drill downs into the complex data fields acquired to provide complete

computational transparency for those physicians able to understand and work at this level of granularity. Until this transformation arrives, universal continuous pulse oximetry surveillance (and/or continuous noninvasive minute ventilation surveillance) can be combined with improved nurse critical thinking and assessment skills as our best transitional strategy for preventing GCF adverse events better known as RECC Types I, II, and III.

Case Scenario

We will conclude here with a 'real life' RECC example that ended badly. Read it through and determine:

- Which of the three PUHD Types is involved?
- Which of our three FRC altering processes is in play and why (Replacement, Substitution, or Bedside Larceny)?
- Was one of the three ways supplemental oxygen could be harmful a possible factor?
- Identify all the things you would have done differently had you been working this shift.

An obese (BMI 34) 54 yo woman with significant osteoarthritis involving her knees presents for a Right Total Knee Replacement. She looks like a potential sleep apnea candidate and tests positive on an admission Stop-bang questionnaire, but has never been formally tested for sleep breathing disorders. She has no other co-morbid illnesses and had a perfectly normal preoperative stress ECHO with an unremarkable family history for any heart disease. She goes through an uneventful afternoon surgery for which she's received a bupivacaine spinal with 0.2 mg intrathecal morphine added at the procedure's start, and an additional 3 mg IV methadone during surgery. She's taken to the PACU around 5 pm where it's noted she's asleep but easily arousable, responsive, and with no complaints of pain. She's sent up to her room at 7 pm stable with a Pasero Opioid-Induced Sedation Score of 2 (sleeping but easily aroused). She's then checked hourly and for the next 3 h is noted to maintain her same Pasero Sedation Score, but the 11 pm check noted a Pasero Opioid-induced Sedation Score of 3 (drowsy, arousable, drifts off to sleep during conversation) and a pulse oximetry reading that had dropped from a stable 97 % on her prior checks to 93 %. No episodic desaturations have occurred and she had been receiving 2 L/min supplemental O_2 by nasal cannula. Her respiratory rate was recorded at 16/min on all but her last evening check (10/min at 11 pm). The continuous pulse oximeter monitor feeds its signal to the central nursing station where its values are displayed at the station's central console. However, the alarms at the central station had been muted because of concerns about 'alarm fatigue'. Instead the pleth and alarm volumes on the patient's private room monitor were turned to full volume to serve as a readymade stimulus should it be needed. At 11:50 pm a lab technician walking past the patient's room hears the oximetry alarm blaring through the closed door and immediately enters to find a non-breathing patient. Once the door was opened everyone heard it and came running. The patient was quickly assessed and a full code blue was called. Resuscitative efforts managed to return a perfusing rhythm

and the patient was transferred off to the ICU where the anoxic brain injury suffered was determined to be massive. She was placed on comfort care and allowed to expire the next day with discontinuation of her life support. No arterial blood gases were drawn at the time of the actual resuscitation, only later once full life support had stabilized adequate respiratory parameters. There were no obvious historical or visible clues to indicate that the patient might have suffered from aspiration or a sudden lethal dysrhythmia. Most everyone involved with this case and its review were flummoxed regarding realistic cause. Guesses of PE, aspiration, and cardiac dysrhythmia prevailed. But there was tacit agreement that the muted central alarms may have played into the problem of untimely rescue. Their solution was to purchase pagers dedicated to notifying floor nurses of all desaturations breaching 90 %, leaving all other policies in place including the current exclusionary selection practices that allow some patients receiving opioids to rely solely on traditional intermittent nursing checks for their monitoring.

What are your answers?

References

1. Lynn LA, Curry JP. Patterns of unexpected in-hospital deaths: a root cause analysis. Patient Saf Surg. 2011;5:3. URL link (Ctrl + click to follow link) http://www.pssjournal.com/content/5/1/3.
2. Curry JP, Lynn LA. Threshold monitoring, alarm fatigue, and the patterns of unexpected hospital death. APSF Newsl. 2011;26(2):32–5.
3. Gravenstein N. No patient shall be harmed by opioid-induced respiratory depression. APSF Newsl. 2011;26(2):21.
4. Hamilton MA, Cecconi M, Rhodes A. A systematic review and meta-analysis on the use of preemptive hemodynamic intervention to improve postoperative outcomes in moderate and high-risk surgical patients. Anesth Analg. 2011;112(6):1392–402.
5. Khuri SF, Henderson WG, DePalma RG, Mosca C, Healey NA, Kumbhani DJ. Determinants of long-term survival after major surgery and the adverse effect of postoperative complications. Ann Surg. 2005;242(3):326–41; discussion 341–3.
6. Lynn LA. The diagnosis of sepsis revisited – a challenge for young medical scientists in the 21st century. Patient Saf Surg. 2014;8(1):1.
7. Hajiha M, DuBord M-A, Liu H, Horner RL. Opioid receptor mechanisms at the hypoglossal motor pool and effects on tongue muscle activity in vivo. J Physiol. 2009;587(11):2677–92.
8. White. Opioid-induced suppression of genioglossal muscle activity: is it clinically important? J Physiol. 2009;587(14):3421–2.
9. VanDercar DH, Martinez AP, DeLisser EA. Sleep apnea syndromes: a potential contraindication for patient-controlled analgesia. Anesthesiology. 1991;74(3):623–4.
10. Berry RB, Kouchi K, Bower J, Prosise G, Light RW. Triazolam in patients with obstructive sleep apnea. Am J Respir Crit Care Med. 1995;151(2 Pt 1):450–4.
11. Wieczorek PM, Carli F. Obstructive sleep apnea uncovered after high spinal anesthesia: a case report. Can J Anaesth. 2005;52(7):761–4.
12. Wilkinson MH, Berger PJ, Blanch N, Brodecky V. Effect of venous oxygenation on arterial desaturation rate during repetitive apneas in lambs. Respir Physiol. 1995;101(3):321–31.
13. Khoo SM, Mukherjee JJ, et al. Obstructive sleep apnea presenting as recurrent cardiopulmonary arrest. Sleep Breath. 2009;13:89–92.
14. Dyken ME, Yamada T, Glenn CL, Berger HA. Obstructive sleep apnea associated with cerebral hypoxemia and death. Neurology. 2004;62(3):491–3.

15. Lofsky A. Sleep apnea and narcotic postoperative pain medication: a morbidity and mortality risk. APSF Newsl. 2002;17(2):24–5.
16. Bellomo R, Goldsmith D, Uchino S, Buckmaster J, Hart G, Opdam H, Silvester W, Doolan L, Gutteridge G. Prospective controlled trial of effect of medical emergency team on postoperative morbidity and mortality rates. Crit Care Med. 2004;32:916–21.
17. Chan PS, Khalid A, Longmore SL, Berg AR, Kosiborod M, Spertus AJ. Hospital-wide code rates and mortality before and after implementation of a rapid response team. JAMA. 2008;300(21):2506–13.
18. Rothschild MJ, Woolf S, Finn MK, et al. A controlled trial of a rapid response system in an academic medical center. Jt Comm J Qual Patient Saf. 2008;34(7):417–25.
19. Chan PS, Jain R, Nallmothu BK, Berg RA, Sasson C. Rapid response teams: a systematic review and meta-analysis. Arch Intern Med. 2010;170(1):18–26.
20. Litvak E, Pronovost JP. Commentary: rethinking rapid response teams. JAMA. 2010; 304(12):1375–6.
21. Pedersen T, Møller AM, Hovhannisyan K. Pulse oximetry for perioperative monitoring. Cochrane Database Syst Rev. 2009;7(4):CD002013.
22. Ochroch EA, Russell MW, Hanson WC, Devine GA, Cucchiara AJ, Weiner MG, Schwartz SJ. The impact of continuous pulse oximetry monitoring on intensive care unit admissions from a postsurgical care floor. Anesth Analg. 2006;102(3):868–75.
23. Giuliano KK, Higgins TL. New-generation pulse oximetry in the care of critically ill patients. Am J Crit Care. 2005;14(1):26–37.
24. Fecho K, Freeman J, Smith FR, et al. In-hospital resuscitation: opioids and other factors influencing survival. Ther Clin Risk Manag. 2009;5:961–8.
25. Looi-Lyons LC, Chung FF, Chan VW, et al. Respiratory depression: an adverse outcome during patient controlled analgesia therapy. J Clin Anesth. 1996;8:151–6.
26. Shapiro A, Zohar E, Zaslansky R, et al. The frequency and timing of respiratory depression in 1524 postoperative patients treated with systemic or neuraxial morphine. J Clin Anesth. 2005;17:537–42.
27. Weinger MB. No patient shall be harmed by opioid-induced respiratory depression. APSF Newsl. 2011;26(2):21.
28. Antic NA, Malow BA, Lange N, McEvoy RD, Olson AL, Turkington P, Windisch W, Samuels M, Stevens CA, Berry-Kravis EM, Weese-Mayer DE. PHOX2B mutation-confirmed congenital central hypoventilation syndrome: presentation in adulthood. Am J Respir Crit Care Med. 2006;174(8):923–7.
29. Littleton SW, Mokhlesi B. The Pickwickian syndrome – obesity hypoventilation syndrome. Clin Chest Med. 2009;30(3):467–78, vii–viii.
30. Casey KR, Cantillo KO, Brown LK. Sleep-related hypoventilation/hypoxemic syndromes. Chest. 2007;131(6):1936–48.
31. Guo F, Xu T, Wang H. Early recognition of myxedematous respiratory failure in the elderly. Am J Emerg Med. 2009;27(2):212–15.
32. Catling JA, Pinto DM, Jordan C, Jones JG. Respiratory effects of analgesia after cholecystectomy: comparison of continuous and intermittent papaveretum. Br Med J. 1980; 281(6238):478–80.
33. Mildh LH, Scheinin H, Kirvelä OA. The concentration-effect relationship of the respiratory depressant effects of alfentanil and fententanil. Anesth Analg. 2001;93(4):939–46.
34. Bouillon T, Bruhn J, Roepcke H, Hoeft A. Opioid-induced respiratory depression is associated with increased tidal volume variability. Eur J Anaesthesiol. 2003;20(2):127–33.
35. Wiedemann K, Diestelhorst C. The effect of sedation on pulmonary function. Anaesthesist. 1995;44 Suppl 3:S588–93.
36. Yamakage M, Kamada Y, Toriyabe M, Honma Y, Namiki A. Changes in respiratory pattern and arterial blood gases during sedation with propofol or midazolam in spinal anesthesia. J Clin Anesth. 1999;11(5):375–9.
37. Mora CT, Torjman M, White PF. Sedative and ventilatory effects of midazolam infusion: effect of flumazenil reversal. Can J Anaesth. 1995;42(8):677–84.

38. Fu ES, Downs JB, Schweiger JW, Miguel RV, Smith RA. Supplemental oxygen impairs detection of hypoventilation by pulse oximetry. Chest. 2004;126(5):1552–8.
39. Barker SJ. "Motion-resistant" pulse oximetry: a comparison of new and old models. Anesth Analg. 2002;95(4):967–72.
40. Goldman JM. Medical Devices and Medical Systems - Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE). ASTM final F-2761-2009.
41. Moldenhauer K, Sabel A, Chu ES, Mehler PS. Clinical triggers: an alternative to a rapid response team. Jt Comm J Qual Patient Saf. 2009;35(3):164–74.
42. Taenzer AH, Blike GT. Postoperative monitoring – the Dartmouth experience. APSF Newsl. 2012;27(1):1–28.
43. Dean NC, Jones J, Sanz Herrero F, Jephson A, Brown S, Jones BE, Vines C. Calculating PaO_2/FIO_2 from SPO_2 in emergency department patients with pneumonia; comparison of the Severinghaus and Rice equations in a Utah population. Am J Respir Crit Care Med. 2012;185:A1806.
44. Galhotra S, DeVita MA, Simmons RL, et al. Mature rapid response system and potentially avoidable cardiopulmonary arrests in hospital. Qual Saf Health Care. 2007;16:260–5.
45. Ankichetty S, Chung F. Considerations for patients with obstructive sleep apnea undergoing ambulatory surgery. Curr Opin Anaesthesiol. 2011;24(6):605–11.
46. Sovik O, Thordarson H. Dead-in-bed syndrome in young diabetic patients. Diabetes Care. 1999;22 Suppl 2:B40–2.
47. Society of Anesthesia and Sleep Medicine consensus recommendations for perioperative management of Obstructive Sleep Apnea. URL link (Ctrl + click to follow link) http://sasmhq.org/?page_id=2552.
48. Lynn LA. Interpretive oximetry: future directions for diagnostic applications of the SpO_2 time-series. Anesth Analg. 2002;94(1 Suppl):S84–8.
49. Dempsey JA, Veasey SC, Morgan BJ, O'Donnell CP. Pathophysiology of sleep apnea. Physiol Rev. 2010;90(1):47–112.
50. Famey RJ, Walker JM, Cloward TV, Rhonduea S. Sleep-disordered breathing associated with long-term opioid therapy. Chest. 2003;123(2):632–9.
51. Wang D, Teichtahi H, Drummer O, Goodman C, Cherry G, Cunnington D, Kronborg I. Central sleep apnea in stable methadone maintenance treatment patients. Chest. 2005;128(3):1348–56.
52. Montandon G, Qin W, Liu H, Ren J, Greer JJ, Horner RL. PreBotzinger complex neurokinin-1 receptor-expressing neurons mediate opioid-induced respiratory depression. J Neurosci. 2011;31(4):1292–301.
53. Saper CB, Chou TC, Scammell TE. The sleep switch: hypothalamic control of sleep and wakefulness. Trends Neurosci. 2001;24:726–31.
54. Nelson A, Battersby BS, et al. Opioid-induced decreases in rat brain adenosine levels are reversed by inhibiting adenosine deaminase. Anesthesiology. 2009;111:1327–33.
55. Gallagher RM, Rosenthal LJ. Chronic pain and opiates: balancing pain control and risks in long-term opioid treatment. Arch Phys Med Rehabil. 2008;89:S77–82.
56. Catley DM, Thornton C, Jordan C, Lehane JR, Royston D, Jones JG. Pronounced, episodic oxygen desaturation in the postoperative period: its association with ventilatory pattern and analgesic regimen. Anesthesiology. 1985;63:20–8.
57. Rosenberg J, Dirkes WE, Kehlet H. Episodic arterial oxygen desaturation and heart rate variations following major abdominal surgery. Br J Anaesth. 1989;63:651–4.
58. Anesthesia Patient Safety Foundation consensus recommendations on continuous electronic monitoring for perioperative patients receiving opioids on hospital general care floors. URL link (Ctrl+click to follow link) http://www.apsf.org/announcements.php?id=7.
59. Weick KE. The collapse of sensemaking in organizations: the Mann Gulch disaster. Adm Sci Q. 1993;38(4):628–52.
60. Taenzer AH, Pyke JB, McGrath SP, Blike GT. Impact of pulse oximetry surveillance on rescue events and intensive care unit transfers. Anesthesiology. 2010;112:282–7.

Effective Communication—Tips and Tricks

9

Philip F. Stahel and Nathan Butler

Pitfalls and Pearls

- Effective communication is one of the most critical safety aspects in any high-risk industry, including patient safety in surgery.
- The root cause of many surgical complications originates from a breakdown in communication, not from technical errors in the operating room.
- Promising new strategies of standardized communication in health care include written checklists and standardized verbal communication strategies, including 'readbacks', and perioperative briefings/debriefings, in alignment with crew resource management programs from professional aviation.
- Structured communication is a critical technical tool for patient safety in surgery. Standardized frameworks with underlying mnemonics (e.g. SBAR, AIDET) have been designed to facilitate effective communication between careproviders and patients and patient families.
- Surgical "time-out" and "readbacks" are examples of successful standardized communication in the clinical setting, characterized by unequivocal clarity and accuracy.

P.F. Stahel, MD, FACS (✉)
Department of Orthopaedics, Denver Health Medical Center,
University of Colorado, School of Medicine, 777 Bannock Street, MC 0188,
Denver, CO 80204, USA
e-mail: philip.stahel@dhha.org

N. Butler
West Virginia School of Osteopathic Medicine,
200 North Lee Street, Lewisburg, WV 24901, USA

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_9, © Springer-Verlag London 2014

Outline of the Problem

Most physicians perceive themselves as 'good communicators', however, less than 20 % of all physicians have been formally trained on how to communicate with patients. A large part of claims and lawsuits originate from patient dissatisfaction related to poor quality communication with their health care providers.

From a patient safety perspective, the importance of standardized communication between and amongst health care team members, patients, and patient's families, is unquestionable. The physician-patient relationship represents the 'cornerstone' of medical practice and relies on mutual trust and respect. The core principle for building and sustaining this relationship is communication. Effective physician-patient communication has been shown to improve patient outcomes as well as patient and provider satisfaction [1, 2]. Pertinent topics related to the impact of communication and patient safety are discussed in other specifically dedicated chapters in this book, addressing the use of verbal communication strategies and 'readbacks' (Prabhakar, Chap. 16), written checklists (Boermeester, Chap. 25), safety team briefings (Moldenhauer, Chap. 13), perioperative briefings/debriefings (Hurlbert, Chap. 31), communication issues in the handover of care (Ferran, Chap. 17), and non-technical aspects of safe surgical performance (Youngson, Chap. 7). The present chapter is designed to provide evidence-based insights and proven successful concepts from the peer-reviewed literature which will help surgeons communicate more effectively with health care teams, their patients, and families.

Limitations of the Current Practice

Patient harm resulting from surgical complications is frequently derived from a communication breakdown within the care team rather than from a technical complication in the operating room [3]. The *American College of Surgeons*' closed claims study revealed impressively that technical errors resulting in surgical complications represent only about half of all events leading to litigation [3]. About 25 % of all claims from patients who sustained surgical harm were attributed to a breakdown in communication before, during, or after surgery [4].

Multiple barriers to effective communication between health care providers and patients have been identified and described in the peer-reviewed literature [5, 6].

Aside from the unquestionable impact of effective and transparent communication to ensure the safety of our patients, impending health care reform will likely link reimbursement modalities to patient satisfaction scores, e.g. tied to the "Hospital Consumer Assessment of Healthcare Providers and Systems" (HCAHPS) system [7].

While most physicians perceive themselves as 'good communicators', in reality, less than 20 % of all physicians have been formally trained on how to

Fig. 9.1 Patients present to a physician's office at some of the worst times of their lives, and are therefore rightfully anxious and intimidated. An open, honest, and transparent communication style allows establishing a true patient-physician 'partnership' which facilitates the 'shared-decision making' process for the patient's medical care

communicate with patients [7]. Patients assume *a-priori* that quality care is provided by their doctors. Ironically, the main predictor of patients' perceptions of whether quality care was provided has no correlation with objective metrics of clinical quality and safety. Instead, patients' ratings of '*quality*' are driven by their subjective perceptions of the quality of communication with their health care providers (Fig. 9.1) [8].

Where Is the "Golden Bullet"?

Principles of Communication Among Healthcare Providers

Multiple tools aimed at promoting effective communication in health care have been developed and validated in recent years. The **SBAR** (situation, background, assessment, recommendation) framework was adopted from military protocols (naval nuclear submarine technology) and successfully extrapolated to the health care setting (Box 9.1).

Box 9.1. The "SBAR" mnemonic: A Standardized Framework for Effective Communication Among Health Care Providers

S—Situation

"*The situation is …*" (What is going on with the patient?)

B—Background

"*The background to the situation is …*" (What is the clinical background or context?)

A—Assessment

"*My assessment of the situation is …*" (How do I interpret the problem?)

R—Recommendation

"*My recommendation is …*" (What do I recommend to resolve the problem?)

SBAR has been adopted by hospitals and healthcare facilities as a simple and effective way to standardize communication and to clarify expectations among health care providers in any clinical domain.

Verbal communication must be timely, precise, directed, and understood. A formal *readback* by the recipient of verbally communicated information ensures understanding. This two-way aspect of effective communication is analogous to a core principle derived from professional aviation safety [9]. *Readbacks* represent a proven example of structured language used to provide clarity and accuracy of verbal orders and critical test results [10]. Another classic example of unequivocally scripted communication in the clinical setting is the surgical time-out as part of the Joint Commission-mandated Universal Protocol [11].

Principles of Physician-Patient Communication

Evidence-based approaches for improved communication are widely published and available as resources for physicians [7]. Why are improved communication skills important to surgeons? Multiple studies have shown that effective communication with patients is associated with a decreased incidence of claims and lawsuits, better clinical outcomes, improved patient compliance with recommended treatment regimens, a decreased unplanned readmission rate, and a subjectively improved perception of the quality of care received by patients [7]. Revealing data from a landmark study showed that 75 % of patients admitted to a hospital were unable to name a single doctor assigned to their care [12]. Of the remaining 25 % who were able to provide a doctor's name, only 40 % were correct [12].

A physician can therefore make a significant difference to the patient's perception of the quality of communication and quality of perceived care, by taking a critical moment of time for a formal introduction [7]. This includes providing the physician's name, ideally in conjunction with handing out a personal business card, and by briefly explaining the physician's role in the patient's plan of care, as well as a brief background on the level of training and expertise [7]. The 'AIDET' mnemonic represents an evidence-based, proven framework of successful communication between physicians and patients (Box 9.2) [7].

In the current age of health care reform, the patient-centered model—characterized by proactive involvement and engagement of patients in the clinical decision-making ("*Nothing about me without me*!")—will play an imminent role in defining benchmarks of 'customer experience' and will likely drive the payors' financial reimbursement strategies in the near future [7]. This notion should provide an additional (financial) incentive for physicians to adopt modern and evidence-based communication strategies with patients and patient families.

Some of the proven concepts which increase patient's perception of being heard and being respected, include the following [7, 13]:

- Nurses should round with physicians whenever possible. Joint rounding increase the patient's perception of teamwork in their care, and allows for nursing staff to reinforce the physician's perspective in later patient interactions.

Box 9.2. The "AIDET" Mnemonic: A Standardized Framework for Effective Communication with Patients and Patient Families

A—"Acknowledge"

Greet people with a proactive and friendly approach. Look them in the eyes and smile. Use their names if you know them. The first delivered impression is the most important and lasting impression. Establish a preferred rapport with the patient and patient family.

Example: "*Good morning Mr. Smith. Welcome to Denver Health*! *We have been expecting you and we are glad that you are here. Would you please take a moment to confirm that we have your most current information*?"

I—"Introduce"

Introduce yourself politely. Tell the patient who you are and how you are going to help. Explain your role, function, experience and skill set. Escort people where they want to go, instead of pointing or giving directions.

Example: *Mr. Smith*, *my name is Anne. I will be performing your sonography today. I am a certified ultra-sonographer and I perform about 20 such procedures each day. The doctors say that my skills are among the best. Do you have any questions for me*?"

D—"Duration"

Outline the expected duration and wait time. Keep in touch regularly to ease the perception of prolonged wait times. Let people know if there is a delay, and provide realistic expectations of expected times. Fix unnecessary wait times where necessary.

Example: "*Dr. Stahel had to take care of an emergency. He was concerned about you waiting to be seen*, *and he wanted to let you know that it may be about 30 minutes before he can see you. Are you able to wait*, *or would you prefer to run some errands and come back later*?"

E—"Explain"

Tell the patient what to expect. Communicate any step and address any question the patient may have. Make time to help by recognizing and diminishing the patient's anxieties and uncertainties.

Example: "*The test will take about 30 minutes. The first step is for you to drink this solution*, *and then we'll have to wait 20 minutes before drawing a blood sample. Would you like to read while you wait*?"

T—"Thank"

End the conversation with the patient by a standardized "*Thank you*!" Foster an attitude of gratitude. Use reward and recognition tools, as appropriate.

Examples: "*Thank you for choosing our hospital*." "*Thank you for putting your trust in my care*." "*Thank you for taking the time for this visit—it has been a privilege to care for you*."

Finalize the communication and interaction with the patient by the standard question: "*Is there anything else I can do for you today*?"

- Always knock on the door of the exam room / patient room before entering.
- Always dress appropriately and maintain strict professionalism throughout the encounter.
- Use a consistent framework of communication. Apply the '**AIDET**' mnemonic for a standardized approach related to introduction and structured content of the encounter.
- Sit down to the same 'eye level' as the patient. This helps building patient's trust by the physician not being perceived as arrogant, condescending or patronizing. Sitting at the same level of the patients implies "*I have time for you*."
- Use nonverbal communication to emphasize interest and understanding for the patient's concerns. Maintain eye contact and a positive attitude, e.g. by smiling.
- Never check your watch during the patient encounter. This leaves the subjective impression of time constraints which negatively affect the quality of the conversation. The patient's perception of quality time devoted by the physician does not correlate with the absolute amount of time spent during the encounter, as long as the physician does not imply any time constraints by nonverbal language.
- Provide notepads to the patients and encourage them to write down questions for nurses and physicians. This strategy increases the patients' perception of being heard and being involved in the plan of care.
- Outline clear expectations to the patients, and share routine schedule information, e.g. the expected times of physician rounds, etc.
- Always re-direct the conversation back to open-ended questions, and ask the patient to repeat important statements for clarification of their understanding and perception ('*readbacks*').
- Avoid the use of technical terminology, and explain specific medical terminology in lay language as needed.
- Provide the patient with a final summary of the conversation, repeat the core essence of important points discussed, and encourage patient's compliance with the treatment regimen and follow-up appointments.
- Explain to families who will talk to them after surgery, and where they are expected to wait. Ensure a timely feedback to patients' families as soon as the surgical procedure is over. Envision the anxiety of family members in the waiting room while their 'loved one' is undergoing a surgical procedure.
- Finalize the conversation with patients and families by the use of the '**AIDET**' mnemonic: "*Thank you for your time and patience. Have I answered all your questions*? *Is there anything else I can do for you today*?"

Take-Home Message

Effective communication among the health care team and between physicians and their patients can be dramatically improved by the use of standardized communication frameworks. Evidence-based communication tools increase patients' and their relatives' trust in their physician and foster their involvement in shared

decision-making for the treatment plan [14]. Furthermore, the quality of communication has been shown to correlate with the patients' perception of the quality of care provided. A professional appearance in conjunction with a proactive and friendly greeting and introduction defines the first impression and sets the stage for an enduring relationship built on mutual trust and respect. In the current age of patient-centered care, surgeons have to move from being excellent technicians to being 'true partners' in the physician-patient relationship.

References

1. Stewart MA. Effective physician-patient communication and health outcomes: a review. Can Med Assoc J. 1995;152(9):1423–33.
2. Stewart M, Brown JB, Boon H, Galajda J, Meredith L, Sangster M. Evidence on patient-doctor communication. Cancer Prev Control. 1999;3(1):25–30.
3. Griffen FD, Stephens LS, Alexander JB, Bailey HR, Maizel SE, Sutton BH, Posner KL. The American College of Surgeons' closed claims study: new insights for improving care. J Am Coll Surg. 2007;204:561–9.
4. Greenberg CC, Regenbogen SE, Studdert DM, Lipsitz SR, Rogers SO, Zinner MJ, Gawande AA. Patterns of communication breakdowns resulting in injury to surgical patients. J Am Coll Surg. 2007;204:533–40.
5. Stein PS, Aalboe JA, Savage MW, Scott AM. Strategies for communicating with older dental patients. J Am Dent Assoc. 2014;145(2):159–64.
6. Lee S, Chen L, Ma GX, Fang CY. What is lacking in patient-physician communication: perspectives from Asian American breast cancer patients and oncologists. J Behav Health. 2012;1:2.
7. Studer Q, Robinson BC, Cook K. The HCAHPS handbook. Gulf Breeze: Fire Starter Publishing; 2010. p. 310.
8. Chang JT, Hays RD, Shekelle PG, MacLean CH, Solomon DH, Reuben DB, Roth CP, Kamberg CJ, Adams J, Young RT, et al. Patients' global ratings of their health care are not associated with the technical quality of their care. Ann Intern Med. 2006;144(9):665–72.
9. Stahel PF. Learning from aviation safety: a call for formal "readbacks" in surgery. Patient Saf Surg. 2008;2(1):21.
10. Prabhakar H, Cooper JB, Sabel A, Weckbach S, Mehler PS, Stahel PF. Introducing standardized "readbacks" to improve patient safety in surgery: a prospective survey in 92 providers at a public safety-net hospital. BMC Surg. 2012;12:8.
11. Stahel PF. The tenth year of the "Universal Protocol": are our patients safer today? Bone Joint^{360}. 2014;3:7–10.
12. Arora V, Gangireddy S, Mehrotra A, Ginde R, Tormey M, Meltzer D. Ability of hospitalized patients to identify their in-hospital physicians. Arch Intern Med. 2009;169(2):199–201.
13. Suk M, Stiefel E. Preventing complications in orthopedic communication. In: Archdeacon M, Anglen JO, Ostrum RF, Hersovici Jr D, editors. Prevention and management of common fracture complications. Thorofare: SLACK, Inc.; 2012. p. 362.
14. Wen L, Kosowsky J. When doctors don't listen. New York: St. Martin's Press; 2012. p. 334.

Professionalism in Health Care

10

Hagen Andruszkow, Frank Hildebrand, Roman Pfeifer, Klemens Horst, and Hans-Christoph Pape

Pitfalls and Pearls

- Physicians are required to be highly professional, accountable, continuously evaluated, trained and assessed.
- The relationship between industry and physicians has recently been scrutinized and strict rules and regulations put in place to prevent conflict of interests and professional misconduct.
- It is important for surgeons, especially in orthopaedics where surgical implants play a central role, to clearly understand hospital management cost reduction pressures while at the same time continue to focus on quality for our patients.

Outline of the Problem

The vast majority of physicians agree that colleagues who are impaired or incompetent should be reported to the authorities. However, when asked about their personal experiences of witnessing medical errors and 'bad doctors', about 50 % of physicians admit to have firsthand knowledge of mistakes and poor behavior by colleagues that they did not report.

The purpose of health care practice is the care for the ailing and the sick at any time, to promote health interests and well-being, and strive towards healing environments [1]. On the other end of the spectrum, standards of what a patient

H. Andruszkow • F. Hildebrand • K. Horst • R. Pfeifer • H.-C. Pape, MD, FACS (✉)
Department of Orthopaedic Trauma, University Hospital Aachen,
30 Pauwels street, Aachen 52074, Germany

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_10, © Springer-Verlag London 2014

should expect from their practitioner include amongst others professionalism [1]. In this context, professionalism is an ideal that should be sustained [1, 2]. The practice of medicine has to be interpreted as the application of scientific knowledge to human health bridging the gap between science and society [1]. However, practice is more than knowledge about disease. It is defined by experiences, feelings, and interpretations of humans in extraordinary moments of fear, anxiety and doubt [1]. With respect to this background, 'professionalism' is supporting the trust the public is lying in healthcare practitioners [1]. Consequently physicians have an ethical responsibility towards their patients. However, the medical profession is undergoing a profound transformation delivering more patient-centered care to individuals and populations, improving quality, and reducing costs and unnecessary diagnostics and treatments [3]. Within the profession, the obligation and opportunities to improve medical professionalism extend from leadership to individual physicians [3]. In this respect, practicing physicians are challenged by a growing demand from multiple participating parties in health care systems [3].

Limitations of the Current Practice

Political, social and economic factors with advances in technology and science have reshaped attitudes and expectations of the public as well as health care practitioners [1]. Historically, physicians' central obligation was not to harm, and most physicians were assumed by the public and themselves to be delivering quality care [3]. Variation in treatment was acknowledged but interpreted as normal part of the art of medicine necessary for adequate individual therapy [3]. Early attempts to standardize treatment procedures or systematical outcome measurements were met with resistance [3]. Consequently, infrastructures and skills to measure outcomes routinely did not exist [3]. During the last three decades, considerable changes have occurred with documentations of outcome regarding different therapeutic options. Evidence-based medicine has demonstrated that the above-mentioned variation of individual therapies is related to failure [3]. We currently are in the midst of a revolution focusing on patient-centered, outcome-based, and efficient health care [3]. This development seems to represent a profound change in the way medicine will be practiced and how health care will be delivered in the future [3]. In this respect, the nature of the practitioner-patient relationship has become transactional, with patients being viewed as customers and health care being comodified [1]. Moreover, we have progressed to an era where professional autonomy is losing to accountability [1]. Physicians will be required to demonstrate accountability and professionalism to their peers, to the society, and to their individual patients in different ways [3]. Accountability does not only include quality of treatment based on outcomes but also resource utilization, cost effectiveness, appropriateness of recommended care, the responsibility to help improve systems of care, and most important to ensure that care is individually patient-centered [3].

Professionalism in Health Care

There are several descriptions of professionalism as it pertains to health practice [1].

The Association of American Medical Colleges describes professionalism as a field of work in which the workers must be implicitly trustworthy and must pursue their work as 'virtuous undertaking, a moral activity' [1]. Health practice should be considered a 'guild' [1]. The Association considers professionalism in health care to be a social good [1].

The Royal College Working Party's definition signifies a set of values, behaviors and relationships describing the trust the public has in health practitioners [1, 4]. Knowledge, clinical skills and judgment are used guaranteeing humans' health by a partnership between patient and practitioner [4]. This partnership should be based on mutual respect, individual responsibility, and appropriate accountability that impacts on collective human dignity [1]. This 'professionalism' should be available in general and everyone can benefit from it [1].

According to Dhai, professionalism in health care requires a high degree of competence, compassion, and autonomy in order to understand and concern persons' distress [1]. This should not be limited to scientific knowledge and technical skills, but also includes ethical knowledge, skills and attitudes [1]. As new ethical issues arise with changes in practice and its social and political environment, it seems important that knowledge and skills are updated regularly [1]. Consequently 'professionalism is not a static concept' according to Bryden et al. [5].

The above mentioned ethical and moral aspects referring to the health care in general distinguish health practice from business and other careers [1]. Pellegrino et al. have stated three reasons for this suggestion [1, 6, 7]. At first, it is the nature of illness itself with patients being in a uniquely dependant, anxious, vulnerable and exploitative state [1, 6, 7]. Secondly, the knowledge gained by the practitioner is not proprietary as it is acquired through society sanctioning [1, 6, 7]. The practitioner's knowledge is therefore not individually owned and should not be used primarily for personal gain, prestige or power [1, 6, 7]. Thirdly, the oath that is taken at graduation is a public promise that the practitioner understands the gravity of her/his calling and promise to be competent, and use that competence in the interests of the sick [1, 6, 7].

Where Is the "Golden Bullet"?

Trust between the patient and his/her practitioner is critical for a successful treatment plan [1]. Individual failures of professionalism accompanied by negative media coverage may undermine the public trust in health practitioners. Consequently, the topic of whether physician accountability is an individual or a group responsibility has gained importance [3]. According to Miles et al. physicians must be accountable as individuals as well as participants in practices and teams, systems, and health care organizations that are responsible for population management [3]. The delivery of better quality with less waste and unnecessary costs requires a change in individual physician behaviors and a change in systems of care [3]. The American Board of Medical Specialties

endorsed the concept of continuous professional development for individual physicians [3, 8]. From the time physicians begin their careers until retirement they are expected to demonstrate the progress of the ongoing individual professional development [3]. This approach highlights a radical change in the level of monitoring of physicians' accountability [3]. However, although some aspects of quality in health care are an individual, physician's responsibility the major determinants of improved outcome are related to systems of care and teamwork [3]. Due to the increasing complexity of patient care, a physician's ability to work in an interdisciplinary team, to collaborate with different team members, and to be a player in improving health care systems are new essential competencies for medical professionals [3].

Professionalism in Orthopedic Surgery

The practice of Orthopedic surgery is becoming increasingly complex [9]. In fact, with the development of new implants and rapid expansion of technology [9], surgeons and hospitals are being push to follow this fast-paced progress. Conflict has arisen between hospitals, developers, suppliers, and physicians, in relation to costs and concerns for industry influences on physicians' choice of products [9]. Physicians' decision-making and their autonomy are challenged by these external factors. Furthermore, the accountability of surgeons has grown [9]. There is an overlap of different factors described with the centrality of professionalism, autonomy and accountability (Fig. 10.1).

Focusing on shared decision-making in the patient-surgeon interaction, surgeons' professionalism for the patients' benefit could be biased due to the complex and sometimes biased patient-surgeon relationship [9]. Shared decision-making in professionalism should include [9]: the patient and the surgeon; the information shared by both parties; the treatment plan agreed by both the patient and his physician; finally, the treatment process itself [9, 10]. This decision-making involves the surgeon, the patient and the hospital [9]. However, a patient may not always be in an adequate mental state to express preferences and to understand and argue on all treatment options [9]. For instance, in emergency situations, or for choices made during the course of surgery, there is little time for the patient to actually make an informed decision [9]. One can summarize that surgery continues to be a mix of active and passive patient participation, but with the patients' benefit in the focus.

The surgeon can be suggested to be part of a complex interaction that brings products, processes, and services to the patients. In the course of professional training and certification, surgeons are exposed to multiple products [9]. The surgeon-supplier interaction is characterized by continuous questioning of the current products and techniques within the context of achieving excellence towards the care of patients [9]. While the importance of implants in orthopedic surgery is obvious [9], the relationship between surgeons and the industry must be clear and well defined to the patient [9]. In this respect, hospital managements are attempting to reshape the interface between suppliers and physicians through supplier credentialing strategies [9]. However, it is noteworthy that hospitals intentions to consider

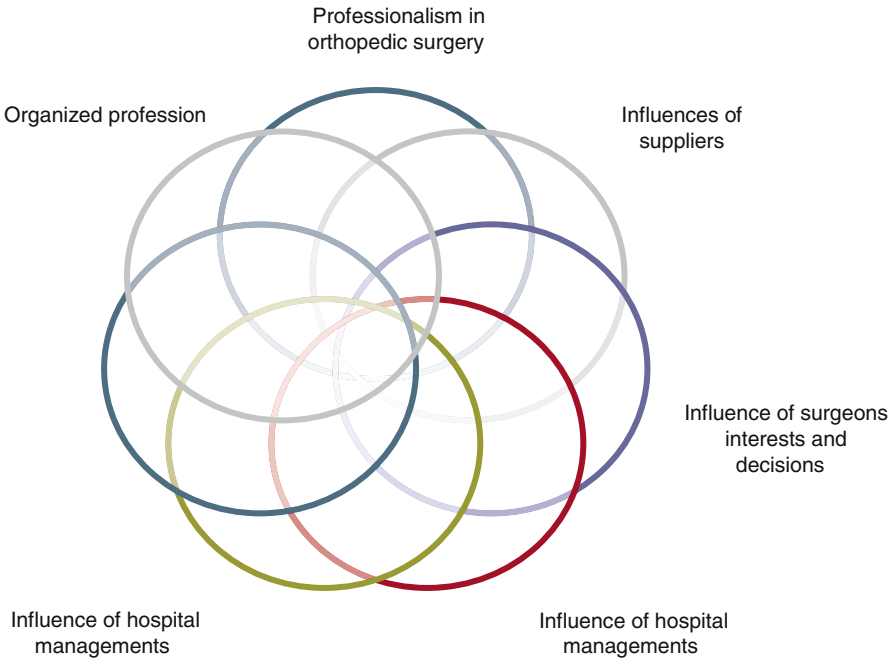


Fig. 10.1 The overlapping involvements towards professionalism in orthopedic surgery (Modified according to Schneller and Wilson [9])

material alternatives are often driven by economic considerations [9]. It is important to consider that hospitals may want surgeons to consider alternative implants for cost reasons rather than for direct benefit for the patients [9].

Healthcare institutions are currently subject to forces that can support or detract from professionalism [9, 11]. Hospital managers often question surgeons' decision-making processes [9]. While hospitals are engaging in much more aggressive programs to control suppliers influences and make surgeons aware of the financial ramifications, it is unclear to which degree the hospital-surgeon interaction influences surgical professionalism [9].

In summary, orthopedic surgeons are challenged due to the involvement of several influencing factors towards the profession of surgery. The most important attempt seems to redefine the ideals of professionalism, autonomy and accountability for the current practice of orthopedic surgery.

Take-Home Message

Professionalism in health care is an ideal based on ethical, scientific and moral duties and suggestions distinguishing the medical profession from other business. Professionalism in the twenty-first century is challenged by an overlapping

involvement of different parties of interest. Health care practitioners, with a special focus on orthopedic surgeons, are challenged to redefine the idea of professionalism, autonomy and accountability for the current practice.

References

1. Dhai A. Understanding professionalism in health care in the twenty first century. SADJ. 2008;63(3):174, 176–7.
2. Cruess RL, Cruess SR, Johnston SE. Professionalism: an ideal to be sustained. Lancet. 2000;356(9224):156–9.
3. Miles PV, Conway PH, Pawlson LG. Physician professionalism and accountability: the role of collaborative improvement networks. Pediatrics. 2013;131 Suppl 4:S204–9.
4. Royal College of Physicians. Doctors in society. Medical professionalism in a changing world. Report of a working party of the Royal College of Physicians in London, London, 2005.
5. Bryden P, Ginsburg S, Kurabi B, Ahmed N. Professing professionalism: are we our own worst enemy? Faculty members' experiences of teaching and evaluating professionalism in medical education at one school. Acad Med. 2010;85(6):1025–34.
6. Pellegrino ED. Altruism, self-interest, and medical ethics. JAMA. 1987;258(14):1939–40.
7. Pellegrino ED. Medical professionalism: can it, should it survive? J Am Board Fam Pract. 2000;13(2):147–9.
8. The American Board of Medical Specialties. www.abms.org.
9. Schneller ES, Wilson NA. Professionalism in 21st century professional practice: autonomy and accountability in orthopaedic surgery. Clin Orthop Relat Res. 2009;467(10):2561–9.
10. Stevenson FA, Barry CA, Britten N, Barber N, Bradley CP. Doctor-patient communication about drugs: the evidence for shared decision making. Soc Sci Med. 2000;50(6):829–40.
11. Pauly M, Redisch M. The non-for-profit hospital as a physicians' cooperative. Am Econ Rev. 1973;63:87–99.

Accountability in the Medical Profession

11

Jeremy A. Long

Pitfalls and Pearls

- Accountability in the medical profession has no precise definition.
- The fragmented healthcare system can cause accountability to be passed from one entity to another.
- The body of evidence guiding accountability is small compared to most clinical topics.
- A historical precedent of physician-centric practice is now juxtaposed with increasing patient autonomy and knowledge.
- Assignment of blame for medical errors is variable; the role of the propagator of error and the culture of the healthcare institution involved leads to disparate penalties.
- Statutory and regulatory measures provide a framework for objective reporting.
- Patient knowledge and activation is leveling the power balance with providers and promises to give patients themselves more accountability.
- Grant funding and collaboration opportunities continue to emerge that can promote safety through accountability.
- Health systems are recognizing the value of a culture of safety and accountability.
- Provider performance measures incentivize accountability.
- Training programs are adopting venues to teach responsibility in a clinical context.

J.A. Long, MD, MPM
Division of General Internal Medicine, Department of Medicine,
Community Health Services, Denver Health Medical Center,
777 Bannock Street, Denver, CO 80204, USA
e-mail: jeremy.long@dhha.org

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_11,

Outline of the Problem

Accountability is poorly wielded as a tool to improve health care delivery and quality.

Definition

Healthcare accountability can be constructed to apply to an individual practitioner, a hospital, a healthcare system, or even a governmental unit. Each of these has its own body of study and warrants a focus as healthcare strives to improve quality and safety for patients. For the purposes of this chapter, accountability will be defined as the responsibility of an individual provider or practitioner (e.g. physician or provider such as PA or NP) in the care that he/she does or does not provide for an individual patient.

Accountability Is Rooted in Fundamental Medical Ethics

Medical professionals face a variety of duties and obligations in providing clinical care. Within this they are accordingly accountable to numerous entities. A provider might be faced with juggling the needs of the patient, the facility, the insurer, and the need to pay his own bills. There is also the need to practice within peer standards, follow guidelines, and adhere to an evidence base as much as it might be available. Modern day medical practice has become bureaucratic enough that it can discourage some providers from clinical practice and may inhibit the career choice of trainees.

The evolution of accountability has led the provider-patient relationship into new frontiers. Healthcare now sits as yet another entity with a global marketplace. Practice innovation occurs across the globe and dissemination of ideas is rapid. Providers are pushed to keep pace with all of these factors, appeal to patients who become their clientele, keep abreast of innovation, leverage the latest technological innovations, and live interesting lives outside of medicine. With the weight of all these factors it should come as no surprise that there are breakdowns in accountability.

Provider accountability cannot be described without placing it into a background of medical ethics. Among past medical and scientific minds credited with establishing modern ethical principles, John Gregory stands out [1]. Gregory linked ethics and obligation in a way that implied a foundational relationship between patient and physician. They were given a more equivalent moral standing than what was typical of that era, where the relationship was easily dominated by the physician. It took time for Gregory's and others precepts to take hold. As medicine evolved it became evident that the bond between patient and provider, however simple, always contains an element of ethics that cannot be ignored. The business of medicine, while driven at times by third parties or financial principles, cannot be uncoupled from a duty that is assumed when one bears the mantle of providing care.

Medical ethics is fundamentally rooted in the concepts of beneficence, nonmaleficence, autonomy, and justice [2]. Accordingly, these must undergird any

patient-provider relationship. From the beginning of a provider's career there is knowledge that one should seek to do good, to do no harm, and to seek patient input in a way that makes patients decision makers as they are able. Attempts have been made to quantify the four primary ethical principles in a way to better understand how they are employed [3]. A provider cannot be described as an accountable agent without recognizing that an ethical obligation is inherent.

Training programs for healthcare providers have taken on the task of teaching accountability. Indeed, it is embedded within core competencies for undergraduate and graduate medical education [4–6]. The object of codifying accountability into curricular pieces remains variable and some of the teaching of accountability must come from clinical mentorship. The intergenerational nature of healthcare providers mirrors society, where one individual might not know of a world without the internet and another was born into a world without broadcast television. Changes in science and medicine have occurred rapidly in only a few decades. The professors of today were socialized in a very different way and might not easily provide space for discourse on social obligation [7].

Historical Perspective on Physician Duty

A look at history elucidates how ethical obligations are profound for healthcare providers. Medieval guilds served as a forerunner to the modern profession of medicine. Medicine developed as a skill with specific training and a natural bond among practitioners. An identity as a physician was perhaps similar to the identity of other vocations. Indeed, it has been suggested that surgeons remain in some ways tied to the guild model [8]. As the healing aspects and abilities of physicians have increased, the tenets of obligation have gained gravitas. The capability to do more and intervene in greater ways has opened up new channels that entwine the service of medicine with duty in ways that are not found in many other careers. In this way and in others medicine has evolved into a profession.

Evolution of Accountability

The beginning of the twentieth century saw the advent of increasing invasive procedures and burgeoning treatment options for acute and chronic disease. Amidst increasing success therapeutically, expectations of patients and the community at large swelled. Healthcare institutions were born and expanded to provide better oversight of medical training and medical practice. The heretofore rare concept of formal continuing medical education began to supplement, if not replace, the time-honored tradition of simply learning from one's own mistakes [9].

The Flexner Report marked a turning point for medical training. Renowned for its sweeping effect on disparate medical training and widely varied standards of education, this report led to the dissolution of substandard institutions and shed light on those of the highest quality [9]. The most effective training models then became a framework in standardizing the educational experience. Licensure became

regulated and the development of sub-specialization prompted advocacy for diverse factions within medicine as the twentieth century progressed.

The concept of litigation grew as a form of accountability for medical practitioners in the twentieth century [10]. The judicial system became a forum where medical errors might be handled. The form of a tort mirrored the way other conflicts were mediated in society, such as property or financial disputes. Physicians have spent the past several decades trying to contextualize the role of legal action as a safety net for society from medical negligence. This no doubt adds to the ways in which a healthcare provider can be deemed accountable.

Healthcare organizations and providers have made progress in developing accountability mechanisms for clinical care delivery. Many physicians and other healthcare providers exist as employees or contractors. This offers a mechanism for health care organizations to deliver regulatory or statutory oversight while also being mindful of autonomy [11]. Provider autonomy has been impacted by the changing landscape in healthcare. Managed care, sweeping health reform, and the ebb and flow of hospital versus provider owned practices have contributed to the current concept of autonomy. The concept of reciprocal accountability, whereby facilities, providers, and regulatory bodies participate in shared accountability, seeks to overcome the fragmenting within healthcare and remain patient-centered [12].

The public's trust in healthcare has been an increasing focus since the landmark report by the Institute of Medicine, To Err is Human, which implicated the healthcare system in more than 100,000 deaths annually [13]. Combined with the emergence of quality improvement as a pillar of both biomedical research and a tool for healthcare re-design, the IOM report has framed a problem that was previously outside of the public's eye. The patriarchal nature of healthcare too often relied on delivery of services with little chance for feedback by patients. Current efforts address this disparity through the lens of safety, thereby maintaining objectivity.

Innovations in information sharing have provided tools to help providers become more accountable. The Health Insurance Portability and Accountability Act of 1996 moved the concept of disclosure toward a more patient-centered focus. The Patient Protection and Affordable Care Act of 2010 expanded patients' access to their own health information. Concurrent with these pieces of federal legislation has been a massive change in access to electronic and digital media. Via the Internet patients now have the ability to research potential providers, treatment alternatives, and compare healthcare institutions in ways that were never possible previously. The options for communicating with providers have expanded far beyond mail or telephone to provide numerous avenues for patients. Patients have come to expect greater ease of communication. Providers, meanwhile, are coming to terms with the additional responsibility of facilitating this communication.

Physicians have traditionally been a group loathe to report its own deficiencies [4, 14–16]. Fortunately, this tradition has been revisited in an effort to ease the fears of physicians who are afraid of repercussions for medical errors. Reporting systems which emphasize "no-fault" have become widespread in hospitals and institutions [17]. These systems have merit for working to uncover system problems but tend to de-emphasize the role of individuals. For physicians and providers working in a climate of *malpractice-lurking-around-the-corner* it can drive them to under-report

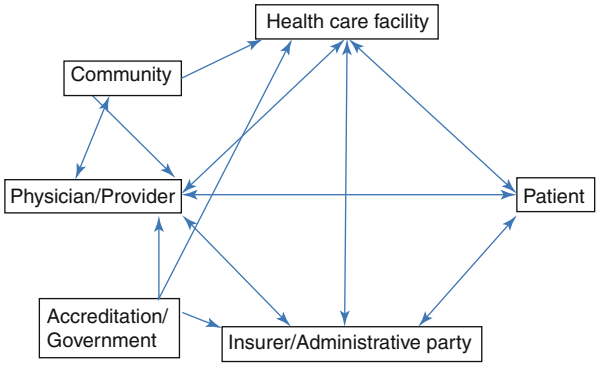


Fig. 11.1 Conceptual framework for stakeholders in patient care

known deficiencies. Thus providers can escape scrutiny amidst a system review when in fact their own missteps are to blame.

No-fault reporting systems lie at the mercy of the power dynamic between physicians and healthcare institutions. Whereas physicians can "take their business" to another facility it behooves a facility to downplay the individual role of a physician. The financial consequences of singling out members of a medical staff are too great to risk physician loyalty [17]. The converse of this is that the front line staff who often carry out the orders of providers, namely those within nursing, are at risk for harsher penalties because they are typically salaried employees. This double standard persists in spite of its obvious injustice.

Finally, the concept of accountability can be summed up within the example of hand hygiene [15]. Of the greater than 100,000 annual deaths associated with receiving healthcare, a substantial amount can be attributed to infections. As a provider moves from patient to patient, a clear checkbox emerges in the assessment of accountability. Proper handwashing represents a provider utilizing best practices within a system, Failure to clean hands is a miss on multiple levels and could lead to the type of sentinel event that so many seek to eliminate. The medical profession must engage others in leading the charge to make this and other issues a priority for individuals as well as for systems.

Figure 11.1 represents a simplified way of placing the patient into the context of multiple healthcare stakeholders. Starting with handwashing, the patient is ultimately at risk from the provider and facility. Insurers and governmental agencies wield financial backlash in the forms of reduced reimbursement or fines. The community wants to know that its members will be safe when they become patients.

Limitations of the Current Practice

The practice of medicine has numerous variables which make it vulnerable to human error, as implied by the title of the Institute of Medicine Report [13]. Although much has been learned about how and why errors occur, too many patients still perish at the hands of a system that struggles to find solutions. Within that

system the delivery of care is shaped largely by providers who practice under the specter of a vast system for medical malpractice. Additionally, healthcare institutions might prioritize financial health over safety to ensure provider retention. These factors undermine the true needed accountability necessary to advance the improvement of healthcare [18].

The physician identity in historical context warrants examination. The assumed infallibility of physicians throughout history now reveals itself as a weakness. An individual viewed as perfect might develop a blind spot and avoid the introspection necessary to anticipate deficiencies. A future world must incorporate the implied responsibility for providers in ways that also acknowledges their vulnerabilities. Systems must continue to evolve which diminish the chance for error while maintaining a sense of autonomy for individual providers.

Where Is the "Golden Bullet"?

Providers are well-positioned to be agents of change for a stronger healthcare system. By taking ownership of accountability and accepting their own imperfections, medical professionals can rally for a new paradigm. A blend of blamelessness and accountability is better-suited for true quality improvement so that the objectivity of one system can complement the responsibility aspect of the other. This area of study should recruit the public's trust as it seeks to undo damage from prior decades of contentious malpractice cases, medical errors, and revelations of other harm.

Ethics and accountability curricula have been modeled for undergraduate and graduate medical trainees [19, 20]. Combined with preeminent faculty stepping forward from such fields as surgery to offer a call to action, there is clear momentum to develop and disseminate best practices [21]. From this can flow ethical standards which must be integrated into clinical standards.

Patient safety is a concern for every person working in the world of healthcare. Indeed, only those so-inclined should be recruited for employment. The movement to protect patients from wrong-site surgeries, lethal dosing miscalculations, or other preventable adverse outcomes sits at a crossroads. The world of healthcare must engage all parties, particularly physicians and providers, in a team-based effort to build a coalition of accountability. If not, business as usual will disproportionately mete out accountability within a shroud of litigated fear. Justice and ethics will ensure that the science of accountability will grow and flourish as the system improves patient safety.

Take-Home Message

- Providers, particularly physicians, are well-suited to overhaul the current state of medical accountability.
- A team approach can spread accountability amongst multiple entities while also preserving the ability to address individual deficiencies.

- Healthcare evolution provides perspective which can be distilled into the most ethical and moral principles to be carried forward.
- The public depends upon a system which will improve itself.

References

1. McCullough LB. John Gregory and the invention of professional medical ethics and the profession of medicine. Dordrecht/Boston: Kluwer Academic; 1998. 347 p.
2. Beauchamp T, Childress J. Principles of biomedical ethics. 5th ed. New York: Oxford University Press; 2001.
3. Page K. The four principles: can they be measured and do they predict ethical decision making? BMC Med Ethics. 2012;13:10. PubMed PMID: 22606995.
4. Laube DW. Physician accountability and taking responsibility for ourselves: washing the dirty white coat, one at a time. Obstet Gynecol. 2010;116(2 Pt 1):248–53. PubMed PMID: 20664382. English.
5. Tsai TC, Lin CH, Harasym PH, Violato C. Students' perception on medical professionalism: the psychometric perspective. Med Teach. 2007;29(2–3):128–34. PubMed PMID: 17701622.
6. Murray RB, Larkins S, Russell H, Ewen S, Prideaux D. Medical schools as agents of change: socially accountable medical education. Med J Aust. 2012;196(10):653. PubMed PMID: 22676883. English.
7. McCullough LB. Holding the present and future accountable to the past: history and the maturation of clinical ethics as a field of the humanities. J Med Philos. 2000;25(1):5–11. PubMed PMID: 10732872. Pubmed Central PMCID: Source: KIE. 65253. English.
8. Hall DE. The guild of surgeons as a tradition of moral enquiry. J Med Philos. 2011;36(2): 114–32. PubMed PMID: 21576372.
9. Duffy TP. The Flexner Report—100 years later. Yale J Biol Med. 2011;84(3):269–76. PubMed PMID: 21966046.
10. Lynch J. Clinical responsibility. Oxfordshire: Radcliffe Publishing Ltd; 2009. http://books.google.com/books/about/Clinical_Responsibility.html?id=-BN6uDQ8k5YC
11. Smith SD, Smith S. Physician autonomy in the age of accountability. Minn Med. 2007;90(10):20–2. PubMed PMID: 18038738.
12. Morath JM, Turnbull JE. To do no harm: ensuring patient safety in health care organizations. San Francisco: Wiley; 2005. http://www.iom.edu/~/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf
13. To err is human: building a safer health system. Washington, DC: Committee on Quality of Health Care in America; 1999.
14. Donaldson LJ. Professional accountability in a changing world. Postgrad Med J. 2001;77(904):65–7. PubMed PMID: 11161069.
15. Goldmann D. System failure versus personal accountability—the case for clean hands. N Engl J Med. 2006;355(2):121–3. PubMed PMID: 16837675. English.
16. Wachter RM, Pronovost PJ. Balancing "no blame" with accountability in patient safety. N Engl J Med. 2009;361(14):1401–6. PubMed PMID: 19797289.
17. Wachter RM. Personal accountability in healthcare: searching for the right balance. BMJ Qual Saf. 2013;22(2):176–80. PubMed PMID: 22942398. English.
18. Emanuel EJ, Emanuel LL. What is accountability in health care? Ann Intern Med. 1996;124(2): 229–39. PubMed PMID: 8533999. Pubmed Central PMCID: Source: KIE. 49315. English.
19. Hochberg MS, Berman RS, Kalet AL, Zabar SR, Gillespie C, Pachter HL, et al. The professionalism curriculum as a cultural change agent in surgical residency education. Am J Surg. 2012;203(1):14–20. PubMed PMID: 21983000.
20. Boelen C. Building a socially accountable health professions school: towards unity for health. Educ Health. 2004;17(2):223–31. PubMed PMID: 15763765. English.
21. Whittemore AD. The competent surgeon: individual accountability in the era of "systems" failure. Ann Surg. 2009;250(3):357–62. PubMed PMID: 19730172.

The Role of the Surgical Second Opinion

12

Ted J. Clarke

Pitfalls and Pearls

- Two Preventable Forces Drive Most Lawsuits: (1) unrealistic patient expectations, and (2) known surgical complications which are surprising to the patient after the fact, and thus perceived as negligent care.
- Second Opinions Educate Patients and Facilitate Effective Communication.
- Patients should seek second opinions when they are confused about the proposed surgery.
- Finally, when the surgical course of care leads to unexpected outcomes, second opinions can help surgeons sort through the subjective bias inherent to being part of the treatment team.
- Perhaps Sir William Osler, the legendary father of American medicine, said it best: "A physician who treats himself has a fool for a patient." How does this relate to today's patient?
- A wise surgeon knows there's no such thing as performing "minor surgery."

Outline of the Problem

> *You're the doctor, you decide.*

Not too long ago, this was a common statement. It now represents a bygone era—a time when a privileged few exclusively held information and knowledge and physicians were perceived as omniscient. Today, doctors and patients share in treatment

T.J. Clarke, MD
Chief Executive Officer,
Colorado Physician Insurance Companies (COPIC),
7351 E. Lowry Blvd., Denver, CO 80230, USA
e-mail: tclarke@copic.com

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_12, © Springer-Verlag London 2014

decision-making. Unfortunately, many conversations that occur in health care happen between two participants with very different perspectives. When a treatment is proposed, a surgeon brings knowledge and experience while a patient brings his or her hopes and fears about the proposed treatment. The conversation begins on unequal ground.

This chapter focuses on how to avoid the unexpected and unwanted that can result from the lack of understanding created by unequal perspectives. It is asserted that by having a clear understanding of the goals, outcomes, and complications of surgery, patients and surgeons can work together to better navigate the potential hazards of an operation and achieve their common objective. Second opinions in surgery can facilitate such understanding.

Throughout this chapter, we'll explore the surgical second opinion by discussing the following:

- Why patients take legal action following surgery
- The role of the second opinion
- How third-party payers started the second opinion movement
- Second opinions from the patient's perspective
- How surgeons can best facilitate the surgical second opinion
- The future of U.S.-based health care

When Patients Take Legal Action

Unfortunately, frank discussions that promote shared understanding do not always happen between surgeons and patients. In my role as Chairman and Chief Executive Officer of COPIC, a medical professional liability insurance company that insures more than 7,000 physicians and 100+ institutions, I see the attempts made to resolve such misunderstanding when patients take legal recourse. Judicial measures are time consuming and emotionally exhausting. Both parties feel victimized: The patient by the health care system, and the surgeon by the legal system.

An average medical liability lawsuit takes approximately 5 years to reach resolution [1], and leaves both the physician and patient embittered. From the patient's legal perspective, his or her current problem was caused by the negligent surgeon. From the surgeon's medical view, the current legal problem stems from either the disease process or a known and unavoidable complication of treatment.

Two Preventable Forces Drive Most Lawsuits

Having reviewed thousands of medical liability cases, I believe there are two preventable driving forces behind most surgical medical liability lawsuits:

1. The unrealistic expectations of the patient, which are often created by the surgeon, another patient, or the media; and
2. An often unavoidable complication of surgery, known by the surgeon but surprising to the patient (and thus perceived as negligent).

Communication failures cause the misunderstandings that drive patients to seek retribution through the legal system. And when communication barriers create an impasse, a second opinion can help facilitate understanding while meeting the needs of patients their families, and physicians.

Second Opinions Educate Patients and Facilitate Effective Communication.

Second opinions offer a valuable and important tool for both patient and surgeon, and both parties should use this tool as an aide in decision-making. Second opinions offer the opportunity for further education and defining expectations.

Patients should seek second opinions when they are confused about the proposed surgery. This is particularly important when controversy about the management of the disease exists—whether the patient needs reinforcement to aid in making a decision, or his or her family has concerns about communication or trust with the surgical team.

Surgeons should encourage a second opinion as a means of reinforcing and educating the patient about the proposed surgical treatment. Surgeons should readily use a second opinion as part of the shared decision process of surgery, to help educate patients about the risk and benefits of the proposed procedure.

Finally, when the surgical course of care leads to unexpected outcomes, second opinions can help surgeons sort through the subjective bias inherent to being part of the treatment team.

Third-Party Payers' Influence on Second Opinions

The origin of the second opinion movement was largely driven by the third party payers of health care. Both government and private health plans have mandated second opinions as cost saving measures, but the results from a cost perspective have historically proven to be disappointing.

Second opinion requests became a trend in 1972, when a California union health plan introduced obtaining a second opinion for surgery as a potential cost saving measure for its members [2].

A similar mandate was introduced in 1977 when the Massachusetts' Medicaid program required individuals to seek second opinions before certain types of elective surgery. The results of this procedural change were documented in a *New England Journal of Medicine* study [3] of 1,597 patients, which reported:

- 180 patients received contradictory advice
- 82 of these 180 patients sought a *third* opinion, of which 70 % of the time, the *third* opinion supported the *first* opinion the patient received
- Eight percent of the total group were denied surgery. (It was not clear why this population was denied, but it is the opinion of this author that perhaps co-existing morbidities as well as changes in surgical practices and techniques, training, and the individual experiences of the surgeons played a role in the denials.)

When second opinions are mandated, effectiveness reports have varied. In 2003, the California state legislature passed Senate Bill 228 requiring workers' compensation patients to receive second opinions before undergoing spine surgery. This well-studied mandate was a response to the escalating cost of care: California workers' compensation payments had tripled in the decade preceding the mandate [4]. Not only was California paying dramatically more for its workers compensation system than any other state, it also appeared that the rate of spine surgery in California far exceeded national standards. Furthermore, outcomes for spine surgery patients, as defined by the workers' compensation "return to work" standard, were being questioned by the compensation system as workers undergoing spinal surgery had lower "return to work" rates when compared to non-operative spinal injury cases.

California Senate Bill 228 also created a mandatory review of the bill's impact. The review made three significant observations:

1. The second opinion requirement had little impact on cost when compared to utilization review plans used by other insurers.
2. Although a slight cost reduction was observed, much of this was attributed to a delay or postponement of surgery, which the study indicated frequently occurred as patients and/or surgeons failed to understand the bill's requirements.
3. The rate in which the surgeon providing the second opinion agreed with the first surgeon's plan of care was comparable to a control group of workers not participating in the California's system (71 % workers' compensation versus 66 % control).

The review concluded that the second opinion requirement for spinal surgery added an unnecessary bureaucratic layer to the system that resulted in marginal cost saving benefits. It suggested that mandatory reviews for proposed surgery only be used to resolve employer/employee disputes about proposed surgery.

Second Opinion from the Patient's Perspective

All health care starts with the patient, and embedded in every patient encounter lies the patient's bill of rights. This term was used by the American Hospital Association in the early 1970s, and many hospitals today exhibit their own version of a patient's rights (Box 12.1).

Perhaps Sir William Osler, the legendary father of American medicine, said it best: "A physician who treats himself has a fool for a patient." How does this relate to today's patient?

Box 12.1. Five Questions Payers, Patients, and Surgeons Should Discuss Prior to Surgery in Non-emergency Situations

1. Is this the right patient?
2. Is this the right surgeon and the right team?
3. Is this the right treatment or procedure?
4. Is this the right place for the surgery?
5. Is this the right time for this procedure?

Today's patient has more health care information available than ever before; however, patients, without the benefit of years of medical study, often lack a depth of knowledge, objectivity, and contextual understanding that allows them to make fully educated decisions about medical procedures. So by listening to Osler's advice, patients would benefit from finding a competent doctor who can guide them through the decisions that must be made.

The internet has enabled and empowered patients. A 2013 Google® internet search for "surgical second opinions" offers more than 1,500 references on this topic. By typing any disease or surgical procedure into a web browser, patients have access to instantaneous discussion about the pros and cons of a proposed therapy.

By the late 1990s, Wagner and Wagner [5] had determined that many surgical second opinions were being used by patients as a seemingly unbiased source for health information. Using survey information, Wagner reported that one in five health care visits in 1999 was for a second opinion. Variances existed, with lower utilization rates being reported for patients who were uninsured, uneducated, and/or non-English speaking.

Although there are no recent surveys on second opinion utilization, it is hard to imagine that use of such consultations have decreased in the current information age. Some believe that the information available from internet has potentially leveled the playing field between doctor and patient [6]. Such reasoning assumes that patients will improve their health care and surgical outcomes as they become bedside researchers who help physicians understand the right solution for their particular needs.

The 'Online Opinion' in the Twenty-First Century

Computer researchers have long been developing software to help clinicians with differential diagnoses [7]. Today's medical student supplements textbooks with handheld, touch screen devices. Such portable programs use given clinical information to create a list of diagnostic possibilities clustering around the array of signs and symptoms. The hope remains that the computer will do for health care what the computer has done for chess masters—assigning value to every piece of information, free of doctrine and dogma. In turn, every patient would have the benefit of the greatest diagnostician, and such information would help all clinicians and their patients.

However, instructors of medical students and residents can quickly see the hazards of such an approach. Not all symptoms are equal, and the art of medicine is learning how to assess the importance of historical and physical clues. Similarly, the effective clinician must learn to prioritize the importance of objective data. Skeptics may argue that a website with clinical information exists primarily as a marketing tool for a clinic, hospital, or surgeon. How can patients cipher through the massive amounts of information provided to make the best decisions about their health care?

It's an exciting time to be a physician given the rapid technologic and therapeutic changes we are seeing in medicine. But the reality is this: No individual physician can keep pace with these changes. This rapid evolution of treatment choices can create confusion for both patients and surgeons.

The American College of Surgeons [8] (ACS) offers some salient questions for patients to ask their surgeon:

- What are the indications for the operation?
- What, if any, alternative forms of treatment are available?
- What will be the likely result if I don't have the operation?
- What are the risks?
- How is the operation expected to improve my health or quality of life?
- Are there likely to be residual effects from the operation?

Often in elective surgery, the referral to the surgeon is coming from a primary care physician. The primary care provider should be aware of the work of surgical colleagues, but it's up to the patient to verify the surgeon's references. Patients should be advised to check on board eligibility or certification as well as verification of accreditation for the proposed institution by a third party evaluator.

Second Opinion from the Surgeon's Perspective

A wise surgeon knows there's no such thing as performing "minor surgery." Such tasks are left for the novice and the uninitiated. Even the most mundane of surgical tasks must emerge through the minefields of complications that plague every operation. Fortunately, modern surgery has become safe and effective; "Good" to "excellent" results are routinely reported in 90–95 % of operations. Unfortunately, this still means up to 5 % of surgical outcomes potentially haunt both patient and surgeon.

The second opinion offers a tool for the surgeon to use to strengthen relationships as well as effectiveness. In fact, in the aforementioned Netherlands study, nearly one-third of second opinions were initiated by the surgeon.

Where Is the "Golden Bullet"?

Selecting the 'Right Surgery' and the 'Right Surgeon'

The patient and surgeon are starting a relationship, and the surgery might have lifelong consequences. Just as one checks with the Better Business Bureau or consumer advocacy groups before making a major purchase or taking on a home improvement project, patients should be encouraged to conduct similar due diligence about surgeons and health care institutions.

In his book, *Second Opinion, the Columbia-Presbyterian Guide to Surgery,* Dr. Eric A. Rose aims to empower patients through a variety of surgical procedures [9]. Whatever the proposed operation, Dr. Rose counsels the patient to understand two important questions:

1. What is the problem we are trying to solve?
2. How will the proposed surgery or procedure solve the problem?

Evaluating the Surgeon and Surgical Practice

It is difficult to determine if one surgeon is right for a particular patient. There are multiple interpersonal factors that underlie such a choice.

It is also important for patients and their families to remember that the relationship extends beyond the surgeon to include the surgical team and institution.

Rosen suggests patients and families observe the staff and office, asking themselves:

- Was the appointment on time?
- Were you treated with respect?
- Do you feel comfortable in the office setting?
- Did you feel rushed or did the doctor seem rushed?
- Were you encouraged to bring a family member or friend with you?

Patients and families are also encouraged to explore procedure-specific questions:

- How many of these procedures have you done?
- What are your results and how do you define good or excellent results?
- What are the most common complications, and how are they treated?
- What will such a complication do to my ultimate result?
- Can you ask some of your patients to speak to me about their experience?
- With whom do you share call, and how are weekends, nights, and emergencies handled?
- Who communicates results to me?
- Who is my anesthesiologist, and how was she chosen? What is her background? Will I meet her before the operation?
- What type of anesthesia do you recommend and why?
- What are my choices for anesthesia and pain control for this operation?
- When will I be able to go back to X (i.e., work, sports, dancing, yoga, sexual activities, etc.)?

Organizations like the American College of Surgeons (ACS) emphasize that patients have complete freedom to seek additional medical opinions by initiating a consultation with another physician concerning care plans or by dismissing the treating physician and transferring all care to another health care professional. In a patient-centered health care system, a patient's course of action is entirely within the patient's prerogative.

Patients may also be advised in circumstances where second opinions are not necessary. The ACS suggests the following language:

> *If, after discussing these questions with your surgeon, you feel confident that a surgical procedure is the best treatment for your condition, you probably don't need a second opinion. If, however, you have doubts about whether the operation should be performed, or if the doctor recommending the operation is not a qualified surgeon, you may want to seek consultation.*

When Second Opinions Count

When a surgery has predictable morbidity or mortality, second opinions offer comfort for both patients and surgeons. To hear confirmation of such risk serves the interest of each party and offers patients and families additional opportunities to raise questions and concerns as well as discuss other means of managing the condition.

Today's surgeon is not threatened or offended by the second opinion process. The American Medical Association (AMA) states that the medical community has "an ethical obligation to offer such opinions." [10] Various medical societies, including the AMA, ACS, and American Academy of Orthopaedic Surgeons (AAOS) offer guidelines to surgeons about second opinions.

Underlying each guideline is the premise that second opinions center around the needs of the patient. According to the AMA, "Physicians should recommend second opinions whenever they believe it would be helpful in the care of the patient."

Surgeons should help patients by finding trusted and respected colleagues to help with such opinions. The primary surgeon should explain to his or her patient and colleague the reason for seeking such advice. The consulting surgeon should give an independent review of diagnosis and treatment to the patient and referring surgeon. If treatment proposals differ, the patient has the option of choosing the plan most suitable for him or her. If such divergence of opinions proves unsettling, the surgeons should assist the patient in finding a third opinion.

Medicare is aware of such divergence and the anxiety that it might cause. "Medicare recognizes this need (for second opinions) and will reimburse for most second opinions …. Medicare recognizes that first and second opinions may differ, and in such a case, it will pay for a third opinion." When a surgeon seeks a second opinion, the primary surgeon should communicate to the secondary surgeon the facts of the case and his or her plans for treatment. The consulting surgeon should communicate his or her opinions to both patient and primary surgeon, and should let the patient know this communication has taken place.

Helping the Patient Obtain a Second Opinion

If a patient wants the opinion of another surgeon, the primary surgeon has a legal and ethical obligation to provide the patient with his or her medical records. The AMA warns that it is unwarranted to terminate the doctor-patient relationship because of the independent need of the patient for such an opinion. When seeing a patient for a second opinion initiated by the patient, the consulting surgeon should review the case and give an independent opinion for diagnosis and treatment to the patient. In such circumstances, the patient must be knowledgeable and in agreement about further communication between the consulting surgeon and the primary surgeon.

Case Studies

Patients' Difficulties in Choosing Surgery

In Box 12.2, we examine a case study of a patient with an elevated prostate-specific antigen (PSA) who received three differing opinions on treatment. Again, we are reminded of the unleveled field patients play on: These opinions seem contradictory to the patient, while physicians can support the differing opinions using their

Box 12.2. Case Study: Elevated PSA Leads Patient to Differing Second and Third Opinions

After his annual medical exam, it is determined that David, a 64-year-old realtor, has an elevated Prostate-Specific Antigen (PSA) level. David's primary care physician recommends observation; however, David's wife, a nurse, insists he consult a urologist for a second opinion.

The urologist evaluates further and obtains a biopsy, which confirms localized, moderately-aggressive prostate cancer. The urologist recommends a robotic prostatectomy to "cure him of cancer." David is told that such surgery carries risks that include incontinence and impotence.

David seeks a third opinion with a urologic oncologist, who recommends radiation therapy. Risks and benefits are reported to be similar to the prostatectomy.

What is the right choice for David?

personal and clinical experience, evidence, and supporting guidelines. In cases where the patient's options are not "black and white", he or she may be left to rely on anecdotal stories and the gestalt to make care choices.

Eventually most therapies will evolve, showing evidence favoring a certain pathway for a particular form of a disease. Until this occurs, the patient may be left with the uncertainties of an evolving science.

When Patients Seek Second Opinions After Surgery

Patients frequently seek a second opinion following an operation. In 2001, the University Hospital, Groningen, Netherlands [11] surveyed 2,079 patients who initiated second opinions in orthopedic surgery. Figure 12.1 shows that communication failures and unfulfilled or unrealistic patient expectations were the major reasons why patients sought additional opinions.

Miscommunication as a Source of Anger

In Box 12.3, we examine a case in which a patient experiences complications known to the surgeon yet surprising to the patient and her husband. It represents a miscommunication between patient, the patient's family, and the treating surgeon. Although the informed consent form for surgery explained the possibility that additional surgery would be needed, the reasons for such additional surgeries were either not heard or not understood by the patient and her family.

Box 12.4 examines how shared decision-making, informed consent, and patient education can reduce the need for patients to seek post-surgery second opinions. In this case study, a known complication occurs, leading the primary surgeon to request a second opinion to ensure patient understanding.

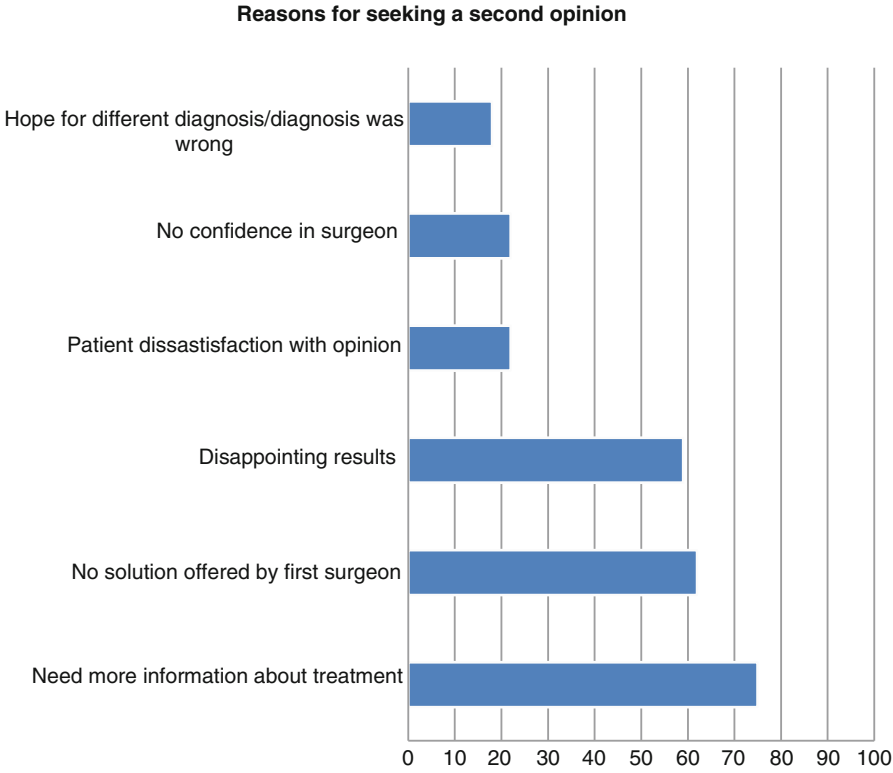


Fig. 12.1 Main reasons for patients to seek a second opinion

Box 12.3. Case Study: The Post-surgical Second Opinion

Bob's wife undergoes hip replacement surgery. Post-operatively, while still in the hospital, the surgeon discovers that Bob's wife has sustained a fracture around the femoral replacement. The surgeon recommends a second operation to fix the fracture.

Bob is furious and seeks an additional opinion. The second surgeon reviews the films with Bob, counseling him that this type of complication occurs in 1–2 % of hip replacements of this type. The second surgeon notes that he would also be "wiring the fracture" back together.

The second surgeon dictates his clinical note with Bob present, and with Bob's consent, sends a copy of the note with a letter to the primary surgeon. The primary surgeon subsequently treated Bob's wife for the fracture, and fortunately the patient had a satisfactory result.

Box 12.4. How Shared Decision-Making, Informed Consent, and Patient Education Can Reduce the Need for Surgical Second Opinions After Surgery
Because informed consent is a process of ***shared*** decision-making, the patient and family need to have a clear understanding of the risk and benefits of a proposed surgery. Common risks such as blood clots and infections need to be specifically referenced. Additionally, discussions about how common risks will be managed should they occur help ensure that patients are not surprised when a complication happens. Patients and their families need to have someone explain, in common language, the specific risks pertinent to particular operations. Patients should receive educational materials, like pamphlets and videos, to supplement discussions. It's the surgeon's responsibility to direct patients to appropriate tools.

Such thoughtful dialog changes what a patient may perceive as an unexpected event into a known complication of surgery. This pre-operative education can reduce the frustration and anger a patient and/or the patient's family may feel should surgery not go entirely as planned.

The Role of the Consulting Physician

The consulting surgeon must make an individual decision as to whether he will assume the care of the patient who is seeking a second opinion. It creates an ethical dilemma for the surgeon when the driving force behind such consultation comes from a surgical colleague. Under such circumstances, professional courtesy necessitates discussion of such options with the primary surgeon. This dilemma is further muddied when the opinion is sought in the midst of treatment when a complication or adverse development has necessitated such opinions. Here, surgical advice is being sought. Assumption of care by the second surgeon may be perceived as threatening the integrity or skill of the primary surgeon. Ideally, in such circumstances, seeking another opinion is a shared decision process between the patient and the surgeon. ***The best interest of the patient addresses the physical, psychological, spiritual and emotional needs for each particular patient***. Such solutions may differ from one patient to the next as cultural, social and economic factors become part of the decision making process. Ideally, involving the primary surgeon in such decision pathways maintains working relationships that will facilitate present and future care of this and other patients.

The Future of Health Care

As the United States continues the implementation of the Patient Protection and Affordable Care Act (PPACA), we hope to see the health care delivery system move toward sustainability.

In part, the PPACA attempts to redefine the economics of health care by changing the financial incentives to providers—substituting *volume* of service with *value* of service. The PPACA demands that providers justify care using an evidence-based perspective. Physicians and institutions will be measured, scrutinized, and judged for their outcomes of care. Care providers will be paid for better performances, as determined by the payer, and outliers may face significant penalties. Certain complications will no longer be reimbursed; however, physicians and institutions remain responsible for the cost, care and treatment of the patient for complications deemed "avoidable" by the payer.

It would not be surprising if this evaluation process requires patients receive second opinions for certain procedures and surgeries. Recognizing the cost to the system, the third party payer will seek confirmation for the necessity of the proposed intervention. Understanding that organizational reimbursements are tied to outcomes, surgeons might find colleagues, hospitals, and their own practices demanding a confirmatory opinion before proceeding with surgery. It is also possible that these second opinion requirements will have little impact on cost, as it slows the elective and urgent treatment process through bureaucratic requirements.

As the PPACA implements population management as a component of reimbursement, we hope to see our fragmented delivery system use a coordinated approach based on evidence-based outcomes. The small group of patients who will be denied treatment due to lack of evidence for the effectiveness of such treatment may be controversial on an individual basis but will be rooted in population studies that determine the effectiveness of the proposed treatment.

How many exclusions will be created by the payer or the system and how much savings will be gained remains to be determined. We remain optimistic that such provisions improve the quality and effectiveness of the health care delivery system while improving sustainability.

Surgeons and Patients Alike Benefit from Prudent Second Opinions

Second opinions are a frequent and necessary part of elective or urgent surgical care. These consultations offer patients and surgeons opportunities to receive confirmation and advice about proposed and ongoing diagnosis and treatment. It must be emphasized that in life or limb threatening emergencies, the luxury of a second opinion is not possible (see Box 12.5 for more information); however, in elective surgery, the second opinion serves as an educational tool for both surgeon and patient.

When Shared Decision-Making Is Not Possible in Surgery

There are times when dialog between patients, families, and surgical teams is not possible. When life or limb threatening problems exist, patients must rely on the medical staff. Patients can feel comforted that the staff in accredited hospitals and

Box 12.5. Case Study Examines a Primary Surgeon's Request for a Second Opinion

Dr. A removes Mr. Smith's thyroid for cancer. Dr. A has told Mr. Smith preoperatively about the possibility of hoarseness from the operation, and unfortunately this complication occurs. Dr. A is comfortable watching the problem, noting that the recurrent laryngeal nerve was visualized and protected interoperatively. Nevertheless, he suggests a second opinion about the management of hoarseness, and refers Mr. Smith to Dr. B. Following an exam and review of the records, Dr. B agrees that observation seems a prudent course, and he calls Dr. A to confirm his rationale.

What has happened? A known complication, discussed preoperatively, occurs following thyroid surgery. The primary surgeon feels comfortable watching for a return of the nerve function that underlies the hoarseness, and he wants the patient to have a similar comfort level about this course. The surgeon initiates a review, and the independent opinion reinforces for the patient and the primary surgeon that the complication is being appropriately managed.

surgery centers are thoroughly vetted and must pass complex background checks related to personality, education, and training. Furthermore, it is an increasing prerequisite that physicians must be certified by specialty boards like the ACS to maintain hospital privileges. Such testimonies of staff privilege or board certification are filters for quality that institutions and insurance panels demand. In emergency situations, these accreditations are the only recourse for quality that exists for the critically ill or injured patient.

Take-Home Message

It's important to remember that second opinions should be seen as part of an ongoing decision-making process for patients, and this process is unique for each patient. Surgeons should be reminded that although they have done a 1,000 appendectomies, it is the first and last for the patient, which can cause the normal reaction of anxiety and apprehension. By obtaining a second opinion, these concerns will be better addressed.

Patients may have more access to information than ever, but it's largely unfiltered and gives a biased view to the unsuspecting patient, particularly when marketing buzzwords like *laser, robotic,* and *minimally-invasive* permeate the information and attempt to "sell" solutions that evidence does not yet support. Surgeons should be aware of the type of information available to their patients, and direct patients to appropriate peer-reviewed sites that can aid in their decision-making. In some cases, surgeons should help patients find additional consultations and opinions.

Every surgeon will experience complications, and occasionally the management of these unanticipated outcomes proves challenging from a surgical, medical, or

psychological perspective. Second opinions offer surgeons the opportunity to view confusing and puzzling clinical situations with fresh perspectives unencumbered by the bias of ongoing treatment.

The second opinion movement began as a means for health care payers to address the spiraling cost of surgical care. As the PPACA unfolds, we can expect that the use of surgical second opinions will increase as organizations will be held financially accountable for the outcomes of care. As hospitals, clinics, and colleagues share in the financial risks of individuals and populations, evidence-based protocols will create templates for the management of various diseases. Deviation from protocols will require second opinions to confirm the rationale for such individual management. Time will tell whether such measures improve individual and population management.

References

1. The Physician's Insurers Association. [Internet]. 2013. Available at: http://www.piaa.us/.
2. California Commission on Health and Safety and Workers Compensation, April 2000. Available at: http://www.dir.ca.gov/chswc/allreports.html.
3. Gertman PM, Stackpole DA, Levenson DK, Manuel BM, Brennan RJ, Janko GM. Second opinions for elective surgery: the mandatory medicaid program in Massachusetts. N Engl J Med. 1980;302(21):1169–74.
4. Kominski GF, Pourat N, Roby DH, Cameron ME. Return to work and degree of recovery among injured workers in California's Workers' Compensation system. J Occup Environ Med. 2008;50(3):296–305. doi:10.1097/JOM.0b013e31815d8d9d. PubMed PMID: 18332779.
5. Wagner TH, Wagner LS. Who gets second opinions? Health Aff. 1999;18(5):137–45.
6. Bauer C, Bozard C. Health information exchanges case history. Leveling the playing field. How one health system competes with a national reference lab for outpatient lab services revenue. Health Manag Technol. 2009;30(2):14–5, 30. PubMed PMID: 19266862.
7. Hafner K. For second opinions, consult a computer. New York Times. Dec 3, 2012.
8. American College of Surgeons. [Internet]. 2013. Available at http://www.facs.org/patienteducation/index.html.
9. Rose E. Second opinion: the Columbia Presbyterian guide to surgery. New York: St. Martin's Press; 2000.
10. American Medical Association. [Internet]. 2013. Available at http://www.ama-assn.org/ama.
11. van Dalen I, Groothoff J, Stewart R, Spreeuwenberg P, Groenewegen P, van Horn J. Motives for seeking a second opinion in orthopaedic surgery. J Health Serv Res Policy. 2001;6(4):195–201.

Compliance to Patient Safety Culture

13

Kendra L. Moldenhauer and Peggy Alder

Pitfalls and Pearls

- Culture of blame asks "who"? Culture of openness asks "why"?
- Implementation of surgical safety checklists using a team approach has led to reduced mortality and complication rates.
- Health care requires skilled and well-trained individuals, operating under reasonable regulations, good policies and utilizing reliable quality data.
- Perfection is the enemy of good. Pursuing the "best" or the "perfect" solution may result in rejecting a solution that, while not perfect, is effective. Insisting on the perfect answer can result in a failure to improve.
- The medical model of physician autonomy and the "art" of medicine present a challenge to the incorporation of best practices and standardization — a key feature of a culture of safety.

K.L. Moldenhauer, BSN, RN (✉) • P. Alder
Department of Patient Safety and Quality, Denver Health Medical Center,
777 Bannock Street, Denver, CO, USA
e-mail: kendra.moldenhauer@dhha.org

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_13,

Outline of the Problem

Healthcare in the United States is not as safe as it should be – and can be.

Over a decade ago, the Institute of Medicine recommended improving patient safety by addressing cultural issues within healthcare systems. While some progress has been made, safety culture continues to be recognized as an important strategic focus if the deficits in patient safety are to be improved.

Hospital leaders are increasingly put under pressure by federal and state regulatory agencies, accrediting organizations and consumers to demonstrate an organizational safety culture. The objective of this chapter is to outline those key elements of a safety culture that must be incorporated into the fabric of the organization in order to achieve the desired improvements in patient safety.

Limitations of the Current Practice

History of Regulation and Accreditation

The American College of Surgeons (ACS) is a scientific and educational association of surgeons that was founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice [1]. The ACS was a pioneering organization in 1917 when it introduced the hospital standardization program, the first model for external quality oversight. After establishing a committee to improve hospital standards, the ACS issued a report recommending investigations, reports and administrative procedures to improve and standardize hospital care. The standards that were developed required medical staff organization; limitation of staff privileges to qualified physicians and surgeons; regular meetings of the medical staff; accurate, complete and accessible medical records; and provision of diagnostic and therapeutic facilities [2]. To this day, all of these standards are still essential components of hospital regulation.

The ACS hospital standardization program was the predecessor of the Joint Commission and the federal and state regulatory framework that is currently in place for all healthcare organizations [3]. The history of the Joint Commission, the largest health care accreditation organization, is shown in Box 13.1 [4].

Box 13.1. The Joint Commission History [4]

1910 – Ernest Codman, MD proposes the "end result system of hospital standardization". Under this system, a hospital would track every patient it treated long enough to determine whether the treatment was effective. If treatment was not effective, the hospital would try to determine why, so that similar cases could be treated successfully in the future.

1913 – American College of Surgeons (ACS) is founded and the "end result" system becomes a stated objective
1917 – The ACS develops the Minimum Standard for Hospitals. The requirements fill one page.
1918 – The ACS begins on-site inspections of hospitals. Only 89 of 692 hospitals meet the requirements of the Minimum Standard.
1951 – The American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association join with the ACS as corporate members to create the Joint Commission on Accreditation of Hospitals, and independent, not-for-profit organization whose primary purpose is to provide voluntary accreditation
1965 – Medicare and Medicaid are founded
1970 – The standards are recast to represent optimal achievable levels of quality, rather than minimum essential levels of quality
1992 – Multiyear transition to standards that emphasize performance improvement concepts
1996 – 1998 The Sentinel Event Policy is established for the evaluation of sentinel events and is revised to promote self-reporting of errors
2000 – Random unannounced surveys
2002 – The first National Patient Safety Goals are established for improving the safety of patient care in organizations
2003 – The JC announces a Universal Protocol ™ for preventing wrong site, wrong procedure, wrong person surgery – effective July 1, 2014
2007 – JCAHO to JC

Medicare/Medicaid and the Regulatory Arena

Prior to the adoption of Medicare in 1965, only about half of older Americans had health insurance. In the late 1950's and early 1960's, discussions were held about how to increase this coverage to all patients aged 60 or over.

President John F. Kennedy proposed a three-pronged agenda for a Social Security cash benefit increase, hospital insurance for the aged through Social Security, and improvements in medical assistance for the needy. President Kennedy's proposal was not considered until President Lyndon B. Johnson was in office. During his presidency a compromise was struck that combined three approaches. Part A of Medicare was a hospital insurance program; Part B covered outpatient physician services through a supplementary program that embodied the principle of voluntary participation by doctors and patients; and a third approach that had been advocated by the American Medical Association (AMA), became the blueprint for the Medicaid program for low-income families with children as well as the aged, blind and disabled. The federal compromise bill, which included an increase to Social Security benefits, was signed on July 30, 1965.

In 1966, after a period of rule making, 1,000 government employees started surveying hospitals to ensure their compliance with the newly defined conditions of participation and regulations, and their eligibility for certification by the federal government. This regulatory oversight was put in place to protect the newly insured elderly population and the federal investment in health care. Two of every seven hospitals had serious deficiencies [5].

The most deliberated and impactful legislation since the adoption of Medicare has been the Patient Protection and Affordable Care Act. It is a federal statute signed into law by President Barack Obama on March 23, 2010. The Act is a step towards expanding coverage and access to health care, improving quality, and providing an additional regulatory push towards promotion of patient safety. While the intricacies of the law itself are regulated at the state and federal level, plans for its implementation continue to evolve and remain unclear. Compliance to patient safety culture is a clear priority; for example, hospitals that have higher than targeted 30-day readmission rates will receive a cut in Medicare reimbursements. While there will be incentives rewarding providers who collaborate to deliver seamless, high quality care for Medicare beneficiaries [6].

Regulation and Accreditation

The Department of Health and Human Services (HHS) exists to protect the health of all Americans (Fig. 13.1) [7]. It is important to recognize the far-reaching impact of HHS and consider the day-to-day operational impact of federal regulation on the health care system.

The federal government works in partnership with state and local agencies, national quality and safety organizations, accrediting organizations, insurers and the health care industry to protect the US public. Field describes the present regulatory structure as one that is regrettably neither uniform nor consistent. Broad range of regulatory bodies and programs apply in different ways to various aspects of the industry. Health care regulations are developed and enforced by all levels of government – federal, state and local, as well as by a large assortment of private organizations that may be operating without coordination [8].

Health care is extraordinarily complex, and hospitals are hierarchical organizations that are resistant to changes. Behavior in health care is often influenced rather than controlled. Behavioral patterns emerge, rather than respond to design [9]. In spite of this, much of the health care environment is controlled by regulations.

Regulation and accreditation are often thought to be identical, and, although they are complementary, they serve different purposes. Regulation involves established principles, rules or standards that must be followed — established by an authority in order to direct or manage specific activities. Defined broadly, external regulators include a range of entities that regulate or influence the behavior of a healthcare organization with respect to performance improvement, quality and safety. These regulators include the state and/or federal entities responsible for monitoring and ensuring compliance with state or federal government standards, rules and regulations.

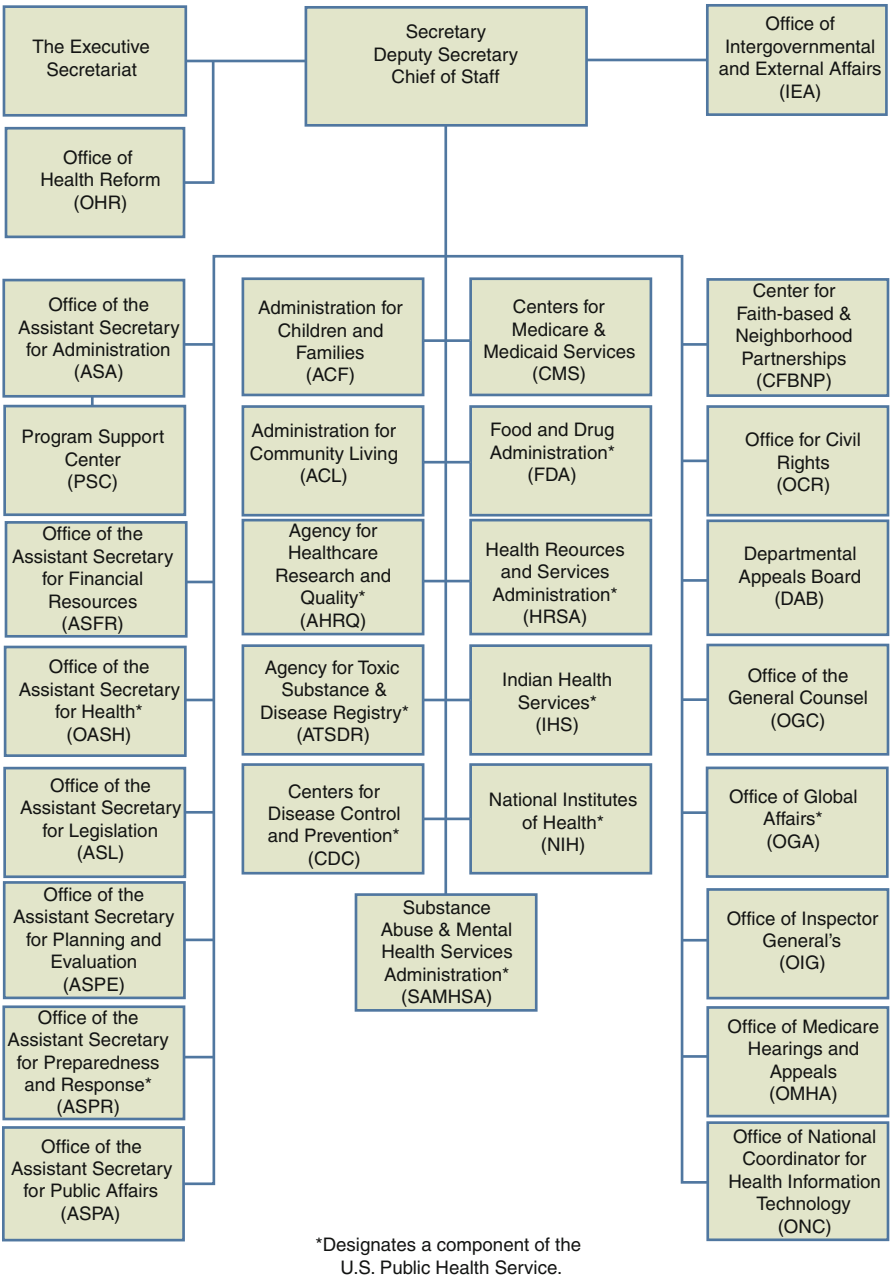


Fig. 13.1 Department of Health and Human Services organizational chart [7]

Accreditation is a seal of approval verifying that an organization has met specific rules, regulations and standards. Accrediting organizations advance high quality patient care and safety through the development and enforcement of standards. Examples of private organizations deemed by CMS to accredit health care organizations are The Joint Commission (TJC), Healthcare Facilities Accreditation Program (HFAP) and Det Norske Veritas (DNV). During accreditation surveys, these organizations evaluate compliance with CMS regulations in addition to their own established standards.

The accreditation process is ultimately a risk-reduction strategy. The premise is that if organizations are doing the "right things right" as reflected in the standards, then errors and adverse events are less likely to happen than if there were no such standards [3]. When the standards and the rules are incorporated into the fabric of the organizational culture, there is an acceptance and expectation for high safety standards at all times.

In most hospitals, accreditation requirements are the primary driver of safety efforts, and because [10] accreditation is frequently such an essential component of payment, insurance coverage and reputation, it is virtually as important and has the same power as regulations. Both hospital leaders and physicians have suggested that the Joint Commission was the most important driver of change and progress towards patient safety [11]. In fact, accreditation has been observed to be more effective in promoting good safety practices than state-required error reporting or public awareness [12]

The challenging environment of health care regulation has become a public-private partnership that despite the scope, complexity and flaws has served to coordinate, support and nurture health care quality and safety [8]. Nevertheless, physicians remain highly individualistic – causing them to resist regulatory solutions and standardization [11]. It is therefore crucial to involve and partner early on with clinicians who will be impacted by the new rules and regulations.

Regulators and accrediting organizations must acknowledge the cost and resources required to implement and adopt safety initiatives and performance improvement activities. Warburton suggests that safety goals and recommended practices have been important drivers in the national efforts to improve patient safety; however the proliferation of requirements threatens to overwhelm the capacity of hospitals to safely implement change in a manner that is meaningful and sustainable [13]. Review and analysis of reliable data and ongoing monitoring of process changes are essential to determine if changes are achieved and sustained. Predictably, this cannot occur without a robust data analysis capacity. Following this analysis it is important to simplify the regulatory system by eliminating non-productive and un-measurable regulations.

In 2009, Wachter evaluated the progress of the patient safety movement 10 years after the Institute of Healthcare Improvement (IOM) landmark publication "To Err is Human" and suggested that situations may arise in which hospitals are being required to collect different data or implement varied solutions for the same problem by state regulators, federal government, Joint Commission, the National Quality Forum, the CDC's National Healthcare Safety Network

Table 13.1 Regulatory strategies

Regulatory category	Examples
Standardizing good medical practices	Reduce medical variation Checklists Practice guidelines Research
Tracking adverse events in hospitals	Patient safety organizations Never events Sentinel events
Disclosing provider performance	Publically reported performance data Disclosure of adverse events to regulators and accrediting organizations Disclosure by the provider to patients
Reforming payment systems	Incentives for safety through pay for performance Penalties for failing to meet minimum standards Insurance exchanges to promote safety and quality improvements
Coordinating and integrating care	Innovation in health care delivery
Expanding provider responsibility	Requirements for: disclosure, fiduciary responsibility and bad outcomes

(NHSN) and a variety of benchmarking organizations. Without harmonization of efforts, there may be a point in time when providers and administrators may become reluctant to implement and work towards competing initiatives and requirements [14].

Unfortunately, the history of regulation is beset with examples of overreaching and unintended consequences, both of which can hamper flexibility and innovation. Examples include the Joint Commission release of National Patient Safety Goals (NPSGs) before evidence to support their implementation or the Accreditation Council for Graduate Medical Education (ACGME) resident work-hour restrictions without careful evaluation of the impact on workflow, communication and patient handoffs. Ultimately, work hour restrictions have not been shown to improve patient safety [11].

If "*first do no harm*" were sufficient to prevent medical error and keep patients safe, there would not be a need for the growing patient safety movement. The field of patient safety has grown since the mid 1990's. Patient safety efforts have included both private and market-based initiatives both state and federally driven. The general strategies can be summarized in six major points: standardizing good medical practices, tracking adverse events in hospitals, disclosing provider performance, reforming payment systems, coordinating and integrating care, and expanding provider responsibility (Table 13.1).

Regulation and accreditation have proven to be beneficial to patient safety efforts, while they are less useful in ensuring more general quality improvements. Rules should be written with attention to clarity, regulations must minimize cost and waste and allow some flexibility in response to variations in healthcare settings and compliance must be observable or measurable [15]

Where Is the "Golden Bullet"?

High-Reliability Concepts

It is essential that health care organizations continue to take an on-going, comprehensive approach to regulation and accreditation in order to improve and maintain health care quality and safety; however, quality improvement and safety programs alone cannot transform organizations [16].

Most health organizations are in a period of transition from a culture in which compliance is the primary focus to a culture that is focused on safety and high reliability concepts. Health care safety experts have turned to high-reliability concepts in order to achieve a higher degree of safety or reliability [17]

In 2005, the Agency for Healthcare Research and Quality (AHRQ) convened a group of leaders from hospital systems committed to the application of high reliability concepts, producing a document that describes the application of those concepts within the field of health care [18].

The high reliability model is intended to focus efforts towards new methodologies designed for performance improvement such as Six Sigma®, Lean, Baldrige, and Total Quality Management (TQM) [18].

Weick and Sutcliffe describe five high reliability characteristics that are helpful towards the transformation of an organization:

- Sensitivity to operations – ability to focus on a specific task while maintaining awareness of the complexity of the system.
- Reluctancy to simplify – recognition that the system can fail in ways that have never been anticipated.
- Preoccupation with failure – focus on predicting and eliminating catastrophes, rather than reacting to them.
- Deference to expertise – team members and organizational leaders defer to the person on the team with the most knowledge relevant to the situation.
- Resilience – errors are quickly contained, a situational assessment is conducted and teams skillfully improvise when difficulties occur [19].

With leadership commitment, an organization can shift from those characteristics that primarily support a compliance culture to one that incorporates attributes of a mindful culture of high-reliability and patient safety concepts (Table 13.2).

The widespread concept of "safety culture" arose in the aftermath of the Chernobyl accident in 1986 and the Clapham junction train accident in London in 1988 [20, 21].

A safety culture is defined by the beliefs, attitudes and assumptions of individual employees, shared across an organization or workgroup, and expressed in the day-to-day practices of a workplace [20, 21]. A number of researchers have sought to define "desirable" characteristics that organizations should strive for in order to reach and maintain an optimal culture of safety [22, 23].

Pidgeon and O'Leary [22] identified three key facets that an organization committed to safety should posess; attitudes of shared care and concern for hazards; realistic and flexible norms and rules about hazards and finally, continuous

Table 13.2 Becoming a high reliability organization: a shift from compliance to culture

Compliance	Key drivers	High-reliability concepts/culture
Focus on rules and standards	Issue Awareness	Focus on patient safety and quality
Tactical	Safety Organizations	Safety as a strategic imperative
Reactive	Fiscal Impact of Safety	Proactive/preoccupation with failure
Manual tracking/audits	Competitive Pressures	Robust data
Fragmented	Transparency	Integrated
Operations that function in silos	Media Attention	Strong leadership/coordinated effort
Departmental responsibility/ effort	Reimbursement	Engaged workforce
Hierarchical relationships	Public Reporting	Team training/deference to expertise
Simplistic solutions/fix with brute force	Consumers	Carefully designed processes
No sustainability	Politics	Sustainability
Provider autonomy	Strategic Planning	Tools, guidelines and checklists
Simplistic solutions/brute force	Analytical Tools/Reliable Data	Preoccupation with failure
Sluggish response to problems	Health Information Technology (HIT)	Situational awareness
Rigidity	Strategic Planning Emergence of Quality Improvement Initiatives Research Funding	Resilience

Adapted from: Agency for Healthcare Research and Quality [18]

reflection upon practice (or organizational learning) through monitoring, incident analysis and feedback systems.

James Reason is renowned for his model of a safety culture subdivided into four subcomponents: a reporting culture, a just culture, a flexible culture and a learning culture (Fig. 13.2). These subcomponents interact to create an informed culture. A reporting culture relies on the presence of an organizational climate in which people are prepared to report errors and near-misses. A just culture is an atmosphere of trust in which people are encouraged, even rewarded, for providing safety related information but clear about the line between acceptable and unacceptable behavior. A flexible culture relies on the ability of an organization to shift from conventional hierarchical mode to a flatter professional structure, where control passes to task experts on the spot in times of crisis. Finally, a learning culture is identified when an organization possesses the willingness and competence to draw the right conclusion regarding safety and the will to implement major reforms when the need is indicated.

According to Reason, an informed culture is a safe culture. The components identify the beliefs and practices present in an organization that is informed about risks and hazards and takes action to become safer. Organization with a successful culture of safety rely upon the willingness of front line workers to report their errors

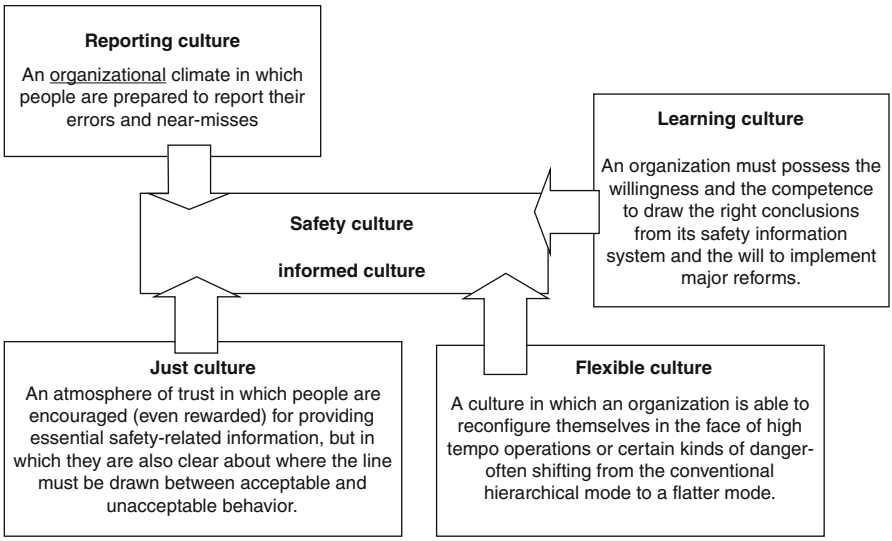


Fig. 13.2 The components of safety culture [23]

and near misses. This willingness depends on the employee's understanding that management will support and reward self-reporting [23].

Just as the Chernobyl accident served as the catalyst for critically researching and defining the concept of a safety culture, the Institute of Medicine (IOM) Report, "To Err is Human" published in 1999 served as the catalyst in focusing national attention on the need for patient safety improvement and higher quality healthcare. The landmark report drew the attention of the healthcare community with its assertion that 44,000–98,000 patients die each year from medical errors. A number of recommendations were contained in the report but the ultimate target was to create safety systems inside healthcare organizations through the implementation of safe practices at the delivery level.

It has been suggested that health care is significantly different than the industries from which it imported the safety culture concept [24, 25]. In fact, in healthcare, the customer experiences unsafe practices rather than the employee. Further noted is the fact that accidents in healthcare usually affect individuals rather than occurring as sweeping disasters.

Although numerous authors suggest there is lack of a universal, clear definition of a safety culture, common characteristics of a strong or effective safety culture can be identified [24, 26–28].

Wiegman et al. reviewed a number of high risk fields including nuclear power, aviation, oil and gas industries, manufacturing and construction and mining. Safety culture was frequently associated with reference to shared values at the group level or higher, formal safety issues related to supervision and management, contributions from every level of the organization, an impact on work behaviors, a relationship between safety behaviors and rewards, the willingness to acknowledge and

learn from safety problems and being relatively enduring, stable and resistant to change [27]. Singer et al. outlined similar components of a culture of safety and suggest the characteristics of a safety culture to be:

- Commitment to safety is articulated at the highest levels of the organization and translated into shared values, beliefs and behavioral norms at all levels.
- Necessary resources, incentives and rewards to allow commitment,
- safety is valued as a primary priority at the expense of other priorities,
- personnel are rewarded for erring on the side of safety,
- communication between workers and across the organization is frequent and candid,
- openness about errors is evident,
- organizational learning is valued, systems approach to analyzing errors instead of focusing on individual blame and acceptance of responsibility for the system.

Additionally, the means by which errors are identified, reported, and communicated to those involved or affected have much to do with how well safety is ingrained in the healthcare organization's culture [28].

The need to continue on the journey to a safe patient culture is without question. Recent evidence in the USA shows that roughly one in three patients experience an adverse event and in 6 % of cases, the adverse event is severe enough to prolong the patient's hospitalization and send them home with a permanent or temporary disability [29].

If the components of a safety culture are identifiable and one can recognize what a safe culture is not, then what are the key ingredients to strengthening the culture of safety in hospitals?

Some key properties become quite evident in reviewing the literature. Sammer et al. reviewed a broad range of properties and organized them into seven subcultures identified as leadership, teamwork, communication, learning, evidence-based, patient centered and a just culture (Fig. 13.3) [30].

Leadership

A common theme throughout the literature suggests the role of leadership is a key element to designing, fostering and nurturing a culture of safety. The impact of effective leadership, both at the helm of the organization and at the unit level is critical. A culture of safety must begin with the chief executive officer (CEO) but it must also permeate throughout every level of the healthcare system. Great leaders know how to wield attitudinal and behavioral norms to best protect against the inevitable dangers created when humans, who are inherently fallible, work in extraordinarily complex environments. Leaders have a profound opportunity to enhance a safety culture by creating an environment of psychological safety (trust) allowing for care givers to readily voice concerns [31].

The leadership chapter in TJC standards manual [32] addresses leadership and safety, specifically relating to the organization's governing body, the chief executive

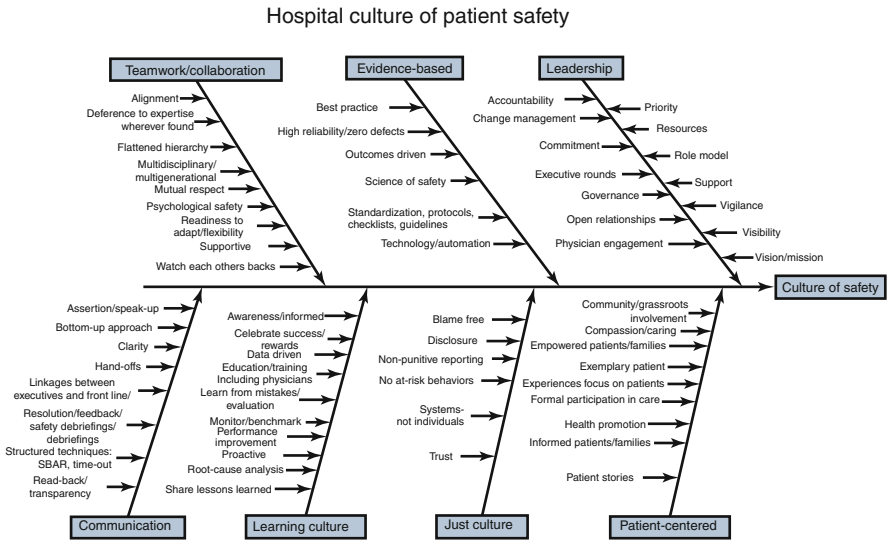


Fig. 13.3 Hospital culture of patient safety (From Sammer et al. [30])

officer and senior managers and medical and clinical staff leaders. The standards require these leadership groups to create a culture of safety by creating an atmosphere of trust and fairness that encourages reporting of risks and adverse events. This includes allocating the resources necessary to support safety, discussing and reporting safety issues and indicators and developing plans to assure and improve safety performance especially in relation to high risk or problem prone processes.

The Institute of Health has described the Patient Safety Leadership WalkRounds™ developed by Allan Frankel. WalkRounds are conducted in patient care departments and provide an informal method for leaders to talk with front line staff about safety issues in the organization and show their support for staff-reported errors. There is an opportunity for leaders to focus on safety and connect with people working on the front line as a way both to educate senior leadership about safety issues and to signal to front-line workers the senior leaders' commitment to creating a culture of safety. Those leaders who focus solely on safety during these rounds are more successful at creating a culture of safety than those who use them as an opportunity to discuss a variety of other topics [33].

Patient Safety Rounds (PSR) are modeled on WalkRounds but with some significant differences. PSRs include the Chief of Staff, area or unit manager, patient safety manager and unit care providers. The team includes representatives from pharmacy, nursing administration, facilities and a patient advocate/family representative. A prepared list of questions is used to maintain the focus on patient safety issues. The success of PSRs has been credited to the active leadership of the medical staff and the engagement of physicians and senior management in process improvement activities resulting from information obtained during Patient Safety Rounds [34].

Another model of direct leadership engagement in patient safety is the adopt-a-unit concept. At the Johns Hopkins Hospital, the patient safety committee created a safety program that focused on encouraging staff in selected units to identify and eliminate potential errors in the patient care environment. As part of the program, senior hospital leadership adopted a unit and worked with the staff to identify issues and empower staff to address safety issues. Keys to program success are identified as the active role of an executive advocate and the staff's willingness to openly discuss safety issues [35].

Teamwork

When the tools of medicine were the doctors intellect, the nurse's empathy, and a few simple procedures and potions, there was little price to be paid for absent safety systems and lack of coordination. As medicine's tools became more powerful and technology sophisticated, highly specialized teams were needed to deliver care [11].

Healthcare organizations are treating patients with increasing complex disease processes with increasingly complex treatments and technologies. As a result, stronger efforts toward teamwork and collaboration among caregivers to achieve a system wide culture of patient safety. An important lesson from other industries is the move from training, regulation, and assessment of individuals to that of teams of health care providers. Given the interdisciplinary nature of health care and the need for cooperation among those who deliver it, teamwork is critical to ensuring patient safety and recovery from and mitigation of error. Teams make fewer mistakes than do individuals, especially when each team member knows his or her own responsibilities as well as those of other team members. Teams elevate the importance of non-physician input and reduce physician autonomy. However, simply installing a team structure does not automatically ensure it will operate effectively. Teamwork is not an automatic consequence of co-locating people and depends on a willingness to cooperate for the sake of a shared goal [16].

The National Aeronautics and Space Administration (NASA) describes a model for organization safety as including deference to expertise wherever found. This property of teamwork includes a multidisciplinary approach crossing all ranks, layers and individuals throughout the organization [36]. This concept has tremendous applicability to the hospital environment. A study conducted by Johns Hopkins Hospital found that patients in ICU improve faster if doctors, nurses and the entire healthcare team together set specific daily goals for each patient including daily rounds as a team [37].

A Kaiser Permanente hospital in Orange County, California has improved patient safety in it operating rooms by implementing team safety briefings before procedures. These briefings have resulted in marked improvement in staff perceptions of safety and teamwork and all associated with decreases in case turnover time and improvements in nursing staff retention [36].

A study described by Jones et al. [38] concluded that patient safety survey scores of an intervention group receiving team training were significantly higher than the

comparison group in three dimensions assessing the flexible and learning components of safety culture. The study concluded that team training can result in transformational change in safety culture when the work environment supports the transfer of learning to new behavior. Effective teamwork facilitates collective learning which is integral to safety culture.

Team STEPPS is a systematic approach developed by the Department of Defense and the Agency for Healthcare Research and Quality (AHRQ) to integrate teamwork into practice. It is designed to improve the quality, safety and the efficiency of healthcare and is based on 25 years of research related to teamwork, team training and culture change [39].

Team training, specifically the Team STEPPS training program has been touted as one methodology for optimizing teamwork among providers and increasing patient safety. Although team training programs have transformed the culture and outcomes of other dynamic, high-risk industries such as aviation and nuclear power, evidence of team training effectiveness in healthcare is still evolving. Providers tend to react positively to many training programs but evidence that training contributes to important behavioral and patient safety outcomes is lacking. A multilevel evaluation of the Team STEPPS training program by Weaver, et al. [40] found the trained group demonstrated significant increases in the quantity and quality of presurgical procedure briefings and the use of quality teamwork behaviors during cases. Increases were also found in perceptions of patient safety culture and teamwork attitudes.

Communication

Communication is an integral component of a safety culture. In a study to identify facilitators and barriers to the implementation of 10 National Quality Forum (NQF) medication processes and the culture of safety practices in Georgia hospitals, having an environment within the hospital that promotes open and clear communication across hospital staff was reported as an important facilitator for the adoption of a culture of safety. It is suggested that an open and transparent channel of communication allows staff to feel comfortable about reporting errors, it provides education and training to staff about patient safety initiatives and it promotes teamwork within and among hospital units.

The barriers to adoption of a culture of safety were identified as resistance to change associated with fear and mistrust. Mistrust stems from experience with a punitive response to patient error reporting. Fear was identified as fear of professional embarrassment, fear of being wrong, fear of retaliation and fear of being alienated. Fear of litigation was also identified. Poor communication was related to the nature of hospitals as silos [41].

Communication failures have been uncovered at the root of over 66 % of sentinel event reported to the TJC [42].

Structured language is an effective communication technique critical to a culture of safety.

One example of structured language is "read-backs" which serve to provide clarity and accuracy of verbal orders and critical results. Time outs are another example of structured communication between team members to verify the correct procedure at the correct site being performed on the correct patient [32].

Originally developed by the US Navy as a communication technique that could be used on nuclear submarines, SBAR was introduced into healthcare settings in the late 1990s. SBAR is a very effective tool that provides a common and predictable structure to communication (Box 13.2).

Box 13.2. SBAR Mnemonic for Improved Efficient Communication
Situation – what is going on with the patient?
Background – what is the clinical background or context?
Assessment – what do I think the problem is?
Recommendation – what do I recommend to correct it?

SBAR has been adopted by hospitals and healthcare facilities as a simple but effective way to standardize communication between care givers and can be used in virtually any clinical domain. SBAR is a tool which promotes patient safety because it helps individuals communicate with each other with a shared set of expectations. Staff and physicians can use SBAR to communicate patient information in a concise and structured format which improves efficiency [43].

Safety Briefings are another method that have been described as a simple, easy-to-use tool that front line staff can use to communicate information about potential safety problems on a daily basis. The concept of Safety Briefings originated with the Institute for Healthcare Improvements Idealized Design of the Medication System (IDMS) team [44]. It is used to increase safety awareness among staff and to develop a Culture of Safety. The IDMS team found the following elements critical to the success of Safety Briefings:

- Safety Briefings must be non-punitive
- Safety Briefings must be brief
- Identify a list of safety issues for discussion in advance
- Safety issues must be easy to use
- Safety Briefings must be applicable to all patient safety issues

A Comprehensive Unit-Based Safety Program (CUSP) is a structured strategic framework for safety improvement that integrates communication, teamwork and leadership to create and support a culture of safety that can prevent harm. The program features evidence-based safety practices, staff training tools, engagement of leadership and tools to improve teamwork among doctors, nurses and other members of the healthcare team. Key steps to a CUSP include:

- Education on the science of safety
- Assessment of patient safety culture
- Partnership with senior executives

- Learning from unit defects
- Tool utilization, including checklists to improve teamwork, communication and other systems.

CUSP was first applied on a large scale in the Keystone Project, which deployed this approach in more than 100 ICUs in Michigan beginning in 2003. The project targeted five evidence-based procedures recommended by the CDC to reduce rates of CLABSI. The findings of dramatically decreased infection rates were published in the *New England Journal of Medicine* in December, 2006. Since that time, AHRQ announced an expansion of CUSP to all states to continue the national implementation of this approach for reducing HAIs. Multiple Keystone Project reports have been published crediting the utilization of the CUSP program with significant improvements [45].

Culture of Learning

A culture of learning exists within a hospital when the organization culture seeks to learn from mistakes and integrates performance improvement processes. A learning culture creates safety awareness among employees and medical staff and promotes an environment of learning through educational opportunities. Education and training should include high reliability concepts, the value of a safe culture assessment and the performance improvement process. A hospital that is data driven has opportunity to learn not only from failures but from successes. Hospitals should be transparent in reporting identified key safety indicators and share results in a timely manner. Learning cultures use root cause analyses to investigate medical errors and near misses. As a hospital safety culture matures, learning cultures will become more proactive in identifying and improving potentially unsafe processes to prevent errors. A learning culture celebrates and rewards successes [17, 41, 46–48].

Evidence-Based Decision-Making

Organizations that demonstrate evidence based practices, including standardized processes, protocols, check lists and guidelines are considered to exhibit a culture of safety [17, 49].

Healthcare leaders refer to the aviation industry as a model for safety. Pilots use a standardized checklist before every flight to assure the aircraft, systems and flight crew are ready and working as designed [36]. Although, hospitals are not airplanes and healthcare is not the aviation industry, it stands to reason that a sound process to review critical components of safety must be in place before proceeding with any high risk endeavor. Patients create variability —whether by choice, access to care, or response to treatment. Regardless of the obvious variability, implementing comprehensive checklists have shown to reduce complications and enhance teamwork and should be encouraged. In the health care environment where the welfare of human beings is at risk, the use of simple, safety checklists can help to reduce errors, ensure performance and safety standards, facilitate more effective use of resources and improve outcomes [50, 51].

The medical model of physician autonomy and the "art" of medicine are still prevalent. Incorporating best practices and standardization can often be a great challenge. Not all physicians embrace checklists as an effective tool. Resistance to checklists is worsened by the general perception that high quality, educated professionals are not susceptible to simple mistakes like forgetting or miscommunication [52]. Checklists are not meant to replace expert knowledge and skill, rather when developed appropriately and implemented correctly checklists save time, facilitate better coordination of teams, minimize rework, and ensure availability of necessary equipment. As new generations of physicians are trained, the use of standardized guidelines is becoming more accepted and utilized.

The World Health Organization launched the Safe Surgery Saves Lives campaign in January 2007 to improve consistency of surgical care and adherence to safety practices. A standardized checklist was developed and recommended for use by operative teams before each surgical procedure. It is designed to help operating room staff improve teamwork and ensure the consistent use of safety practices. The results of a year long pilot study of the surgical safety checklist in eight developed and developing countries were published in January, 2009 in the New England Journal of Medicine. The study revealed a significant reduction in mortality and morbidity and a positive impact on performance after implementation of the checklist. The mechanisms for improvement are unclear and likely multifactorial, but have influenced both system changes and development of surgical teams [52–54].

An OR requires an expert team that has technical skills, cognitive skills and interpersonal skills. Unfortunately, many operating rooms still have teams made up of experts who do not work in concert with one another. Lingard et al. in an observational study of communication failures in operating theatres found that 31 % of all communications could be categorized as a failure in some way—whether the information was missing or timing was poor, or where issues were not resolved or key people absent. Ultimately one third of OR communication fails in its purpose [55].

Some have been unconvinced about the effectiveness of surgical checklists and question the supporting evidence. In response, the Agency for Healthcare Research and Quality (AHRQ) commissioned a team led by investigators at Rand Health, UCSF and Johns Hopkins to examine the evidence to support key patient safety practices (PSP). The report released in 2013 evaluated PSPs based on five criteria: scope, strength of evidence, harm, costs, and implementation. AHRQ concluded that preoperative checklists (WHO checklist, SURPASS checklist, the Universal Protocol, and anesthesia checklists) encourage a non-hierarchical team-based approach; enhanced communication; a process to catch near misses; and anticipation of potential complications. These factors contribute to the prevention of errors and complications related to surgery. As a result of these findings, AHRQ strongly encourages a team-based approach to surgical checklist implementation.

There is mounting evidence to suggest that surgical checklists should be implemented; however, development and design is not a straightforward process and not all checklists demonstrate benefit or improve reliability of performance. The process requires analysis of the context in which the checklist will be used, thoughtful evaluation of the problem or procedure that requires standardization, leadership, and motivation of team members who will be required to utilize the checklist [56].

The "Just Culture"

A just culture is a key characteristic of a safety culture. A just culture promotes safety by supporting the fact that humans are vulnerable to errors; errors that will always occur. There is recognition that some errors should not carry with them a personally harsh, punitive resolution when, in fact the system itself might be flawed. However, there is clear understanding about the differentiation between what is common every day human error versus flagrant or willful violations that could and should be dealt with in stricter manner. There is an on-going need for organizations to instill a sense of individual accountability while understanding the impact that system flaws can have on a well meaning, attentive, informed practitioner in a complex, coupled environment. There are situations when individuals demonstrate reckless behavior which makes the case for making sure everyone understands performance expectations [57].

Patient- and Family-Centered Care

A patient centered culture embraces the patient and family as the sole reason for the hospital's existence [47]. A key aspect of a patient safety culture is the involvement of patients and their families in the process. Sorrel King, the mother of Josie King, who died tragically in 2001 because of medical errors during hospitalization has become one of the nation's foremost patient advocates for promoting the field of patient safety around the world. Sorrel speaks openly that her daughter would be alive today if only there had been more attention to those things as simple as listening, looking and communicating—not only with each other but with her –the patient's mother [58].

There are countless ways that patients and families can be involved in enhancing quality and safety.

- Change the concept of families as visitors and view families as allies for quality and safety
- Create patient and family organizational advisory council with a consistent agenda item of patient safety and appoint patients and family members to serve on patient safety committees
- Include patients and families advisors on teams developing systems and approaches to enhance safety and consistency of care in discharge planning and other transitions and handoffs
- Include patients and families in the development of educational materials and staff orientation processes. Patient stories about care experiences can have a profound impact.
- Include patients in the professional orientation process by inviting them to share stories about the experience of care
- Apply patient and family centered concepts to Rapid Response Teams [59]

Twenty-one participants in the diverse population of individuals attending the Chicago Patient Safety Workshop sponsored by Consumers Advancing Patient Safety were interviewed about their experience as hospitalized patients. An analysis of the participant transcripts revealed three findings: the impact and meaning of communication and relationship within the health care setting, trust and expectation for the patient and family with the health care provider and the meaning and application of patient centeredness. The study concluded that successful planning toward enhanced patient-centered care requires multiple perspectives, including the voices of the patient and family members who have experienced the trauma of preventable medical error.

One participant quoted provided a poignant reminder that the result of preventable medical harm has long-lasting consequences and multiple losses (Box 13.3) [60].

Box 13.3

Loss is a cavernous, empty place, filled with pain and longing for something that can't be restored. It defines you in particular ways that nothing else does. You begin to know the journey, dreaded and unannounced, sometimes too well, the sickening sense of being abandoned, the dread when you remember after you have briefly forgotten, the sense of something missing that never really leaves, and the sadness and the waste of someone's life unlived [60].

Patient Safety Culture – Today

Process changes like a new computer system or the use of a checklist may help a bit according to Dr. Wachter but if they are not embedded in a system in which safety efforts, education about how to identify safety hazards and fix them and have a culture of strong communication and teamwork, progress may be painfully slow [14].

Although there is much work to be done in the field of patient safety culture development, there is also progress to be applauded. After a 4 year period of conducting an evidence-based assessment of patient safety strategies, an international expert panel concluded that 22 patient safety strategies are ready to be encouraged for adoption by healthcare providers. Included are preoperative checklists and anesthesia checklists to prevent operative and postoperative events, checklists to prevent central line-associated bloodstream infections, interventions to improve prophylaxis for venous thromboembolisms and number of others [61].

Take-Home Message

A take-home lesson from rock climbing:

One simple, but insightful suggestion for improving patient safety originates from experience with rock climbing. Before climbing, the knots are checked, the necessary equipment is accounted for, and the buddy is assessed to be sure they are physically well. These checks need to become so routine that it is impossible not to do them — it must 'feel' wrong not to do the checks. No climb begins without them [62].

Likewise, a culture of safety in healthcare (a safe climb) will exist:

- When it feels wrong not to verify the right patient, right treatment, right procedure, right site (checking the knots)
- When it feels wrong not to ensure all equipment and processes are operational and safe (checking the environment)
- When it feels wrong that a colleague may not be fully engaged in safe care (checking the buddy for complete focus and engagement)
- When all these "feelings" cause one to pause and resolve the problem before starting the 'climb' (providing safe patient care)

References

1. American College of Surgeons. What is the American College of Surgeons?. Chicago: American College of Surgeons; c1996-2012.
2. Jost TS. The Joint Commission on Accreditation of Hospitals: private regulation of health care and the public interest. Boston Coll Law Rev. 1983;24(4):835–923.
3. O'leary DS. Accreditation's role in reducing medical errors. West J Med. 2000;172(6):357–8.
4. The Joint Commission. Chicago: The Joint Commission; 2013. The Joint Commission history; 2013;[15 p.].
5. Gluck MG, Reno V, editors. NASI.org. Washington, DC: National Academy of Social Insurance; Reflections on implementing Medicare 2001;[72 p.].
6. Patient Protection and Affordable Care Act, P.L. No.111-148, §2702, 124 Stat. 119, (2010). Available from: http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/content-detail.html.
7. HHS Organizational Chart. Washington, DC: U.S. Department of Health and Human Services; 2012 Apr 16. Available from: http://www.hhs.gov/about/orgchart/.
8. Field RI. Why is health care regulation so complex? P T. 2008 Oct;33(10): 607–8.
9. Rouse WB. Health care as a complex adaptive system: implications for design and management. The Bridge. 2008 Spring;38(1): 17–25.
10. Devers KJ, Pham HH, Liu G. What is driving hospitals' patient-safety efforts? Health Aff (Millwood). 2004 Mar-Apr;23(2):103–15.
11. Wachter RM. The end of the beginning; patient safety five years after 'To Err is Human'. Health Aff. 2004 Jul-Dec; Suppl Web Exclusives:W4-534-45.
12. Hosford SB. Hospital progress in reducing error: the impact of external interventions. Hosp Top. 2008;86(1):9–19. doi:10.3200/HTPS.86.1.9-20.
13. Warburton RN. Patient safety – how much is enough?. Health Policy. 2005 Feb;71(2): 223–32.
14. Wachter RM. Patient safety at ten: unmistakable progress; troubling gaps. Health Aff. 2009 Dec 1;29(1): 165–73.

15. Warburton RN. Accreditation and regulation: can they help improve patient safety?. AHRQ WebM&M [serial online]. 2009 Apr;[5 p.]. Available from: http://webmm.ahrq.gov/perspective.aspx?perspectiveID=74.
16. Amalberti R, Auroy Y, Berwick D, Barach P. Five system barriers to achieving ultrasafe health care. Ann Intern Med. 2005;142(9): 756–64.
17. Pronovost P, Holzmueller CG, Needham DM, Sexton JB, Miller M, Berenholtz S, Wu AW, Perl TM, Davis R, Baker D, Winner L, Morlock L. How will we know patients are safer? An organization-wide approach to measuring and improving safety. Crit Care Med. 2006 Jul;14(2): 117–34.
18. AHRQ.gov. Rockville: Agency for Healthcare Research and Quality. Becoming a high reliability organization: operational advice for hospital leaders. 2008 Apr;[3 p.].
19. Weick KE, Sutcliff KM. Managing the unexpected: assuring high performance in an age of complexity. 1st ed. San Francisco: Jossey Bass; 2001.
20. Pidgeon NF. Safety culture and risk management in organizations. J Cross Cult Psychol. 1991 Mar;22(1): 129–40.
21. Clarke S. Safety Culture on the UK railway network. Work Stress. 1998;12(3): 285–92.
22. Pidgeon NF, O'Leary M. Man-made disasters: why technology and organizations (sometimes) fail. Saf Sci. 2000 Feb;34(1–3): 15–30.
23. Reason JT. Managing the risks of organizational accidents. Farnham/Surrey: Ashgate Publishing Limited; 1997.
24. Pizzi LT, Goldfarb N, Nash DB. Chapter 40. promoting a culture of safety. In: Shojania KG, Duncan BW, McDonald KM, Wachter RM, editors. Making health care safer: a critical analysis of patient safety practices. Evidence Report/Technology Assessment No. 43, AHRQ Publication No. 01-E058; July 2001. Full report available at http://www.ahrq.gov/clinic/evrptfiles.htm.
25. Colla JB, Bracken AC, Kinney LM, Weeks WB. Measuring patient safety climate: a review of surveys. Qual Saf Health Care. 2005 Oct;14(5): 364–6.
26. Provonost P, Sexton B. Assessing safety culture: guidelines and recommendations. Qual Saf Health Care. 2005 Aug;14(4): 231–3.
27. Wiegmann DA, Zhang H, von Thaden TL, Sharma G, Gibbons AM. Safety culture: an integrative review. Int J Aviat Psychol. 2004;14(2): 117–34.
28. Singer SJ, Gaba DM, Geppert JJ, Sinaiko AD, Howard SK, Park KC. The culture of safety: results of an organization-wide survey in 15 California hospitals. Qual Saf Health Care. 2003 Apr;12(2): 112–8.
29. Classen DC, Resar R, Griffin F, Federico F, Frankel T, Kimmel N, Whittington JC, Frankel A, Seger A, James BC. 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. Health Aff. 2011 Apr;30(4): 581–9.
30. Sammer CE, Lykens K, Singh KP, Mains DA, Lackan NA. What is patient safety culture? a review of the literature. J Nurs Scholarsh. 2010 Jun;42(2): 156–65.
31. Leonard M, Frankel A. Health.org.uk. London, England: The Health Foundation; 2013. How can leaders influence a safety culture?; 2012 May;[11 p.].
32. The Joint Commission. Comprehensive accreditation manual for hospitals: the official handbook. Oak Brook: Joint Commission Resources; 2013.
33. IHI.org. Cambridge: Institute for Healthcare Improvement; c2013. Patient safety walkrounds™; 2004;[5 p.].
34. Campbell DA Jr, Thompson M. Patient safety rounds: description of an inexpensive but important strategy to improve the safety culture. Am J Med Qual. 2007 Jan-Feb;22(1): 26–33.
35. Pronovost PJ, Weast B, Bishop K, Paine L, Griffith R, Rosenstein BJ, Kidwell RP, Haller KB, Davis R. Senior executive adopt-a-work unit: a model for safety improvement. Jt Comm J Qual Saf. 2004 Feb;30(2): 59–68.
36. Frankel A, Haraden C. Shuttling toward a safety culture. Healthcare can learn from probe panel's findings on the Columbia disaster. Mod Healthc. 2004 Jan 5;34(1): 21.
37. Pronovost P, Berenholtz S, Dorman T, Lipsett PA, Simmonds T, Haraden C. Improving communication in the ICU using daily goals. J Crit Care. 2003 Jun;18(2): 71–5.

38. Jones KJ, Skinner AM, High R, Reiter-Palmon R. A theory-driven, longitudinal evaluation of the impact of team training on safety culture in 24 hospitals. BMJ Qual Saf. 2013 May;22(5): 394–404.
39. AHRQ.gov. Rockville: Agency for Healthcare Research and Quality. About Team STEPPS. 2013 Jan;[about 2 p.].
40. Weaver SJ, Rosen MA, DiazGranados D, Lazzara EH, Lyons R, Salas E, Knych SA, McKeever M, Adler L, Barker M, King HB. Does teamwork improve performance in the operating room? A multilevel evaluation. Jt Comm J Qual Patient Saf. 2010 Mar;36(3): 133–42.
41. Blake SC, Kohler S, Rask K, Davis A, Nayloer DV. Facilitators and barriers to 10 National Quality Forum safe practices. Am J Med Qual. 2006 Sep-Oct;21(5): 323–34.
42. JointCommission.org. Chicago (IL): The Joint Commission; 2013. Sentinel Event Data Root Causes by Event Type 2004–2012;[29 p.].
43. Leonard M, Graham S, Bonacum D. The human factor: the critical importance of effective teamwork and communication in providing safe care. Qual Saf Health Care. 2004 Oct;13(Suppl 1): 85–90.
44. IHI.org. Cambridge: Institute for Healthcare Improvement; c2013. Safety briefings tool; 2004;[10 p.].
45. AHRQ.gov. Rockville: Agency for Healthcare Research and Quality. Using a comprehensive unit-based safety program to prevent healthcare-associated infections, 2013 Jan;[about 2 p.].
46. Davies KA, Farrell VE. Shaping and cultivating a perioperative culture of safety. AORN J. 2006 Nov;84(5): 857–61.
47. McCarthy D, Blumenthal D. Stories from the sharp end: case studies in safety improvement. The Milbank Q. 2006;84(1): 165–200.
48. Nadzam DM, Atkins PM, Waggoner DM, Shonk R. Cleveland Clinic Health System: A comprehensive framework for a health system patient safety initiative. Qual Manag Health Care. 2005 Apr-Jun;14(2):80–90.
49. Clarke JR, Lerner JC, Marella W. The role for leaders of health care organizations in patient safety. Am J Med Qual. 2007 Sep-Oct;22(5):311–8.
50. Hales BM, Pronovost PJ. The checklist–a tool for error management and performance improvement. J Crit Care. 2006 Sep;21(3): 231–5.
51. Drews FA, Wallace J, Benuzillo J, Markewitz B, Samore M. Protocol adherence in the intensive care unit. Hum Fact Man. 2012 Jan/Feb;22(1): 21–31.
52. Gawande AA. The checklist manifesto: how to get things right. New York: Metropolitan Books; 2009.
53. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA; Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med. 2009 Jan 29;360(5): 491–9.
54. Singh N. On a wing and a prayer: surgeons learning from the aviation industry. J R Soc Med. 2009 Sep;102(9): 360–4.
55. Lingard L, Regehr G, Orser B, Reznick R, Baker GR, Doran D, Espin S, Bohnen J, Whyte S. Evaluation of a preoperative checklist and team briefing among surgeons, nurses, and anesthesiologists to reduce failures in communication. Arch Surg. 2008 Jan;143(1):12–7.
56. Verdaasdonk EG, Stassen LP, Widhiasmara PP, Dankelman J. Requirements for the design and implementation of checklists for surgical processes. Surg Endosc. 2009 Apr;23(4): 715–26.
57. Marx D. Patient safety and the "just culture": a primer for health care executives. New York: Columbia University; 2001.
58. King S. Josie's story: a mother's inspiring crusade to make medical care safe. New York: Grove Press; 2009.
59. Ipfcc.org. Bethesda: Institute for Patient – and Family – Centered Care. Partnering with patients and families to enhance safety and quality: a mini tool kit. 2011 Feb;[26 p.].
60. Hovey RB, Dvorak ML, Burton T, Worsham S, Padilla J, Hatlie MJ, Morck AC. Patient safety: a consumer's perspective. Qual Health Res. 2011 May;21(5): 662–72.

61. Shekelle PG, Pronovost PJ, Wachter RM, McDonald KM, Schoelles K, Dy SM, Shojania K, Reston JT, Adams AS, Angood PB, Bates DW, Bickman L, Carayon P, Donaldson L, Duan N, Farley DO, Greenhalgh T, Haughom JL, Lake E, Lilford R, Lohr KN, Meyer GS, Miller MR, Neuhauser DV, Ryan G, Saint S, Shortell SM, Stevens DP, Walshe K. The top patient safety strategies that can be encouraged for adoption now. Ann Intern Med. 2013 Mar 5;158(5 Pt 2): 365–8.
62. Robertson N. Improving patient safety: lessons from rock climbing. Clin Teach. 2012 Feb;9(1): 41–4.

The Universal Protocol: Pitfalls and Pearls

14

Philip F. Stahel

Pitfalls and Pearls

- The Universal Protocol was launched by the *Joint Commission* in the United States on July 1, 2004, as a new regulatory compliance standard with the primary intent of reducing the occurrence of wrong-site and wrong-patient surgery.
- Despite the global implementation of surgical safety checklists in the past decade, general compliance appears poor, and serious preventable adverse events continue to occur.
- The degradation of the Universal Protocol to a pure "robotic" ritual leads to a distraction from the surgeon's focus on the initial intent to provide safe surgical care.
- Inadequate and inaccurate surgical site marking modalities represent a major root cause of wrong-site surgery.
- The incidence of wrong-site and wrong-patient surgery has not decreased since implementation of the Universal Protocol, likely due to inherent shortcomings and vulnerabilities in the protocol.
- This book chapter provides practical "tips & tricks" for correct performance of pre-procedural verification process, surgical site marking, and the pre-operative "time out".
- Future success and compliance to the protocol requires an unrestricted physician-driven initiative to achieve full "buy-in" by the entire surgical team, with the goal of implementing a sustainable long-term culture of patient safety.

P.F. Stahel, MD, FACS
Department of Orthopaedics, Denver Health Medical Center,
University of Colorado, School of Medicine, 777 Bannock Street, MC 0188,
Denver, CO 80204, USA
e-mail: philip.stahel@dhha.org

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_14,

Outline of the Problem

Specific shortcomings and inherent vulnerabilities of the Universal Protocol (UP) place patients at risk for perioperative complications and surgical "never-events".

Despite the widespread implementation of surgical safety checklists, including the WHO "Safe Surgery Saves Lives" checklist [1], the "Surgical Patient Safety System" (SURPASS) checklist [2, 3], and the Universal Protocol (UP) [4, 5], general compliance appears poor and we are still awaiting a dramatic impact in the global reduction of preventable adverse events and surgical complication rates [6–10]. The current chapter will discuss "pitfalls and pearls" of the Joint Commission's UP at the current time of its 10th year after formal implementation in the United States.

The Universal Protocol (UP)

The UP was initially designed to ensure correct patient identity, correct intended procedure, and surgery performed at the correct surgical site [11, 12].

In essence, the UP consists of the following three components:

1. A pre-procedure verification process.
2. Surgical site marking.
3. Surgical "time out" immediately prior to initiating a procedure.

While the pre-procedure verification process and surgical site marking are performed in the preoperative holding area, the "time out" is accomplished in the operating room (OR) prior to initiating the surgical procedure [13, 14]. All three steps of the UP are dedicated to ensuring correct patient identity, correct intended procedure, and correct surgical site. The "time out" was later expanded (and diluted!) to include the verification of correct patient positioning, availability of relevant documents, diagnostic images, instruments and implants, and the need for preoperative antibiotics and other essential medications, e.g. the use of beta-blockers [15]. Of note, the UP also applies to any interventional setting outside the operating room, for invasive procedures requiring patients' written informed consent.

Limitations of the Current Practice

The National Quality Forum (NQF) defines wrong-site and wrong-patient procedures as "serious reportable surgical events" which should theoretically 'never' occur (Table 14.1) [16]. However, despite the widespread implementation of the Universal Protocol since July 1, 2004, recurring reports document the continued occurrence of wrong-site and wrong-patient procedures in the United States [10,

Table 14.1 Serious reportable surgical events, as defined by the National Quality Forum (NQF)

Surgical "never-events"
1. Surgery performed on the wrong body part.
2. Surgery performed on the wrong patient.
3. Wrong surgical procedure performed on a patient.
4. Unintended retention of a foreign object in a patient after surgery or other procedure.
5. Intraoperative or immediate postoperative death in an ASA class I patient.

17–21]. Clarke et al. published an analysis of hospital reports on reported wrong site, wrong patient, and wrong procedure surgery in the state of Pennsylvania during a 30-month period from 2004 to 2006 [12]. The authors detected 427 reports of wrong-site occurrences, of which 56 % were "near miss" events. In their series, a formal "time out" was unsuccessful in preventing wrong-site surgery in 31 cases [12]. Jhawar and colleagues performed a National survey to estimate the incidence of wrong-side and wrong-level craniocerebral and spinal surgery among practicing neurosurgeons in the Unites States [22]. Among the 138 responding neurosurgeons, 25 % admitted to having performed incisions on the wrong side of the head at one point during their careers. In addition, 35 % of all neurosurgeons who had been in practice for more than 5 years disclosed a wrong level lumbar spine procedure at some point of their careers [22]. A review of the National Practitioner Data Bank and closed claims studies revealed that wrong-site surgery continues to occur approximately 1,300–2,700 times annually in the United States [23]. The shortcomings of most studies designed to determine the incidence and frequency of wrong-site and wrong-patient procedures consist of a selection bias related to the restricted selection to malpractice claims, which may just represent the "tip of the iceberg". To overcome this limitation, a study from our own group analysed a prospective physician insurance database of 24,975 physician self-reported adverse events [10]. A total of 25 wrong-patient and 107 wrong-site procedures were identified during a 6½ year study period before and after implementation of the UP [10]. The main root causes leading to wrong patient surgery were errors in diagnosis (56 %) and errors in communication (100 %), whereas wrong site occurrences were related to errors in judgment (85 %) and the lack of performing a surgical "time-out" (72 %). Nonsurgical specialties were found to be involved in the etiology of wrong-patient procedures and to contribute equally with surgical disciplines to adverse outcome related to wrong-site adverse events. These data emphasize that surgical "never-events" keep occurring despite implementation of the UP, and that this widespread mandatory protocol does not keep our patients safe [5, 10].

Pitfalls and limitations which render the UP vulnerable to a breach in effectiveness and compliance are hidden in each component of the protocol [24]. Arguably, the degradation of the UP to a pure "robotic" ritual leads to a distraction from the surgeon's focus on the initial intent to provide safe surgical care to our patients. Furthermore, the inappropriate or inaccurate marking of the correct surgical site represents another major root cause of wrong-site surgery. Finally, the continuing

expansion of the "time out" to include secondary safety issues, such as antibiotic and venous thromboembolism prophylaxis (so-called "expanded" time out) [15, 25], further dilutes the mission of the UP in its core essence, and likely contributes to decreased compliance and credibility of the protocol related to the "buy-in" by the surgical team [5].

Another underestimated risk factor for wrong-site surgery is reflected by multiple simultaneous procedures performed in the same patient, which dilute the focus of the "time out" on a single procedure. In addition, specific anatomic locations may represent "black boxes" for adequate site marking, which may increase the risk of wrong-site procedures. Finally, a significant loophole in the system is the lack of a global implementation of the UP. This notion is supported by the demonstration that non-surgical specialties, such as internal and family medicine, are predominantly involved in the etiology of wrong-patient surgery and contribute significantly to patient harm after wrong-site procedures [10]. Based on these insights, we advocate for strict adherence to the UP also for non-procedural medical specialties.

How to Do It – The Pre-procedure Verification Process

Strikingly, about one third of all wrong-site and wrong-patient procedures originate before patient admission to the hospital. Potential root causes include inaccurate clinic note dictations related to the surgical site, mislabelling of radiographs and other diagnostic tests, or a mix-up of patient identities with similar (or identical) names.

The rationale for conducting a pre-procedure verification process is to confirm: (1) patient identity, (2) the scope of the planned procedure, and (3) the surgical site. Each patient is unequivocally identified by an identification bracelet which includes the patient's name, birth date, and a medical record number. The surgical consent form is presented to the patient, with the intended surgical procedure and the name of the responsible surgeon being spelled out. The patient signs the consent form only after all pertinent information has been confirmed. Surgical site marking is performed by the surgeon, as part of the pre-procedure verification process. Finally, the team's understanding of the planned procedure is confirmed to be consistent with the patient's expectations. A checklist is used to review and verify that all documents and pertinent information are available, accurate, and completed, prior to moving the patient to the operating room.

Pitfalls in Surgical Site Marking

Inadequate or inaccurate surgical site marking (i.e. erroneous marking of the wrong side/site, imprecise marking of the correct site, and inadequate modality of site marking) represents an important underlying root cause contributing to the risk of wrong site surgery.

Examples of "classic" pitfalls related to site marking include:

- The relegation of site marking to a junior member of the surgical team (e.g. intern) or to any other provider who will not be personally involved in the surgical procedure.
- Wrong modality of marking the correct site, e.g. using an "X" which may be misunderstood as "not this side".
- Marking of the wrong site based on misleading pre-procedure documentation, e.g. erroneous clinic note dictation, faulty documentation in chart and consent form, and mislabelling of diagnostic studies, e.g. radiographs.
- Imprecise site marking, such as: (1) Marking the correct anatomic location without specifying the operative site (e.g. medial vs lateral incision, etc.); (2) Marking the correct extremity, without specifying the exact location, e.g. joint, fingers, etc.; (3) Marking the correct spinal level on skin, but fusing the wrong level after surgical dissection.
- The use of non-permanent markers may lead to the faulty assumption that the absence of visualized site markings prior to skin incision may be acceptable, secondary to the marks being washed off during the surgical preparation.
- Obsolete marking of the contralateral side (e.g. "no" or "not this side") will create confusion and uncertainty, particularly in presence of illegible or partially washed-off markings (Fig. 14.1).

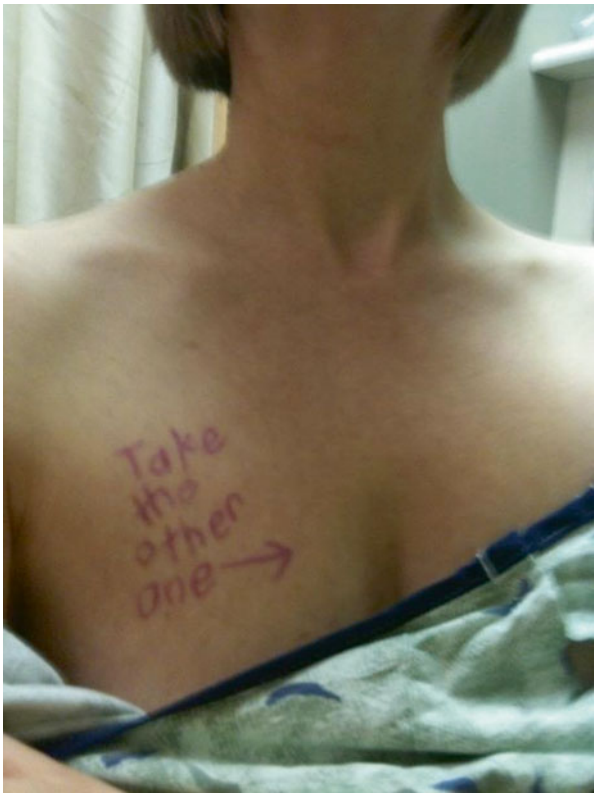


Fig. 14.1 Anecdotal example of an incorrect surgical site marking modality prior to a scheduled mastectomy on the contralateral side

- Residual marks from a previous surgery in the same patient may distract from the correct surgical site during a follow-up intervention, e.g. in multiply injured patients with staged procedures at different time-points.
- Inability (or contraindication) to mark the surgical site.

A number of specific circumstances may impede the adequate surgical site marking for technical or anatomic reasons. For example, site marking is impracticable on mucosal surfaces, on teeth etc. Site marking is furthermore considered contraindicated in premature infants, due to the risk of introducing a permanent skin tattoo. Some surgical sites are inaccessible for accurate external marking, including in visceral surgery (internal organs), neurosurgery (brain, spine), interventional radiology (vascular procedures), and orthopaedic surgery on the torso (pelvis, spine). Rarely, patients may refuse surgical site marking for cosmetic reasons or other personal preferences.

To overcome these limitations and potential pitfalls, a defined alternative process must be in place. Radiological diagnostics may need to be consulted pre- and intraoperatively to determine the correct surgical site with accuracy. For example, spine surgeons must ensure the correct intervertebral level using intraoperative fluoroscopy in conjunction with meticulous scrutiny in assessing preoperative radiographs (CT scans, MRI) in order to avoid a wrong-level spine fusion, particularly in presence of unusual spinal anatomy [21]. General surgeons have to rely on preoperative imaging and/or "on-table" cholangiogram to ensure clipping the correct bile duct during a laparoscopic cholecystectomy. In a similar situation, interventional radiology providers are at risk of erroneous coiling of a wrong artery. Finally, neurosurgical interventions on the wrong part of the brain keep being reported in regular intervals [18, 22, 26].

Unlike symmetric external body parts (e.g. extremities, eyes, ears), any "hidden" surgical site is not easily identified, confirmed and marked prior to surgery. Thus, such particular circumstances mandate the scrutiny of intraoperative surgical site localization under fluoroscopy, in conjunction with a careful evaluation of available preoperative diagnostic tests, such as CT, MR, angiography, or cholangiography.

How to Do It – Surgical Site Marking

- Site marking must be performed by a licensed practitioner who is a member of the surgical team and will be present during the surgical "time out" and the entire procedure. Ideally, this should be done by the lead surgeon in charge.
- Site marking must occur in the preoperative holding area, before moving the patient to the operating room or to any other procedural location.
- Patients should be involved in the site marking process whenever possible.
- Site marking must be unambiguous, using clearly defined terminology such as "YES", "GO", "CORRECT", or "CORRECT SITE". The exact marking modality must be defined and consistent within a specific institution.
- Responsibility of site marking should be confirmed by adding the surgeon's initials (Fig. 14.2). The exception is a surgeon's name with the initials "N.O." which may be confounded with "no" implying that the marked site should *not* be operated on.

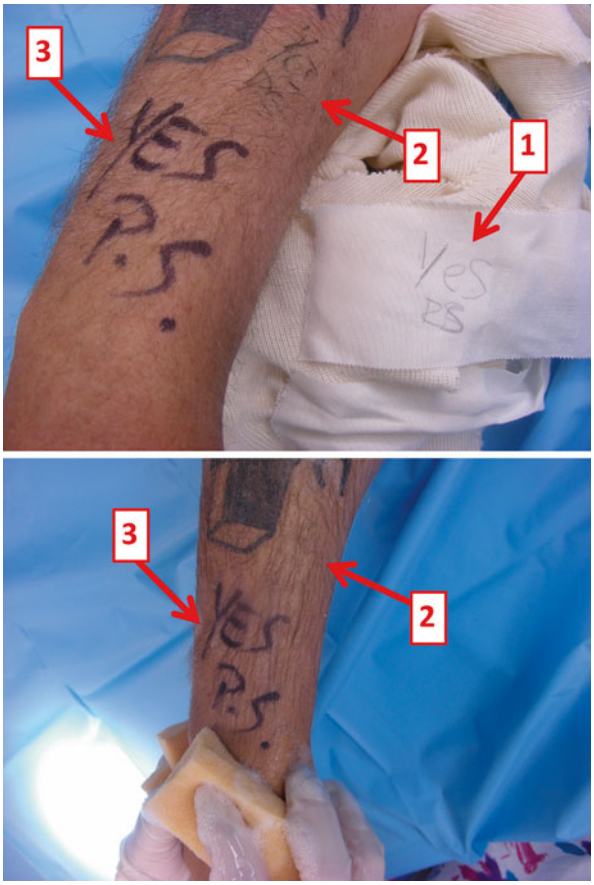


Fig. 14.2 "Do's and don'ts" of technical options for surgical site marking. *Upper panel*: This patient was scheduled for a surgical procedure on his right forearm. The intern marked and initialed the site on the dressing, which came off prior to surgery (*1*). The resident corrected the mistake by marking the surgical site on skin, using a regular pen (*2*). Neither the marking, nor the initials, are well legible (*2*). Finally, the site was again marked and initialed by the attending surgeon with a permanent marker (*3*). *Lower panel*: During the surgical preparation, the site marking with the regular pen was washed off immediately (*2*), whereas the permanent marker remained visible throughout the surgical preparation (*3*). This example emphasizes the crucial importance of using a permanent marker, large and well legible letters, and to sign the marking with the surgeon's initials. "YES" is the designated, standardized identifier for the correct surgical site at Denver Health Medical Center (Adapted with permission from: Stahel et al. [24]. © 2009 Stahel et al., licensee BioMed Central Ltd)

- Site marking must be applied by indelible ink on skin, using permanent markers. The use of temporary or removable markers, e.g. using stickers or marking on casts or dressings, is not feasible (Fig. 14.2).
- Site marking must be resistant to the surgical preparation process and remain visible at the time of skin incision.
- Sterility of the marking ink or marking pen is not required, and the use of non-sterile markers does not increase the risk of postoperative infections [27–30].

- Site marking must be applied near or at the incision site. The side, level, and location of the procedure must be unequivocally defined by the marking, whenever possible. Marking takes into consideration the side (laterality), surface (flexor/extensor, medial/lateral), the spinal level, and the specific digit or lesion to be operated on.
- Increased awareness in all cases where precise site marking is not possible (see "pitfalls" paragraph above).
- Knowledge of contraindications for surgical site marking, including premature infants (risk of permanent tattoo), mucosal surfaces, teeth, and patients refusing a surgical site marking for personal reasons.
- Implementation of defined alternative processes for any circumstance where surgical site marking is not feasible. Include pre- and intraoperative radiological diagnostics to increase the accuracy of determining the correct surgical site.

How to Do It – The Surgical "Time Out"

The last part of the UP, the surgical "time out", is performed in the operating room, before the procedure is initiated. The "time out" represents the final recapitulation and reassurance of accurate patient identity, surgical site, and planned procedure. In addition, the correct patient positioning, the need for perioperative antibiotics, presence of allergies, and the availability of relevant documents and diagnostic tests, instruments, implants and other pertinent equipment are confirmed during this time. The following parameters are key to success for a surgical "time out":

- A "time out" is called by any member of the surgical team, typically by a specifically designated person who is not directly involved in the procedure, e.g. the circulating nurse.
- In a two-tiered "time out", the patient is awake and participating in the verification process (so-called "awake time out"), followed by a repeat "time out" immediately before skin incision, with the intent of avoiding prepping and draping of the wrong surgical site after the verification process.
- The "time out" process must be standardized in every institution.
- All immediate members of the procedural team (surgeon, anaesthesia provider, circulating nurse, operating room technician, etc.) must actively participate in the "time out".
- All routine activities are suspended during the "time out", to an extent which does not compromise patient safety.
- The "time out" must be repeated intraoperatively for every additional procedure performed on the same patient.

Take-Home Message

Despite widespread implementation of the UP in the United States, the standardized protocol has failed to prevent severe complications and "never-events" from occurring [10, 16, 17, 21]. This article addresses potential technical pitfalls and selected

loopholes and vulnerabilities in the system. All healthcare institutions (not just in the United States) across all specialties (not just surgical disciplines) should commit to adherence to the UP as a standardized quality assurance tool. Individual practitioners' preferences in site marking modalities should be avoided by introducing formal standardization across institutions [24, 31].

The ultimate determinant of success is the commitment and "buy-in" by the entire surgical team. Patients should be involved in the site marking process and encouraged to inquire of their surgeons whether a formal "time out" procedure will occur in the surgical suite. Our long-term aim is directed towards educating ourselves, the next generation of health care providers, and our patients, to strive for a sustainable and unfailing patient safety culture. Beyond a doubt, this requires a physician-driven team approach.

References

1. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, et al. A surgical checklist to reduce morbidity and mortality in a global population. N Engl J Med. 2009;360:491–9.
2. de Vries EN, Dijkstra L, Smorenburg SM, Meijer RP, Boermeester MA. The SURgical PAtient Safety System (SURPASS) checklist optimizes timing of antibiotic prophylaxis. Patient Saf Surg. 2010;4:6.
3. Ram K, Boermeester MA. Surgical safety. Br J Surg. 2013;100:1257–9.
4. Norton E. Implementing the universal protocol hospital-wide. AORN J. 2007;85:1187–97.
5. Stahel PF. Lessons learned from wrong-site, wrong-patient surgery. Phys Week. 2011;28(11).
6. Sparks EA, Wehbe-Janek H, Johnson RL, Smythe WR, Papaconstantinou HT. Surgical safety checklist compliance: a job done poorly! J Am Coll Surg. 2013;217:867–73.
7. Hannam JA, Glass L, Kwon J, Windsor J, Stapelberg F, et al. A prospective, observational study of the effects of implementation strategy on compliance with a surgical safety checklist. BMJ Qual Saf. 2013;22:940–7.
8. O'Connor P, Reddin C, O'Sullivan M, O'Duffy F, Keogh I. Surgical checklists: the human factor. Patient Saf Surg. 2013;7:14.
9. Clarke JR, Johnston J, Blanco M, Martindell DP. Wrong-site surgery: can we prevent it? Adv Surg. 2008;42:13–31.
10. Stahel PF, Sabel AL, Victoroff MS, Varnell J, Lembitz A, et al. Wrong site and wrong patient procedures in the era of the Universal Protocol – analysis of a prospective database of physician self-reported occurrences. Arch Surg. 2010;145:78–84.
11. Wrong site surgery and the Universal Protocol. Bull Am Coll Surg. 2006;91:63.
12. Clarke JR, Johnston J, Finley ED. Getting surgery right. Ann Surg. 2007;246:395–403.
13. Dillon KA. Time out: an analysis. AORN J. 2008;88:437–42.
14. Edwards P. Ensuring correct site surgery. J Perioper Pract. 2008;18:168–71.
15. Hunter JG. Extend the universal protocol, not just the surgical time out. J Am Coll Surg. 2007;205:e4–5.
16. Lembitz A, Clarke TJ. Clarifying 'never events' and introducing 'always events'. Patient Saf Surg. 2009;3:26.
17. Catalano K. Have you heard? The saga of wrong site surgery continues. Plast Surg Nurs. 2008; 28:41–4.
18. Shinde S, Carter JA. Wrong site neurosurgery – still a problem. Anaesthesia. 2009;64:1–2.
19. van Hille PT. Patient safety with particular reference to wrong site surgery – a presidential commentary. Br J Neurosurg. 2009;23:109–10.
20. Wong DA, Herndon JH, Canale ST, Brooks RL, Hunt TR, et al. Medical errors in orthopaedics – results of an AAOS member survey. J Bone Joint Surg Am. 2009;91:547–57.

21. Lindley EM, Botolin S, Burger EL, Patel VV. Unusual spine anatomy contributing to wrong level spine surgery: a case report and recommendations for decreasing the risk of preventable 'never events'. Patient Saf Surg. 2011;5:33.
22. Jhawar BS, Mitsis D, Duggal N. Wrong-sided and wrong-level neurosurgery: a national survey. J Neurosurg Spine. 2007;7:467–72.
23. Seiden SC, Barach P. Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events: are they preventable? Arch Surg. 2006;141:931–9.
24. Stahel PF, Mehler PS, Clarke TJ, Varnell J. The 5th anniversary of the "Universal Protocol": pitfalls and pearls revisited. Patient Saf Surg. 2009;3:14.
25. Altpeter T, Luckhardt K, Lewis JN, Harken AH, Polk Jr HC. Expanded surgical time out: a key to real-time data collection and quality improvement. J Am Coll Surg. 2007;204:527–32.
26. Mitchell P, Nicholson CL, Jenkins A. Side errors in neurosurgery. Acta Neurochir (Wien). 2006;148:1289–92.
27. Cronen G, Ringus V, Sigle G, Ryu J. Sterility of surgical site marking. J Bone Joint Surg Am. 2005;87:2193–5.
28. Cullan DB, Wongworawat MD. Sterility of the surgical site marking between the ink and the epidermis. J Am Coll Surg. 2007;205:319–21.
29. Rooney J, Khoo OK, Higgs AR, Small TJ, Bell S. Surgical site marking does not affect sterility. ANZ J Surg. 2008;78:688–9.
30. Zhao X, Chen J, Fang XQ, Fan SW. Surgical site marking will not affect sterility of the surgical field. Med Hypotheses. 2009;73:319–20.
31. Stahel PF. The tenth year of the "Universal Protocol": are our patients safer today? Bone Joint^{360}. 2014;3:7–10.

Patient Safety in Graduate and Continuing Medical Education

15

Alan Lembitz

Pitfalls and Pearls

This chapter provides a practical framework for incorporating lessons learned from 'patient safety events' (PSEs) into the education and training of all health care providers, including:

- How the aviation industry created a culture of safety and its application to health care.
- Sample curriculum developed by various leaders in patient safety education. The core principles of graduate medical education (GME) and discussion of how to apply the principles to advance patient safety. The core principles of continuing medical education (CME), including examples of educational programs that use PSEs and liability claims to meet the principles.
- A unique approach to graduate medical education developed by a professional medical liability insurance carrier.
- Additional medical education opportunities using PSEs and methods for prevention.

A. Lembitz, MD
Department of Patient Safety and Risk Management,
Colorado Physician Insurance Companies (COPIC),
7351 Lowry Blvd, Denver, CO 80230, USA
e-mail: alembitz@copic.com

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_15, © Springer-Verlag London 2014

Outline of the Problem

> *Although progress has been made, the concept of comprehensive learning from adverse events to advance patient safety has only recently been included in the standard education physicians receive in medical school* [1], *through graduate medical education* [2], *or via continuing medical education for maintenance of certification* [3].

The Joint Commission published "Health Care at the Crossroads: Strategies for Improving the Medical Liability System and Preventing Patient Injury," [4] (Table 15.1) more than 5 years after the Institute of Medicine increased the public's awareness of medical errors through its report "To Err is Human". The Commission's publication essentially served as a "seminal call to arms," advocating access to open medical liability claims to aid health care researchers in the identification of problematic trends in clinical care.

ASA—The Patient Safety Pioneers

Some medical specialties have successfully used closed claims analysis to improve outcomes. In 1982, a media exposé reported the risk of death or serious brain injury in normal preoperative patients undergoing general anesthesia was approximately 1 in 3,000. In 1983, the American Society of Anesthesiology (ASA) safety committee was formed to investigate why a healthy patient undergoing a standard general anesthetic faced such an inordinate risk. The ASA safety committee performed an extensive analysis of closed medical liability claims, which led to the development of guidelines for increased monitoring and preoperative safety assessments based on identified errors, oversights and systems problems. The ASA Patient Safety Foundation was formed in 1985 and continues to perform detailed analysis of all anesthesia-related medical liability closed claims. The ASA analysis led to the implementation of education, training, and guidelines now used by the entire specialty. The dramatic success of such programs in unparalleled in health care: Today, the risk for complications in a healthy patient undergoing standard general anesthetic has been reduced to 1 in 300,000—a 100-fold decrease and an incidence nearly approximating six sigma [5].

Learning from Aviation Safety

The aviation industry has successfully incorporated transparency and the assessment of safety event data into its business practices and culture. The industry has transformed itself into a "high-reliability organization," meaning it operates with remarkable consistency and effectiveness. Aviation's model can serve as a framework for safety training and educational principles in health care.

Table 15.1 Health care at the crossroads recommendations

Recommendation	Strategy
Pursue patient safety initiatives that prevent medical injury	Strengthen oversight and accountability mechanisms to better ensure the competencies of physicians and nurses Allow health care researcher access to open liability claims to permit early identification of problematic trends in clinical care Encourage appropriate adherence to clinical guidelines to improve quality and reduce liability risk Support teamwork development through team training, "crew resources management," and high-performing microsystem modeling Continue to leverage patient safety initiatives through regulatory and other quality oversight bodies Encourage the adoption of information and simulations technology by building the evidence base of their impacts on patient safety, and pursue proposals to offset implementation costs Leverage the creation of cultures of patient safety in health care organizations Establish a federal leadership locus for advocacy of patient safety and health care quality Pursue "pay-for-performance" strategies that provide incentives to focus on improvements in patient safety and health care quality
Pursue "pay-for-performance" strategies that provide incentives to focus on improvements in patient safety and health care quality	Involve health care consumers as active members of the health care team Encourage open communication between practitioners and patients when an adverse event occurs Pursue legislation that protects disclosure and apology from being used as evidence against practitioners in litigation Encourage non-punitive reporting of errors to third parties that promotes sharing of information and data-analysis as the basis for developing safety improvement strategies Enact federal patient safety legislation that provides legal protection for information report to designated patient safety organizations
Create an injury compensation system that is patient-centered and serves the common good	Conduct demonstration projects of alternatives to the medical liability system that promote patient safety and transparency, and provide swift compensation to injured patients Encourage continued development of mediation and early-offer initiatives Prohibit confidential settlements—so-called "gag clauses"—that prevent learning from events that lead to litigation Redesign or replace the National Practitioner Data Bank Advocate for court-appointed, independent expert witnesses to mitigate bias in expert witness testimony

From: The Joint Commission. Report: Health care at the crossroads: strategies for improving the medical liability system and preventing patient injury. Available at: http://www.jointcommission.org/assets/1/18/Medical_Liability.pdf

A pilot's training is centered on safety. It includes extensive simulation, crew resource management, principles of effective communication and effective re-engineering of unsafe systems. Most importantly, the training fosters a culture of change for furthering safety. Every day, nearly 36,000 commercial flights take off and land worldwide; yet, a passenger's risk of dying in a crash is 1 in 1,000,000—or six sigma.

Learning from adverse event data has been central to the aviation industry's successful safety initiatives that led to more than six sigma reliability. Physicians and health care leaders would marvel at the public transparency of aviation incident reports: Anyone can access information from transcripts of the cockpit communication, engineering reports, and safety analysis of the crash (Fig. 15.1). An introduction to their transparent approach can be found on the Federal Aviation Administration incident reporting website at http://www.faa.gov/data_research/accident_incident/ [6].

While there are many parallels, there are also many crucial differences between health care and aviation. Both are industries which depend on an inherent trust of their people (whether patients or passengers) that coexists with the possibility for catastrophic harm. Yet, the differences in implementation of safety measures from aviation to healthcare are more glaring and argue against simply applying an "if you can fly a plane, you can do safe surgery" mentality. This is not a value judgment relative to the skills of a pilot vs. a surgeon; physicians are notoriously likely to die from single engine pilot error crashes, and pilots have no corollary since they do not perform surgery on their passengers [7–10].

While a full discussion of what constitutes effective pedagogy is beyond the scope of this chapter, education that modifies behavior is most successful when it incorporates effective methods with inherent motivators. Experiential learning via the study of actual cases has been a traditional method of medical education, and for good reason: When a resident tries to solve a patient-specific diagnostic dilemma by reading related literature or assisting in a surgery, the resident tends to retain the information. The motivation of fear: fear of failure, fear of harm, and fear of adverse effects on one's reputation are also very potent.

Limitations of the Current Practice

While some positive outcomes have been achieved from education provided by traditional morbidity and mortality conferences, much could be improved when using adverse patient safety events in education and as a process improvement for prevention.

Currently, most morbidity and mortality discussions focus on fear-based motivators, including:

- Shame and blame which leads to the hiding of errors [11]
- A focus on the crisis *du jour* without long-term engagement
- A lack of the entire health care team's involvement

Los Angeles International Airport Runway Incursion
August 16, 2007

1952:45	WJA900	And WJA900 with you for two four right.
1952:54	LC-2	WJA900, L A Tower, you're following an airbus four mile final Runway Two Four Right cleared to land.
1953:01	WJA900	Cleared to land following an airbus, WJA900.
1955:55	LC-2	NWA A180, L A Tower, Runway Two Four Left, cleared for takeoff, wind's uh two four left, NWA180.
1956:01	NWA180	Cleared for takeoff, two four left, NWA180.
1956:36	WJA900	Ground, WJA900 with you uh reverse Yankee for Gate 35.
1956:40	GC-2	WJA900, Los Angeles Ground, taxi Echo to the gate.
1956:44	WJA900	Echo, gate, 900.
1956:46	GC-2	AWE104, at uh Yankee pass behind the uh seven three exiting the runway.
1956:51	AWE104	At Yankee, pass behind the uh West Jet exiting the runway.
1956:55	GC-2	Thank you.
1956:57	WJA900	Conform cleared to cross for 900?
1957:01	GC-2	Uh, who was that?
1957:02	WJA900	WJA900, confirm cleared to cross.
1957:04	GC-2	Uh, not if you, no, no sir, hold there, hold there.
1957:08	WJA900	Holding here, WJA900.
1957:23	LC-2	WJA900, uh cross two four left, ground point six five.
1957:29	LC-2	WJA900?
1957:39	GC-2	WJA900, uh continue across the runway and taxi Echo.
1957:44	WJA900	Across the runway, check, taxi Echo, WJA900.
1957:45	LC-2	NWA180, contact So Cal Departure.
1957:48	NWA180	NWA180, good day.

Fig. 15.1 Sample dialogue of the cockpit to ground communication of a runway incursion at Los Angeles International Airport. What if similar transparency existed following adverse medical events? (Source: FAA.GOV–Accident and incident transcripts)

- The inherent bias toward an individual, rather than the unsafe system in which the individual operates
- An inability to share lessons from one institution to another while retaining peer review protections

An improved approach that uses PSEs from various institutions provides a wealth of material to analyze. Serious PSEs are fortunately a rare event for a given institution or system; however, broad data exists nationally via patient safety organizations or medical professional liability insurance carriers that require detailed information and analysis of each adverse PSE. There is enormous untapped potential in the data collected by entities tasked with managing risk in medicine. A proposed framework has been included of different approaches to achieving the ultimate goal of a safer health care system.

Where Is the "Golden Bullet"?

The number of curricula has greatly increased since the IOM report. Small, institution-specific programs multiplied; Large, national and international curriculum followed. The following provides an overview of the progression.

One of the earliest approaches described in the literature following the IOM report was a half-day curriculum proposed, described, and implemented by Halbach et al. [12]. The abstract of this work appears in Table 15.2.

Subsequent to this, Mayer et al. [13], described the design of a patient safety undergraduate medical curriculum. It included the following critical factors:

1. Inter-professional education.
2. Longitudinal curricular approach.
3. Advanced patient safety educational opportunities for senior students.
4. Teaching methodologies.
5. Assessment strategies.

Mayer and his team also synthesized a "Specific Content for a Patient Safety Curriculum" in which roundtable participants agreed on 11 specific elements of curriculum content that they believed were essential for an effective patient safety curriculum at the undergraduate medical education level. The roundtable agreed the following aspects should be included:

1. History of the medical error crisis.
2. Interdisciplinary teamwork skills.
3. Time and stress management.
4. Health care microsystems.
5. Informatics, electronic medical records, and health care technology.
6. Error science, error management, and human factor science.
7. Communication skills.
8. Full-disclosure applications.
9. Risk management and root cause analysis.
10. Outcome measures and continuous quality improvement.
11. Medication errors and reconciliation.

Table 15.2 Halbach et al. curriculum

Methodology	Results	Conclusion
From 2000 to 2003, third-year medical students at New York Medical College, Valhalla, New York, were required to participate in a new curriculum on patient safety and medical errors during their family medicine clerkships. Five hundred seventy-two students participated in a 4-h curriculum that included interactive discussion, readings, a videotape session with a standardized patient, and a small-group debriefing facilitated by a family physician. Before and after participating in the curriculum, students were asked to complete questionnaires on self-awareness about patient communication and safety. Curriculum evaluations and follow-up surveys were also distributed. Responses to each statement on the before and after questionnaires were compared using the Wilcoxon signed-rank test for matched data.	Five hundred eleven (89 %) students reported that the opportunity to present an error to a patient increased their confidence about discussing this issue with patients, and 537 (94 %) students reported that they strongly agreed or agreed that the standardized patient and feedback exercise was a useful learning experience. A total of 535 before and after questionnaires were used in the analysis. A comparison of before and after questionnaire data revealed statistically significant increases in the self-reported awareness of students' strengths and weaknesses in communicating medical errors to patients ($p \leq .01$).	These findings suggest that awareness about patient safety and medical error can be increased and sustained through the use of an experiential curriculum, and the students rated this as a valuable experience.

Halbach and Sullivan [12]

More recently, Kirch, president and CEO of Association of American Medical Colleges (AAMC) and Boysen, executive associate dean of medical education at the University of North Carolina-Chapel Hill, described the five factors they deemed critical to changing the culture of medical education to teach patient safety [14].

1. Explicit leadership at the top
2. Early engagement of health professions students
3. Having residents teach each other about patient safety
4. The use of health information technology
5. Promoting teamwork among health professionals

The World Health Organization (WHO) prepared a comprehensive curriculum titled "Patient Safety Curriculum Guide for Medical Schools" [15]. It includes 11 topics, listed in Table 15.3.

Table 15.3 World Health Organization topics for patient safety curricula from medical school

Topic 1—What is patient safety?
Topic 2—What is human factors and why is it important to patient safety?
Topic 3—Understanding systems and the impact of complexity on patient care
Topic 4—Being an effective team player
Topic 5—Understanding and learning from errors
Topic 6—Understanding and managing clinical risk
Topic 7—Introduction to quality improvement methods
Topic 8—Engaging with patients and carers
Topic 9—Minimizing infection through improved infection control
Topic 10—Patient safety and invasive procedures
Topic 11—Improving medication safety

Another patient safety curriculum has been developed by the U.S. Department of Veteran's Affairs, and was one of the original efforts all the other curricula summarized above [16].

The VA National Center for Patient Safety (NCPS) was founded in 1999. This curriculum includes resources directed at three audiences:

1. Workshop faculty development for trainers and teachers
2. Instructor prep for teachers
3. Class materials for students

The topics of the curriculum are grouped into five general areas and include extensive resources to reach of the different target audiences.

1. Patient Safety Introduction
2. Human Factors Engineering
3. Evidence-Based Patient Safety
4. Root Cause Analysis (RCA)
5. Healthcare Failure Mode Effect Analysis (HFMEA)

There has been much progress in the education of medical students in patient safety. Hopefully, the seed of the principles of patient safety planted in medical school will be nurtured in the subsequent training in residency, which is described next.

Core Principles of Graduate Medical Education

Many residencies are being thrust to the forefront by adherence to the American College of Graduate Medical Education (ACGME) [2] core competencies. Recently the Clinical Learning Environment Review (CLER) [17] assessment has been added to further motivate incorporation of just culture and a safe environment. The study of PSEs and the discussions, processes, and improvements that occur following that analysis bring together all of the core competencies in a unique way.

Table 15.4 Clinical diagnoses most commonly occurring in failure or delay of diagnosis in copic medical liability claims

Heads	Acute neurologic syndromes, cerebrovascular accident (CVA), subarachnoid hemorrhage, anterior and/or posterior circulation dissections, subdural hematoma, epidural hematoma, epidural abscess, encephalitis (especially herpetic), and meningitis.
Hearts	Unstable coronary artery disease, myocardial infarction, pulmonary embolism and aortic dissection.
Bellies	Acute surgical abdomen including appendicitis, perforation, abscess, bleed and ischemic bowel
Bugs	Serious infectious disease including impending sepsis, necrotizing fasciitis, disciitis, epidural abscess, septic arthritis and pneumonia/acute respiratory distress syndrome (ARDS)
Cancer	In current descending order of costs related to claims: colorectal cancer, breast cancer, lung cancer, prostate cancer, malignant melanoma with most others such as cervical, ovarian, pancreatic and osteogenic much lower.
Trauma	Underappreciated mechanism of injury leading to missed diagnosis of serious fractures, dislocations and instability.

The following outlines the six core competencies of the ACGME and include the following core competencies. We address specific uses of patient safety event information and techniques to meet each of these core competencies.

1. *Patient care that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health.*

Much of medical education either in training or in continuing medical education centers on how to deliver appropriate and effective treatment. The study of adverse events, and particularly the skills of disclosure following an adverse event, are critical to teaching providers to be compassionate. Through the study of patients and their families who chose to take legal action following an adverse event, one can see how the difference between a patient's "chief complaint" is not often his or her "chief concern." Failure to address the chief concern, either before or after an adverse event, is often the triggering factor to litigation. Analysis of liability claims allows for a subset of patient safety events in which opportunities for compassion may have been missed prior to entry into the adversarial tort system.

2. *Medical knowledge about established and evolving biomedical, clinical, and cognitive (e.g., epidemiological and social-behavioral) sciences and the application of this knowledge to patient care.*

Not all medical knowledge is equal in the delivery of quality medical care and in avoiding serious adverse events.

The clustering of liability cases in primary care is in the failure to diagnose certain conditions as listed in Table 15.4 [18].

Liability cases in the procedural specialties are grouped around seven elements, listed in Table 15.5 [18].

3. *Practice-based learning and improvement that involves investigation and evaluation of their own patient care, appraisal and assimilation of scientific evidence, and improvements in patient care.*

Table 15.5 The top seven elements present in liability cases for procedural specialties

1. Appropriate procedure selection for appropriate patient indications
2. Informed consent and shared decision-making
3. Technical performance of a procedure
4. Taking all known preventive steps to ensure the highest possible quality outcome
5. Vigilance to the timely recognition of a complication
6. Ability to timely marshal the resources necessary to rescue the patient from that complication prior to serious harm
7. Resolution of all patient concerns following an adverse outcome

Source: COPIC Insurance Company

The study of adverse patient safety events is often the best and most motivating practice-based learning. The analysis of the root causes of PSEs involves all elements of care—not just medical knowledge. This core competency can be developed through the learning techniques using PSEs and liability claims throughout this chapter. These are examined in case studies, outlines of existing programs, and exploration of the ideal program later in this chapter.

4. *Interpersonal and communication skills that result in effective information exchange and teaming with patients, their families, and other health professionals*

The Joint Commission attributed communication failures as part of the cause of a sentinel event in more than 70 % of adverse events [19]. Providers currently receive very little training that focuses on team communication. Medical professionals are trained in professional silos: physicians in their medical schools, nurses in their nursing schools, therapists in their given professional track, and pharmacists in schools of pharmacy. Rarely does the team come together in training; yet, teamwork failure often causes adverse events. Teamwork resources, culture, and empowerment advances more quickly the recognition and rescue of an event prior to harm.

TeamSTEPPS Improves Inter-professional Training

Techniques to improve teamwork include TeamSTEPPS [20] developed by the U.S. Department of Defense, and now overseen by the Agency for Healthcare Research and Quality (AHRQ).

TeamSTEPPS is a teamwork system designed for health care professionals that is:

- A powerful solution to improving patient safety within your organization.
- An evidence-based teamwork system to improve communication and teamwork skills among health care professionals.
- A source for ready-to-use materials and a training curriculum to successfully integrate teamwork principles into all areas of your health care system.
- Scientifically rooted in more than 20 years of research and lessons from the application of teamwork principles.
- Developed by Department of Defense's Patient Safety Program in collaboration with the Agency for Healthcare Research and Quality.

TeamSTEPPS provides higher quality, safer patient care by:

- Producing highly effective medical teams that optimize the use of information, people, and resources to achieve the best clinical outcomes for patients.

- Increasing team awareness and clarifying team roles and responsibilities.
- Resolving conflicts and improving information sharing.
- Eliminating barriers to quality and safety.

TeamSTEPPS has a three-phased process aimed at creating and sustaining a culture of safety with:

- A pre-training assessment for site readiness.
- Training for onsite trainers and health care staff.
- Implementation and sustainment.

A critical element of teamwork is the debriefing that occurs following a PSE. Ideally, this debriefing process will be extended to the "near-miss" so that unsafe systems can be improved.

5. *Professionalism, as manifested through a commitment to carrying out professional responsibilities, adherence to ethical principles, and sensitivity to a diverse patient population*

Analysis of PSEs often show elements that were not medical knowledge or traditional training, but included elements of professionalism. These include disruptive behaviour, adherence to safe practices, building a culture of safety, lifelong improvement and ethical responsibilities. Often, the most critical pieces of the disclosure and resolution process involve professionalism.

6. *Systems-based practice, as manifested by actions that demonstrate an awareness of and responsiveness to the larger context and system for health care and the ability to effectively call on system resources to provide care that is of optimal value.*

Analysis of PSEs is the most critical way to see a system of practice in all of these elements, and how the interplay within this system and its inherent failures can lead to harm. Again application of this core competency will be described subsequently in this chapter.

Clinical Learning Environment Review (CLER) Program

A recent development for sponsoring institutions of graduate medical education is the Clinical Learning Environment Review (CLER) program, in which unannounced assessments of residency programs are used to encourage programs to comply with certain safety standards. This program does not currently affect the accreditation of a program.

CLER Assesses Sponsoring Institutions in the Following Six Focus Areas

- ***Patient safety***, including opportunities for residents to report errors, unsafe conditions, and near misses, and to participate in inter-professional teams to promote and enhance safe care.

- ***Quality improvement***, including how sponsoring institutions engage residents in the use of data to improve systems of care, reduce health care disparities and improve patient outcomes.
- ***Transitions in care***, including how sponsoring institutions demonstrate effective standardization and oversight of transitions of care.
- ***Supervision***, including how sponsoring institutions maintain and oversee policies of supervision concordant with ACGME requirements in an environment at both the institutional and program level that assures the absence of retribution.
- ***Duty Hours Oversight***, ***Fatigue Management and Mitigation***, including how sponsoring institutions: (i) demonstrate effective and meaningful oversight of duty hours across all residency programs institution-wide; (ii) design systems and provide settings that facilitate fatigue management and mitigation; and (iii) provide effective education of faculty members and residents in sleep, fatigue recognition, and fatigue mitigation.
- **Professionalism**, **in** regard to how sponsoring institutions educate for professionalism, monitor behavior on the part of residents and faculty and respond to issues concerning: (i) accurate reporting of program information; (ii) integrity in fulfilling educational and professional responsibilities; and (iii) veracity in scholarly pursuits.

Case Study Examples

The following demonstrate how the analysis of two real, but de-identified cases and the subsequent questions can meet many of the core principles of GME.

Case Assessment

What is the error? The immediate answer is the physician's inattention to the result of the chest X-ray, the failure to communicate the result to the patient, and the failure of the patient to have follow-up studies done and acted on. Each of these steps are indicative of an inherently unsafe system.

Could we have predicted this as an unsafe system? The physician had biannual office reviews performed by a nurse reviewer from his medical liability carrier. The nurse reviewer performed a standardized review of common risk areas including medication list standards, problem list standards, consistency of allergy documentation, test/report result tracking, test/report patient notification, consultant or critical problem follow-up system, legibility, and documentation of complete vital signs in acute illness. Samples of his reviews from two different years demonstrate identification of an unsafe system appear in Fig. 15.2 [18].

Box 15.1. Parallels and Differences Between Health Care and Aviation

- ***Complexity***. An individual airplane is complex unto itself, but standardized in some form. Its mission is clear: Take off and land safely with passengers and cargo intact. Health care is also complex; however, there is no standard "flight plan" for a given patient. Although evidence-based practice and protocols are striving to standardize care, patients are widely more diverse than an aircraft.
- ***Teamwork***. Safe aviation requires a team of many professionals all charged with different roles—mechanics, ground crew, air traffic control, and more. However, once a flight is airborne, the team in control does not change, and the flight safely lands in a number of hours. A health care team changes often and the care provided can last for years. Transitions in health care are much more complex. Aviation has a hub of respite in which systems are safe, teams are rested, passengers and equipment have been transferred, and the process begins again. For an individual patient, the complexity does not reach equilibrium easily. Unstable and complex issues are transferred to ever changing teams, and the concept of a safe landing and preparation for the next take off rarely occurs.
- ***Standardized communication***. Later in this chapter, we will discuss how some industry leaders are applying the standards learned from the aviation industry to health care.
- ***Learning from mistakes and 'near misses***.' For decades, the aviation industry has been transparent about mistakes and near misses, using each incident as a learning opportunity. Healthcare is a relative newcomer to this culture of safety. Significant barriers remain, including fear of shame, blame, and legal retaliation.
- ***Risk to the provider***. The aviation industry also has the inherent motivation that a failure or crash will not only harm the passengers but the pilot and crew as well. Death and catastrophic physical injury rarely happen in medicine. Yet just because a physician is not physically harmed, doesn't mean he or she is not motivated to avoid harmful errors. Numerous studies have been published detailing the effects of medical errors on physicians. Dr. Albert Wu popularized the concept of "the second victim," or the adverse consequences that occur to the emotional, psychological and professional wellbeing of the health care professional following an adverse outcome [7]. Scott et al. detailed the definition of second victims. The prevalence of health care professionals meeting the definition following an adverse event varied from 10.4 to 43.3 %. They subsequently developed a comprehensive institutional rapid response to meet the needs of physicians after an adverse event [8, 9].
- ***Other risks***. Today, extensive literature exists detailing the effects of errors on physicians. West et al. in the Journal of the American Medical Association described feelings of distress in resident physicians associated with medical errors. Thirty-four percent of participant resident physicians reported making at least one major medical error during the study period. There was a statistically significant decrease in measures of quality of life and all domains of burnout. Perhaps most distressing is its effect on subsequent patient care, as medical errors also resulted in a serious reduction in empathy [10].

Questions for Further Discussion

1. Who are the others involved in the error?
2. What was the radiologist's role and should he have done more?
3. Was it sufficient that a clinical call to White House Pulmonology was recorded by a non-clinical person?
4. What was the patient's involvement and responsibility in the error?
5. Who are the potential rescue agents?
6. What are the liability issues?
   What are the solutions? *How would aviation have approached this error*?

Questions for Discussion

1. Where did the error most likely occur?
2. If the person doing the labeling was fearful that reporting she might lose her job for noticing that she mislabeled the specimens, would this be a factor?
3. What TeamSTEPPS communication techniques should be routinely used to reduce the likelihood of such errors?
4. Most mislabeled specimen cases cannot be interrupted until they cause potential harm to both parties, who was the rescue agent in this case for the second patient?
5. Is an early resolution program appropriate to compensate the first patient who underwent the unnecessary prostatectomy? What are fair damages?
6. What is the incidence of mislabeled specimens?
7. What are some of the techniques to prevent such errors?
8. Is it possible to drive this error type to zero?

Box 15.2. Case Study of Actual Professional Liability Claim

Switched biopsies lead to an unnecessary radical prostatectomy resulting in incontinence and impotence for one patient and possible delay of diagnosis of prostrate cancer for another patient.

Analysis
Date: Aug. 8, 2007
Patient G. Clooney
Age 53
Caucasion
Elevated PSA of 4.7 (increase in 2005 results of 2.1)
Labor law attorney
Patient B. Pitt
Age 60
Caucasion
Abnormal digital prostate exam
Engineer

OFFICE SYSTEMS

INFORMATIONAL ASSESSMENT	**Status**
ELECTRONIC MEDICAL RECORD UTILIZED	NO
NURSE PRACTITIONERS UTILIZED	NO
PHYSICIAN ASSISTANTS UTILIZED	NO
CNMW UTILIZED	DOES NOT APPLY
COLLABORATIVE AGREEMENT DOCUMENT SIGNED & DATED WITH IN LAST 2 YEARS BY MIDLEVEL & SUPERVISING PHYSICIAN	DOES NOT APPLY
WRITTEN POLICY FOR PATIENT EMERGENCIES	NO
ON-SITE AUTOMATIC EXTERNAL DEFIBRILLATOR	NO
ASSESS AND DOCUMENT THE USE OF OTC MEDICATIONS	YES
DIABETIC FLOW-SHEET UTILIZED	DOES NOT APPLY
WRITTEN GUIDELINES FOR MANAGEMENT OF BREAST PROBLEMS	DOES NOT APPLY
WRITTEN SCREENING PROTOCOLS FOR BREAST CANCER	DOES NOT APPLY
WRITTEN SCREENING PROTOCOLS FOR CERVICAL CANCER	DOES NOT APPLY
WRITTEN SCREENING PROTOCOLS FOR COLORECTAL CANCER	DOES NOT APPLY
WRITTEN SCREENING PROTOCOLS FOR HEART DISEASE	DOES NOT APPLY
WRITTEN SCREENING PROTOCOLS FOR PROSTATE CANCER	DOES NOT APPLY
INFORMED REFUSAL DOCUMENTATION	YES
PHYSICIAN ADMITS PATIENTS TO A HOSPITAL	YES
WHAT PERCENT OF YOUR HOSPITALIZED PATIENTS DO YOU TREAT YOURSELF AS OPPOSED TO USING A HOSPITAL BASED GROUP	51–100%
ON-SITE RADIOLOGY	NO
RADIOLOGIST OVER-READS X-RAYS	DOES NOT APPLY
IN OFFICE IV SEDATION	NO
IN OFFICE GENERALIREGIONAL ANESTHESIA	NO
OFFICE PERFORMS TREADMILL TEST	DOES NOT APPLY
OFFICE PERFORMS FLEXIBLE SIGMOIDOSCOPY	DOES NOT APPLY
RESUSCITATIVE/MONITORING EQUIPMENT AVAILABLE (PULSE OXIMETRY, REVERSAL AGENTS SPECIFIC TO DRUG USED, 02 & ABILITY TO BREATHE FOR THE PATIENT USING A MASK OR VIA INTUBATION)	DOES NOT APPLY
OFFICE PERFORMS BOTOX OR OTHER COSMETIC PROCEDURES	DOES NOT APPLY
OFFICE PERFORMS ACUPUNCTURE	DOES NOT APPLY
OFFICE PERFORMS MANIPULATIONS	DOES NOT APPLY
OFFICE PERFORMS HOMEOPATHIC TREATMENT	DOES NOT APPLY
POLICY FOR HANDLING UNSOLICITED TEST RESULTS (PREFERABLY WRITTEN)	YES
ADDITIONAL PATIENT IDENTIFICATION USED WHEN CORRESPONDING WITH OTHER PROVIDERS	NO
WRITTEN POLICY FOR AUTHORIZATION OF MEDICATION REFILLS	NO

SYSTEMS	**Status**
*PATIENT FOLLOW UP TRACKING	CRITERIA MET
CONSULTATION TRACKING	CRITERIA NOT MET
*TEST TRACKING	CRITERIA NOT MET
*REVIEW/SIGNING OF INCOMING REPORTS AND CORRESPONDENCE	IMPROVEMENT NEEDED
*TEST FOLLOW-UP CONTACT SYSTEM FOR LABS/X-RAYS/OTHER TESTS	CRITERIA NOT MET
*INFORMED CONSENT DOCUMENTATION	CRITERIA NOT MET
*DOCUMENTATION OF TELEPHONE ENCOUNTERS	CRITERIA NOT MET

PRACTICE COVERAGE	**Status**
24 HOUR PRACTICE COVERAGE	CRITERIA MET
SCHEDULING DELAYS EXPLAINED	CRITERIA MET

MEDICAL RECORDS HANDLING & SECURITY	**Status**
MEDICAL RECORDS SECURE	IMPROVEMENT NEEDED
MINIMIZE MISFILING	CRITERIA MET
WRITTEN EMPLOYEE CONFIDENTIALITY POLICY	CRITERIA MET
UNABLE TO HEAR CONVERSATIONS OF A CONFIDENTIAL NATURE	CRITERIA NOT MET
RELEASE OF PROTECTED HEALTH INFORMATION (PHI)	CRITERIA MET
SECURE COMPUTER SCREENS	CRITERIA MET

Fig. 15.2 Biannual physician office review in 2005 and 2007, presented in the case example

OFFICE SYSTEMS

INFORMATIONAL ASSESSMENT	**Status**
ELECTRONIC MEDICAL RECORD UTILIZED	NO
NURSE PRACTITIONERS UTILIZED	NO
PHYSICIAN ASSISTANTS UTILIZED	NO
CNMW UTILIZED	DOES NOT APPLY
COLLABORATIVE AGREEMENT DOCUMENT SIGNED & DATED WITH IN LAST 2 YEARS BY MIDLEVEL & SUPERVISING PHYSICIAN	DOES NOT APPLY
ASSESS AND DOCUMENT THE USE OF OTC MEDICATIONS	YES
DIABETIC FLOW-SHEET UTILIZED	YES
WRITTEN GUIDELINES FOR MANAGEMENT OF BREAST PROBLEMS	DOES NOT APPLY
WRITTEN SCREENING PROTOCOLS FOR BREAST CANCER	DOES NOT APPLY
WRITTEN SCREENING PROTOCOLS FOR CERVICAL CANCER	DOES NOT APPLY
WRITTEN SCREENING PROTOCOLS FOR COLORECTAL CANCER	DOES NOT APPLY
WRITTEN SCREENING PROTOCOLS FOR HEART DISEASE	DOES NOT APPLY
WRITTEN SCREENING PROTOCOLS FOR PROSTATE CANCER	DOES NOT APPLY
INFORMED REFUSAL DOCUMENTATION	YES
WHAT PERCENT OF YOUR HOSPITALIZED PATIENTS DO YOU TREAT YOURSELF AS OPPOSED TO USING A HOSPITAL BASED GROUP	51-100%
ON-SITE RADIOLOGY	NO
RADIOLOGIST OVER-READS X-RAYS	DOES NOT APPLY
IN OFFICE IV SEDATION	NO
IN OFFICE GENERAUREGIONAL ANESTHESIA	NO
OFFICE PERFORMS TREADMILL TEST	DOES NOT APPLY
OFFICE PERFORMS FLEXIBLE SIGMOIDOSCOPY	DOES NOT APPLY
RESUSCITATIVE/MONITORING EQUIPMENT AVAILABLE (PULSE OXIMETRY, REVERSAL AGENTS SPECIFIC TO DRUG USED, 02 & ABILITY TO BREATHE FOR THE PATIENT USING A MASK OR VIA INTUBATION)	DOES NOT APPLY
OFFICE PERFORMS BOTOX OR OTHER COSMETIC PROCEDURES	DOES NOT APPLY
OFFICE PERFORMS ACUPUNCTURE	DOES NOT APPLY
OFFICE PERFORMS MANIPULATIONS	DOES NOT APPLY
OFFICE PERFORMS HOMEOPATHIC TREATMENT	NO
POLICY FOR HANDLING UNSOLICITED TEST RESULTS (PREFERABLY WRITIEN)	YES
ADDITIONAL PATIENT IDENTIFICATION USED WHEN CORRESPONDING WITH OTHER PROVIDERS	YES
OFFICE ENGAGES IN ON-LINE COMMUNICATION WITH PATIENTS	NO

SYSTEMS	**Status**
*PATIENT FOLLOW UP TRACKING	CRITERIA MET
CONSULTATION TRACKING	CRITERIA NOT MET
*TEST TRACKING	CRITERIA NOT MET
*REVIEW/SIGNING OF INCOMING REPORTS AND CORRESPONDENCE	CRITERIA MET
*TEST FOLLOW-UP CONTACT SYSTEM FOR LABS/X-RAYS/OTHER TESTS	IMPROVEMENT NEEDED
*INFORMED CONSENT DOCUMENTATION	IMPROVEMENT NEEDED
*DOCUMENTATION OF TELEPHONE ENCOUNTERS	IMPROVEMENT NEEDED

PRACTICE COVERAGE	**Status**
24 HOUR PRACTICE COVERAGE	CRITERIA MET
SCHEDULING DELAYS EXPLAINED	CRITERIA MET

MEDICAL RECORDS HANDLING & SECURITY	**Status**
MEDICAL RECORDS SECURE	IMPROVEMENT NEEDED
WRITTEN EMPLOYEE CONFIDENTIALITY POLICY	CRITERIA MET
UNABLE TO HEAR CONVERSATIONS OF A CONFIDENTIAL NATURE	CRITERIA MET
RELEASE OF PROTECTED HEALTH INFORMATION (PHI)	CRITERIA MET
SECURE COMPUTER SCREENS	CRITERIA MET

DOCUMENTATION	**Status**
MISSED APPOINTMENTS	CRITERIA MET
PRESCRIPTION REFILLS	CRITERIA MET
WRITTEN POLICY FOR AUTHORIZATION OF REFILLS	CRITERIA NOT MET

Fig. 15.2 (continued)

Both patients underwent a biopsy procedure performed in the office by Dr. Lazzeri with the assistance of an employee, D. Barrymore, L.P.N. Nurse Barrymore labels and processes tissue specimens. The tissue specimens were sent to the pathology department at St. Elsewhere Hospital (the Hospital).

Mr. Clooney's report indicated: *Prostate right side—adenocarcinoma, Gleason score 4+3=7; prostate left side—adenocarcinoma, Gleason score 3+3=6.*

He elected to have a radical prostatectomy at Holy Hills Hospital in December 2007.

After prostatectomy, the pathology examination of the prostate revealed there was no cancer in Mr. Clooney's prostate.

The pathology department at Holy Hills notified the patient and Dr. Lazzeri. Investigation revealed the pathology specimens had been switched. This resulted in an erroneous report to Mr. Clooney that he had cancer and also resulted in Mr. Pitt being advised that he did not require further treatment for prostate adenocarcinoma.

Mr. Clooney retained an attorney who requested settlement negotiations. Mr. Pitt has been advised of the error in the initial pathology report, and he sought treatment at the St. Elsewhere Hospital.

Source: Redacted claim file, COPIC Insurance Company

Core Principles of Continuing Medical Education

Similar to graduate medical education of physicians in training programs, continuing medical education (CME) carries its own principles. CME is often required for state medical licensure, for facility credentialing, and overlaps with maintenance of certification that is now common among many specialties of the ABMS.

The essential criteria for continuing medical education per the ACCME is found in Table 15.6 [21]. This section discusses how using adverse PSEs and liability cases can lead to effective CME learning courses.

Based on these principles, potential topics have been developed from the analysis of patient safety events, and particularly resultant medical liability claims. Examples of some titles and objectives that incorporate education based on the criteria and the cases are found in Table 15.7 [18].

Having examined the core principles and critical factors of education at the medical student level, the resident level, and the continuing medical education of attending physicians, several unique programs will be highlighted. This field is currently erupting with new ideas and methods, and there are many other programs with unique features worthy of highlighting. Time, space and local environment should be considered in determining which program will fit what sponsoring entity and what audience. Because professional liability insurers have traditionally not been part of education and training, yet contain enormous amounts of case information, we focus particularly on them.

Table 15.6 Accreditation council for continuing medical education

Institutional requirements		
Level	Term	Requirements for compliance
Provisional accreditation	Two years	Criteria 1, 2, 3, and 7–12
Full accreditation (or reaccreditation)	Four years	Criteria 1–15
Accreditation with commendation	Six years	Criteria 1–22

Criteria for accreditation	
Essential area 1: purpose and mission	The provider has a CME mission statement that includes all of the basic components (CME purpose, content areas, target audience, type of activities, expected results) with expected results articulated in terms of changes in competence, performance, or patient outcomes that will be the result of the program.
Essential area 2: education and planning	The provider incorporates into CME activities the educational needs (knowledge, competence, or performance) that underlie the professional practice gaps of their own learners. The provider generates activities/educational interventions that are designed to change competence, performance, or patient outcomes as described in its mission statement. The provider generates activities/educational interventions around content that matches the learners' current or potential scope of professional activities. The provider chooses educational formats for activities/interventions that are appropriate for the setting, objectives, and desired results of the activity. The provider develops activities/educational interventions in the context of desirable physician attributes [e.g., Institute of Medicine (IOM) competencies, Accreditation Council for Graduate Medical Education (ACGME) Competencies]. The provider develops activities/educational interventions independent of commercial interests. (SCS 1, 2, and 6). The provider appropriately manages commercial support (if applicable, SCS 3 of the ACCME Standards for Commercial Support[SM]). The provider maintains a separation of promotion from education (SCS 4). The provider actively promotes improvements in health care and NOT proprietary interests of a commercial interest (SCS 5).
Essential area 3: evaluation and improvement	The provider analyzes changes in learners (competence, performance, or patient outcomes) achieved as a result of the overall program's activities/educational interventions. The provider gathers data or information and conducts a program-based analysis on the degree to which the CME mission of the provider has been met through the conduct of CME activities/educational interventions. The provider identifies, plans and implements the needed or desired changes in the overall program (e.g., planners, teachers, infrastructure, methods, resources, facilities, interventions) that are required to improve on ability to meet the CME mission. The provider demonstrates that identified program changes or improvements, that are required to improve on the provider's ability to meet the CME mission, are underway or completed. The provider demonstrates that the impacts of program improvements, that are required to improve on the provider's ability to meet the CME mission, are measured.

Table 15.6 (continued)

Accreditation with commendation	The provider operates in a manner that integrates CME into the process for improving professional practice. The provider utilizes non-education strategies to enhance change as an adjunct to its activities/educational interventions (e.g., reminders, patient feedback). The provider identifies factors outside the provider's control that impact on patient outcomes. The provider implements educational strategies to remove, overcome or address barriers to physician change. The provider builds bridges with other stakeholders through collaboration and cooperation. The provider participates within an institutional or system framework for quality improvement. The provider is positioned to influence the scope and content of activities/educational interventions.

The 'COPIC Model' for Resident Education

COPIC [18] is a professional liability carrier that provides medical liability insurance to more than 7,000 physicians in Colorado, Nebraska, Iowa, and Wyoming, as well as more than 100 hospitals and health care delivery facilities. From its inception in 1982, COPIC has favored the approach of reducing the potential for claims via a rigorous patient safety education program.

Beginning in the 1990s, COPIC, along with University of Colorado Denver Health Emergency Medicine residency program, developed a teaching rotation for all specialties to educate residents about patient safety and risk management. Subsequent to the success of the earlier COPIC resident rotation, many residency programs began to mandate that their residents complete the COPIC rotation prior to graduating from their programs. The goal of widespread and uniform participation of residents training in all programs in Colorado in all specialties is now close to complete. Currently more than 180 residents and medical students participate in the program annually. The following are the elements of the current 1 week resident rotation hosted by COPIC in Denver, Colorado.

Aspect #1: Assessment of Actual Claim Data

- **Discussion and logical dissection of real events in the case files of the institution or the liability carrier**. Previously in this chapter we have examined two real cases and demonstrated some of the unique learning opportunities from them. Figure 15.3 is a document that serves as a guide for the analysis of liability claims. Included in the analysis are: origin of error, type of error, contributing factors- human, system, biologic, inherent, preventability assessment and strategies. Similar to the national transportation safety board of aviation, the COPIC repository of the actual claim files and summaries of hundreds of cases, sorted by specialty, are available to the resident.
- **Discussion and logical dissection of real events they have personally been involved in**. The same elements as described above from case files are included:

Table 15.7 Professional liability carrier copic develops educational seminars based on liability claims and patient safety events

Seminar title	Objectives
Emergency medicine "best hits"	Identify high risk areas for emergency department physicians. Understand dynamics of these high risk areas through exposure to actual case studies. Develop behavior modification methods to decrease claim exposure. Recognize importance of documentation of good care.
Medical malpractice cases and topic update	Debate the national malpractice crisis and why Colorado is one of a few states that are considered "not in crisis," to include an update of recent legislation. List trends in claims and occurrences for newly emerging or persistent risk areas, specialty by specialty. Recognize the value of early incident reporting and early intervention programs such COPIC's 3Rs program. Restate the importance of communication in disclosure of unanticipated adverse outcomes.
Breast cancer screening and managing high risk patients	Describe risk factors for developing breast cancer. Understand risk assessment models. Understand screening recommendations for average risk and high risk patients. Understand genetic testing recommendations.
Clinician-clinician communication and miscommunication	Define a team in the healthcare setting and how a lack of teamwork contributes to errors in medicine. Determine composition of the team and their methods of communication. Identify what information needs to be communicated. Develop methods for effective communication, ensuring that key information is delivered to the right people.
Guidelines for colorectal cancer (CRC) screening	Recognize the importance of screening in reducing death rates from CRC. Identify four screening methods and the pros and cons of each. Define the population at risk as the target for CRC screening. Apply CRC screening guidelines to increase the screening rates in their individual practices. Describe work-up protocols for patients with a positive screen. List risk management issues involved in CRC.
Computing and communication	Demonstrate how computing affects communication in the examination room Examine the 3 "Cs": connect, collaborate, and close Practice the skill set of computing and communicating in the medical setting.
Case studies in closed claims	*Define features of a claim which determine defensibility.* *Examine differences between malpractice claims and medical errors in the real world.* *Investigate types of medical errors in your specialty which lead to unanticipated outcomes in closed claims and develop methods to avoid them.*
Case studies in documentation	**Explore examples of documentation mishaps** **Examine dangers of electronic medical records** **Apply skill sets to better documentation**

Table 15.7 (continued)

Seminar title	Objectives
Case studies in infectious diseases	Describe current antimicrobial therapy. Articulate optional treatment of selected conditions. Review case examples to discuss common barriers to timely diagnosis of infectious diseases. Articulate evidence-based strategies for specific infectious diseases.
Medication errors	Identify causes and types of medication errors. Develop strategies to avoid medication errors and mitigate their effects. Summarize the complex causes, attitudes, and systems that contribute to these types of errors as well as potential suggestions and solutions for reduction. List trends in claims and occurrences and describe actions to decrease medication errors.
Handoffs in medicine	Recognize when handoffs occur. Describe the risks of poor handoffs. Understand tools to help develop effective and efficient handoffs.
Preventing errors and improving patient safety in clinical medicine	Describe the many ways in general that errors originate, including human factors research. Demonstrate multiple examples of how errors are generated. Examine the concepts of propagation, failure to recognize, and failure to rescue. Discuss practical solutions to reduce errors, including the value of systems and communication.
Medications of controversy—opioids, medical marijuana, and others	*Opioids* State the difference between tolerance, physical dependence, and addiction. Distinguish the specific liability risks in the medical treatment of pain, including misdiagnosis; overprescribing or under prescribing; overdose; abandonment; diversion; and vicarious liability. Review materials related to recently adopted guidelines for the treatment of chronic non-cancerous pain as developed by a consortium of experts and reported in the *Journal of Pain* [1]. Apply tools to use in prescribing in the setting of chronic pain, including opioid agreements, long term opioid informed consent, pain specialist consultation, pain diagrams and appropriate documentation. *Medical Marijuana* Discuss the scope of medical marijuana in Colorado: Numbers, ages, principal diagnoses, and dispensaries. State the components of appropriate certification for medical marijuana from a regulatory and a risk perspective. Recognize potential issues for the interaction of your medical management of your patient when they are also taking medical marijuana, certified by yourself or another provider. Consider the risks for vicarious liability and strategies to manage those risks.

Origin of error, type of error, contributing factors- human, system, biologic, inherent, preventability assessment and strategies. But most importantly is the discussion of the effect on the provider and the patient. The same elements as described above from case files are included: Origin of error, type of error, contributing factors- human, system, biologic, inherent, preventability assessment and strategies. But most importantly is the discussion of the effect on the provider and the patient. This was described previously in this chapter.

Aspect #2: Managing Adverse Outcomes

- **Management of adverse outcomes using the COPIC 3Rs approach**. The 3Rs (Recognize, Respond and Resolve) was one of the first large early intervention programs. The lessons learned from the now nearly 3,000 cases resolved via this process are shared and discussed. We stress the importance of early reporting of adverse events. Open, honest and factual disclosure skills are coached and implemented. Finally, accountability for the adverse outcome is assumed by the health care provider and COPIC. Apology in the absence of accountability rings hollow with patients and their families.
- **Management of adverse outcomes through the seven Pillars of Patient Safety**. Developed by Tim McDonald MD of the University of Illinois-Chicago [22], the seven pillars approach is a comprehensive framework for the necessary steps from the recognition and reporting of an adverse event to resolution of the event and system improvement to prevent recurrence. The Pillars include:

1. Reporting.
2. Investigation.
3. Communication. This includes communication with the patient and family as well as a care for the care provider program.
4. Apology with remediation—including waiver of hospital and professional fees.
5. Process and performance improvement.
6. Data tracking and analysis.
7. Education—of the entire process.

- **Training in reporting unsafe systems**. The residents participate in a focused discussion of what should be reported, who should report it, how can it be reported and the barriers to reporting.
- **Disclosure training and practice**. The culture of safety, accountability and transparency requires specific training that only rarely comes when a physician encounters an adverse event. Didactic training is followed by open discussion of PSEs the resident has been directly involved in, or has seen involving others. Finally, simulation via standardized patients of disclosure of adverse events. Examples of brief case scenarios that can be used in standardized patient simulation training in disclosure appear in Tables 15.8 and 15.9.

Aspect #3: Informed Consent

- **Informed consent and shared decision making**. The elements of the informed consent process are reviewed, cases in which this process was lacking and led to harm or an adverse legal outcome are discussed, and the optimal goal of shared decision making and its principles are outlined. We show a video case study in which shared decision making could have saved the life of a young man named Michael Skolnik, and allowed his parents to find peace following this tragedy

GENERAL

Specialty

_____

Issue/Diagnosis/Procedure _____

_____

_____

Disposition (jury award, dismissal w/ or w/o prejudice, settlement, precautionary or claim not pursued)

_____

_____

Indemnity amount (amount paid to plaintiff) $_____

LAE (loss adjustment expense) (means legal defense/expert costs)
$_____

ANALYSIS BY ALLEGATION TYPE

FAILURE TO DIAGNOSE (PROLONGED INTERVAL BETWEEN PRESENTATION AND ULTIMATE DIAGNOSIS)

Cognitive Error or Judgment Issue?

_____

_____

System Failure?

_____

_____

Adequate documentation of follow-up instructions and need for monitoring or problem/medication list?

_____

_____

Communication failure? Provider to partner, to specialist, to other provider, to patient/family?

_____

_____

What action and/ or documentation would have prevented the case?

_____

_____

IMPROPER PERFORMANCE OF TECHNICAL PROCEDURE

Is there evidence of an adequate consent process?

Fig. 15.3 Guidelines and self-assessment questions for chart reviews (Chou et al. [25])

Are there concerns regarding patient or procedure selection; including consideration of non-invasive treatments?

Were all known preventative measures taken?

Was the procedure performed in a technically competent manner?

Is there a delay in recognition of the complication, and does this affect the clinical course?

Is there anything that could reduce the likelihood of this event, or would anything in the documentation have been helpful in the defense of the care?

IMPROPER CARE AND TREATMENT OF KNOWN MEDICAL CONDITION

Is the adverse outcome due to the natural history of the disease?

Could an intervention or change in the intervention have changed the clinical course?

Was there reliance on inadequate or faulty information?

Is there anything that could reduce the likelihood of this event, or would anything in the documentation have been helpful in the defense of the care?

Fig. 15.3 (continued)

MEDICATION ERRORS

Is this an error in prescribing, delivery, monitoring, or education about known consequences of the medication?

Were systems issues involved?

How many contributed to the error?

What safeguards or systems changes could prevent this from recurri ng?

SYSTEMS FAILURES PRESENT?

Definition: A systems failure occurs whenever there is a breakdown in the flow of or communication of information from the time a health care professional considers a test, consult, intervention or procedure. Until the result returns to the ordering professional, the appropriate action is taken based on the information, and that action is communicated to the patient and completed.

Are there systems failures issues present in the case?

Was this due to absence of a system, failure of a system, failure to use the system, or failure to take individual accountability in the system?

Can you think of ways to prevent the recurrence of this systems failure?

OTHER ISSUES (BME, CONFIDENTIALITY, JOUSTING)

Family anger or unrealistic expectations?

Fig. 15.3 (continued)

Billing or future care concerns driving the action?

Jousting-the criticism of one professional's care by another professional, ***in the presence of the patient, family or in the record***, without a complete review of the care provided and/or communication with that professional. Is jousting present?

Altered records present?

Anything that would anger a jury of lay persons or prejudice them against the physician?

Board of Medical Examiners issues (impaired physician, boundary issues, etc.)?

Managed Care issues?

EMR Issues?

Fig. 15.3 (continued)

- **The elements of defending a surgical complication**. These are reviewed from patient selection to informed consent to taking all know preventative measures to proper technical performance to recognition of complications to rescue of the patient from that complication to resolution through disclosure and accountability are illustrated via surgical case studies.

Table 15.8 COPIC resident rotation: case scenario for standardized patient roleplaying

Date	History
8 months ago	Samantha Cook comes in complaining of vague on and off pain in mouth and tongue for 2 weeks. You examined the throat and said you could see nothing specific.
7 months ago	Two week later Samantha returns with the same symptoms and you found some white discoloration on the inside of the cheek next to the molars on the right side and prescribed antibiotics.
1 month ago	Samantha went to the dentist and the hygienist found a tongue mass. Patient was referred to an oral surgeon. The surgeon biopsied and found cancer. Surgery and radiation are planned.
Today	Samantha returns to discuss the situation. You missed the tongue cancer!

Table 15.9 COPIC resident rotation: case scenario for standardized patient roleplaying

Discussion with Jennifer Anderson, Mother of Patient Abbey Anderson
1. Abbey Anderson, age 8, presented to you in the emergency department 24 h ago. The patient reported abdominal pain and mild fever occurring over 2 days.
2. You ran a CBC and it was normal. The patient felt better and you discharged her with instructions for abdominal pain.
3. 20 h later, the patient returned with increased pain. A CT showed appendicitis. Abbey was scheduled for surgery 1 h from now.
4. You are now coming on your next shift. Abbey's mother wants to know why you did not do a more thorough work-up. Furthermore, she notes that you dismissed her concerns. You were present for less than 7 min with Abbey, appeared distracted and stood the entire time. You were overheard speaking to the nursing staff about your evening's plans as you were going off shift as soon as Abbey was discharged.

Aspect #4: Professionalism

- **Broadening the professional perspective of practice through ethics, professionalism, and accountability**. Interviews and discussion with physicians in leadership roles: the president of the state medical society, the physicians who administer the state physician's health program, and the leadership of COPIC all focus on the concepts of physician wellness coupled with an adherence to the principles of ethics, professionalism, and accountability.

Aspect #5: Literature Review

- Literature review: Table 15.10 contains a sample of the sentinel articles currently used in the education of residents [23]
- **Knowledge of assessment tools of unsafe systems or culture of safety**, using the Practice Quality office site review and the Agency for Healthcare Research and Quality (AHRQ) Safety Attitudes Questionnaire on safety culture.
- **Care for the care provider**. Literature is reviewed and personal experiences are discussed.

Aspect #6: Online Educational Opportunities

- **Online educational opportunities**. Included in the experience, trainees do online education courses in:
  - Disclosure,
  - Case studies in documentation,

Table 15.10 Literature review from Transparent Health, Inc. for the telluride patient safety resident workshop scholarship program

Gunderson, AJ, Smith, KM, Mayer, DB, McDonald, T, & Centomani, N. Teaching medical students the art of medical error full disclosure: evaluation of a new curriculum. Teaching and Learning in Medicine. 2009;21:229–232.
Halbach, JL, Sullivan, LL. Teaching medical students about medical errors and patient safety: evaluation of a required curriculum. Academic Medicine. 2005;80:600–606.
Kane, JM, Branne, M, Kern, M. Impact of patient safety mandates on medical education in the United States. Journal of Patient Safety. 2008;4:93–97.
Kirch, DG, Boysen, PG. Changing the culture in medical education to teach patient safety. Health Affairs, 2010;29(9):1600–1604.
Leape, L. Institute at the National Patient Safety Foundation. Unmet needs: teaching physicians to provide safe patient care. 2010; Available from: http://www.npsf.org/download/LLI-Unmet-Needs-Report.pdf.
Madigosky, W, Headrick, L, Nelson, K, Cox, K, Anderson, T. Changing and sustaining medical students' knowledge, skills, and attitudes about patient safety and medical fallibility. Academic Medicine. 2006;81:94–101.
Mayer, D., Klamen, D.L., Gunderson, A., & Barach, P. Designing a patient safety undergraduate medical curriculum: the Telluride interdisciplinary roundtable experience. Teaching and Learning in Medicine. 2009;21:52–28.
Moskowitz, E, Veloski, JJ, Fields, SK, Nash, DB. Development and evaluation of a 1-day inter-clerkship program for medical students on medical errors and patient safety. American Journal of Medical Quality. 2007;22:13–17.
Patey, R, Flin, R, Cuthbertson, BH, MacDonald, L, Mearns, K, Cleland, J, Williams, D. Patient safety: Helping students understand error in healthcare. Quality and Safety in Health Care. 2007;16:256–259.
Sandars, J, Baz, N, Mayer, D, Wass, V, Vickers, R. Educating undergraduate medical students about patient safety: Priority areas for curriculum development. Medical Teacher. 2007;29:60–61.
Seiden, SC, Galvan, C, Lamm, R. Role of medical students in preventing patient harm and enhancing patient safety. Quality and Safety in Health Care. 2006;15:272–276.
Walton, M, Woodward, H, Van Staalduinen, S, Lemer, C, Greaves, F, Noble, D., Ellis, B, Donalson, L, Barraclough, B. Expert group convened by the World Alliance of Patient Safety, as expert lead for the sub-programme. The WHO patient safety curriculum for medical schools. Quality and Safety in Health Care. 2010;19:542–546.

  - Case studies in handoffs and transitions in care,
  - Informed consent,
  - Management of adverse outcomes,
  - Working safely with physician assistants and advanced practice nurses,
  - Liability aspects of electronic health records, and
  - Several additionally prepared case studies which simulate the process of care from before the adverse event through to its discovery and final outcome and force the participant to assess and interact throughout the course of the case.

Aspect #7: Observational Study Opportunities

- **Attendance at local malpractice trials**. When available, attending portions of a malpractice trial is highly rated by resident feedback in the program. The legal elements of duty, negligence, causation and damages are experienced directly by the attendees.

- **Interviews and discussion with claims professionals**.
- **Interviews and discussion with medical liability professional attorneys**.
- **Participation in real time claims analysis via attendance at a claims committee board meeting**. In a one-half to full day meeting, defense attorneys present real cases to a panel of clinical and claims experts. Pertinent records are available. Important imaging studies are reviewed by an expert radiologist in attendance. Significant discussion and analysis subsequently occurs about the nature of the medical care, the preventability of the outcome, and the legal direction of the claim.
- **Participation in real time claims analysis via roundtable process**. A less formal internal process of real claims early in their course is conducted on all claims, led by the defense attorney and the claims professional. Resident attendees review all pertinent records and images in advance and their input is actively solicited.
- **Legal system participation**; **participation in mock trials**, **interaction with liability claims professionals**, **risk managers and defense attorneys**. Learning the "hot button" issues of liability claims as well as the anatomy of a claim, elements of a claim, damages determination, definition of the elements, and processes and different pathways from initial report to resolution in the legal system.

The Telluride Patient Safety Resident Workshop Scholarship Program

This week long course is titled "Transforming Mindsets, The Power of Change Agents: Teaching Caregivers Effective Communication Skills to Overcome the Multiple Barriers to Patient Safety and Transparency" [24]. Since 2004, this summer event has been held at the Telluride Scientific Research Center.

The program was envisioned by Timothy McDonald, MD of University of Illinois-Chicago (UIC), and David Mayer MD then of UIC and now at the MedStar system. Leaders from across the spectrum of patient safety form the faculty: members of academic medicine, the National Patient Safety Foundation, patient advocacy groups, residency faculty, residency leadership such as the Council for Interns and Residents, medical professional liability carriers, executives from hospital administration, leaders in hospital systems, experts in communication, and international persons providing a unique perspective have all attended in one or more sessions since 2004.

Residents are chosen from their programs nationwide and receive scholarship funding to attend from sponsoring. The intensive interactive program has been called "a life changing event in my professional career" by residents.

The vision of the interactive workshop is to create an annual retreat where stakeholders in patient safety, patient advocacy and health science education come together in a relaxed and informal setting to discuss, develop and refine curricula that support a culture of patient safety, transparency and optimal outcomes in health care.

Its objectives include:

1. Give an in-depth presentation that provides at least three reasons why open, honest and effective communication between caregivers and patients is critical to the patient safety movement and reducing risk in healthcare.
2. Utilize tools and strategies to lead change specific to reducing patient harm.
3. Implement, lead and successfully complete a safety/quality improvement (QI) project at their institution over the next 12 months.

The residents carry these projects back to their institutions. Of note, the framework for the previously cited "7 Pillars" program germinated at this workshop.

Additional Elements for Education

Whether woven longitudinally into the curriculum of medical students, GME, CME or maintenance of certification, the following activities are also valuable to comprehensive patient safety education. Many have already been described or are described in more detail in other chapters.

- Participation in sentinel event investigations. Principles of data collection, analytic tools, systems based practice improvements.
- Training in reporting unsafe systems.
- Simulation in situ of rare but significant events at regular intervals.
- TeamSTEPPS training
- Simulation via standardized patients for optimal communication, cultural awareness, and training to increase empathic connection in the physician-patient relationship.
- Participation in management of adverse outcomes programs such as the UIC 7 pillars.
- Participation in Care for the care provider programs.
- Data analysis of quality metrics and exposure to systems based improvement techniques.
- Continued literature review.

Take-Home Message

Patient safety events and liability claims can be powerful inspiration for the education of healthcare providers. Educational curricula have been developed by many—this chapter reviewed several of the prototypical programs. The unique program of a professional liability carrier demonstrated how their large, central repository of adverse events and medical liability claims can be used for a comprehensive program to meet many patient safety objectives as well accreditation standards for graduate and continuing medical education.

The critical elements of these programs and curriculum are extensive. There are also many similar shared principles including transparency, involvement of the

entire healthcare delivery system, and development of a just culture in which an institution and its members can learn from its adverse events and near misses to prevent recurrences.

Collection of data, use of principles of continuous quality improvement, system improvement, and monitoring of outcomes data are critical to a system that can learn and improve itself for the benefit of its patients and its workers. Fundamental to the process is the inspiration of its leaders and the entire institution. And the ability for institutions and others to share powerful stories—the stories of near-misses, adverse, and unexpected outcomes—are critical.

The resources for educating medical students and residents about patient safety are numerous, and can be readily applied.

References

1. Association of American Medical Colleges. [Internet] 2013. Available at: https://www.aamc.org/advocacy/teachphys/134260/phys0043.html.
2. Accreditation Council for Graduate Medical Education. [Internet]. Available at: http://www.acgme.org/acgmeweb/tabid/375/ProgramandInstitutionalGuidelines/InstitutionalAccreditation.aspx.
3. American Board of Medical Specialties. [Internet]. 2012. Available at: http://www.abms.org/Maintenance_of_Certification/.
4. The Joint Commission. Report: Health care at the crossroads: strategies for improving the medical liability system and preventing patient injury. Available at: http://www.jointcommission.org/assets/1/18/Medical_Liability.pdf.
5. American Society for Anesthesiologists. [Internet]. 2013. Available at: http://www.apsf.org/.
6. The Federal Aviation Administration. [Internet]. 2013. Available at: http://www.faa.gov/data_research/accident_incident/.
7. Wu AW. Medical error: the second victim. The doctor who makes the mistake needs help too. BMJ 2000;320:726–7.
8. Scott SD, Hirschinger LE, Cox KR, McCoig M, Brandt J, Hall L. The natural history of recovery for the health care provider "second victim" after adverse patient events. Qual Saf Health Care. 2009;18:325–30.
9. Scott SD, Hirschinger LE, Cox KR, McCoig M, Hahn-Cover K, Epperly KM, Phillips EC, Hall LW. Caring for our own: deployment of a second victim rapid response system. Jt Comm J Qual Patient Saf. 2010;36:233–40.
10. West CP, Huschka MM, Novotny PJ, Sloan JA, Kolars JC, Habermann TM, Shanafelt TD. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. JAMA. 2006;296(9):1071–8.
11. Wolf ZR, Hughes RG. Error reporting and disclosure. In: Hughes RG (ed), patient safety and quality: an evidence-based handbook for nurses. Rockville, MD; Agency for Healthcare Research and Quality; 2008, Chapter 35.
12. Halbach JL, Sullivan LL. Research report: teaching medical students about medical errors and patient safety: evaluation of a required curriculum. Acad Med. 2005;80(6):600–6.
13. Mayer D, Klamen D, Gunderson A, Barach P. Designing a patient safety undergraduate medical curriculum: the Telluride interdisciplinary roundtable experience. Teach Learn Med. 2009;21(1):52–8.
14. Kirch D, Boysen P. Changing the culture in medical education to teach patient safety health affairs. Health Aff (Millwood). 2010;29(9):1600–4.
15. Patient safety curriculum guide for medical schools. [Internet]. 2009. Available at: http://www.who.int/patientsafety/education/curriculum/EN_PSP_Education_Medical_Curriculum/en/index.html.

16. Patient Safety Curriculum. [Internet]. 2012 [reviewed/updated date: 2012 Dec 13] Available at: http://www.patientsafety.gov/curriculum/.
17. Accreditation Council for Graduate Medical Education. Clinical Learning Environment Review (CLER) Program. [Internet]. 2012. Available at: http://www.acgme-nas.org/cler.html.
18. COPIC Insurance Company, Internal documents (Lembitz A; unpublished data).
19. The Joint Commission. [Internet]. 2013. Available at: http://www.jointcommission.org/.
20. TeamSTEPPS. [Internet]. 2013. Available at: http://teamstepps.ahrq.gov/about-2cl_3.htm.
21. Accreditation Council for Containing Medical Education Accreditation Criteria. [Internet]. 2013. Available at: http://www.accme.org/.
22. McDonald TB, Helmchen LA, Smith KM, Centomani N, Gunderson A, Mayer D, Chamberlin WH. Qual Saf Health Care. 2010. Published Online First: 1 Mar 2010. doi:10.1136/qshc.2008.031633.
23. Transparent Health. [Internet]. 2009. Available at: http://www.transparent-health.com/.
24. Telluride Resident Conference. Available at: http://telluridescience.org/meetings/workshop-details?wid=439.
25. Chou R, Fanciullo G, Fine PG, Adler JA, Ballantyne JC, Davies P, Donovan MI, Fishbain DA, Foley KM, Fudin J, Gilson AM, Kelter A, Mauskop A, O'Connor PG, Passik SD, Pasternak GW, Portenoy RK, Rich BA, Roberts RG, Todd KH, Miaskowski C. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. J Pain. 2009;10(2):113–30.

Translation of Aviation Safety Principles to Patient Safety in Surgery

16

Hari Prabhakar

Pitfalls and Pearls

- Aviation and surgery are two 'high risk' domains where safety oversights can lead to catastrophic results.
- Commercial aviation has achieved an enviable record of safety and error reduction, a feat that remains unrealized in surgery.
- Pilots, surgeons, and anesthesiologists are often seen to be similar in terms of responsibility, skill requirements, accreditation, and team organization/dependence.
- Over the past several decades, there has been an increasing attempt to integrate aviation-based safety practices to improve surgical safety.
- Several aviation-based practices including the use of checklists, briefings, simulation, incident reporting/analysis, and *Crew Resource Management* strategies have gradually been adapted in the surgical setting, with varying results.
- Despite recent criticisms of the aviation safety paradigm not being applicable to medicine, many studies validate adaptation of aviation safety principles to improve surgical safety.
- The success of *Crew Resource Management* programs, checklists, verbal communication strategies, and briefings largely depends on establishing a baseline culture of safety and open communication in the organization.
- Without a baseline culture of safety and open communication, the assimilation of aviation-based safety techniques is less likely to be successful.
- Identifying champions in the organization to promote the interventions is critical to successful implementation.
- Much work, however, remains to be done in assuring that aviation principles are implemented realistically into the framework of an organization, taking into account the differences between the aviation and surgical industries.

H. Prabhakar, MD, MSc, MIHM
Department of Anaesthesiology, Harvard Medical School, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114, USA
e-mail: hari.prabhakar@post.harvard.edu

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_16, © Springer-Verlag London 2014

Outline of the Problem

Crew Resource Management, *checklists*, *briefings*, *simulation*, *incident reporting systems*, *and verbal communication strategies are some of the key techniques which can and have been adapted from aviation to improve surgical safety*.

In 1999, the *Institute of Medicine* published a landmark report entitled "To Err is Human: Building a Safer Health System," which revealed that 100,000 s of patients were dying each year in the United States due to medical errors, a significant portion of which occurred in the operating room [1, 2]. In response to these shocking findings, the *Institute of Healthcare Improvement* initiated the "100,000 lives campaign" in 2004 that aimed to curb medical errors through implementation of various patient safety standards and algorithms [3]. In the surgical setting, these included the implementation of a standard surgical "time-out" to ensure the correct patient identity and surgical site, as well as structured perioperative briefings [4, 5]. The use of perioperative briefings, in turn, has been shown to significantly reduce the incidence of wrong-site surgery [4]. In 2006, the "100,000 lives campaign" was estimated to have saved over 120,000 lives. Additionally, the recent development and implementation of surgical safety checklists have also been shown to reduce death rates and inpatient complications associated with surgery [6].

Many of these innovations in patient safety, however, have not evolved directly from the practice of medicine. Rather, the medical and surgical fields as a whole have shown increasing interest in the practices and procedures of other industries required to perform at the highest standards of safety and reliability, despite the potentially hazardous nature of their endeavors. Among these designated high-reliability organizations, or HROs, the commercial aviation industry has become a benchmark for safety and reliability, and many practices and lessons have been adapted from it to improve patient safety [7]. In this chapter, we explore work done to date on translating aviation-based strategies to the perioperative setting, with an emphasis on presenting the progress, potential, criticisms, and challenges that have faced this gradual movement of emulating a seemingly disparate industry.

Aviation Safety as a Model for High Reliability

The commercial aviation industry is responsible for the operation of tens of thousands of flights per day which transfer of millions of passengers seamlessly from point to point. Indeed, the potential risks of aviation are significant, and while aircraft accidents are relatively infrequent, those which do happen often result in a significant loss of life followed by an extensive review of the causal factors, public dissemination of the findings, and remedial action to help prevent similar

occurrences. Currently, the risk of dying in an air crash in the United States is around 1:500,000, as compared to an around 1:20,000 chance of dying in a car crash [8]. In the high-reliability framework of flight operations, therefore, key stakeholders such as the airlines, labor unions, and overseeing bodies such as the Federal Aviation Administration (FAA) and National Transportation Safety Board (NTSB) have come together to devise strategies to jointly improve flight safety [9]. Over the past 50 years, cooperative programs such as the Aviation Safety Action Partnership and the Flight Operational Quality Assurance program, in addition to organization-specific maintenance and employee training programs have played a key role in developing the safety management systems that are beginning to be emulated by the medical industry [10]. Indeed, both physicians and pilots operate in complex environments, where safety concerns and paramount and many tasks require team interaction with technology [11]. Professor Lucian Leape of Harvard, one of the most influential individuals in error prevention in medicine and an original proponent of adapting aviation-based safety strategies to improve safety, references Dr. Allnutt's comparison of doctors and pilots in his 1994 article, *Error in Medicine*:

> *Both pilots and doctors are carefully selected highly trained professionals who are usually determined to maintain high standards, both externally and internally imposed, whilst performing difficult tasks in life-threatening environments. Both use high technology equipment and function as key members of a team of specialists…both exercise high level cognitive skills in a most complex domain where about where much is known but where much remains to be discovered.* [12]

Furthermore, Richard Karl, the noted surgeon, pilot, and founder of the Surgical Safety Institute, notes that through a combination of simulator training, line-oriented safety audits, check airmen, *Crew Resource Management*, checklists, and various communication strategies, the aviation industry has established itself as a leader in safety protocols [13].

The surgical field has taken a particular interest in aviation-derived risk management strategies and adverse events reduction [14]. McGreevy and colleagues, building on the suggestions from aviators to reduce perioperative adverse events, proposed the following perioperative and hospital practices to improve patient safety: Mandating *Crew Resource Management*-type training to improve provider teamwork for hospital credentialing, mandatory perioperative briefings prior to an operation, recognition of fatigue and age as major factors in performance, and frequent "check-ride" style evaluations for credentialing. Additionally, the author proposes mandatory and random drug-testing for all perioperative employees, as done in aviation, as well the abandonment of the mortality and morbidity conference in lieu of a data collection system, similar to that used by NASA, the airlines, and the National Transportation Safety Board, for the purposes of examining aviation-specific adverse events and their root causes [15].

However, the safety climate established in the aviation industry seems far ahead of that found perioperatively, thus indicating the continued progress that needs to be made to ensure a uniform priority of patient safety. A survey study done in 2003 by the noted patient safety advocate, Dr. David Gaba, found that hospital staff were

significantly more likely to point out that there was a lack of a safety climate than naval aviators, indicating that further efforts were needed to assure a high-reliability safety climate [16]. A similar follow-up study in 2010 examining the perceptions of safety climate amongst naval aviators and hospital staff in 67 hospitals throughout the United States found that the safety climate among naval aviators was three times better than that among hospital personnel [17]. As such, there appears to be much potential in the adapting of aviation to improve safety in the perioperative setting, and several key initiatives have taken place to begin translating aviation-based principles to the surgical setting [18]. In this chapter, we review the progress and potential for continued translation of flight safety strategies to improve perioperative safety, while also discussing the major criticisms and challenges that have faced this developing aviation-centered movement for high reliability in surgical safety. Table 16.1 outlines some of the major aviation-based concepts applicable to surgical safety.

Crew Resource Management

In 1979, a workshop sponsored by NASA entitled "Resource Management on the Flightdeck," served as the origin of *Crew Resource Management* (CRM) training in the United States. The workshop was a result of NASAs research into the cause of

Table 16.1 Core aviation safety practices applicable to surgical safety

Safety practice	Aviation safety example context	Surgical safety example context
Crew resource management	Team, communication, and leadership training for flight and cabin crews	Team, communication, and leadership training for all perioperative staff
Checklists	Pre-takeoff, after-takeoff, cruise, approach, and landing checklists to assure critical item completion	Pre-incision/induction and post-incision/induction checklist to assure critical item completion
Simulation	Six-month recurrent training on full-motion flight simulator with emphasis on system failure management	Recurrent surgical skills simulator training and case-based scenarios with emphasis on procedural methods and rapid patient deterioration and management
Incident reporting/ root cause analysis	Reports and analysis of near-misses in the air/ground, systems failures, and crew mismanagement	Reports and analysis of surgical errors, retained items, wrong-site surgery
Briefings	Before takeoff/approach/landing briefings on flight conditions, weather, alternates, emergency procedures, and flying authority	Pre-procedure briefings on critical procedural tasks, patient comorbidities, emergency actions
Readbacks	Repeating of clearance provided by Air Traffic Control by pilots to assure that critical instructions are noted correctly	Repeating of request from surgeon by surgical scrub nurse to ensure that critical instructions are noted correctly

air transport accidents, with a particular emphasis on the human error aspects surrounding these disasters. At that time, it was estimated that 70 % of air crashed involved human error rather than mechanical or weather issues [19]. The major factors scrutinized, with regards to the interaction of the flightdeck crew, were interpersonal skills, decision making, and leadership. The development of *Cockpit Resource Management*, therefore, had the goal of reducing "pilot errors" by improving cockpit crew's utilization of available human resources on the flightdeck. Specifically, *Cockpit Resource Management* was defined as a "management system that makes optimum use of all available resources, equipment, procedures, and people to promote safety and efficiency" [19]. Effectively, the program had the goals of teaching pilots to improve communication, prioritize tasks, delegate authority, and monitor automated equipment. At the end of the this meeting, several of the major air carriers participating in the program, with United Airlines leading the CRM movement, pledged to the create programs to improve the coordination and interpersonal aspects of flight operations amongst their flight crews. Understanding, however, the importance of non-pilot team members (flight attendants, dispatchers, maintenance crews, air traffic control, etc…) the terminology of *Cockpit Resource Management* evolved to *Crew Resource Management*. Since that time, numerous CRM programs have been developed in the United States and throughout the world. In the United States, the Federal Aviation Administration has mandated that all airlines implement a CRM program within the scope of their flight operations. Charter operations in the general aviation setting have begun to adopt similar principles in the scope of their flight operations as well [20]. Indeed, the aviation industry, as a high-reliability organization tasked with the risk-laden responsibility of transporting millions of passengers across the globe every day, has many similarities with medicine. The flightdeck has often been compared to the emergency room, operating room, or intensive care unit, where trained professionals must make sound decisions in a framework of potentially stressful situations, fatigue, and overwork, responsibility, and high technology. Particularly, both industries are focused on risk reduction and place heavy emphasis on appropriate interpersonal relationships and human resources for successful completion of tasks [19].

Not surprisingly, health care providers, administrators, and quality improvement staff have been quick to endorse *Crew Resource Management* as a potential mechanism by which to improve healthcare team functionality and to reduce medical errors.

Recently, in a large academic center with 27 operating rooms and approximately 19,000 procedures per year, mandatory CRM training for anesthesiologists, surgeons, nurses, technicians, and OR assistants was implemented. Additionally, several aviation-based safety techniques including pre-operative checklist and brief, post-operative debrief, and reading and initializing of files was mandated, with an emphasis at looking at compliance of briefings/debriefings and the number of wrong-site surgeries and retained foreign bodies. Wrong site surgeries and retained foreign bodies decreased from a high of seven in 2007 to none in 2008, but, after 14 months without additional recurrent training, these rose to five in 2009. Indeed, these findings attest to the benefits of CRM training programs, checklists, and

briefings, while also stressing the need for recurrent training of staff to maintain a high level of reliability in the perioperative setting [21].

Several studies indicate that many organizations using the team structure to achieve organizational outcomes including safety and productivity are not always effective, and could benefit from high-reliability team training taken from aviation [22]. France and colleagues illustrate an example of the integration of a CRM program in a large academic medical center committed to training its entire workforce in CRM to improve team communication and patient safety. Much like other medical establishments, the hospital called in a commercial vendor to train its clinicians and administrators in an 8-h course which included lectures, case studies, and role playing. Given that a single day of training may not be effective enough to ensure system-wide change, senior administrators and clinical leaders devised a customized CRM program for perioperative services. Post training, and after observational analysis of 30 surgical teams, the authors found that teams were compliant with only 60 % of the safety and CRM practices taught during the course. Indeed, this finding has called for further development and testing of team training methods that are acceptable in the perioperative setting [23].

McCulloch and colleagues also examined the effect of CRM training on surgical staff in a single hospital with an initial 9-h CRM session followed by 3 months of twice-weekly CRM coaching. The results of the study indicated that the CRM training improved technical performance in the OR, but that the effects of improvement varied considerably between teams. Considerable cultural resistance was encountered during the implementation of debriefing and challenging higher authority, particularly from medical staff. The authors, therefore, recommended that more research be done in determining the optimal CRM training package and exploring further the cultural barriers to implementation [24].

On a positive note, Grogan and colleagues studied the impact of CRM on the attitudes of healthcare professionals, and studied the implementation of CRM among clinical trams for the trauma unit, emergency department, perioperative services, cardiac catheterization laboratory, and hospital administration. The 489 participants were then asked to complete a End-of-Course Critique and a Human Factors Attitude Survey to assess attitudinal changes on the usefulness of CRM training. The study demonstrated significant belief in the appropriateness of CRM implementation in improvement of fatigue management, team building, communication, adverse event recognition, team decision making, and performance feedback. Participants believed that CRM training has a positive impact on their outlook and practices to reduce medical errors and reduce patient safety [25]. Another study found that over the course of 7 years, training surgical staff in *Crew Resource Management* improved patient safety attitudes in the perioperative setting. In an observational study of 857 perioperative staff participants trained in one of ten CRM courses, there was a significant increase in perioperative checklist use, self-initiated reports of adverse events, perceived self-empowerment, and improved perceived culture of safety [26]. Additionally, CRM training has been demonstrated to improved nurse retention and changed nurse attitudes towards teamwork in the OR, thus improving the important safety climate and contributions from an important component of the surgical team [27].

However, while CRM training has been incorporated to some extent in the healthcare setting, the training is often piecemeal and voluntary, with few systematic approaches in linking training material with conventional practice. Further work is required to identify key non-technical skills (incl. cognitive and social) required in medicine, such that CRM can appropriately be applied in various healthcare settings, particularly perioperatively. Continuing to call upon the experiences of other high-reliability organizations is critical in development and integration of an effective curriculum [28]. Hugh and colleagues examined the use of CRM techniques, error analysis, and other strategies taken from high reliability organizations such as the nuclear power and maritime industry, as a means to reducing common laparoscopic bile duct injuries. A major cause of these injuries is spatial disorientation during the surgery, analogous to navigational errors while flying in either visual or instrument conditions. A customized set of CRM and other high reliability principles were put together as a training program for laparoscopic cholecystectomy and provided to one surgery unit, which later carried out 2,000 successive laparoscopic cholecystectomies. During this time, no bile duct injuries were reported, thus supporting the potential role of CRM and system-based risk management techniques perioperatively [29].

Indeed, communication, cooperation, and coordination are vital to effective perioperative care. As such, the principles of CRM have been integrated into a team training program developed by the Department of Defense and the Agency for Healthcare Research and Quality, known as the Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS). While the evidence for the continued use of team training programs perioperatively is still evolving, a multilevel evaluation of the TeamSTEPPS program in a single perioperative unit indicated that there was a significant increase in the quality and quantity of procedural briefings, the use of teamwork during cases, and an improvement in perceived safety climate and teamwork attitude [30]. A recent multicenter study looking at the effect of aviation team-style training on the incidence of time-outs, briefings, and debriefings did find significant increases in these safety strategies, noting, however, that continuing the benefits of aviation-based training would require collaboration of all OR staff [31].

Simulator Training and Competency Assessment

In commercial aviation, recurrent simulator training and ground school are an important part of pilot training and competency assessment. Captains are required to undergo recurrent simulator checks every 6 months, and during that time, they are evaluated, provided information on new policies, and provided information on collective experience of other pilots. In the perioperative setting, this level of commitment to recurrent training and competency assessment is yet to reach the levels of that found in commercial aviation [13, 32].

With the increasing work hour restrictions, emphasis on competency-based curriculum, and the growing burden of patient safety failures, McGreevy examines the aviation paradigm and its applicability to surgical education, comparing and

contrasting the training required to become a fighter pilot. He comes to the conclusion that aviators are often more carefully monitored and mentored than surgeons, and that acquisition of skills to become either a proficient pilot or perioperative team member requires an education that emphases systematic checklist use, particular learning objectives, briefings and debriefings, and assuring currency with performed tasks [33].

The rapid change in training methods for surgical staff has required a "team training" approach that integrates crises resource management and *Crew Resource Management* theory. These techniques include mock operating rooms and simulators including inanimate video trainers, human patient simulators, and virtual-reality computer-based trainers. The development of accredited skills-training centers, endorsed by the American College of Surgeons, appears to be a positive step towards catalyzing continued movement towards simulator-based training to improve perioperative safety [34, 35].

Indeed, financial and time constraints have made teaching outside of the operating room, using a variety of simulator platforms, an attractive option. With the establishment of simulator standards, an unprecedented endorsement of simulation as an education tool, and expansion of CRM training, surgical simulation seems to play a key role in training and multidimensional competency verification [36]. In addition to training for surgeons, there has been increasing emphasis on assuring that anesthesia personnel are trained in human factors and *Crew Resource Management*, given their important in assuring patient safety during the operation [37].

Incident Reporting

Incident reporting systems are frequently used in aviation, and one particularly successful program is the Aviation Safety Action Program administered by the National Aeronautics and Space Administration (NASA). Under this program, NASA, and not the Federal Aviation Administration (FAA) collects data reported anonymously by flight operators. Certain hospitals have incident reporting systems, though these are used infrequently and many clinicians are unaware that they exist [13]. The United States, Britain, and other countries also have non-punitive incident reporting systems in aviation which are shared between aviation bodies. These systems are important in allowing organizations to learn from failures in the delivery of care [11].

Choy notes the importance of critical incident monitoring in anesthesia as a means for quality improvement and maintenance of high safety standards. Noting the importance of human error in contribution to mortality and morbidity perioperatively, he also points out that that growing acceptance that human error perioperatively is often due to a failure of systems rather than an individual fault. As such, critical incident monitoring in healthcare allows more lessons to be learnt on a system-wide level, and the growth of information systems technology allows for wider implementation of monitoring systems. However, further research is necessary to ensure the benefits of critical incident monitoring in healthcare, particularly

with devising a system that meets the needs of the organization [38]. Additionally, whether or not the reporting system for critical incident monitoring should be anonymous is a matter of much debate, given that an anonymous system may not allow for further information gathering from the reporter.

A recent incident reporting system developed in a department of neurosurgery involved asking all neurosurgery staff members to report near misses on a voluntary, confidential, and protected form. These reports were then entered into an online database and reviewed by facilitators who performed an aviation-derived root cause analysis. The results revealed predominantly human factors as the causal factors for surgical errors, with technological, organization, and procedural factors being far less likely to be causal. Indeed, this is consistent with aviation accidents, where human factors are identified and targeted as the most likely to contribute to unsafe flight [39].

Other studies have investigated appropriate modalities of feedback from incident reporting systems as a means to improving patient safety. Through a mixed methods review to study established incident review programs in a variety of high-reliability industries, one study identified the essential components of a critical incident feedback reporting system in the healthcare setting. These included the role of leadership, credibility and content of information, the timely dissemination of feedback throughout the organization, the capacity for rapid action, and the establishment of feedback mechanisms at all levels of the organization. Most importantly, the study noted that the safety-feedback mechanism must be closed by assuring that corrective action be taken based upon addressing the feedback provided [40].

Checklists

Dr. Richard Karl, founder of the Surgical Safety Institute, aptly notes that "the fact that an elementary checklist's efficacy would warrant publication in one of our most prestigious journals signals how far we have to go to match the kinds of safety techniques viewed as commonplace and unremarkable…" [13]. Indeed, checklists have been routinely used by airline personnel over the past 70 years, while they have been sporadically used by perioperative personnel. Checklists serve as methodical reminders to ensure that that critical tasks have been completed successfully, and in aviation, are actively used during pre-flight, pre-start, taxi, takeoff, cruise, approach, landing, and post-flight phases. Indeed, structured checklists in the perioperative session can achieve great success as they have the potential to standardize human performance and ensure that procedures are followed correctly without overt dependence on memory [41].

Two predominant methods on checklist use have been developed by the aviation industry, namely the "do-list" and the "challenge-response" method. These methods have been developed based on different operational philosophies. In the "do-list," the checklist is used as a method by which the pilot goes through the checklist and configures the aircraft after reading each item. In the challenge-response method, the more common method used by commercial operators, the checklist is a backup

tool to verify all items have been accomplished after the pilot configures the aircraft for memory. The latter method, argued by some, reduces the possibility of missing an item during a single review of all the critical items [42].

David Gaba, a noted patient safety advocate and private pilot, notes that "simulation in healthcare can be categorized by 11 dimensions: aims and purposes of the simulation activity; unit of participation; experience level of participants; healthcare domain; professional discipline of participants; type of knowledge, skill, attitudes, or behaviors addressed; the simulated patient's age; technology applicable or required; site of simulation; extent of direct participation; and method of feedback used." While noting that the global costs and benefits of simulation are difficult to ascertain, he points out the various driving forces behind integration of simulation to improve patient safety: Surgical/medical professional societies, insurers, health financiers/payers, and the public at large [43].

Not surprisingly, there has been significant work done in translating checklists to the perioperative setting. Atul Gawande and colleagues, as part of the World Health Organization "Safe Surgery Saves Lives" Program, introduced a 19-item checklist to improve team communication and patient safety in eight hospitals around the world. The results indicated a significant decrease in morbidity and mortality after introduction of the checklist and are a major focus of surgical safety in the present day [44].

In a study highlighting the potential pitfalls of perioperative checklists, however, major objections included the checklist diverting attention away from the patient and reducing doctor-nurse cooperation. However, the study did note that the checklist did improve confidence of surgical providers during unfamiliar situations, though it was used in some situations for which it was not intended. Nevertheless, participants believed that having a head physician being the champion of checklist introduction would be critical in its success [45].

The use of verbal checklists may also be of significant benefit in reducing patient safety perioperatively. Hart and colleagues conducted a pilot study on the benefits of a verbal checklist for anesthesiologists during Cesarean delivery. Ninety-five percent of participants felt that the checklist was useful and 80 % wanted to use it in simulated scenarios. However, 60 % of participants preferred a written checklist while 40 % preferred a verbal checklist [46]. As such, a combination of a written checklist with verbal affirmations may be a step in the right direction.

Recently, a major academic pediatric ambulatory center recognized that surgical staff were expected to memorize a set of "do-not-forget" items at critical stages of the patient's surgical process. Realizing the potential for memory failures and error in these critical times, the center created aviation-style flow checklists for stage tasks to be completed prior to the departure from induction room, arrival in the operating room, departure from operating room, and arrival in the postanesthesia care unit. The checklists were centered around the challenge and response system widely used in aviation for critical tasks such as configuring an aircraft for takeoff, cruise, approach, and landing with different flap, trim, power, and fuel settings. A staff survey post deployment of the multiple stage checklists revealed that till date, none of the 24 critical stage items were missed, and that a majority of staff believed

that the checklist improved patient safety. Additionally, the study found no measurable increased in turnover times or reduction in operating room efficiency, bolstering the net benefits of multi-stage checklist use [47].

Verbal Communication – 'Readbacks'

A recent analysis of the American College of Surgeons' closed claims study revealed that a significant source of surgical errors can be attributed to a breakdown in communication before, during, and after surgery. Breakdowns in verbal communication accounted for around 85 % of adverse events related to communication breakdown, with only 4 % of breakdowns attributed to written communication [48]. As such, the patient safety community has increasingly called for formal *readback* orders among healthcare professionals who care for surgical patients in order to reduce the high incidence of perioperative complications related to verbal communication breakdowns. As with many other surgical safety interventions, the concept of *readbacks* has been taken from the aviation industry, and *readbacks* in aviation represent a core safety concept in reducing communication breakdown between flightcrews and between flightcrews and air-traffic control (ATC) [11, 49]. The Agency for Healthcare Research and Quality define *readbacks* as "When information is conveyed verbally, miscommunication may occur in a variety of ways, especially when transmission may not occur clearly (e.g., by telephone or radio, or if communication occurs under stress). For names and numbers, the problem often is confusing the sound of one letter or number with another. To address this possibility, the military, civil aviation, and many high-risk industries use protocols for mandatory "*readbacks*," in which the listener repeats the key information, so that the transmitter can confirm its correctness." The Joint Commission, as part of its National Patient Safety Goals, has recommended the implementation of *readbacks* in the healthcare setting, particularly during telephone medication orders or verbal transfer of critical tests results [50].

While many hospitals have begun to implement *readbacks* in many of their departments, the use of *readbacks* is still progressing slowly, and a 2007 editorial on surgery and patient safety notes that "*Getting surgeons to readback orders and instructions will age you 10 years, yet the Navies of the world have demonstrated for eons that it improves efficiency, promotes safety, and saves lives*" [51].

In a recent survey for perioperative staff in a major academic research center, respondents overwhelmingly recognized the role of *readbacks* in reducing communication errors and improving patient safety. There was a strong agreement among respondents to support participation in a *readbacks* training programs, though resident physicians were less likely to endorse the importance of *readbacks* and attend a short training model on *readbacks*. Overall, however, respondents strongly felt that *readbacks* had an important role in patient handoffs, patient orders regarding critical results, counting and verifying surgical instruments, and delegating multiple perioperative tasks. Looking forward, however, assuring section-wide enthusiasm for *readback* introduction and deciding the optimal phrases/commands to be

readback is critical in successful cross implementation from aviation to perioperative safety [52].

It is of note, however, that Vallance and colleagues note that the practicing surgeon is an often overlooked member of the quality-safety team. Based on the authors' experiences in developing a quality and cost-control initiative over the span of 10 years, the empowering of surgeons to take leadership positions in these initiatives met with great success, culminating in the opportunity to collaborate with the Centers for Medicare and Medicaid Services (CMS) in the 2004 Surgical Care Improvement Project pilot [53]. These experiences, the authors believe, are evidence that surgeons can actively participate in quality initiatives if provided the appropriate environment, resources, and position of responsibility. However, the role of verbal communication errors perioperatively has been called into question by certain investigators, who believe that human factors, primarily technical errors, as opposed to communication errors, are the major causes of surgical errors [54].

Other aviation-based verbal communication strategies in the operating room are also of interest. The "sterile cockpit" rules in the flightdeck, prohibiting non-essential communication during critical phases of flight including taxi, takeoff, approach, and landing, has been noted to be a potentially effective tool in improving surgical safety. A study looking at communication patterns among anesthesiologists during the critical phases induction, maintenance, and emergence from anesthesia, found a high level of non-essential conversation particularly during the emergence phases. It has been suggested, therefore, that applying principles of the "sterile cockpit" perioperatively may minimize and distractions and potentially improve patient safety [55].

Limitations of the Current Practice

While there is much literature reporting the potential benefits of employing the aviation paradigm to improve perioperative safety, criticisms also exist on relying too heavily on the aviation model for guidance in assuring high-reliability performance. Hunt and Callaghan point out that the differences between aviation and medicine are widespread, particularly in the differences in hierarchy structure, knowledge diversification, decision-making, and followership. In terms of hierarchy, the authors point out that the hierarchy in aviation is much more straightforward than in the perioperative setting, where aircrew members have specific duties, uniforms, designations, and authority. These designations and explicit *command-and-control* authority are not as clear in medicine, where there are numerous team members with overlapping skill sets. Additionally, the authors note that the aircraft are fairly predictable and generalizable in their actions during phases of flight, while in the perioperative setting, this is not necessarily the case. The fluid situation surrounding a patient's physiology and the diversity of comorbidities and level of surgical risk may be more complex than inflight variables including weather, pilot competency, aircraft airworthiness, and passenger structure. Additionally, during an emergency, the redundancy of systems in aircraft, external guidance from Air Traffic Control,

and a vast Quick Reference Handbook (QRH) available to flightcrew provide standardized solutions for a plethora of non-normal occurrences. Perioperatively, however, the availability of standardized approaches and designated crew roles during a medical emergency may not be as straightforward [56]. Additionally, the perioperative environment, according to Hunt and Callaghan, often allows for disagreement among team members about values and the best course of action for the patient. Health care, the authors remark, is often considered a social construct, and thus, applying standardized protocols and algorithms, as done in aviation, may not be appropriate [56]. Given these organizational differences between the two industries, many investigators call into question the appropriateness of CRM and other aviation-based strategies to improve patient safety.

Naturally, measuring outcomes of aviation training on surgical teams is key to validating these techniques in improving perioperative safety. To that end, the Safety Attitude Questionnaire, modeled broadly off the Flight Management Safety Questionnaire, has been used to evaluate the effects of educational interventions dealing with pre-surgery briefings. The Safety Attitudes Questionnaire, in turn, is a validated measure of patient safety culture that has been associated with improved patient outcomes and demonstrated good utility in measuring improvement of safety improvement activities. In a multi-year study of operating staff, the Safety Attitude Questionnaire found that practitioners who believe that "briefings are common in the operating theatre" also reported a better "safety climate" in the operating theater. As a result, there is evidence indicating a strong link between briefing practices and perceived safety operating climate, though the success of introduction of briefing methods seems highly dependent on establishing a baseline patient safety culture [57].

Where Is the "Golden Bullet"?

Addressing the Royal College of Surgeons, safety expert James Reason notes that "*aviation is predicated on the assumption that people screw up…[healthcare professionals] on the other hand, are extensively educated to get it right and so you don't have a culture where you share readily the notion of error…its is something of a big sea change*" [32]. However, with an enviable safety record, aviation certainly stands as a key industry from which much can be learned for the benefit of patients in the perioperative setting. While many differences between medicine and aviation exist, the similarities and demands of both high reliability industries are significant and merit further exploration. *Crew Resource Management*, *readbacks*, critical incident monitoring, and simulator training have all contributed to the safety of air travel, and their potential in improving perioperative safety cannot be understated. As demonstrated throughout the paper, numerous studies have been conducted to exploring ways to integrate the wisdom of aviation safety into healthcare delivery, many of which have yielded positive results. Much remains to be done, however, in terms of developing perioperative-specific training curriculums for *Crew Resource Management*, defining what components of the perioperative experience would benefit from the use of *readbacks*, and determining the optimum use of simulator

training in maintaining perioperative proficiency. Given the relatively recent adoption of aviation-based strategies perioperatively, continued evaluation of the long term impacts of aviation-based training on patient safety are necessary to further the confluence of aviation and medicine for the benefit of patients.

Take-Home Message

- The adoption of aviation-based strategies to improve safety in the surgical setting is a movement that has been in place for several decades.
- The impetus for adopting aviation strategies to improve patient safety in surgery has been the observation of similarities between aviation and surgery.
- While there are several technical differences between aviation and surgery, the necessity for high reliability, the inevitable manipulation of technology, the role of human error, and the team structure both fields lends itself to adaptation of safety techniques.
- A variety of preliminary studies have been conducted on the use of *Crew Resource Management* programs, checklists, briefings, simulator training/assessment, other verbal communication strategies, and incident reporting systems. These studies highlight both the advantages and pitfalls of introducing aviation-based strategies in the perioperative setting.
- The success of adapting aviation-based safety interventions largely depends on a combination of establishing a baseline culture of safety and open communication, appointing surgical champions of the intervention to build consensus, and ensuring recurrent training, particularly for *Crew Resource Management.*
- Measuring the benefits of surgical safety interventions, particularly from aviation, can be difficult, and may often be met by resistance from healthcare staff.
- Tools such as the Safety Attitudes Questionnaire can be used as metrics to measure the qualitative benefits of aviation-based surgical safety strategies, though further metrics must be developed and employed to measure quantitative impact.

References

1. Nance J. Why hospitals should fly: the ultimate flight plan to patient safety and quality care. Bozeman: Second River Healthcare Press; 2008.
2. Institute of Medicine. To err is human: building a safer health system. Washington, DC: National Academy Press; 1999.
3. Wachter RM, Pronovost PJ. The 100,000 lives campaign: a scientific and policy review. Jt Comm J Qual Patient Saf. 2006;32(11):621–7.
4. Makary MA, Mukherjee A, Sexton JB, Syin D, Goodrich E, Hartmann E, et al. Operating room briefings and wrong-site surgery. J Am Coll Surg. 2007;204(2):236–43.
5. Michaels RK, Makary MA, Dahab Y, Frassica FJ, Heitmiller E, Rowen LC, et al. Achieving the National Quality Forum's "Never Events": prevention of wrong site, wrong procedure, and wrong patient operations. Ann Surg. 2007;245(4):526–32.

6. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med. 2009; 360(5):491–9.
7. Kao LS, Thomas EJ. Navigating towards improved surgical safety using aviation-based strategies. J Surg Res. 2008;145(2):327–35.
8. Stahel PF. Learning from aviation safety: a call for formal "readbacks" in surgery. Patient Saf Surg. 2008;2:21.
9. Sexton JB, Helmreich RL, Neilands TB, Rowan K, Vella K, Boyden J, et al. The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research. BMC Health Serv Res. 2006;6:44.
10. Logan TJ. Error prevention as developed in airlines. Int J Radiat Oncol Biol Phys. 2008;71(1 Suppl): S178–81.
11. Helmreich RL. On error management: lessons from aviation. BMJ. 2000;320(7237):781–5.
12. Leape LL. Error in medicine. JAMA. 1994;272(23):1851–7.
13. Karl R. Briefings, checklists, geese, and surgical safety. Ann Surg Oncol. 2010;17(1):8–11.
14. Sockeel P, Chatelain E, Massoure MP, David P, Chapellier X, Buffat S. Surgeons can learn from pilots: human factors in surgery. J Chir (Paris). 2009;146(3):250–5.
15. McGreevy J, Otten T, Poggi M, Robinson C, Castaneda D, Wade P. The challenge of changing roles and improving surgical care now: Crew Resource Management approach. Am Surg. 2006;72(11):1082–7; discussion 1126–48.
16. Gaba DM, Singer SJ, Sinaiko AD, Bowen JD, Ciavarelli AP. Differences in safety climate between hospital personnel and naval aviators. Hum Factors. 2003;45(2):173–85.
17. Singer SJ, Rosen A, Zhao S, Ciavarelli AP, Gaba DM. Comparing safety climate in naval aviation and hospitals: implications for improving patient safety. Health Care Manage Rev. 2010; 35(2):134–46.
18. Bagnara S, Parlangeli O, Tartaglia R. Are hospitals becoming high reliability organizations? Appl Ergon. 2010;41(5):713–8.
19. Zeltser MV, Nash DB. Approaching the evidence basis for aviation-derived teamwork training in medicine. Am J Med Qual. 2010;25(1):13–23.
20. Helmreich RL, Merritt AC, Wilhelm JA. The evolution of Crew Resource Management training in commercial aviation. Int J Aviat Psychol. 1999;9(1):19–32.
21. Ricci MA, Brumsted JR. Crew resource management: using aviation techniques to improve operating room safety. Aviat Space Environ Med. 2012;83(4):441–4.
22. Wilson KA, Burke CS, Priest HA, Salas E. Promoting health care safety through training high reliability teams. Qual Saf Health Care. 2005;14(4):303–9.
23. France DJ, Leming-Lee S, Jackson T, Feistritzer NR, Higgins MS. An observational analysis of surgical team compliance with perioperative safety practices after crew resource management training. Am J Surg. 2008;195(4):546–53.
24. McCulloch P, Mishra A, Handa A, Dale T, Hirst G, Catchpole K. The effects of aviation-style non-technical skills training on technical performance and outcome in the operating theatre. Qual Saf Health Care. 2009;18(2):109–15.
25. Grogan EL, Stiles RA, France DJ, Speroff T, Morris Jr JA, Nixon B, et al. The impact of aviation-based teamwork training on the attitudes of health-care professionals. J Am Coll Surg. 2004;199(6):843–8.
26. Gore DC, Powell JM, Baer JG, Sexton KH, Richardson CJ, Marshall DR, et al. Crew resource management improved perception of patient safety in the operating room. Am J Med Qual. 2010;25(1):60–3.
27. Powell SM, Hill RK. My copilot is a nurs--sing crew resource management in the OR. AORN J. 2006;83(1):179–80, 183–90, 193–8 passim; quiz 203–6.
28. Glavin RJ, Maran NJ. Integrating human factors into the medical curriculum. Med Educ. 2003;37 Suppl 1:59–64.
29. Hugh TB. New strategies to prevent laparoscopic bile duct injury–surgeons can learn from pilots. Surgery. 2002;132(5):826–35.

30. Weaver SJ, Rosen MA, DiazGranados D, Lazzara EH, Lyons R, Salas E, et al. Does teamwork improve performance in the operating room? A multilevel evaluation. Jt Comm J Qual Patient Saf. 2010;36(3):133–42.
31. Catchpole KR, Dale TJ, Hirst DG, Smith JP, Giddings TA. A multicenter trial of aviation-style training for surgical teams. J Patient Saf. 2010;6(3):180–6.
32. Karl RC. Aviation. J Gastrointest Surg. 2009;13(1):6–8.
33. McGreevy JM. The aviation paradigm and surgical education. J Am Coll Surg. 2005;201(1): 110–7.
34. Rehrig ST, Powers K, Jones DB. Integrating simulation in surgery as a teaching tool and credentialing standard. J Gastrointest Surg. 2008;12(2):222–33.
35. Moorthy K, Munz Y, Adams S, Pandey V, Darzi A. A human factors analysis of technical and team skills among surgical trainees during procedural simulations in a simulated operating theatre. Ann Surg. 2005;242(5):631–9.
36. Scott DJ. Patient safety, competency, and the future of surgical simulation. Simul Healthc. 2006;1(3):164–70.
37. Buerschaper C, Hofinger G. Patient safety and training in human factor–challenge for anaesthesia training. Z Arztl Fortbild Qualitatssich. 2004;98(7):601–7.
38. Choy CY. Critical incident monitoring in anaesthesia. Curr Opin Anaesthesiol. 2008;21(2): 183–6.
39. Ferroli P, Caldiroli D, Acerbi F, Scholtze M, Piro A, Schiariti M, et al. Application of an aviation model of incident reporting and investigation to the neurosurgical scenario: method and preliminary data. Neurosurg Focus. 2012;33(5):E7.
40. Benn J, Koutantji M, Wallace L, Spurgeon P, Rejman M, Healey A, et al. Feedback from incident reporting: information and action to improve patient safety. Qual Saf Health Care. 2009;18(1):11–21.
41. Verdaasdonk EG, Stassen LP, Widhiasmara PP, Dankelman J. Requirements for the design and implementation of checklists for surgical processes. Surg Endosc. 2009;23(4):715–26.
42. Degani A, Weiner E. Cockpit checklists: concepts, design, and use. Hum Factors. 1993;35(2): 345–59.
43. Gaba DM. The future vision of simulation in healthcare. Simul Healthc. 2007;2(2):126–35.
44. Weiser TG, Haynes AB, Lashoher A, Dziekan G, Boorman DJ, Berry WR, et al. Perspectives in quality: designing the WHO Surgical Safety Checklist. Int J Qual Health Care. 2010; 22(5):365–70.
45. Thomassen O, Brattebo G, Heltne JK, Softeland E, Espeland A. Checklists in the operating room: Help or hurdle? A qualitative study on health workers' experiences. BMC Health Serv Res. 2010;10:342.
46. Hart EM, Owen H. Errors and omissions in anesthesia: a pilot study using a pilot's checklist. Anesth Analg. 2005;101(1):246–50, table of contents.
47. Low DK, Reed MA, Geiduschek JM, Martin LD. Striving for a zero-error patient surgical journey through adoption of aviation-style challenge and response flow checklists: a quality improvement project. Paediatr Anaesth. 2013;23(7):571–8.
48. Greenberg CC, Regenbogen SE, Studdert DM, Lipsitz SR, Rogers SO, Zinner MJ, et al. Patterns of communication breakdowns resulting in injury to surgical patients. J Am Coll Surg. 2007;204(4):533–40.
49. Gaba DM. Out of this nettle, danger, we pluck this flower, safety: healthcare vs. aviation and other high-hazard industries. Simul Healthc. 2007;2(4):213–7.
50. Joint Commission. National patient safety goals. 2010. Available at: http://www.jointcommission.org/patientsafety/nationalpatientsafetygoals. Accessed 25 June 2010.
51. Hoover EL. Patient safety and surgeons: why the resistance? Arch Surg. 2007;142(12): 1127–8.
52. Prabhakar H, Cooper JB, Sabel A, Weckbach S, Mehler PS, Stahel PF. Introducing standardized "readbacks" to improve patient safety in surgery: a prospective survey in 92 providers at a public safety-net hospital. BMC Surg. 2012;12:8.

53. Vallance SR, Schell RH, Robbins RE. The practicing surgeon as a member of the quality-safety team. Am Surg. 2006;72(11):1112–4; discussion 1126–48.
54. Fabri PJ, Zayas-Castro JL. Human error, not communication and systems, underlies surgical complications. Surgery. 2008;144(4):557–63; discussion 563–5.
55. Broom MA, Capek AL, Carachi P, Akeroyd MA, Hilditch G. Critical phase distractions in anaesthesia and the sterile cockpit concept. Anaesthesia. 2011;66(3):175–9.
56. Hunt GJ, Callaghan KS. Comparative issues in aviation and surgical crew resource management: (1) are we too solution focused? ANZ J Surg. 2008;78(8):690–3.
57. Allard J, Bleakley A, Hobbs A, Coombes L. Pre-surgery briefings and safety climate in the operating theatre. BMJ Qual Saf. 2011;20(8):711–7.

Handovers: The 'Hidden Threat' to Patient Safety

17

Tom J. Grundy and Nicholas A. Ferran

Pitfalls and Pearls

- Handover between shifts are a weak link in patient safety.
- Increasing handovers are a risk to continuity of care.
- Current teaching curricula fail to incorporate handover practice.
- Verbal only handovers carry a high risk of data loss.
- Handover should be taught using a robust system that highlights patient safety issues.
- Handover should be standardized.
- Where possible information technology should be used to supplement and support handover.
- There are guidelines for the acceptable minimum data transfer during surgical handover.
- Institutions should support handover by providing a conducive environment.

T.J. Grundy • N.A. Ferran, MBBS, MSc, FRCS (✉)
Department of Trauma and Orthopaedic Surgery,
University Hospitals of Leicester NHS Trust, Leicester, LE1 5WW, UK
e-mail: nferran@uku.co.uk

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_17,

Outline of the Problem

The reduction of junior doctors' working hours has resulted in increased number of shifts, decreased continuity of care, increased number of handovers, and risk of data loss during handover with potentially detrimental effects on patient safety.

"Handover," "hand-off," or "sign-out" are terms used to describe the transfer of vital patient clinical information between doctors completing their shift and those about to take over clinical responsibility for the patients in that unit. Handover is not new to healthcare. Nurses have been performing handover for many years as they have always had a shift pattern of working. Some medical specialties such as anaesthetics and intensive care have also been practising and refining the art of handover for some time.

In many countries around the world, policies have been implemented to reduce junior doctors working hours. In 2002, the Accreditation Council for Graduate Medical Education (ACGME) introduced an 80 h per week limit on junior doctor working hours across all specialties in the United States of America (USA) [1]. In 2009 the European Working Time Directive (EWTD) became fully active in the United Kingdom (UK) reducing junior doctors' working hours to 48 h per week [2]. The rationale for these reductions in working hours was the perceived reduction in medical errors made by tired junior doctors working long hours.

Whilst reduction in junior doctor working hours was hailed as a step forward in patient safety, it has naturally introduced shift patterns of working which have a knock on effect on continuity of patient care. Ever reducing hours mean ever increasing number of shifts causing handover between shifts to become a major focus of patient safety. In surgical specialties long hours with 24 h calls were the norm and the benefit was continuity of care. The surgical community in particular is still grappling with the effects that reduced working hours have had on training and on continuity of care. In New Zealand it has been estimated that the average medical patient sees six doctors per hospital admission while the average surgical patient sees ten [3]. Other studies suggest that the introduction of reduced working hours in the USA resulted in an average of 15 handovers per patient during a 5 day in hospital stay [4], The main concern about this increase in handovers, is the risk of data loss between shifts and the effects of this on patient safety.

In 2004 the British Medical Association published "Safe Handover: Safe Patients" providing guidance on handover for junior doctors [5]. This guidance suggested that handover should be at a fixed time, of adequate duration, should be ideally "bleep-free," and should be supervised by the most senior clinician on the team. They recommended that handovers should have information systems support and access to clinical information such as investigation results and radiographs [5].

In 2007 The Royal College of Surgeons of England published its handover guidance and went further to suggest minimum standards for information transfer. They recommended as a minimum that patients' names and age, date of admission,

location, responsible consultant, current diagnosis, and results of significant or pending investigations be handed over [6].

Limitations of the Current Practice

Handover Training

The major concern that the health care profession had with handover is the risk to patient safety that can occur when it falls short of expectation. With each handover there is a risk of error and studies have shown that even patients are concerned about the frequency of handovers [7]. Handover remains a weak link in the patient safety process where information may be lost, distorted, or misinterpreted [8]. Handover training is not a formal part of the undergraduate or post graduate curriculum and the effect of this is that handovers vary widely across institutions and departments with little understanding of what it is meant to achieve [9]. A recent survey of 16 (50 %) UK medical schools revealed 81 % of respondents felt that handover was an important educational issue and needed specific training. However, 81 % of respondents did not agree that handover is an important issue for undergraduate education [8]. The lack of published educational evidence on handover, means that medical schools respond to the issue of handover in varying ways with difference in the provisions being offered [8].

Defining the Scope of Handovers

To reduce the risk to patients, and improve handover we must first understand what it is meant to achieve so that we can measure the effect of any improvement or changes made [10]. Patterson and Wears attempted to look beyond data transfer in order to analyse and define the functions of handover with the goal of measuring its effectiveness. They defined seven conceptual frames around which good handover should be built: information processing, stereotypical narratives, resilience, accountability, social interaction, distributed cognition, and cultural norms [10].

The primary function of information processing is the transfer of data accurately through noisy communication. This conceptual frame is the one most often focused on when assessing handover. One of the main goals of handover is accurate data transfer. There are several ways this function can be enhanced, including the use of read backs, or the supplementation of verbal data with a written or electronic summary [10].

Stereotypical narratives make use of the default patient narrative to highlight variances from the norm. The key to this frame is effective patient summary that highlights variances. Asking the oncoming physician to relay their understanding of the issues in the summary provided can test this frame [10].

The aim of the third frame, resilience, is to cross-check data transfer. The oncoming physician is encouraged to ask questions of the person delivering the handover to clarify any misconceptions. The environment in which the handover process takes place needs to encourage participants to question openly [10].

Accountability ensures that both responsibility and authority are handed over. Tasks are directly assigned to specific individuals and a task checklist may help support this. Assessing this frame can be done by assessing the completion of tasks at the end of shift [10].

The fifth frame, social interaction, highlights the importance of the interaction of participants in a handover process who may each have a different perspective on the patients being discussed. This is particularly important in multidisciplinary handover [10].

Distributed cognition is the sixth frame which addresses how the handover to the oncoming physician may affect the whole oncoming team. Using white-boards to aid communication and the handing over of communication devices to the oncoming team may aid in the smooth running of the shift [10].

The final frame is cultural norms which relate to the group values of an institution that impact on how things are done. It is in effect, the environment within which handover occurs. This can be enhanced by having organizational support for handover such as supporting dedicated handover time, overlapping shifts, adequate staffing to support handover, and making handovers bleep free [10].

Jeffcott et al. described the key pillars of handover [11], some of which overlap with the framings of Patterson et al. [10]. The three key pillars are: transfer of information, transfer of responsibility and accountability, and the context of teams and their work environments (clinical setting) (Table 17.1). The authors suggested handover information transfer needs more rigorous research to assess process and outcome data. Responsibility and accountability needs more work to define and develop this aspect, and clinical settings require translational research in order to explain variations [11].

Measuring the Effect of Handovers

Whilst defining handover and its purpose is challenging given its varied nature, another difficulty is measuring its effectiveness and the effect of changes made. Literature on handover is limited considering its importance to patient safety. Despite limited literature the methodologies used are vast and include surveys [12], simulated with direct observation [13], and monitoring of data collection tools [14].

Surveys can be useful in exploring some aspects of handover such as physician knowledge, behaviours, and attitudes, overall satisfaction with the process, and can delve into the cultural norms. The use of surveys to determine the accuracy of data transfer is, however, limited by recall bias.

Bhabra et al. use a novel method to test handover methods by simulating handovers [13]. The authors of this paper created a number of fictional patients with set data points required for handover. They then had junior doctors simulate handing over these patients in an environment similar to their usual environment. The handover was audio taped and directly scored by two observers present in the room. This allowed observers to analyse the entire handover process and use the audio recordings to gain consensus amongst observers [13]. It is unknown whether the simulated nature of this

Table 17.1 Three pillars of handover education

Handover practice element	Related theory	Implications for education
Information transfer	Egocentric heuristic: doctors often do not communicate vital information at handover. It was not that they didn't know what to communicate, but rather that they overestimated their own communication skills. This egocentric heuristic led them to be less likely to verify whether the receiving doctor fully understood the situation.	Communication skills training to encourage improved checking of information transferred and understanding
Responsibility and accountability	Agency theory: patients do not have access to the information needed to make an accurate judgment regarding whether a doctor is behaving in their best interest. The 'agency problem' is the potential for doctors to shirk professional responsibility. This outlines the importance of professional attitudes to safe handover.	Discussion of consequences of poor handover to enhance professional responsibility
Systems to facilitate handover	Coordination cost: cost, either in terms of time or finance, of coordination increases in increasingly complex systems, including the costs of information management and communication	Education on mnemonic devices, handover checklists and systems to ensure safe practice

Reproduced with permission from Darbyshire et al. [16]. © Blackwell Publishing Ltd 2013

experiment, and the presence of observers, could have altered the handover given by the junior doctors under study thereby introducing a level of observer bias. Caution must therefore be exercised in extrapolating these findings to actual practice.

Another methodology has been to collect and analyse handover documents used in actual practice [15]. This can allow a direct measure of the data transferred in written format without directly influencing the handover process. This method is limited however as it cannot capture the verbal aspects of handover and may underestimate the amount of data transferred as some of this may be done verbally.

Handover Delivery

The way handover should be delivered or facilitated continues to be a source of debate. One consensus however seems to be that verbal handover alone is often inadequate and carries a higher risk of data loss. In an experimental comparison of handover methods Bhabra et al. concluded that verbal only handover was associated with 66 % data loss after the first handover [13]. Note-taking improves handover with only 8 % of data lost when notes were taken, if pre-printed computerised notes are used data loss reduces to 0 % [13].

Ferran et al. looked at the effect of using standardised handover proformas in an audit against the Royal College of Surgeons of England guidelines [6] for

acceptable minimal data sets to be handed over. The authors found that when doctors handed over using their own handover sheets only 72.6 % of data was handed over [14]. In 8 % of cases date of birth was not handed over and in 2 % unique hospital identifier was not handed over. With the introduction of a standardised handover proforma, which prompted the use of pre-printed labels, the authors saw a significant improvement in data handed over from 72.6 to 93.2 %. They concluded that standardised proformas were a practical way to accumulate handover data as a doctor progressed though a busy shift without the need for regular stops at a computer to input data [14]. This method may have continued relevance in an environment where costs are a priority and fully integrated patient record software is not available.

Studies have looked at using computers to assist in handover. The introduction of electronic patient records has allowed the development of handover software that can integrate with hospital systems to download patient identifiers, vital signs, laboratory results, and progress notes, into a template for handover [12]. The advantage of such a system is that it allows data to be standardised and pulls the data from already existing records thus preventing the need for duplication of data entry. In this study the authors found that doctors reported fewer patients missed on rounds, more time spent seeing patients, and better quality of handover [12].

Where Is the "Golden Bullet"?

The continued reduction in doctors working hours worldwide means that handover is not only here to stay but is likely to increase in frequency. Handover remains a weak link in patient safety and there are several established limitations; training, definition of function, measurement and delivery. While the literature is growing in this area handover research remains limited.

Training in handover techniques and the risks to patients of poor handover is likely to be key to the battle to improve patient handover. It is enlightening that medical schools do not agree that handover training is an issue for undergraduate education [8]. With doctors having to perform handovers as soon as they graduate it is difficult to understand the argument that safe and effective handover training should not be part of the undergraduate curriculum. While the debate goes on as to the timing of the delivery of this training some researchers and educators are already focusing their efforts on developing handover training that is pedagogically sound.

Darbyshire et al. reported on their design of a handover training session, based around Gagne's nine events of instruction [16], which are mapped to the three key aspects of handover [11] (Table 17.2). The session featured group discussions, role play, handouts, and a video on handover and had good feedback from medical students taking part in the sessions [16]. This model for a handover training session appears robust and may be a good framework on which other institutions can build training sessions suited to their local circumstances.

Table 17.2 Session map related to Gagne's nine events and the pillars of handover education

Session map	Gagne's nine events	Pillars of handover education
Introduction		
Presenting a difficult handover	1—gains attention	Responsibility and accountability
Learning objectives	2—describes the goal; learning objectives	
Group discussion		
Explore learners' own experiences	3—stimulate the recall of prior knowledge	All three pillars
Facilitated discussion	4—present material to be learned	
Role-plays		
Introduced	5—provide guidance for learning	Information transfer
Practise	6—elicit performance	
Peer and facilitator feedback	7—provide informative feedback	
	8—assess performance test	
Second group discussion		
Focus on practicalities and structure	3 and 4	Systems to facilitate handover
Second role-play	5, 6, 7 and 8	Information transfer
Video	1, 2, 3 and 4	Information transfer Systems to facilitate handover Some responsibility and accountability
Multi-disciplinary team role play	6, 7 and 8	All three pillars
Closure		
Attend and reflect on a handover	9—enhance retention and transfer	All three pillars preferably

Reproduced with permission from Darbyshire et al. [16]. © Blackwell Publishing Ltd 2013

There is little doubt that training and education are key to improving handover, however, measuring quality of handover and the effect of any intervention continues to escape us. There remains no validated tool for measuring quality of handover.

The 'Observed Simulated Hand-off Experience' (OSHE) is an interesting model for measuring handover. The authors designed the OSHE around the principle of an observed structured clinical examination (OSCE). In order to test measure the effect handover teaching the OSHE uses standardised patients. Medical students were given access to mock history, clinical examination, and transcript of notes for a standardised patient. Students were able to study the information and make notes on a blank handover template. Students were asked to produce a written handover form and then give handover to a standardised resident who acted as the receiver. Students were scored using a "Hand-off CEX" based on the validated Mini-CEX (clinical examination) assessment tool [17]. While this novel approach represents

an important step forward validation is needed to make the method universally accepted.

While the best way to handover is still unknown there is agreement that handover should be structured. Several structured models have been proposed and employed in practice. Two common methods in practice are SBAR and SIGNOUT.

The 'Situation, Background, Assessment, and Recommendation' (SBAR) method was initially developed by the US military. It has been adapted and implemented for use in medical handover as it serves as an effective tool to standardise communication and promote patient ownership. Telem et al. assessed surgical resident responses to SBAR training and found overall satisfaction with the method of handover [18]. SIGNOUT is a mnemonic for: Sick or DNAR, Identifying data, General hospital course, New events of day, Overall health, Upcoming possibilities and plan, Tasks to complete. In a survey of interns and medical students SIGNOUT received higher satisfaction scores than SBAR [19]. Whatever the standardisation method used, we recommend The Royal College of Surgeons of England, minimum data set be used for patients in surgical specialties [6].

Where feasible, handover software, that interacts with existing hospital systems to allow relevant patient identifiers, laboratory results, and clinical course to be downloaded into a standardised handover form, should be used to supplement data transfer during handover. Electronic patients records and handover software packages are continuing to be developed to improve handover communication.

The guidance on the clinical setting for handover from the British Medical Association remains relevant regardless of the institution [5].

Handovers should:

- Be held at a fixed time and be of sufficient length
- Ideally be "bleep-free"
- Be supervised by the most senior clinician present
- Have overlapping shifts to allow attendance in working time
- Have access to laboratory results, radiographs, clinical information, internet access and telephones
- Be supported by information systems that identify all relevant patients.

Take-Home Message

Handover remains a weak link in patient safety, with decreasing junior doctor working hours and increasing shifts. Increasing frequency of handovers pose a risk to continuity of care. There currently are several limitations to handover:

- Training
- Definition of function
- Measurement of effect
- Delivery

Despite these limitations, however, the research in this field, though limited, is ever expanding. Advances have been made in:

- Developing teaching methods

- Designing assessment tools
- Standardising data transfer
- Software development to support handover

The following remain out of reach but are goals for the future:

- Curriculum based handover training
- Validated assessment tool
- Universal handover method

References

1. Philibert I, Friedmann P, Williams WT. ACGME Work Group on Resident Duty Hours. Accreditation Council for Graduate Medical Education: new requirements for resident duty hours. JAMA. 2002;288:1112–4.
2. Fitzgerald JEF, Caesar BC. The European working time directive: a practical review for surgical trainees. Int J Surg. 2012;10:399–403.
3. Whitt N, Harvey R, McLeod G, Child S. How many health professionals does a patient see during an average hospital stay? N Z Med J. 2007;120:U2517.
4. Vidyarthi AR, Arora V, Schnipper JL, Wall SD, Wachter RM. Managing discontinuity in academic medical centers: strategies for a safe and effective resident sign-out. J Hosp Med. 2006;1:257–66.
5. British Medical Association. Safe handover: safe patients. Guidance on clinical handover for clinicians and managers. London: British Medical Association; 2004.
6. Royal College of Surgeons. Safe handover: guidance from the working time directive working party. London: The Royal College of Surgeons of England; 2007. p. 1–7.
7. Warrier S. Improving physician hand-offs. Med Health R I. 2011;94:344–5.
8. Gordon M. Training on handover of patient care within UK medical schools. Med Educ Online. 2013;18:369.
9. Van Eaton E. Handoff improvement: we need to understand what we are trying to fix. Jt Comm J Qual Patient Saf. 2010;36:51.
10. Patterson ES, Wears RL. Patient handoffs: standardized and reliable measurement tools remain elusive. Jt Comm J Qual Patient Saf. 2010;36:52–61.
11. Jeffcott SA, Evans SM, Cameron PA, Chin GSM, Ibrahim JE. Improving measurement in clinical handover. Qual Saf Health Care. 2009;18:272–6.
12. Van Eaton EG, Horvath KD, Lober WB, Rossini AJ, Pellegrini CA. A randomized, controlled trial evaluating the impact of a computerized rounding and sign-out system on continuity of care and resident work hours. J Am Coll Surg. 2005;200:538–45.
13. Bhabra G, Mackeith S, Monteiro P, Pothier DD. An experimental comparison of handover methods. Ann R Coll Surg Engl. 2007;89:298–300.
14. Ferran NA, Metcalfe AJ, O'Doherty D. Standardised proformas improve patient handover: Audit of trauma handover practice. Patient Saf Surg. 2008;2:24.
15. Ferran NA, Metcalfe AJ. Audit of handover practice. Ann R Coll Surg Engl. 2008;90:350.
16. Darbyshire D, Gordon M, Baker P. Teaching handover of care to medical students. Clin Teach. 2013;10:32–7.
17. Farnan JM, Paro JAM, Rodriguez RM, Reddy ST, Horwitz LI, Johnson JK, Arora VM. Hand-off education and evaluation: piloting the observed simulated hand-off experience (OSHE). J Gen Intern Med. 2009;25:129–34.
18. Telem DA, Buch KE, Ellis S, Coakley B, et al. Integration of a formalized handoff system into the surgical curriculum: resident perspectives and early results. Arch Surg. 2011;146(1):89–93.
19. Horwitz LI, Moin T, Green ML. Development and implementation of an oral sign-out skills curriculum. J Gen Intern Med. 2007;22:1470–4.

Public Safety-Net Hospitals–The Denver Health Model

18

Philip S. Mehler

Pitfalls and Pearls

- Hospitals that provide a large proportion of the inpatient care to the uninsured are \referred to as 'safety-net hospitals.' More than half of their hospital discharges are either uninsured or Medicaid patients.
- Public safety-net hospitals represent just 2 % of acute care in the United States hospitals, but provide 30 % of uncompensated care to the most vulnerable populations, with annually more than $6 billion in uncompensated care.
- Safety-net hospitals in the United States provide specialty care to 20 million individuals, and 40 million non-emergency outpatient visits each year.
- Multiple studies have shown that safety-net hospitals manage patients with a greater burden of illness than higher-income populations. These 'vulnerable' patients include the poor, ethnic minorities, non-English speakers, substance abusers, the homeless, individuals on public assistance programs, and the chronically and severely mentally ill.
- Although the Medicaid program is slated to expand coverage to millions of additional adults in 2014 under the 'Affordable Care Act,' estimates are that there will remain in excess of 20 million Americans who will lack any form of insurance. The reality is that there will actually be increased reliance on safety-net hospitals.

P.S. Mehler, MD
Department of Medicine, Denver Health Medical Center,
777 Bannock Street, MC 0188,
Denver, CO 80204, USA
e-mail: pmehler@dhha.org

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_18, © Springer-Verlag London 2014

- Notwithstanding their criticality, public safety-net hospitals will increasingly be challenged to maintain fiscal viability.
- The Denver Health experience demonstrates that excellent patient quality and safety can be advanced within America's health care institutions.
- The amount of uncompensated care that Denver Health peaked at $487 million in 2012.
- As a result of a structured approach to quality and safety, Denver Health was ranked number one out of 111 academic medical centers with the lowest observed-to-expected mortality ratio in the 2011 University HealthSystem Consortium ranking.

Outline of the Problem

Preventable hospital errors continue to adversely affect hospitalized patients in unacceptably high numbers.

Preventable hospital errors continue to adversely affect hospitalized patients. The Department of Health and Human Services (HHS) recently released a report suggesting that up to one third of all acute-care hospital admissions result in harm to a patient, and also that 180,000 Medicare beneficiaries die on an annual basis from such accidents and errors. Moreover, about 400,000 medication-related injuries occur each year in hospitals and nearly 100,000 people die each year die from an infection contracted while hospitalized, including a staggering 20,000 patients who die each year from central line infections. Also, 15 % of hospitalized patients suffer a fall which results in a serious injury up to 30 % of the time. These are but few of the telling examples of the breaches in patient safety which occur in hospitalized patients, despite the more than 10 years during which there has been a sharp focus on patient safety.

Limitations of the Current Practice

Over the past 15 years since the seminal publication of the Institute of Medicine's report *To Err is Human: Building a Safer Health System*, improving patient safety has been a focus of considerable public and professional interest. These have been directed to education, workforce, health care financing, organizational structure and health care delivery. Unfortunately major gaps remain, both on the evidence side as well as on the overall improvement side. Very recently, with support from the Agency for Healthcare Research and Quality (AHRQ) there was a rigorous effort

expended to try and define the top evidence-based healthcare safety practices [1], to help bridge this gap.

In general, the patient safety movement, which is galvanizing support both in the lay public as well as by hospital medical leadership, is focusing an increased emphasis on provider accountability and transparency, better processes of care, rigorous performance measurements and the standardization of care delivery. This has not been smooth sailing nor has it been a course of action devoid of perils and pitfalls. As an example, although there is agreement that performance measurement is an essential tool for implementing strategies aimed at achieving these goals, a number of unintended consequences of implementing performance measurements have also been identified. These include provision of inappropriate clinical care, decreased attention to patients concerns and adverse effects on team dynamics to name but a few [2]. Similarly, the overall documented beneficial effects of pay-for-performance ("P4P") remain lacking in the medical literature. Yet payers continue to implement these systems and new schemes appear all the time in the health care delivery armamentarium. One area of major recent interest in the patient safety movement is whether safety-net hospitals are able to provide high quality and safe patient care as compared with the much larger group of "non-safety-net" designated hospitals.

Safety-Net Hospitals

Public safety-net hospitals represent just 2 % of acute care in the United States hospitals, but they provide 30 % of U.S. uncompensated care. Hospitals that provide a large proportion of the inpatient care to the uninsured are all referred to as safety-net hospitals. More than half of their hospital discharges are either uninsured or are Medicaid patients. Safety-net hospitals annually provide more than $6 billion in uncompensated care to the most vulnerable populations in America, operate with an average margin of only 1.3 % and indeed may actually have negative operating margins on a regular basis. These "vulnerable" patients include the poor, ethnic minorities, non-English speakers, substance abusers, the homeless, those on public assistance programs, and the chronically and severely mentally ill. The safety-net hospitals provide close to 40 million non-emergency outpatient visits each year and also provide specialty care to 20 million individuals. In addition, they provide 65 million emergency department visits each year, deliver one of five babies, serve as first receivers in emergency situations and operate the only burn centers in many communities across the nation. More than 80 % of the safety-net hospitals are teaching hospitals that train the next generation of physicians and indeed almost one quarter of all physicians have received their graduate training at a safety-net hospital system. In addition, these hospitals employ more than one million individuals and contribute nearly $150 billion in total economic output.

Although the Medicaid program is slated to expand coverage to millions of additional adults in 2014 under the Affordable Care Act (ACA), estimates are that there

will remain in excess of 20 million Americans who will lack any form of insurance. This segment of the population will continue to rely on the safety-nets for their care. Some reasons why the role of the safety-net will not diminish under the ACA is that they have historically provided culturally competent and linguistically concordant care to the large number of ethnic minorities they serve. The experience from Massachusetts and their almost universal insurance coverage indicates that the traditional safety-net hospitals became even busier in the last decade and the vulnerable population increasingly relied upon them for their health care needs.

Notwithstanding their criticality, public safety-nets will increasingly be challenged to maintain fiscal viability. Some of the likely causes for this are the lingering concerns that pay for performance may lead providers and hospitals to avoid the most vulnerable and the chronically and seriously ill while shifting these patients to the safety-nets. Moreover, under the ACA, the recent Supreme Court ruling enables States to choose whether to expand Medicaid, and many states facing budget pressures are instead considering cutbacks. Yet, the proposed cuts to Medicaid Disproportionate Share (DISH) program, which is a form of Federal-State remuneration to hospitals with a large burden of uninsured care, will proceed beginning in 2014. By 2019, these forms of payment, which are crucial to the safety-net's survival, will be half of their current amount. Thus, public safety-net hospitals could face over $50 billion in additional costs for uncompensated care by 2019, further compromising their ability to remain open and succeed with ongoing fiscal viability.

Safety-Net Quality of Care

Indeed, the tenuous financial framework of the public safety-nets, along with their inherent patient demographics and characteristics, which embody health care disparities, might be expected to impede the intended outcomes of a safety-net's quality and safety interventions [3]. This is a debated issue. Intuitively, a hospital system which is financially poor and takes care of the vulnerable populations, might well be expected to have suboptimal quality of care and substandard patient safety practices. A recent study by Jha et al showed that hospitals with low quality scores in Medicare's Hospital Compare Program, care for twice as many minority and low income patients [4]. These hospitals also served more Medicaid recipients. These investigators found that patients with acute myocardial infarction or community-acquired pneumonia admitted to the low-scoring hospitals, were 10 % more likely to die than were their peers admitted to the best hospitals. The author's cautionary message was that hospitals who care for a disproportionately large number of minorities and poor will fare poorly with the plan to expand value-based purchasing initiatives. This in turn could further worsen health care disparities in the process of efforts, which are ostensibly designed to promote better health care quality. Other studies have demonstrated that the evidenced-based care given to patients following

an acute myocardial infarction is too often constrained by a gradient between income and the limitation of evidenced-based medical therapies.

Many studies have also suggested that safety-net hospitals manage patients with a greater burden of illness than higher-income populations. Although safety-nets are in a unique position to prevent deteriorating health in these underserved patients, the reality is that research has demonstrated disparities in quality and access to care for the poor and uninsured. For instance in colorectal cancer, a large proportion of patients seen in a safety-net health system were transferred from outside systems after their diagnosis was established, wherein the delay in care drove the advanced stage at diagnosis at the time of presentation to the safety-net system [5].

Indeed, the thought that a public safety-net hospital can be in the top decile of quality care and have exceedingly low mortality rates, seems counterintuitive. These hospitals are typically found in areas in which the uninsured are concentrated—inner-city neighborhood, and economically depressed rural areas. As a result and as previously mentioned, many safety-nets have negative operating financial margins. When this is coupled with a patient population who are often the disenfranchised, chronically medically ill and not well connected or committed with preventive care or healthy diets, delivering high quality and safe care seems a stretch. Yet, safety net hospitals are increasingly recognized as high- quality and low-cost health care providers, despite their notoriously low operational margins. In fact, evidence of any directional association between health care cost and quality is inconsistent at best and probably unrelated. A higher cost for the delivery of care does not ensure better or safer care [6].

There are however, persisting contentions that both the quality of care and the rates of improvement in patient safety at safety-net hospitals are lower than in non-safety net hospitals. Part of this confusion might emanate from how "safety-net" is being defined. The authors from a recent study, who concluded that quality of care at safety-nets is inferior to that delivered at other hospitals, identified a group of more than 900 "safety-net hospitals" based solely on the percentage of patients insured by the public payor Medicaid [7]. This is, however, way too expansive as it lumps small rural and large urban hospitals together, even though the large urban hospitals have trauma centers, burn units and other clinical services which are very different than the small rural hospitals. The National Association of Public Hospitals (NAPH) has only a few hundred hospitals in its membership rosters. Indeed, this study has been rebutted in heated debates by some well-respected safety-net hospital systems in which definitions, patient demographics and outcomes were discussed as means to buttress the contention that safety-nets often actually perform better than the national average on quality measures, notwithstanding their inherent financial and cultural challenges.

One particular impediment to the deliverance of safe and high quality care is that of health literacy. The scope of this problem in the safety-nets is especially

daunting since only about ten percent of adults are considered to have proficient health literacy levels. More than 30 % of U.S. adults are actually categorized as having basic or below basic levels of health literacy. Thus, patients cared for in the safety-nets have difficulty performing basic health–related tasks such as reading nutrition labels, following medication instructions or adhering to hospital discharge instructions. It is no surprise that these low literacy rates are more common in the racial and ethnic minorities, the poor, and the uninsured, the very patients who seek care at the safety-net hospitals. Suboptimal outcomes would therefore not be totally surprising when a patient does not understand how to care for themselves by following written instructions. Providers in these institutions must put forth effort to change their language and speak differently in order to improve adherence in these patients. Safety-net hospitals have long made it a priority to provide services such as translation, navigators and transportation in their ongoing quest to optimize patient outcomes and deliver safe and high quality care.

A related issue is the need for accurate communication across language barriers. Estimates are that currently almost one quarter of the adult United States population speaks a language other than English. It is also known that limited English proficient patients tend to congregate in safety-net systems and tend to receive fewer preventive health series and have worse control of chronic metabolic conditions. Therefore, to deliver excellent patient safety and high quality care, safety-net systems must employ interpreters to help them and their patients to maximize the utility of health care services and to efficiently navigate the often complex medical visit and the requisite aftercare. It is not sufficient to rely on a patient's limited language abilities or on family members acting as ad hoc interpreters because this is known to compromise the quality of clinical communication. Rather, when an interpreter is needed, a trained professional interpreter should be remotely used. In addition, optimal care delivery to limited English proficiency patients can also be achieved by hiring language concordant care. Many studies have demonstrated that care processes and the care itself can be improved by delivery language concordant care. Thus, many physicians employed by safety-net hospitals are proficient in a second language, such as Spanish which optimizes the health care visit and interaction. These issues are again most relevant to the safety-net hospitals, and further tax their resources and complicate their care delivery.

Ironically, one might posit that, with the imminent implementation of the Patient Protection and Affordable Care Act (PPACA), by which an additional 20 million people who currently are uninsured will now have health insurance, that the safety-net hospitals will be less important to the overall health care system. The reality is that there will actually be increased reliance on these safety-net hospitals. The implementation of health care reform in Massachusetts has already proven this false. Currently, more low-income patients than ever are receiving their care at the safety-net hospitals of Massachusetts despite now

being able to obtain care at other hospitals. This is likely attributable to these hospitals having a long track record of being able to address the complex issues these patients face in terms of their health and socioeconomic barriers that stand in the way of them receiving care. Moreover, the safety-nets have the infrastructure in place which facilitates these patients feeling comfortable at the safety-nets such as case management, transportation and language translation services. There will also always be uninsured patients in need of a safety-net, including large number of undocumented immigrants and those with chronic and severe mental illness who will not be eligible or are eligible but who will not enroll and will therefore not be able to benefit for health care reform. Estimates are that of the estimated 57 million uninsured persons in the United States, 23 million will remain uninsured even under the Affordable Care Act. Additionally, the cost of health insurance premiums available through exchanges may be unaffordable to some patients, or others who can afford coverage may choose to pay the less costly penalty instead and remain uninsured and reliant on the safety-nets. Furthermore, there will be a need for a viable safety-net system to care for all those who newly gain insurance as they learn to navigate through the morass of health care.

As mentioned above, undocumented migrants will likely be the largest group of individuals without insurance coverage once the coverage expansion of the Affordable Care Act takes effect in those states who opt to implement the law's Medicaid provisions. It is estimated that close to seven million undocumented will be without coverage and that number may indeed increase because not all of those people currently lack health insurance, but they are specifically prohibited from purchasing insurance through the insurance exchanges. Therefore safety-net hospitals are already expressing concern regarding additional burdens on emergency services that they must provide under federal law.

Given the irrefutable evidence that being uninsured is associated with increased morbidity and mortality [8], strengthening safety-net hospitals, and the quality of care they deliver to this segment of the patient population who often seek care at the safety-nets, will be increasingly important as health reform evolves forward. While this may be an argument in favor of providing forms of insurance coverage to undocumented migrants, that remains an unresolved national question which continues to be grappled with. However, in the current context, those patients do have a right to emergency care and will continue to gain access to the safety-nets at least through this route and thus the challenges to care for these patients will be persist.

Yet, the optimal way for clinicians at safety-nets to manage these limited English proficient patients is devoid of robust scientific evidence. Language concordance (i.e clinician speaks the patient primary language fluently) is felt to be the "gold standard" to ensure safe, high quality care. There is some evidence, in clinical areas such as diabetes, that this is the optimal way for clinicians to manage these patients.

Trained-certified interpreters can also help to deliver higher quality care to these patients and better outcomes.

Where Is the "Golden Bullet"?—The Success Story of Denver Health

Given the critical role of the safety-net hospitals in the health system enterprise, and given the fact that there are increasing costs and growing evidence of gaps in health care quality, there is increased emphasis on accountability, quality, transparency safety and patient experience. Similarly, there is increasing awareness of the importance of quality improvement and high reliability organizations as borrowed from other non-health-related industries. Moreover, hospitals are operating under vastly altered educational and clinical environments with an expectation that there will be an increased degree of oversight by attending physicians with a new attending-trainee ecosystem being set in place to guarantee the high quality and safe patient care imperative [9]. While there are many excellent safety-net hospital systems, Denver Health (Fig. 18.1) has rightfully developed a reputation as a bellwether for industry and public leaders because of the superb level of health care quality that it delivers, notwithstanding its safety-net status. Therefore it is worth relating some of the component parts of Denver Health's quality and safety agenda to help inform others of this public safety-net's successful model for providing safe, high quality care.

As mentioned, Denver Health is a public, academic health system and Colorado's principle safety-net institution. The system includes an emergency paramedic system; an acute care 479 bed hospital and level one trauma center; all eight of Denver's federally qualified health centers which see over 600,000 visits per year; 12

Fig. 18.1 Denver Health Medical Center

school-based clinics; the city's public health department; a health maintenance organization; a 100-bed nonmedical detoxification unit; correctional care; and a call center staffed by nurses, and centralized appointment function. The system serves one-third of Denver's adults and 40 % of the city's children. Almost half of the system's patients are uninsured. It is one of the busiest hospitals in Colorado with 28,000 discharges and 3,200 deliveries.

As a safety-net institution, Denver Health faces clear disadvantages compared to other health systems. These barriers, as mentioned above, include limited resources coupled with a population of socially disadvantaged and clinically complex patients. For example, in 2009 the Denver Health system provided more than $100 million of care to patients classified as homeless. In 2012 the system provided approximately $480 million of uncompensated care to patients with no insurance, Yet, Denver Health has been in the black every year since 1991. However, its operating margin in 2012 was only 0.4 %, leaving few resources for quality and safety initiatives.

Although characteristics of the health care system are important in achieving high-quality, safe, and efficient care, health is the result of mutual efforts by the patient and the care system. A safety-net institution's patients are often society's most vulnerable, including the poor, the mentally ill, and many non-English-speaking members of minority groups. For example, the majority of Denver Health's patients have incomes below 185 % of the federal poverty level. Three-quarters of the system's patients are ethnic minorities, and one-third do not speak English. These patient characteristics embody health care disparities which can impede the intended outcomes of a systems' quality and safety interventions [10].

A Journey to Quality Improvement

Despite these struggles, in 2004 Denver Health's leadership was inspired to begin a quality improvement journey in part because of these substantial challenges that it faces as a safety-net institution. A number of foundational elements were already in place, including a vertically integrated health care system. Denver Health believes that this integrated system is key for achieving high levels of quality and safety because it provides people with geographically convenient access to care, seamless continuity of care across a person's life and health care needs, and the right care, at the right time, with the right provider.

Another foundational element is that the system is staffed by almost 300 employed and salaried physicians, all of whom have academic appointments at the University of Colorado School of Medicine. This employed-physicians model promotes the alignment of goals across the enterprise and helps implement quality and safety interventions, perhaps more so than a hospital whose physicians have medical staff privileges but who are not employed by the hospital system. Nationally, there is a definite trend towards more employed physician models of hospital staffing.

In addition, the delivery of safe, high-quality, and efficient health care depends on the provider's having comprehensive patient care information at the point of care. Denver Health is an advanced user of health information technology, which is becoming even more widespread at Denver Health, in response to incentives in the Health Information Technology for Economic and Clinical Health (HITECH) provisions in the American Recovery and Reinvestment Act of 2009. These foundations of an integrated system, employed academic physicians, and health information technology, provided a springboard for Denver Health's structured approach to health care quality and patient safety.

An important step in Denver Health's approach to creating high-quality care and patient safety was to identify a responsible person and department to lead this effort. Although decentralizing and integrating these safety and quality strategies into every clinical department is important, Denver Health saw a need for a centralized and distinct department of patient safety and care quality to facilitate the application of a broad array of changes in process, organization, and teamwork. An associate medical director position was created, with the responsibility of developing safety goals and an agenda for leading the department. This arrangement drew on the quality improvement literature, which demonstrates the association between developing broad and shared improvement goals and achieving substantial quality improvement, through the provision of administrative support to mine data fields for quality improvement purposes, having strong physician leadership and using credible and timely data feedback [11].

Medical Education

The inclusion of the director of medical education within Denver Health's Department of Patient Safety and Quality reflects the criticality of oversight of medical education in effectuating improvement in health care quality. Physician-trainees are at the hub of many care delivery systems, especially in safety net hospitals and academic medical centers. Housestaff education is therefore an important ongoing topic which is inextricably related to the provision of high quality and safe care. Thus, medical trainees must work in concert with evidence-based quality initiatives. This has been facilitated at Denver Health by the components of team rounding, increased emphasis on attending oversight, checklists and computerized physician order entry (CPOE) with standard order sets. Moreover, the Accreditation Council for Graduate Medical Education (ACGME) now mandates housestaff work hour restrictions and therefore an increased level of attending supervision.

Infection Control

The inclusion of infection control in Denver Health's Department of Patient Safety and Quality reflects a growing recognition of the severity of hospital acquired infections. An infectious disease physician with epidemiology training was appointed to

Table 18.1 Approach used to address high-risk and high-opportunity clinical settings at Denver Health

High risk/high opportunity	Approach
Failure to rescue	Clinical triggers/rapid response system
Medical problems on surgical services	Hospitalist co-management or consultation
Antibiotic overuse or misuse	Antibiotic stewardship program Mandatory consultation for specific conditions/ situations
Central-line infection	Checklists/posting of results
Venous thromboembolism	CPOE-embedded prophylactic therapy guidelines

head infection control and was supported by qualified infection control nurses. This structure facilitated the implementation of interventions in high risk areas discussed below. Previously, infection control was in the Department of Medicine. Of note, in this regard, sterile processing was just recently moved from the nursing department into the Department of Patient Safety and Quality, to further maximize this national synergy.

High Risk/High Opportunity Areas

The third element in Denver Health's approach to creating quality and safety was programs to manage high risk and/or high opportunity areas. This reflects the notion that safety is not only freedom from injury or damage but also the freedom from the risk of injury or damage. Some of the high risk/ high opportunity areas chosen were those identified from the literature which were of clinical relevance at Denver Health (Table 18.1). Each is discussed below.

"Failure to rescue" refers to failure to identify patients who are deteriorating and to intervene in a timely manner to prevent their deterioration. In a recent study of postoperative morality, "failure to rescue," rather than the number of complications, was the key variable in explaining differences in mortality rates across hospital [12]. Thus, we opted to institute a rapid response system (RRS) to identify and intervene for such patients and intervene in their care. Given that the literature only showed modest evidence of success for the commonly accepted rapid response team approach, Denver Health opted for a variation therein. We defined our own "clinical triggers," such as a systolic blood pressure less than 90 mmHg, which would trigger activation of RRS. However, our system did not involve a separate team of responders. Instead, it utilized the patient's intern and resident teams who were called by the patient's nurse, in response to the presence of a clinical trigger. Then in a structured and ordered sequence team members were expected to evaluate the patient at *his or her bedside* within 10 min of the nurse's call. Using this new rapid response system, Denver Health reduced its cardiopulmonary arrest rate from a median of 5.9 per 1,000 discharges to 2.2 per 1,000 discharges ($p < 0.001$). The number of patient who required transfer back to the intensive care unit within 48 h after being moved to

hospital floor units also decreased significantly, from 4.62 to 3.27 per 100 intensive care unit transfers ($p = 0.03$) [13].

Furthermore, we initiated hospitalist co-management or consultation for all patients on the orthopedic service, patients on low-volume inpatient surgical specialty services, such as oral maxillofacial, bariatric surgery and urology, as well as patients on the psychiatric ward with medical comorbidities. This facilitated the care of their medical problems, such as diabetes or cardiac disease, by providers whose expertise was in these areas.

Antibiotic Use

Another Denver Health quality and safety initiative was related to infectious disease care. Antibiotic use is considered one of the most important aspects of infection control and their overuse and underuse have both been deemed by the Joint Commission to be a significant barrier to quality improvement. Almost 60 % of Denver Health's inpatients were being treated with an antibiotic during their hospital stay. Therefore, a formal and robust antibiotic stewardship program was established to provide careful oversight and guidance to our clinical services who were using antibiotics. The approach spawned new programs, including mandatory infectious disease consultation for certain common and serious infections; concurrent and timely feedback to a prescribing team when multiple antibiotics were used for the same patient; new rules-driven guidelines embedded within our computerized physician order entry system for common inpatient infections such as pneumonia and cellulitis; and formal weekly infectious disease consultant rounds with intensive care unit teams.

As a result, Denver Health's antibacterial drug use, in days of therapy per 1,000 patient days, was the lowest of 35 US academic health centers reporting through the University HealthSystem Consortium [14]. Moreover, proper treatment has increased and adverse consequences from illness have decreased for the highly prevalent *Staphylococcus aureus* bacteremia [15].

Venous Thromboembolism Prophylaxis

Another high risk hospital acquired condition is venous thromboembolism (VTE), blood clots occurring after surgery. These blood clots are the most common preventable cause of hospital deaths, and their prevention results in a cost avoidance of $25,000–$40,000 for each VTE prevented. A week long Lean 'rapid improvement event' (RIE) focused on the proper and cost-efficient utilization of prophylactic anticoagulation in high risk inpatients. Low molecular weight heparin (LMWH), a blood thinning medication used to prevent this complication, had become the most costly line item in the hospital pharmacy's budget. Yet, Denver Health incidence of postoperative VTE was significantly worse than national benchmarks. The RIE

produced an evidence-based risk assessment tool and clinical practice guideline which were embedded into CPOE admission order sets. Thereafter, compliance with the guideline began approaching 100 %, overall utilization of LMWH decreased more than 60 % and Denver Health's occurrence of VTE achieved a UHC ranking for VTE in the top 10 % of outcomes [16]. Indeed many of the aforementioned patent safety strategies, which have been instituted at Denver Health, are amongst the recently released group of strategies which have been endorsed for immediate application by the AHRQ and an international panel of stakeholders [1], intended to promote optimal patient safety in patient care settings.

Ambulatory Care

The aforementioned interventions have all focused on hospitalized patients. Improving ambulatory care poses very unique challenges [17]. Despite the fact that there are 900 million outpatient visits versus 35 million hospital discharges [18], there has been less effort directed towards outpatient quality improvement. However, with the growing focus on medical homes and health reform's emphasis on accountable care organization, it is crucial that high quality safe care is also delivered to outpatient populations which heretofore had been relatively neglected [19]. Indeed, the very nature of ambulatory care safety lapses is different than those in the hospital practice both in the nature of the errors, i.e, diagnostic versus treatment errors and in the nature of the patient provider relationship. Yet, ambulatory patient safety was also a priority at Denver Health because the initiatives in this area have been encouraged by Denver Health's integrated delivery system and HIT system, along with a robust data warehouse and dynamic patient registries. For example, Denver Health has a very mature immunization registry enabling an 88 % immunization rate in the 1 year olds served by our system. Denver Health was awarded the prestigious Codman Award by the Joint Commission for this effort. There are similar registries for asthma, trauma, cancer screening, hypertension, diabetes, anticoagulation and an obstetric care, with the newest one being in the area of chronic narcotic usage. These registries effectuate improved quality by providing aggregated point of care performance data by clinic site and by clinician to avail data to audit and provide timely, concurrent and specific feedback. The cancer registries' patient-specific data serve as a visual prompt to the physician, during a patient encounter, to bring current breast, cervical and rectal cancer screening at the appropriate time and generate automatic notifications of patients if they miss scheduled testing. Thus, these registries are also tools for the proactive management and outreach to patients between visits to improve clinical indicators which may be suboptimal such as reminders about cancer screening. As an example, almost 75 % of Denver Health patients with hypertension have their blood pressure controlled compared to 50 % of Americans, and Denver Health record of hypertension control has exceeded the national rate for many years running.

Standardized Care Through a 'Lean' Approach

The fourth element in Denver Health's approach was a reduction in variability in patient care processes, such as the administration of preoperative antibiotics. This was achieved both through meaningful utilization of health information technology and the implementation of Lean's core concept of standard work, which is concept that there is one consistent way to do a process. Despite the usefulness of computerized physician order entry systems, only about 20 % of health care institutions have implemented them, and even fewer are using these systems with decision support-reminders and links for physicians about guidelines and best practices. Denver Health has had computerized physician order entry systems for almost 8 years and has linked these systems with standard order sets to enable evidence-based care as the standard approach. Computerized physician order entry systems eliminate handwriting errors; enable pharmacies to check doses, allergies, and drug interactions; and produce clinician alerts. Approximately 250,000 inpatient orders are entered each month into the Denver Health system.

As a result of this structured approach to quality and safety, Denver Health was ranked number one out of 111 academic medical centers with the lowest (0.55) observed to expected (O/E) mortality ratio- in the 2011 University HealthSystem Consortium's (UHC's) ranking. Moreover, in 2011 Denver Health was the first true safety-net hospital to be in the top ten of UHC's annual Quality and Accountability Aggregate Score and thus became the only one ever to be the top ten 2 years running when Denver Health again placed in that lofty level in 2012. Of note, in 2008 Denver Health was ranked only 28 in this indicator. Every subsequent year since, Denver Health has been in the top 5 % of UHC hospitals with some of the lowest morality rates, despite the fact that the vast majority of UHC hospitals are not of the true safety-net type. In addition, in 2011 the Colorado Department of Public Health and Environment released the most current (2007–09) risk-adjusted trauma inpatient morality for all level 1 trauma facilities in Colorado. The mortality rate for Denver Health was the lowest in the state, with a mortality odds ratio of 0.74. Therefore, although the demographics of Denver Health's patient population predict health care disparities, which can be associated with an impediment to achieving the intended outcomes of a systems quality and safety program, this has not been the case at Denver Health.

Cardiology

A few other examples of Denver Health's commitment to quality and safety now follow, which may be somewhat unexpected for a safety-net hospital. These provide a glimpse of some unique Denver Health initiatives which add to the cache of programmatic breadth at our safety-net.

With the aging population, coronary artery disease (CAD) and chronic heart failure (CHF) represent a substantial burden to both inpatient and ambulatory care

delivery [20]. Denver Health therefore initiated a quality improvement program designed to ensure successful transitions of care within its integrated system. The cardiac risk reduction program (CRRP) was founded in 2000 and sought to enhance guideline-based care for patients hospitalized with CAD, particularly acute myocardial infarction (AMI), and acute exacerbations of CHF. The CRRP is a nurse-managed initiative integrated into our broader quality program to ensure Joint Commission benchmarks are met. Since its inception, almost 7,000 CAD and CHF inpatients have been served by the program which entails point-of-service nurse education and closely supervised post-discharge follow-up visits. Once care is optimized, patients are transitioned directly into primary ambulatory care at one of Denver Health's federally qualified community health centers (FQHC).

The CRRP program also participates in the nation's largest inpatient quality improvement program, the American Heart Association's Get with the Guidelines program as a safety-net. Denver Health was among the first hospitals to demonstrate temporal improvement in a bundled metric of cardiovascular care quality [21]. A number of key program components have enabled program sustainability. First, there is a strong multi-disciplinary team which meets monthly and includes representation from Cardiology, Hospital medicine, the Chief Medical Resident, Nursing Quality and Administration, Pharmacy, as well as ad-hoc participation of Managed Care. Second, we utilize 'multiply redundant systems' to ensure eligible patients are recognized on admission. Although many patients are identified through direct nurse-manager participation in coronary care unit rounds and through direct referral by inpatient physicians, daily electronic alerts are provided in real-time via our electronic medical record system for AMI and CHF patients. This alert system is based upon a matrix of presenting symptoms, initial assigned diagnosis, and a past history of CAD or CHF. Moreover, the nurse program manager receives electronic alerts within 24-h from the echocardiography laboratory of any inpatient with a left ventricular ejection fraction of <40 % and reviews a daily medical resident physician sign-out logs to ensure eligible patients are not missed. A unique program feature is the provision of concordant cardiology care. That is the nurse manager generally schedules post-discharge visits on days when the patients' hospital-based Cardiologist is staffing that outpatient care transition cardiology clinic. In this way, greater familiarity, continuity, and trust are afforded, given the myriad of social complexities inherent in caring for a safety net population.

Because approximately half of cardiovascular inpatients at Denver Health Medical Center are uninsured [21], the CRRP, was initially funded solely by external grants and charitable contributions. In order to secure ongoing institutional support within the framework of our Lean processes, we conducted a randomized trial (Clinicaltrials.gov identifier NCT00381030) to assess outcomes with this model among patients hospitalized with CHF. Inpatients were randomized to the CRRP intervention or usual care. Usual care patients were scheduled for follow-up in Cardiology or Primary care clinic at the discretion of their attending physician. CRRP patients were seen by a single nurse manager once during hospitalization to establish rapport, provide counseling, and initiate low-dose β-blocker prior to

discharge. The nurse program manager then saw the patient within 2 weeks post-hospitalization, and at 2-week intervals thereafter to optimize care. The program was in concert with the Joint Commission quality of care bundled metric for heart failure, as it reinforced medication adherence, smoking cessation, weight monitoring, dietary salt restriction, and provider contact should symptoms worsen. Among 64 patients randomized, NYHA functional class and β-blocker utilization were significantly improved in the intervention group at 6-months and CHF re-hospitalizations were significantly reduced by 84 % compared with usual care. A trend towards greater improvement in left ventricular ejection fraction and time to death or heart failure hospitalization was also observed. Although the present Joint Commission guidelines emphasize only ACE-inhibitor therapy among CHF inpatients with LV systolic dysfunction, these data reinforced a strategy that included inpatient β-blocker therapy and validated our nurse-led approach to care that bridges both inpatient and outpatient arenas.

Given success in the CHF care arena, Denver Health provided institutional support for a comprehensive program in 2007, which presently includes the nurse-manger, a nurse-practitioner, and two exercise physiologists who constituted a nascent cardiac rehabilitation program. This combined effort is termed the Healthy Hearts program. From 2010 to 2012, a follow-up visit with Healthy Hearts was associated with an annual readmission rate of just 5.3 % in patients with CHF markedly less than published national averages upwards of 20 %. By contrast, those who did not complete a visit had a 15.6 % readmission rate. Although this difference may in part reflect selection bias, such observational data coupled with the significant reductions in hospitalization the setting of a randomized, controlled trial, suggest that Denver Health's cardiovascular quality improvement program is effective. This is particularly relevant in the era of pay for performance where reimbursement will be tied to rehospitalizations rates, which will be challenging for safety net institutions, and the vulnerable patient populations that they traditionally have served.

Cardiac rehabilitation is often not a formidable presence at safety net institutions given expense and limited reimbursement for underserved patients. Our program has recently been certified by the American Association of Cardiovascular and Pulmonary Rehabilitation. Among participants in 2012, greater improvements in exercise capacity, quality of life, and biometric data (lipids, blood pressure) relative to 149 other US rehabilitation facilities of similar size was demonstrated for Denver Health. Although our rehabilitation program is small, it has become an integral part of the overall Healthy Hearts program where AMI, cardiac surgery, and increasingly CHF patients (although not reimbursed by CMS) now have access to Phase I -III cardiac rehabilitation services. It represents another mechanism to bridge the potential gap between inpatient acute care and ongoing outpatient prevention efforts. Because the individual components of Healthy Hearts are inextricably linked within Denver Health's vertically integrated system, this ensures comprehensive and equitable cardiac care for all patients in need.

Uncompensated Care

The amount of uncompensated care that Denver Health, delivered to uninsured patients increased from $275 to $338 million from 2007 to 2010 [22] and peaked at $487 million in 2012, creating challenges to institutional solvency during the ongoing recession. Complicating matters, the Hospital Readmissions Reduction Program of the Affordable Care Act ties a hospital's payments to readmission rates—where 1-month readmission rates are significantly higher at safety net hospitals [23], creating a new threat to safety net hospital viability. Given these challenges, the current Healthy Hearts program at Denver Health could serve as a successful model for other safety net systems seeking to reduce hospitalization rates among the nation's poor and underserved patients with cardiovascular disease. It along with Denver Health's successful trauma outreach, its widely recognized quality and safety program [24], provide margin to effectuate high quality and safe patient care.

'ACUTE'

Another unique program which demonstrates overall creativity which is possible from a safety-net hospital, is a national referral center for the medical stabilization of patients with severe eating disorders (EDs). The 'ACUTE' Center for Eating Disorders at Denver Health, which started in 2008, is under the leadership of Dr. Philip Mehler, an expert in the medical complications of anorexia and bulimia nervosa. The inpatient unit at Denver Health provides care for some of the most medically unstable and medically ill eating-disordered patients in the United States, and internationally. All patients admitted to ACUTE are insured or private-pay, providing a unique source of revenue within a safety-net hospital that operates on extremely thin margins. Since its inception, nearly 300 patients have received care at ACUTE, with the vast majority transferring directly to a specialized eating disorder center once medially stable.

Patients are often severely ill upon admission to ACUTE, presenting with dangerous electrolyte derangements, and frequently at less than 50 % of ideal body weight, with body mass indexes (BMI) of <8, at the time of admission. After a prolonged period of starvation, these patients are at risk for life-threatening cardiac arrhythmias and refeeding syndrome, among other complications, and must be monitored very closely upon commencement of caloric intake. If these patients are mismanaged, the consequences are often extremely distressing and harmful to the patient.

Hospitalization at ACUTE involves daily multi-disciplinary care by several providers, including one of four hospitalist physicians who specialize in internal medicine and have taken a keen interest in the medical management of EDs. Patients are seen daily by one of two dieticians and a psychologist, and a psychiatrist from an outside facility visits the patients three times weekly regarding medication management. Inpatient physical therapists work with each ACUTE patient, and Denver

Health surgeons and medical subspecialists are available for consults on an as-needed basis. ACUTE patients are admitted to one medical unit of the hospital where the registered nurses and certified nursing assistants have shown an interest in learning about and working with the ED population. All providers and staff involved with ACUTE also spend a portion of their clinical time caring for the general patient population at Denver Health, primarily the under- and uninsured.

Ultimately, patients with anorexia and bulimia nervosa are in need of aggressive, comprehensive treatment aimed at their underlying psychiatric disease. However, patients' medical instability and extreme low body weight often preclude their appropriateness for treatment within a traditional eating disorder center in the United States. Given the relative rarity of medically unstable patients with eating disorders, knowledge of the proper approach to treatment is not widespread among medical providers. Many patients present to ACUTE with disturbing stories of past medical hospitalizations complicated by the development of life-threatening refeeding syndrome. At ACUTE, highly specialized, expert care is provided for a unique subset of patients [25]. This mutually beneficial relationship offers these eating disordered patients the optimum medical care available while also providing a vital source of revenue for Denver Health.

Take-Home Message

The Denver Health experience demonstrates that excellent patient quality and safety can be advanced within America's health care institutions, even among those entities, the safety-net systems, which are challenged by lack of resources and by socially complex patients. Denver Health demonstrates one pathway and model to achieve the deliverance of high quality and safe patient care [26]. Its integrated system of care, employed medical staff, and strong health information technology infrastructure has allowed the creation of a structured approach to patient safety and quality of care.

References

1. Shekelle PG, Pronovost PJ, Wachter RM, McDonald KM, Schoelles K, Dy SM, Shojania K, Reston JT, Adams AS, Angood PB, Bates DW, Bickman L, Carayon P, Donaldson L, Duan N, Farley DO, Greenhalgh T, Haughom JL, Lake E, Lilford R, Lohr KN, Meyer GS, Miller MR, Neuhauser DV, Ryan G, Saint S, Shortell SM, Stevens DP, Walshe K. The top patient safety strategies that can be encouraged for adoption now. Ann Intern Med. 2013;158:365–8.
2. Powell AA, White KM, Partin MR, Halek K, Christianson JB, Neil B, Hysong SJ, Zarling EJ, Bloomfield HE. Unintended consequences of implementing a national performance measurement system into local practice. J Gen Intern Med. 2012;27(4):405–12.
3. Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ. Temporal trends in rates of patient harm resulting from medical care. N Engl J Med. 2010;363(22):2124–34.
4. Jha AK, Orav EJ, Epstein AM. Low-quality, high-cost hospitals, mainly in South, care for sharply higher shares of elderly black, Hispanic, and Medicaid patients. Health Aff (Millwood). 2011;30(10):1904–11.

5. Shah JP, Valdes M, Rockey DC. Transformed and delayed care of patients with colorectal cancer in a safety-net system-manifestations of a distressed healthcare system. J Gen Intern Med. 2012;27(9):1142–9.
6. Hussey PS, Wertheimer S, Mehrotra A. The association between health care quality and cost: a systematic review. Ann Intern Med. 2013;158(1):27–34.
7. Warner RM, Goldman LE, Dudley RA. Comparison of change in quality of care between safety-net and non-safety-net hospitals. JAMA. 2008;299(18):2180–7.
8. McWilliams JM. Health consequences of uninsurance among adults in the United States: recent evidence and implications. Milbank Q. 2009;87(2):443–94.
9. Wachter RM, Verghese A. The attending physician on the wards: finding a new homeostasis. JAMA. 2012;308(10):977–8.
10. Lundrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek P. Temporal trends in rates of patient harm resulting from medical care. N Engl J Med. 2010;363(22):2124–34.
11. Bradley EH, Holmboe ES, Mattera JA, Roumanis SA, Radford MJ, Krumholz HM. A qualitative study of increasing beta-blocker use after myocardial infarction: why do some hospitals succeed? JAMA. 2001;285(20):2604–11.
12. Ghaferi AA, Birkmeyer JD, Dimick JB. Variation in hospital mortality associated with inpatient surgery. N Engl J Med. 2009;361(14):1368–75.
13. Moldenhauer K, Sabel A, Chu ES, Mehler PS. Clinical triggers: an alternative to a rapid response team. Jt Comm J Qual Patient Saf. 2009;35(3):164–74.
14. Pakyz AL, MacDougall C, Oinonen M, Polk RE. Trends in antibacterial use in the US academic health centers: 2002 to 2006. Arch Intern Med. 2008;168(20):2254–60.
15. Jenkins TC, Price CS, Sabel AL, Mehler PS. Impact of routine infectious disease service consultation on the evaluation, management, and outcomes of staphylococcus aureus bacteremia. Clin Infect Dis. 2008;46(7):1000–8.
16. Biffl WL, Beno M, Goodman P, Bahia A, Sabel A, Snow K, Steele AW, Swartwood C, Thienelt C, MacKenzie T, Mehler PS. Maximizing value and minimizing waste inpatient safety: "leaning" the process of venous thromboembolism prophylaxis. Jt Comm J Qual Patient Saf. 2011;37(3):99–109.
17. Leas BF, Goldfarb NI, Browne RC, Keroack M, Nash DB. Ambulatory quality improvement in academic medical centers: a changing landscape. Am J Med Qual. 2009;24(4):287–94.
18. Gandhi TK, Lee TH. Patient safety beyond the hospital. N Engl J Med. 2010;363(11):1001–3.
19. Bishop TF. Pushing the outpatient quality envelope. JAMA. 2013;309(13):1353–4.
20. American Heart Association. Heart disease and stroke statistics: 2012 update. Dallas: American Heart Association; 2012.
21. Krantz MJ, Estacio R, Mehler PS, Fonarow GC, Baker WA, Long CS. Comprehensive coronary artery disease care in a safety-net hospital: results of get with the guidelines quality improvement initiative. J Manag Care Pharm. 2007;13(4):319–25.
22. Gabow P. ACA and the safety net. Presentation at the National Health Policy Conference sponsored by Academy Health, Washington, DC, Feb 2011.
23. Common Wealth Fund. Higher readmissions at safety-net hospitals and potential policy solutions. 2012. Available at: http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2012/Dec/1647_Berenson_higher_readmissions_at_safety_net_hosps_ib.pdf. Accessed 4 Jan 2013.
24. Gabow PA, Mehler PS. A broad and structured approach to improving patient safety and quality: lessons from Denver Health. Health Aff (Millwood). 2011;30(4):612–8.
25. Gaudiani JL, Sabel AL, Mascolo M, Mehler PS. Severe anorexia nervosa: outcomes from a medical stabilization unit. Int J Eat Disord. 2012;45(1):85–92.
26. Mehler PS, Colwell CB, Stahel PF. A structured approach to improving patient safety: lessons from a public safety-net system. Patient Saf Surg. 2011;5(1):32.

Electronic Health Records and Patient Safety

19

Michael S. Victoroff

Pitfalls and Pearls

- When computers are embedded in high-performance systems, they fail just like people do, in sometimes simple but more often complicated ways.
- Blaming adverse events on "computer error" is like blaming them on "human error": These labels have no value in causation or remedy analysis.
- A starting point for the risk analysis of a given system is to look at what it is supposed to do when it works right, and anticipate what will happen when it works wrong.
- A lot of health information technology is designed with almost comical inattention to user experience. Clumsy interfaces are responsible for a large proportion of EHR-related errors. Ironically, users often are the safeguards that prevent errors and injuries from health information technology, rather than the other way around.
- Many design flaws ubiquitous among EHRs stem from their legacy as "cash registers" that create documentation for charge capture. Unfortunately, this business case continues to distort the design of systems, making clinical value a secondary goal.
- There is growing interest in systematically capturing reports of adverse events associated with the use of health information technology. These efforts will eventually produce theories about causes and patterns of EHR-related errors, design considerations, training issues, usability, interactions with users and systems, and other insights that will be useful in building a better generation of products.
- The single greatest concern about current tools for facilitating electronic documentation is their propensity for generating inaccurate records.

M.S. Victoroff, MD
Department of Patient Safety and Risk Management, COPIC Insurance Cos,
5195 E Weaver Dr, Denver, CO 80121, USA
e-mail: michael.victoroff@ucdenver.edu

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_19, © Springer-Verlag London 2014

Outline of the Problem

For every function, there is an equal and opposite malfunction.

Health information technology (HIT) has two faces with respect to patient safety. One regards ways HIT solutions can potentially improve almost every aspect of the patient experience, certainly including safety, but also convenience, timeliness, appropriateness, effectiveness and cost of care, as well as furthering research. A growing body of research suggests HIT can improve clinical quality [1–6] and patient safety [7]. These benefits will grow exponentially as HIT proliferates. Just as aviation analogies have been valuable to students of healthcare safety, an analogy with the contribution of technology to aviation safety is perfectly apt. Bright days are ahead.

The other face of HIT is darker. It is a source of errors, injuries, impaired clinician productivity, dilution of effort and diversion of resources from pressing needs, and high costs—now and forthcoming [8]. It is not exaggerating to call the impact of HIT on healthcare prodigious.

This chapter focuses more on risk than benefits of HIT. Although the tone of what follows is cautionary, this imbalance must not be read as a polemic on the evils of automation. On the contrary, the author is an evangelist for EHRs, a former EHR developer and keen advocate of creative information technology. The infancy of any science entails missteps and embarrassments, and we are still in the early days of medical informatics. The pattern in the history of technology is net benefit to human well-being, and HIT will be in the ranks of mankind's most successful inventions.

That said, Newton's Law of Computing states, "*For every function*, *there is an equal and opposite malfunction*." Any combination of hardware, software and humans will produce an undesired result at some point. While the intent of technology is to improve the performance of tasks, information systems in healthcare must be thought of as *medical devices*, and should be developed and tested with the same caution as pacemakers, surgical tools or laboratory equipment.

What Is an EHR?

For this discussion, "Electronic Health Record" (EHR) is the current label for a category of health information technology that automates **clinical documentation**, the transmission of **orders**, **results and messages** and the delivery of **alerts**, **prompts**, **reminders** and other '**clinical decision support**' content to users at the time of care.

There are other ways to define EHRs, and there has been nit-picking over differences between EHRs and EMRs ("Electronic Medical Records") and other labels out of popular favor such as "Computerized Patient Records" "Electronic Patient Records" and even "Personal Health Records" (which are quite different). These nuances are responsible for some of the difficulty practitioners face when shopping for systems. When the American Recovery and Reinvestment Act (ARRA, 2009) [9] began offering subsidies to providers for installing EHRs, it had to define exactly what an EHR was for purposes of reimbursement. But, the discussion in this chapter does not depend on any particular definition and none will be provided beyond that above.

EHRs are merely a subset of a wide range of health information technology that this discussion will not address. Some tangential topics that are seriously important to patients and providers are going to receive less attention than they deserve.

In particular, this chapter largely avoids hazards falling under the rubrics of privacy and security. Although patients can suffer grievous harm from the disclosure of their personal information (and this risk does occupy a great amount of attention in the fields of technology, law and public policy), the dangers contemplated in this discussion are the most tangible kinds, such as bodily harm, disability and death.

Also ignored is much to do with the safety and regulation of medical devices like robots, diagnostic equipment and methods, radiological systems, implanted devices and many other varieties containing software that are not properly classified as "Electronic Health Records." The question whether (or which) software products should be considered "medical devices" for legal and regulatory purposes is currently an active focus of discussions between the U.S. Food and Drug Administration and the vendor community. There is no doubt that the FDA currently has legal authority to regulate software used for healthcare purposes. In the most general sense, the agency foresees software falling into three categories [10]:

1. Subject to regulatory review and standards applicable to medical devices
2. Some form of regulatory oversight is appropriate but not to the same degree as traditional medical devices
3. Regulatory review is not envisioned

What Is Safety?

No medical procedure, device or remedy is safe. For the purposes of this chapter, safety will be understood as the likelihood of a product or system performing as intended, without causing undue or unanticipated risk or harm. Patient safety is entwined with other problems like efficiency, effectiveness, cost and legal liability. There is no effort made here to keep them rigorously separate, although the focus of the current discussion is chiefly preventable risk and harm.

Obstacles

Several obstacles confront any attempt to analyze the impact of Electronic Health Records upon patient safety. First is scarcity of case material. Although EHR users are becoming familiar with a range of hazards, design flaws, malfunctions, inefficiencies and other shortcomings, and increasingly able to share anecdotes about near misses and injuries attributable to EHRs, there are currently few repositories of standardized reports about EHR-related safety events that have enough depth for comparative research. This chapter will touch upon some efforts to standardize reporting and develop a reliable epidemiology of EHR-associated errors.

Second, EHR-related events tend to be complex. Interpreting unanticipated effects typically requires input from both involved users and IT experts. Analyzing the root cause of an HIT event often blossoms into a justifiable exercise in onion-peeling. For example, a seemingly straightforward blunder—ordering the wrong drug through a dropdown-list-off-by-one selection error—should not naively be laid off to "user error." Factors like the font size of the list, the stability of the menu, the dimensions of the selection zone, spacing between items, number of items displayed, number of characters in their names, color, margins, user familiarity with the system, lighting and location of the terminal, sensitivity of the pointing device, and similar usability factors can play critical roles in error rates. As the aviation industry has learned, when "pilot error" falls into a pattern, someone needs to ask whether something in the cockpit might be inducing pilots to make mistakes.

Third, like everything in the field of patient safety, data gathering and review take place under the shadow of potential legal liability. Ironically, misgivings about reporting are a barrier to safety research. This problem is amplified when technology is involved because product liability potentially raises the stakes for damages into a higher range than ordinary malpractice. This risk (and the lack of legal sanctuaries for professional discussion) inhibits developers and vendors from forthrightly addressing (or even sometimes acknowledging) flaws in their own systems, or participating in reporting networks. For this reason, investigators with the best intentions wishing to study HIT hazards face a perverse inhibition. Since public analysis generates discoverable records, some see open discussion as counterproductive because it could draw roadmaps for litigators. On the other hand, from the standpoint of users and patients, there is not enough dialog about hazards of HIT products, some of which exhibit audaciously poor design.

At this writing, relatively few legal claims for patient injuries have been directly attributed to HIT, even when sophisticated analysis points to technology as a contributing factor. But, this may change, as electronic systems play ever larger roles in the way care is provided.

Risk Assessment

What follows is a catalog of safety risks to patients that can be induced by EHRs common in the U.S. today. There is no reason why EHRs in other countries would not be susceptible to the same vulnerabilities. Not every risk applies to every system, because of differences in feature sets, configuration, implementation and myriad other factors that are fluid. Vendors and products are not identified. And, there is no attempt to create a hierarchy of severity. It is well known that trivial errors can give rise to serious harms, and catastrophic failures can be intercepted without causing any harm. Since the stream of reports and issues grows daily, it is impossible to create anything like a comprehensive survey or even a "top ten" list of dangers to watch out for. In fact, every organization's "top ten" EHR risks should differ from the organization's next door. The message for CEOs, CIOs, CMIOs, CNIOs, Safety and Privacy Officers and the rest of the army of Os responsible for EHRs is, "If you are complacent that you've solved the top ten problems in your organization this year, you're going to get blindsided by the eleventh."

There are two ways to build a list of EHR risks: (1) Predicting them from insight into system functions, and (2) by collecting actual event reports.

"Capability Is Vulnerability"

To predict potential hazards of a technology, a good start can be made by examining what its functions are when they operate correctly and imagine them operating incorrectly. The formal exercise of *risk analysis* entails a 360-degree survey of a healthcare provider's information environment and itemizing known and potential hazards to the "confidentiality, integrity and availability" of electronically stored Protected Health Information (Box 19.1) [11].

Box 19.1
Confidentiality: PHI is accessible only by authorized people and processes
Integrity: PHI is not altered or destroyed in an unauthorized manner
Availability: PHI can be accessed as needed by an authorized person

This process is required under the Security Rule which is a component of the Health Insurance Portability and Availability Act of 1996 (HIPAA) [12]. A careful risk assessment will evaluate *vulnerabilities*, *threats*, *risks and impacts* (Box 19.2) [13].

Box 19.2

Vulnerability—A weakness that provides an opening for a harmful event.

Weakness in an information system, system security procedures, internal controls, or implementation that could be exploited by a threat source.

Threat—Something that can cause a harmful event.

Any circumstance or event with the potential to adversely impact organizational operations (including mission, functions, image, or reputation), organizational assets, individuals, other organizations, or the Nation through an information system via unauthorized access, destruction, disclosure, or modification of information, and/or denial of service.

Risk—The likelihood of a harmful event happening.

A measure of the extent to which an entity is threatened by a potential circumstance or event, and typically a function of: (i) the adverse impacts that would arise if the circumstance or event occurs; and (ii) the likelihood of occurrence.

Impact—The kind of effect a harmful event would have on people, organizations and property (e.g., legal, operational, reputational, business or financial).

The magnitude of harm that can be expected to result from the consequences of unauthorized disclosure of information, unauthorized modification of information, unauthorized destruction of information, or loss of information or information system availability.

Parallel with risk assessment is the task of enumerating the *safeguards* in place—and safeguards needed—to defend against vulnerabilities. Safeguards fall into 3 general domains (Box 19.3).

Box 19.3

1. **Physical safeguards**—Locks, doors, keys, fences, ID badges, signs, emergency power supplies, receptionists, guards, etc.
2. **Technical safeguards**—Anti-virus, encryption, passwords, firewalls, software updates, access control lists, offsite backup, etc.
3. **Administrative safeguards**—Training, policies, audits, IT support, credentialing, background checks, disaster plan, etc.

A detailed discussion of information technology risk assessment methods, standards and guidelines is beyond the scope of this chapter. Many resources are available to technology professionals, administrators and end users; a few are listed in Box 19.4.

Box 19.4
Office of the National Coordinator for Health Information Technology (ONC)
- www.HealthIT.gov
- Mobile devices: www.healthit.gov/providers-professionals/how-can-you-protect-and-secure-health-information-when-using-mobile-device
- Security and risk auditing: www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidancepdf.pdf
- Meaningful Use Security and Privacy Requirements: www.hrsa.gov/healthit/toolbox/HIVAIDSCaretoolbox/SecurityAndPrivacyIssues/howdoicomplywitmu.html

Office for Civil Rights
- Health Information Privacy/HIPAA resources: www.hhs.gov/ocr/privacy/index.html
- Basics of Risk Analysis and Risk Management: www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/riskassessment.pdf
- Guidance on Risk Analysis Under the HIPAA Security Rule: www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidancepdf.pdf

The National Institute of Standards and Technology
- A wealth of information available for download about security and the risk auditing process: http://csrc.nist.gov/
- Guide for Conducting Risk Assessments http://www.nist.gov/manuscript-publication-search.cfm?pub_id=912091

The Agency for Healthcare Research and Quality (AHRQ)
- Standardized reporting formats for patient safety events, including HIT-specific events
- Software and device reporting form: https://www.psoppc.org/c/document_library/get_file?uuid=75912503–7bd1–4e99-a678–5dbb70008e95&groupId=10218
- Hazard Manager: http://healthit.ahrq.gov/sites/default/files/docs/citation/HealthITHazardManagerFinalReport.pdf

Capturing Event Reports

A second way to identify risks is to analyze adverse events that have actually occurred. Among the challenges to research on EHR safety is the lack of a standard taxonomy for classifying types of hazards and adverse events. A number of researchers are actively interested in creating theories, or at least a categorization schema, that would allow the sorting and classification of case reports. One model devised by Sittig and Singh [14] suggests an 8-dimensional "socio-technical" framework for evaluating events involving HIT systems (Box 19.5).

Box 19.5. Sociotechnical Framework
- Hardware and software computing infrastructure
- Clinical content
- The human computer interface
- People
- Workflow and communication
- Internal organizational features (e.g., policies, procedures, and culture)
- External rules and regulations
- Measurement and monitoring

The ECRI Institute [15] used another taxonomy devised by Magrabi et al. [16]. to help analyze over 3,000 reports of HIT-related patient safety events in Pennsylvania occurring 2004–2012.

Under the authority of the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) [17] the Agency for Healthcare Research and Quality (AHRQ) coordinates the development of a set of Common Formats for reporting patient safety events to Patient Safety Organizations (PSOs) [18]. One set of CF templates is dedicated to HIT-related events. Using these formats, AHRQ is building a repository of reports from PSOs. Data on EHR-related safety events are also being collected in various formats by the Canadian Medical Protective Association (CMPA), the Physician Insurers Association of America (PIAA), COPIC, Inc. (whose taxonomy has been used in research at the University of Colorado [19]) and other quality and safety organizations. However, as yet there is no central repository where researchers can access a full spectrum of cases.

Limitations of the Current Practice

Medical Documentation Systems

The core of a medical information system is the documentation of physician-patient encounters. Against all intuition, it is difficult to quantify the value of the medical chart strictly in terms of safety. Of course, there are innumerable instances where missing information at the point of care resulted in preventable harm [20]. Malpractice archives (and cemeteries) are full of stories that would have been different, "If only the doctor had known . . ." It would be absurd to deny the importance of records in the process of care. But, the convoluted data gathering rituals that support medical practice generate such redundancy that they function as superior error-trapping mechanisms, so missing information does less harm than might be expected.

Providers are accustomed to untrustworthy information; they are trained to expect it and develop portfolios of techniques to compensate for never having a complete data set for the patient before them. The "Oslerian conceit" is that a skillful practitioner should be able to extract a "complete history" from a patient during the course of an oral interview. The fallacy of this notion should be obvious in the

modern world, in which patients may have only vague and limited technical information about their own care; or whose care has been so extensive that memory is next to useless. Today's medical graduates are accustomed to looking for records to orient themselves to a patient's situation, and using the interview primarily to refine it. But, the fallacy of the latter approach is that the quality and completeness of available documents can be very weak.

Data Loss

Despite these practical shortcomings, it is obvious that better information at the point of care supports better care altogether. Therefore, the definitive risk to the "confidentiality, integrity and availability of electronically stored information" is that of losing it. This can be accomplished in countless ways, of which the simplest is physical destruction. Of course, paper records are vulnerable to the same risk. The great advantage of electronic information is the ease of duplicating it and keeping authentic copies in several locations. Unfortunately, cases still regularly surface from organizations that failed to make adequate provisions for data backup. This is essentially inexcusable in today's technology-dependent world. Both local and offsite copies of critical information are inexpensive and easy to create, and should be cardinal elements of any I.T. infrastructure.

Patients have a right to their records. In one instance, a patient moving out of town filed a state medical board complaint against a doctor who could not give her a copy of her chart. The office EHR had suffered a hard drive failure and some records were permanently lost. The patient argued that this fell below an acceptable standard of practice.

Data Dropped in Transition

The implementation phase of a new electronic system is a time of high risk for data. At least one appellate court case addressed an injury caused when key information from a legacy paper chart (manually summarized) did not make it into the electronic version of the patient record, and necessary treatment was delayed. The court confirmed provider liability, concluding that an organization installing an EHR is responsible to "implement a reasonable procedure during the transition phase" to ensure that data isn't lost [21].

Data Conversion

Transitions in healthcare are not occasional but routine. Patients establish themselves in practices, then move, graduate, get married, change jobs, change insurance, change doctors, retire. Likewise doctors, hospitals and systems are in continuous flux. Today, 25 % of EHRs are being installed to replace a prior EHR, and the pace of this churning will increase over time. Unfortunately, the internal database structures and definitions of each EHR are different (despite serious efforts to create data exchange standards). This makes mass conversion of a dataset from one EHR to another extremely difficult and highly risky from the standpoint of data integrity. The same problem applies to data interchange between institutions. The process of **mapping** information from one system to another is fraught with problems, because no two systems define or store the same data in the same way. A single mis-matched field out of many thousands can set an error in motion in patient care.

Data Deletion

Data loss can occur during normal operations through operator error, routine purging and archiving, import/export and file updating processes, as well as numerous types of software malfunctions. Many systems have provisions for restoring deleted data, but there are instances where retrieved files are older or incomplete versions of the ones lost. The author was involved in a disaster in which 6 months of patient records in a large orthopedic practice were wiped away when a technician reconfigured a drive without knowing what it contained.

Data Corruption

In another case, an EHR software version upgrade corrupted several thousand patient charts in a small practice. The data on individuals apparently remained, but was scrambled into records under different names, and the vendor apparently was not able to find a way to undo the damage. This case was complicated by the fact that the mixup was not recognized until several rounds of backups had been made, so the backups were corrupt, too. (A pre-update copy of the data was not stored.) Although the vendor accepted responsibility for the costs of installing a new system, it did not agree to any liability for the cost of re-creating several thousand charts, or—more concerning to the practice—liability for any consequential injury to patients that might arise from lost information.

Disaster, Malice and Coffee

Among infinite other causes of data loss are power surges and blackouts, flood, fire, storm, untrained users, misplaced devices, mechanical failures, deliberate sabotage by disgruntled employees, hacking, cyber terrorism and every kind of accident. During hurricane Katrina, millions of patient records in New Orleans (paper and electrical) were lost to water damage. Defenses against record loss include physical safeguards (locks, fire extinguishers), technical safeguards (backup, more backup) and administrative safeguards (planning, training).

Cloud Computing

Cloud computing is an arrangement in which patient data (and sometimes the programs that run the data) are kept on secure servers in a remote location, allowing users to access them through a communications network (usually the Internet). This avoids many risks of locally stored data, and reduces expenses of local administration, security, backup, etc. However, if network access becomes unavailable (for example in a storm), or if connectivity fails for technical reasons, all remote data is out of reach.

Data Displacement

Rather than actually being lost, information may simply not be found. Since there is no standard architecture for EHRs, the location of specific types of information is left to the vendor, designer, configurator, and individual user. In one effort to audit about a million patient records with the goal of simply tabulating the occurrence of flu shots, reviewers found they needed to inspect at least 27 different locations in the chart to say confidently whether a shot had been received (Wilson Pace, MD (2010), personal communication). The information might be in the immunization log, or a medication administration record, a nurse's note, a pharmacy order, or perhaps in the medical assistant's comment, "*Patient states flu shot at pharmacy last week*."

If this is a problem with flu shots, how much is the ante raised for items like anticoagulants, near fatal drug reactions, rare diseases, and so on? Many patients have a powerful illusion that EHRs give providers access to "everything" (including things that may not be there at all). But, actual users know that having a giant repository of data is not the same thing as "access." Our ability to collect information far exceeds our ability to retrieve it.

Data Sequestration

The law in its wisdom can mandate things that are technically impossible. With the best intentions, HIPAA allows patients to restrict disclosure of specific portions of their medical records because of sensitivity or other reasons. Some state laws (which generally grant parents the right to view their children's protected health information), nevertheless forbid parental access to some types of minors' information (e.g., treatment of sexually transmitted disease, pregnancy, drug abuse, psychiatric conditions). In spirit, this notion is laudable. However, not only is there currently no technology that can automatically dissect out the bits of information deemed "sensitive," but the very concept of redacting selected threads of data from an integrated body of information without touching the remainder may be a physical impossibility, like taking the flour out of a cake.

From a safety standpoint, even if reliable redaction can committed upon a medical chart, clinicians need to be concerned about mistakes they can make if they rely on the doctored version—particularly if there is no indication that vital facts have been withheld. Sequestration presents particular safety challenges in the fields of—and to clinicians interacting with patients in—behavioral health and addiction medicine. Many drugs and conditions managed by behavioral health specialists have important ramifications for neurology, cardiology, endocrinology, nephrology, and other specialties, which can be missed or misinterpreted if not disclosed.

Data Breach

Potentially more injurious to patients than the loss of their information is the unintended disclosure of it. This can occur by accident (e.g., lost laptops), carelessness (e.g., online postings) or through active intrusion by hackers. Health facilities have become rewarding targets for cyber criminals. At this writing, healthcare data is the chief source of stolen identities in the U.S., as well as an ocean of fraud. Stolen insurance cards allow imposters to obtain services under false identities. Stolen physician credentials can be used to forge prescriptions. Most lucrative of all, patient identities and physician billing information can be combined to submit fraudulent charges to payers, a multi-billion dollar enterprise in which organized crime is deeply invested.

The vulnerability of healthcare operations to cyber-crime is partly due to the great amount of confidential data it distributes across numerous locations, the high volume of healthcare transactions adjudicated without human intervention, and a lesser degree of security-mindedness in the healthcare workforce than other industries that handle confidential information. But, the real dilemma is that the ethical obligations of patient care and safety take priority over privacy when the two conflict. For this reason, privacy and confidentiality are not perfectible goals for healthcare institutions.

Data Quality

A dramatic metamorphosis began to occur in the content of professional notation, as electronic records replaced paper charts. Some of the most powerful advantages and weaknesses of EHRs show themselves in this area.

It was recognized from the time of the first EHRs that the bottleneck was getting physicians to type. A primary design challenge for EHRs from the beginning has been to find ways to make data entry as easy as possible. Dozens of technologies have been incorporated into various EHRs to reduce the pain of documentation. Each of these has opportunities for errors and some can create outrageous errors. Generating notes has never been easier, including notes that are inaccurate and unreliable.

Unreliable Notes

The most serious risk to patient safety presented by EHR documentation is the creation of inaccurate records. While other risks (drug errors, misidentification, etc.) can also be catastrophic, the long-term, insidious accumulation of unreliable documents across entire populations can adversely impact not only individual bedside decisions, but health planning and management for entire populations.

Before electronic records, the most notorious shortcoming of clinical documentation was illegibility. Computer assisted notation has eliminated that terrible problem for all intents and purposes; but in so doing unroofed an abscess of other deficiencies that were certainly present all along. In addition, electronic documentation has enabled a new set of hazards that could never occur in a paper environment. These novel hazards meaningfully threaten patient safety, quality of care, the validity of data aggregated for research, and also weaken the credibility of records used in professional liability claims.

Many providers view note-taking as an unrewarding chore. While everyone appreciates a concise, relevant, well-written, informative note, creating one is an art form. For many reasons, the quality of clinical documentation across health care has never been optimal. Even ignoring the reality of variation among authors in writing skill, today at least two other major factors work against the quality of notes. The first is production pressure, which burdens practitioners with schedules that can be physically and ethically unsustainable. One of the first corners to be cut under time pressure is note writing. Also, medical records have become sustenance for a hoard of secondary consumers of clinical data, with financial, administrative, quality, performance measurement, epidemiology, public health, education and other agendas, each of which imposes its own interests on standards for documentation. Plus, the ever-present shadow of liability risk management hovers over the process. These and other forces—however legitimate—dilute the value of the medical record to practitioners. To be fair, many physicians have never given much attention to record review. But, low expectations for the value of records is not an incentive to improve them; hence the expectation is fulfilled that they aren't very useful anyway.

In the early days of EHRs, the FDA was confronted with the question whether to regulate medical documentation software in the same way as software incorporated in devices like EKG machines. At that time, there was a feeling that electronic notation systems were basically word processors, passively recording input from expert users. Any liability related to content was the responsibility of the author, not the machine designer. This differed from the regulatory approach to black box devices in which

software is embedded in such a way that its operation is not apparent to the operator. However, contemporary EHRs contain numerous automated features that give them capabilities—and vulnerabilities—far beyond any typewriter. Such features can operate outside the control of note-makers, and even against their intentions.

Auto-populated Text

Many technologies allow data fields to be populated with pre-recorded content. Names for these actions vary between systems, but their functions should be familiar to regular computer users (Box 19.6).

Box 19.6

Paste forward: Inserting content from a previous note (or the entire note) into the current note

Templates and macros: Pre-programmed commands invoke a series of actions, which could be to insert a text block, signature, etc.

The ways these features can misfire are fairly self-evident. The final result of a malfunction in documentation is inaccurate documentation.

Spell-Checking

Users of texting apps on smartphones are uncomfortably familiar with errors that can arise when the system substitutes its choice of a word for the one the user intended (and may even have typed correctly). Some word replacements are merely humorous, but some cause serious miscommunication.

Copy-Paste

Most systems allow a block of text to be copied and inserted elsewhere. This function can be manual or automatic, and is heavily used by providers [22] despite generating a high rate of errors [23]. It can be efficient (and more accurate) to copy a complex item from a previous note and drop it into the current one. This prevents transcription errors and insures that critical content receives attention. Used judiciously, this is a valuable feature. Problems occur when it is used to simply avoid creating a new note. In situations (such as multi-day hospitalizations) when lengthy notes are sometimes generated over and over with minimal changes from one to the next, it is tempting simply to enter a copy of the last note and edit it as needed. The potential for creating false documents is so real that the Veteran's Administration has issued policy cautioning providers about the use of this function [24].

Paste Forward

In the extreme form of copy-paste, some systems automatically append the text of the old note at the beginning of the new one. Either way, the obvious danger is incorporating stale or false data into the current note. In some cases practitioners (or juries) have been presented with long threads of records, containing snowballs of accumulated notes that mostly reflect past visits, sometimes with no attempt even to edit them with the current facts.

Pasting a prior entry can be a system function, or a manual process performed by users. In some settings where patients have prolonged stays generating many notes that can be largely similar from one to the next (intensive care, long term care, rehabilitation), providers may choose—or may be encouraged—to copy a previous entry and simply update the bits that have changed. The laws of nature assure that sometimes these necessary edits will not occur.

Templates and Macros

Found in both clinical documentation and also order-entry systems (discussed below), templates have tremendous value in prompting clinicians into remembering important elements of their history collection, differential diagnosis, therapy protocols, patient instructions, and similar packages of information. However, many EHRs exploit this capability by using it to generate highly detailed and seemingly complete (but pre-fabricated) records upon a click of a mouse. The danger arises when the "canned" documentation does not reflect the actual care provided. Also, sometimes it can reflect care that should not have been provided. Both errors mislead everyone later relying on the false record, including subsequent treating providers, researchers, and attorneys trying to reconstruct events for legal purposes.

To an extent, the compulsion to generate extensive documentation arises from the hijacking of the original mission contemplated for EHRs (as clinical support tools) to become cash registers for insurance reimbursement. It would not be wrong to say that EHRs would never have proliferated without a business case that justifies their expense by their ability to generate revenue. In a healthcare economy firmly rooted in the tradition of fee-for-service, provider compensation remains tied in several ways to the completeness of provider records. Another reason EHRs are sometimes built with excessively elaborate checklists is because of a notion that this helps defend against lawsuits. Both ideas are counterproductive.

Completeness is not the same as quality (Box 19.7). Imagine a patient with a sore ankle. According to the byzantine rules of coding, the physician might get better reimbursement if he/she documents an exam of the eyes and ears in addition to the leg. Doing a clinically inappropriate exam is a different ethical violation than documenting an exam that wasn't done (the offense against the patient is worse if a useless procedure was actually performed, but the fraud is worse if it wasn't).

Box 19.7

Name: Person, Edgar T. **MR #:** 34390228
DOB: 1984-06-14 **Sex:** Male

Visit: 2009-08-02
S: Sore R shoulder x 2 months.
O: X-ray – lucency head of R humerus.
A: Lytic?
P: Ortho.

William Osler, MD

Sparse but intelligible documentation

Some templates generate long lists of historical or physical findings that may have no conceivable relevance to a case, and just clutter the record with irrelevant nonsense (Box 19.8). A cluttered record is hard to use, and invites mistakes. Some templated records are so uniform, bland and wordy that clinicians simply don't read them. This defeats the entire clinical purpose of patient data. Secondary uses of the chart (e.g., billing, process measurement) can still proceed with false data, but their integrity is sabotaged.

Box 19.8

HAPPY CLINIC EHR HEALTH DATA RECORD P-21-489660000

Name: Person, Edgar T. **MR #:** 34390228
DOB: 1984-06-14 **Sex:** Male

CHECKIN TIME 14:23:22 | ROOM TIME 14:41:12 | PROVIDER TIME 14:59:16 | RECEPTIONIST: WD | NURSASST: MM | INSURANCE VERIFIED | CONTACT INFO VERIFIED | HIPAA INFO PROVIDED | CONSENT OBTAINED | 234.987-097F.0D-32P ver12.09.87655.

Visit: 2014-08-02

History: Denies parachute accident, bear attack, domestic violence, prior suicide, hallucinogenic mushrooms, family history of Chagas Disease; collects stamps. Sore R shoulder x 2 mos. Confirms: Allergy to potato, plays flute, family history of complications, adopted. ROS: No depression, rash, headache, chest pain, dyspnea, dysuria, dysphoria, paraphilia, erectile dysfunction, hematochezia, scotomata, tinnitus, seizures or chilblains. Likes fruit.

Exam: HEENT normal, CNN I-XIII intact, identifies vanilla, no dysdiadokokinesia, PERRLA, EOMs intact, visual fields full to confrontation, sclerae and conjunctivae WNL, thyroid normal size, firm, no masses, tongue protrudes in midline, teeth show a possible cavity in #12, jugular pulse wave is normal at 45°, PMI is in 4thICS without gallop, murmur or rub, soft 4thheart sound present, lungs present, abdomen present, liver percussion = 216 mm in L mid-clavicular line, spleen approx. 149 gm., genitalia appreciated, limbs x 4, R shoulder pain = 5.2/10, mental status exam deferred. X-ray: Lucency head of R humerus.

Assessment: 354.4, need rule out 170, probably not E906.3 or E845.0; still have to consider 079.9.

Plan: Patient informed of pros, cons, plusses, minuses, advantages, drawbacks and probable and possible consequences of things done, not done, contemplated, foreseeable and unforeseeable in the near and remote future. Agrees, understands and applauds treatment plan. Handouts given for flu shot, vision screening, smoking cessation and vasectomy. All conceivable questions answered in astonishing detail. Ortho referral.

TIME SPENT 00:03:08. DEPARTED 15:06:33 AMBULATORY. ELECTRONICALLY REVIEWED, SIGNED, LOCKED AND LOADED. I CONFIRM THAT I AM NOT COMMITTING ANY KIND OF FRAUD [WO] 2009.08.02:19:44:18 GPS 120798604.3287-986076 USDA CHOICE 2010.01.02

Extensive documentation; but unintelligible and unreliable

Structured vs. Narrative Data

In the older days, computers could not perform many operations on unstructured text. To make it possible to count, sort, tabulate and compute data, it was necessary to encode it into fixed-length fields of carefully defined types. The legacy of this limitation of early data processing is the persistence of the many code sets now in place to capture the vast majority of clinical data. There is at least one (if not a dozen) coding system for symptoms, diagnoses, procedures, tests, results, drugs, devices, outcomes, fees, settings, and practically every type of healthcare information captured, stored or exchanged. Almost all of this data is expected to be encoded by users.

Programmer demand for well-structured data made a marriage with practitioner demand for efficient data entry. The result is now a plethora of interfaces that allow—and also may force—providers to record their findings as items picked from lists. This has created new ways to distort and corrupt data. Structured data is only reliable if fields are defined in standard ways and used with a degree of discipline that may not be achievable by clinicians. Furthermore, reliance on structured data sacrifices nuances of information that can only be captured in natural language. This trend has led to the general impoverishment of clinical records, as authors' vocabularies are constrained to selections provided by programmers. In the contest between the sins of too verbose and too sparse, replacing dictation with "click-tation" is more likely to create a record missing essential facts. Furthermore, while slips of the tongue can (and do) produce false records, slips of the mouse may have a higher propensity, because of the precision they inflict on data entry.

Drop-Down Lists and Checkboxes

In the eternal quest to protect practitioners from keyboarding, most EHRs provide menus that can be managed by pointing devices like mouse and touchscreen. These are susceptible to hand-eye coordination errors, such as "off-by-one" checklist errors, "drag-and-drop-in-the-wrong-location" errors, "double-click-instead-of-single-click" (and vice versa) errors, and similar.

Transcription and Voice Recognition

The astonishing revolution in voice recognition, voice response and natural language processing (NLP) technologies has only begun to be felt in healthcare. It is hard to imagine a more disruptive technology in human history than the ability to speak to and be understood by machines. The sluggish, frustrating and often comic early efforts at machine transcription of voice input have made enormous progress due to increased processor power (and clever science). Voice recognition software is becoming effectively usable and widely used in medical settings.

While human dictation-transcription has been universally accepted for decades, and automated dictation-transcription now offers serious competition, both are subject to production errors. Entire books and websites are devoted to funny malapropisms, freudianisms and other slips attributable to either the speaker or the transcriber, human or otherwise. But, the serious side of transcription error is when actual patient harm devolves from reliance upon false records.

Both human and software transcriptionists are likely to hear correctly a word like "electroencephalogram," even recorded by a person with a heavy accent in a noisy room. Whereas, both humans and machines are more likely to miss small words like "no," "not," and "doesn't." A radiologist dictated, "*I don't believe the lesion in the right upper lobe merely represents scarring from the prior procedure . . .*" The final report read, "*I believe the lesion in the right upper lobe merely represents scarring from the prior procedure . . .*" Consequently, a lung cancer went without investigation for 18 months.

That error involved an automated system, but a human could have made the same mistake. However, human transcriptionists vigorously point out that they have a superior ability to question (as well as intelligently correct during transcription) obvious slips, and will highlight words they can't interpret for later correction. Thus output errors can be intercepted during transcription, or can be appreciated and compensated for by later readers, who knowledgeably re-interpret obvious flubs. No harm, no foul. But, occasionally a discrepancy in output will mislead a clinician or patient, causing harm.

This brings up an unresolved legal conundrum for providers using any kind of transcription. There is an irreducible minimum error rate for any method of data entry, but explaining this to an injured party is problematical. There is no explicit norm for an accepted percent of "complications" caused by erroneous information. There is no comfortable cultural acceptance that sometimes records are wrong and sometimes this can cause harm. Patients (and juries) may have a general (but unachievable) expectation of zero defects. Some dictation systems append a disclaimer to their work product like, "*Dictated but not read*." It isn't clear that such a notice has any legal force. Furthermore, even if providers try (or are mandated) to proofread their documentation product, this would not result in perfect notes. Every editor knows the fallacy of authors proofreading their own writing. And, duplication of effort markedly reduces data entry efficiency. Knowing that perfect documentation is impossible sharpens our questions about how much we depend on medical record accuracy, for all purposes. One safety-minded approach to an inherently fallible process is to layer it inside another process with different failings. A defense against imperfect medical documentation is having many readers; another is taking every record with a bit of salt.

Multi-media

The difference between electrical and paper records is most apparent in a radically expanded definition of "information." Most EHRs today have the ability to incorporate virtually any kind of data into the record, including photography, graphics, audio, video, digital images, device outputs, large documents and special effects reminiscent of Hollywood. Multimedia and diagnostic images attached to medical records can powerfully improve patient care. Their greatest hazard is becoming attached to the **wrong** records.

Identity Management

Few incidents in the patient safety literature create more consternation than "wrong patient" events, and EHRs play a part in generating them. The ease of moving

information (creating, copying, importing, exporting, transmitting, etc.) also makes it easy to move it where it doesn't belong. Paper charts become contaminated with pages that stick together, faxes that are mislabeled, sticky notes that wander across desktops, and reports on patients with similar names. EHRs can commingle records through mis-clicking, mis-dragging, mis-typing, etc., and also have a serious potential for mis-identifying patients because of their dependence upon imperfect lists.

Every master patient index contains duplicates, misspelled names, former names, married names, nicknames, aliases, homonyms, middle initials, middle names and names from cultures that don't fit the pattern of "last, first, middle." An office may receive a prostate biopsy report on James Jones. The medical assistant might have to make a judgment whether to attach it to the record of "Jones J.," "Jones Jim," "Jones James T.," "Jones James [looks like a T might be an F]" or some other incarnation. Data incoherence, co-mingling, splitting, detachment and similar defects form a kind of electronic rubbish in information systems. This sort of corruption proliferates when data are exchanged automatically among systems.

Since the invention of EHRs, there has been contention between forces promoting a national system of unique patient identifiers, and forces concerned about the threat to privacy this could represent. The de facto standard of Social Security numbers has long been known to be hopelessly flawed, but in the U.S. no politically palatable alternative seemed possible to find. However, the need for authentication (and widespread use) of identities for various online activities may finally give birth to a solution, in the form of the National Strategy for Trusted Identities in Cyberspace (NSTIC) [25]. This is a 2011 White House initiative assigned to the National Institute of Standards and Technologies (NIST) that envisions, "Individuals and organizations [will] utilize secure, efficient, easy-to-use, and interoperable identity solutions to access online services in a manner that promotes confidence, privacy, choice, and innovation."

Its guiding principles are:

1. Identity solutions will be privacy-enhancing and voluntary
2. Identity solutions will be secure and resilient
3. Identity solutions will be interoperable
4. Identity solutions will be cost-effective and easy to use

There is reason to think this effort will succeed in creating a trusted, national, user-centered "identity ecosystem" that will be of considerable value in reducing both misunderstandings and crimes related to patient mis-identification.

Record Alteration

When we catch a mistake in a medical record, there are accepted practices for correcting it. In paper charts, the custom is to cross out the error without making it unreadable, and enter the right information with a notation of the date and the identity of the person who made the edit. There is no implication of deception, and subsequent readers can recognize and rely on the corrected information in its context.

In contrast, in some EHRs corrections are much more difficult to make, and can induce errors. In the infancy of EHRs, legal consultants were concerned about fraud, impersonation, and unattributed entries. A fetish evolved for electronically signing, stamping and sometimes even locking notes so they couldn't be edited after saving. This satisfied a perceived legal need for strong assurance about record authorship and provenance. Except in very ancient systems, these practices are now redundant to the database technology that routinely captures *meta-data* about transactions like "create," "save," "view," "print," "edit," "delete," and so on; which are typically linked (with timestamps) to the login credentials of the user who performed them. Meta-data logs may also include details like the port number of the network connection used for access, the location of the terminal, and other arcane facts of interest to technicians.

An incidental effect of EHR meta-data is to add wrinkles to the process of legal discovery involving electronic information of all types.

From the standpoint of user-experience, meta-data renders obsolete the older-than-Egypt need for signatures on official documents, and merely adds an annoying, unnecessary step in requiring users to "sign" notes. But, record-locking becomes a safety issue when corrections need to be made. In some EHRs, it is frankly impossible to edit a saved note, no matter what errors it contains. (It is far from uncommon to insert a long, complex note into entirely the wrong chart. Being unable to delete a note on the wrong patient creates both a safety hazard and a privacy violation.) The more rigid systems only allow the user to write an "addendum" to the original, erroneous note, and in the worst examples, the addendum may be separated in some way from the original. In some systems, it is hard to tell looking at the erroneous note that an addendum needs to be hunted down; and it may not be evident what exactly is wrong. For example, if the note on June 12th incorrectly lists "warfarin" as a current medication, and this is corrected with a supplement on June 19th, a reader of the June 12th note in some EHRs might have no way of knowing where to look for the correction. At very least, keeping bad data alongside the good requires extra steps by users, creating yet another potential error pathway.

Personal Health Records

The task and challenges of clinical documentation have traditionally fallen to practitioners, with the patient record always being tethered to the provider's practice or facility. EHRs for the first time open the possibility of making patient records portable across sites, which is not shocking to providers, or even putting them in the custody of patients themselves, which is quite shocking indeed. The term "Personal Health Record" is not well defined, but refers to clinical information in the custody and control of patients, usually organized in a kind of summary format.

One profoundly underused safety mechanism that becomes possible with PHRs is to expose the record to the patient's review. It is essentially unheard of to find a medical record that does not contain serious errors, many of which are immediately apparent to the patient. Including the patient in the quality improvement process is

an obvious, yet radical innovation that may have significant benefits for organizations that take advantage of it. Ironically, the traditional, oral patient history is the primary source of information in most medical records. However, importing files of patient-created information into EHRs (whether structured data from devices or unstructured data from templates) introduces yet another in-box problem for providers, and another potential source of variance (if not contradictions) that need to be reconciled in the provider's record.

At the time of this writing, Personal Health Records (PHRs) come in three basic flavors, each of which has serious safety concerns (Box 19.9). (The PHRs discussed here do not include raw provider work product that patients may be able to view through electronic portals into provider-controlled EHRs.)

Box 19.9

1. "**Do-It-Yourself PHR**." The patient is presented with an empty template (basically a version of the waiting room clipboard) and is invited to fill it out with what he or she can reconstruct from memory and available documents.
2. "**Insurance Transaction PHR**." The patient's insurance carrier can sometimes deliver a register of transactions it has captured through the provider payment stream.
3. "**EHR Lists and Logs**." Some EHRs can print a summary report comprised of the sentinel lists (e.g., Problems, Procedures, Medications, Immunizations, "Allergies," etc.) contained in the provider record.

All the factors that can make provider-tethered records unreliable similarly apply to patient-controlled records, with added complications.

- Do-It-Yourself PHRs are almost invariably incomplete and can be wildly divergent from physician records—with either more or less reliability. Patients rarely possess complete collections of their records over their lifetimes. They may not accurately recall their medical histories, and may not be able to read, interpret or accurately transcribe record content; they may deliberately withhold or edit material they do not want providers to see.
- Transactional PHRs may amount to little more than "cash register tape," representing items submitted to that carrier for claims processing. These are subject to numerous distortions in the procedure and diagnosis encoding processes; and cannot capture events that are not billed by a provider, or which are billed to other carriers.
- Files exported from EHRs are only as accurate as systems and users make them. Since virtually no EHR is a complete repository of facts on any patient (newborns possibly excepted), excerpts from one EHR would ideally need to be merged with all others to create a "master" record. Formats and standards (e.g., the HL7 Clinical Document Architecture – CDA® [26]) are becoming perfected to allow aggregation of properly compliant files from different systems, but few PHRs that can be maintained by patients are currently designed

to accommodate this need. More problematic is the way EHRs generate summary information that would be exported. Manually maintaining lists of problems, medications and procedures, etc., is a labor intensive activity for practitioners and consequently is often be neglected. Automatically generating such lists is subject to numerous sources of error because of the professional judgment needed to define, label, reconcile and assign items correctly.

While portable, patient-controlled, untethered, professionally created and properly reconciled, authoritative personal health information would have tremendous value to a system with millions of mobile patients interacting with multiple providers, resources and caregivers, this vision is not yet within reach.

In summary, with respect to documentation functions, EHRs:

- Offer the priceless benefit of legibility.
- Have an enormous advantage over paper records with respect to accessibility in multiple locations, by multiple simultaneous users.
- Can be efficiently mined for content by both legitimate and unauthorized parties.
- Provide numerous ways to create more complete and helpful records.
- Provide numerous ways to create false, misleading and harmful records that are indistinguishable from good ones.

Ordering, Reporting and Communication Systems

The documentation process—although it can be enhanced by technology—is not fundamentally different in the paper and electrical worlds. The case is far different for order entry, result reporting and messaging. These are the most powerful ways in which EHRs have altered provider workflow, and are the sources for the most dangerous errors that directly impact patients.

Automating the activities of entering and executing provider orders and receiving and responding to test results have drastically changed the human roles in both in-patient and out-patient environments. And, electronic communication and digital media (e-mail, voicemail, texting, social media, Internet, Wi-Fi, etc.) have wrought the same changes upon healthcare as upon civilization as a whole.

CPOE

Computerized Provider Order Entry (CPOE) is the label for technology that transmits instructions from people who can give them to people who can carry them out. Since orders are likely to:

- Be written repetitively in the same way for many patients
- Be tedious to write under time pressure
- Contain so many components that even experts tend to forget some details
- Cause serious harm if written incorrectly
- Require calculations or adjustments that differ between patients

The CPOE functions of EHRs lend themselves perfectly to shortcuts and automation. According to the laws of Newton (as modified earlier) and Murphy (who is

in charge of all computer programming), any labor saving and safety promoting contrivance can misfire with harmful effects. The work of writing orders is cognitively quite different from writing notes. But, the user interfaces available to providers are very similar, and so CPOE is subject to all of the data input and output risks outlined in the previous section.

Wrong Thing Entered

The primary danger of computer-assisted data entry is entering the wrong thing. In its analysis of 3,099 EHR-related safety events in Pennsylvania, The ECRI Institute attributed the vast majority (1,867) to "wrong input" [27]. This can be achieved through all the functions listed in the prior section, and a few more specifically built for CPOE.

Pharmacy Errors

Reading the literature on EHR errors, it is easy to gather the impression that the vast majority of events are prescribing errors occurring in hospitals. This is mostly an artifact of reporting. The volume of hospital pharmacy transactions is enormous, because of the variety and effectiveness of today's drug armamentarium (and its overuse); pharmacy systems are among the most widely implemented applications in hospitals because of their good cost-benefit ratio; mistakes in drug administration are fairly easy to spot (if one looks) because of the number of individuals involved with them; agencies interested in quality metrics have an easier job finding pharmacy mistakes than many other kinds.

Artifact or not, there is no question that millions of drug errors occur annually across every part of the healthcare system, involving a serious percentage of patients. Although CPOE also has been shown to have benefits of lower error rates related to ambiguous abbreviations, legibility issues, impossible doses and duplications (intercepted by pharmacy logic checks), it can also induce errors. Han et al. found an unexpected increase in mortality among pediatric patients after the installation of a CPOE system in a children's hospital [28].

In a classic article, Koppel, et al. enumerated 22 different categories of medication errors in a mature, teaching hospital CPOE system, with errors occurring almost daily [29]. Among the issues identified were:

1. Information errors
   - Accepting the dose on the screen
   - Duplicating orders
   - Automatic orders linked to procedures
   - Automatic discontinuations
   - Diluent interactions not captured
   - Delayed recognition of contraindications
   - Failure to capture info from all systems
2. Human-machine interface flaws
   - Can't clearly identify the patient
   - Can't view all meds on a single screen
   - Log-in/log-out failures

- Extra steps required to "activate" orders
- Automatic cancellation of pre-surgical orders
- Downtime delays
- Orders near midnight interpreted as "tomorrow"
- Cumbersome interface makes charting difficult

Bar Codes

Because of its far superior accuracy to human keying (by perhaps a factor of millions), bar coding is widely employed by hospitals in pharmacy order entry systems. However, in another study, Koppel, et al. found 31 different causes of misread data (e.g., crinkled, smudged, torn, missing, covered labels; malfunctioning scanners; unreadable, damaged or missing patient wristbands; non-barcoded medications; low batteries; poor wireless connections; emergencies) plus 15 ways users could defeat its benefits with workarounds (e.g., affixing patient barcodes to computer carts, scanners, doorjambs, or nurses' belt-rings; carrying pre-scanned medications on carts) [30].

Auto-completion

A patient with heart failure presented to the Emergency Department, and the hospitalist prescribed a drug by entering the letters "L," and "A," and hitting ENTER. The intended prescription was "Lasix" but the system entered "Labetalol." The patient was dead in 30 min.

Putting the Fault in Default

One valuable service automation can provide is populating fields with default values. This avoids variance and mistakes in data content and format, and restricts choices to a set of selected entries. However, default data entry is the CPOE analog of paste-forward discussed above, and a sure source of wrong-input errors. Defaults can be positive (entering orders) or negative (removing orders). In different facilities narcotic overdoses were caused by a default dose of hydromorphone that was in the clinically appropriate range but too high for many patients; dangerous gaps in treatment were caused by a default that canceled all ICU orders on patients transferred to the medical floor; duplicate orders were written on patients because a rule triggered standing orders that had already been manually entered.

Order Sets

Younger physicians will marvel to learn that doctors once disparaged "cookbook medicine," and prided themselves on not relying upon reference material. Using the crutch of prompts, reminders and standardized order sets was felt to degrade professionalism and even to be dangerous to patients who deserved individualized attention. This sentiment is headed in the direction of leeches. The complexity of diagnosis and treatment today virtually mandates reliance on checklists, guidelines and other forms of prompts and reminders.

However, these tools are not benign. Someone has to build them, and someone cannot envision every possible contingency, which preserves a sliver of validity in

the old protest about cookbooks. There is serious risk to patients in templates being reflexively executed. Like the problem of auto-proofreading, it can be difficult for providers conditioned to invoking a package of tests or treatments to review them critically each time.

Still, the benefit of standard order sets outweighs their risks. Even when only presented to users in the form of general suggestions, they can promote safer care by being useful memory aids. When customized according to rules triggered by individual patient circumstances, they can be even more valuable. But, they need to be thoughtfully designed, their performance must be audited, consensus about their use must be built across different users and groups, they must be updated in the face of new standards of practice, and care must be taken that they function properly after updates, upgrades and modifications to external systems that they depend on for inputs.

Pre-programmed activities are like scalpels: *indispensable*, *but capable of mischief*.

Calculated Data

What computers do best is rapidly calculate numbers. Automatic execution of formulas with data from numeric fields has certainly saved patients from countless errors in diagnosis and therapy. But, even the simplest computer trick can backfire. One case involved converting between different units of measurement. EHRs used in pediatric settings in particular need to accept data entered in feet, inches, centimeters, pounds, kilograms, milliliters, ounces, days, weeks, months, years, and a slew of other units. In one system, programmers created a clever shortcut whereby a pediatric weight field (displaying "kg") would automatically divide whatever was entered by a factor of 2.2 if the number was followed by a space and a tab, but would leave it alone if it were followed by a tab alone. This allowed providers to type either pounds or kilograms, and conveniently convert whatever was entered to the right units. Of course, hundreds of errors were caused by users inadvertently confusing the keyboard sequence. The doctors in the affected practice described their growth charts as looking like seizure recordings.

Usability testing would almost certainly revealed the problem with an idea that must have seemed ingeniously useful in the programmer's imagination.

Programming Error

In any contest between user-error and machine-error, the machines will prove more reliable by a vast margin. Nevertheless, software is designed, built, installed, configured, updated and tested by humans before it reaches end-users, and is subject to flaws at each step. Often, internal flaws in logic, function or data resources will not be apparent to users. Such "black-box" malfunctions can go unnoticed for significant periods, since users may have no immediate ways to recognize that things are going wrong.

A patient with seizures, on phenobarbital, came to the ER in a coma. The resident smartly ordered a phenobarbital blood level, which was reported as "zero." The patient was admitted to ICU and managed on a ventilator overnight. In the morning,

the lab tech called the resident, "To talk about that pentobarbital level." As it turned out, the CPOE system had a list of some thousands of possible drugs that might be measured, and the lab analyzer had been updated with a list of some thousands—plus or minus a few—of drugs it could test. During a software update, the two lists became de-synchronized somewhere before the letter "p," with the result that the resident had correctly ordered phenobarbital, and the system had dutifully tested pentobarbital.

Display Errors

In addition to dangers on the EHR-input side, patients can also be harmed by problems with EHR outputs, including screen displays, reports and notifications.

In a highly publicized case, a software update resulted in a hospital CT scanner delivering eight times the intended dose of radiation to several hundred patients. An FDA investigation revealed that the machines involved were functioning as designed [31]. However, the interaction between the new software—which performed some automatic calculations actually intended to make the process safer—and the user, who needed to evaluate and respond to several inputs on a screen—produced patient injuries. This case illustrates the delicate relationship between designers and users, both of whom must collaborate to generate good or bad outcomes.

Users are faced with many kinds of computer displays, which are subject to countless variables that affect readability, including:

1. Color, focus, brightness, backlighting, contrast, resolution
2. Font, size, style, background, spacing, margins, highlights
3. Physical location, glare, viewing angle
4. Overlays, animations, transparency, graphics

All of these are intended to make it easier to apprehend and interact with information on the screen. All of these can be used brilliantly or horribly by designers and configurators.

Accommodations for users with disabilities (e.g., color-blindness, near- or farsightedness) may not be available or thoughtfully designed; mobile devices with tiny screens are especially challenging; shared devices require multiple users to compromise.

Awful Printouts

Some EHRs seem to have invested all their development funds in designing online interfaces and then run out of money when time came to build their reports. It is common to find that printouts, even ostensibly of on-screen activity, do not faithfully resemble what's displayed. Moreover, many printed reports, particularly those holding themselves to be "copies of the medical record," look nothing like what the EHR user sees in actual use, and can be extremely difficult to interpret by providers who receive them for continuity of care.

Interoperability

In early EHR days, developers had hundreds of combinations of programming languages, operating systems, database platforms, hardware and information coding

standards to choose from in building EHRs they hoped would be clinically and commercially appealing. There was no way of knowing in 1985 which of those building blocks would survive to 1995, let alone today. (Cynics also point out that some vendors may have calculated a market advantage if their software used data formats that could not be transferred to other systems.) Over time, many brilliant designs and concepts proved unmarketable, regardless of clinical worth. Still, today, there remain over 300 active vendors in the EHR space, most of which format patient data in different ways.

Moreover, patients are mobile, doctors are mobile, medical practices come and go, hospitals and groups merge and spin off. EHRs undergo version updates, vendors go out of business, merge and spin off, re-engineer themselves. And, technology evolves. This means the tenure of a given patient within a given EHR environment is transitory. The data has got to become portable.

The demand for—and value of—data exchange across disparate EHRs has engendered (in a Darwinian fashion) both industry standards and regulatory mandates to permit, if not actual interoperability, at least the possibility of exporting a file from one system and importing it without too much damage into another. Every year at the HIMSS Interoperability Showcase (Healthcare Information and Management Systems Society [32]), vendors demonstrate better integration of devices, inputs, outputs and work product across manufacturers, versions, hardware and platforms. Nevertheless, sharing data between EHRs is fraught with risk.

Despite better industry understanding and adherence to technical data standards (of which there are many specialized sets), the process of transmitting even a single record across systems creates a procrustean dilemma.

A. The record can be automatically absorbed into the recipient system. This means each item in the record (e.g., problems, drugs, procedures, immunizations, allergies) will either join an existing list, overwrite an existing item on a list, or be discarded as outdated or duplicative.
B. The record can be directed to some user's "inbox," where it must be deliberately, consciously, accepted or rejected before it joins the existing data.

Both options can create data entry errors, for all the reasons previously outlined. But, the problem become unmanageable when scaled up to thousands or millions of records, which is necessary when a large hospital system switches EHRs, or merges with another.

The transition of an acutely ill patient between points of care is perhaps the most dangerous procedure in medicine. Transferring their data with them is very often bungled. Currently, direct, peer-to-peer verbal sign-offs are the only safe way to insure that critical information is transmitted along with the person, to the embarrassment of EHRs everywhere.

The "Cuckoo's Egg"

A frequent call to risk managers is prompted when a provider receives an orphaned report. This could be a lab, imaging or pathology result with serious and time-sensitive consequences that may slip out of a fax machine or pop up in an inbox (e.g., biopsy positive for cancer), for a patient that the recipient does not recognize. Sometimes this happens because the fax number was misdialed. Or the report may have been intended for a colleague or a provider with a similar name;

or it might be for a patient who has been referred for a visit next week and isn't registered yet.

In any case, the report represents a latent hazard. If it was meant for another recipient, then that provider is presumably unaware of the result. Delay could hurt the patient. The only thing to do is to investigate and take responsibility for getting the right thing done. This takes a bit of effort, but there's no other ethical solution.

The Inbox Problem

Now, imagine this situation multiplied by a thousand. "*Good morning doctor*, *there are 2*,*345 items in your inbox*." Many are results the doctor ordered. Many are duplicates. Many are "for your information" copies. But, the one critical item that doesn't belong and really needs to be addressed is likely to be missed in the workflow. There is currently no automatic way to filter the clinician's incoming task stream. Like e-mail, it needs to be managed, but nobody has figured out how.

Electronic Communication

The discussion of order entry and result reporting was focused on structured data. But, unstructured data represents 80 % of medical information. Among safety issues, miscommunication and failure to communicate stand out as sentinel hazards. Among safety promotion measures, improved communication would be among anyone's top choices. All the tools and devices available to general and consumer markets for electronic communication are available for healthcare purposes—sometimes with "professional" enhancements (e.g., encryption). These offer great value and great risks to physicians and patients (Box 19.10).

Box 19.10

Synchronous (*real-time*) *communication channels*

- Telephone, cell phone, Voice-Over-IP-Phone (VOIP)
- Audio conferencing
- Video conferencing, telepresence

Asynchronous (*store-and-forward*) *communication channels*

- Voicemail
- Fax
- Pager
- E-mail, secure e-mail
- Text messaging, secure messaging
- Portals, file sharing, collaboration environments

Infrastructure

- "Plain old telephone service" (POTS)
- Cell service
- Wired networks
- Wireless networks
- Satellite networks, Global Positioning Systems
- Short area networks (radio, infrared)

However, communication needs to be managed. While security and privacy of electronic communications have (appropriately) received intense attention, other safety issues are just as relevant. All the interface issues outlined for CPOE and result reporting can impact messaging systems. Just about every kind of misdirection, delay, duplication; loss/deletion; failure to notice, respond, forward, reconcile; disposition and delegation errors can easily be envisioned for any set of electronic messages, and has been recorded in the archives of patient safety events.

Patient Connectivity

Finally, the communication capabilities of EHRs are not limited to providers and hospitals. Partly because the multiuser power of EHRs liberates information from being hoarded by physicians; partly because of cultural upgrades that make healthcare knowledge and processes much more transparent to patients, it is today taken for granted that patients are expected to be consumers of and contributors to their own health records.

One effect this has is to add another population of EHR users, who can both create errors and intercept them. The error-trapping potential of including the patient in the loop of documentation, order validation and result management is potentially phenomenal. It will also add complexity to the challenges of designers and implementers, who must plan for the needs and impact of this diverse population. It is important to establish ground rules and norms that are currently not standard among institutions, practitioners and patients for the safe, secure and effective exchange of clinical information across the many nodes in the healthcare network.

Decision Support Systems

The patterns of risk and error above apply to fairly straightforward interactions between humans and computers. Perhaps documentation systems are just fancy word processors. Perhaps order entry systems are just electronic prescription pads and reporting systems are basically printers. None of this is true, but at a simplistic level, each of these applications might be mistaken for a labor-saving device. In contrast, the domain where computers conclusively prove their difference-in-kind from other technology is when they are used to augment human thinking.

Granted, it stretches the concept of "heath record" to mention functions like dose calculation, guideline presentation, therapy planning, alerts, prompts, warnings, reminders, interpretation of clinical findings, access to reference material and diagnostic suggestion systems in a chapter on EHRs. But these categories of HIT are often invoked as the most valuable rewards EHR user can expect, after suffering the pain of converting from paper.

Computer-Assisted Diagnosis

One of the hardest types of safety events to analyze and mitigate is the category labeled "Diagnostic error." Virtually since the day a patient history was first captured electrically, there were dreams of using the associative and correlative power

computers to help with diagnosis. Indeed, the 1990s were boom years for the application of artificial intelligence (and other programming techniques) to this purpose [33]. It is a little hard to know why CADx applications have not been among the most gloriously popular and commercially successful segments of the HIT market. Most of the legacy systems from the early years have fallen out of use, failed commercially or have not been maintained (although a few stalwarts have [34, 35]), but several promising applications have emerged in the last few years that will hopefully rekindle interest.

The safety issue for a diagnostic assistance (or diagnostic suggestion) program is obviously the same for the software as for the human. (There may also be liability issues, although developers rely heavily on the law's "learned intermediary doctrine," which can insulate vendors of products used by experts on behalf of consumers from the liability they have for products intended for use directly by consumers themselves.) In this respect, whether the system points outright to a potential diagnosis, or produces a list of differential possibilities, or calculates a likelihood, or highlights a set of diagnoses associated with a certain set of findings, there will be both Type I and Type II errors (pointing users at the wrong one, or leaving the right one off the list).

Alerts, Alarms and Triggers

Another way technology can be recruited to the cause of safety is to build alarms that alert inattentive or distracted humans when some triggering condition has occurred. EHRs have many locations where alerting functions can be installed—many more if non-EHR devices are included. Doses that need adjustment, therapeutic duplication, orders outside recommended guidelines, contraindications, IV admixtures that are incompatible, lab values or physiological parameters out of range, scheduling, calculating, monitoring, counting; there is no end.

Each of these systems is a mini-program that had to be designed, written, installed, tested, configured and updated, and needed user training. Applying Newton's computer law, any one can misfire in each of these steps. But, most alarm failures are not technology issues, but problems in the way they interact with their human targets. From the standpoint of users, many alarms have only two settings, "Too sensitive" and "Not sensitive enough."

Alarm Fatigue ("Wolf, wolf!")

Alarm fatigue leads to users ignoring and overriding valid warnings, and even disabling systems that generate annoying ones, with obvious consequences. A dilemma that most designers have not seemed to recognize is that users in different situations benefit from different alarm settings. Novices (new employees, interns, consultants who use the system infrequently) may need and tolerate relatively low thresholds for alerting, and fairly verbose messages. High volume experts who develop automaticities through frequent use only want to be interrupted for actual anomalies. Intermediate users need another tuning. The problems that tend to occur with alerts and alarms are when users are confronted with an interruption at a point in the workflow or with a frequency that has no meaning for them. It is in

these cases that users stop responding. Allowing users to customize own alarm levels, while retaining the ability for the system to override user settings just as users can override system settings presents both tricky programming and administrative challenges.

Clinical Calculators

At the time of writing, there have been at least 100,000 "medical" applications developed for mobile devices alone [36]. Some of these products become defunct weekly, many are consumer facing products for fitness and diet management. But, a growing number are explicitly aimed at professional audiences, performing sophisticated functions like helping calculate radiation doses, pediatric drug doses and physiologic parameters like creatinine clearance, etc. The FDA is deeply perplexed about how to review, monitor and regulate the performance of products in this market.

Recall and Reminder Systems

In the world of safety, one of the largest categories of failure is breakdown in the chain of notifying a provider or a patient of the need for follow up. One might think the time honored custom perfected by dentists of sending reminder postcards would have been implemented EHR systems from the beginning. In practice, this turns out to be an immensely complex problem, involving a web of interdependent contingencies and decisions. That said, it is exactly the kind of rule-based conundrum that computers excel at, and do so much better at than humans. In face of the high impact recall failures can have upon patients (and the high prevalence of recall failures among malpractice claims), it is surprising that this category has been given relatively little attention by EHR developers (and their efforts often offhand and occasionally unworkable). The reason is not technical; much harder problems have been attacked successfully in software. The author's experience is that the problem is cultural. There is simply nothing in the traditional autistic, exam-room-centered, face-to-face-biased workflow of physicians that calls for tools to manage recall. This is consistent with the absence of acknowledgment of task recall as a reimbursable item in the pay-for-procedure system that governs physician behavior; thus EHR developers are not used to hearing a demand for such features.

Data Analytics

Behind the scenes of real-time EHR-user interactions, information about patients, providers, institutions, diseases, therapies, costs, outcomes and a thousand other variables is being collected in vast warehouses. Like the (even larger) quantities of consumer data available to marketing analysts, healthcare data increasingly is being sought and used for epidemiology, quality measurement, law enforcement and security, genetics, economics, education and every purpose of pure (and marginal) science and commerce. It is being discussed that in some cases, the need for prospective clinical trials may be able to be avoided because models of treatment effects can be built from streams of existing data. Many of the design challenges of clinical

research may become solved, or at least re-defined, because managing multiple variable statistics is a different undertaking in the context of "big data."

Enormous databases do have some power to mitigate imprecise and muddy data, but less so with actually wrong data. A challenge for miners of healthcare megadata is that several generations of EHRs have passed whose content has been encoded (ICD-9, CPT, etc.) in "lossy" formats that sacrifice accuracy and completeness. Just as poorly designed (or dishonestly conducted) research trials have at times mislead health science with invalid conclusions, care needs to be taken in accepting the products of large data analysis.

Where Is the "Golden Bullet"?

Training

In most high-performance industries (aviation, nuclear power, military), training is embraced as a critical safety control and essential cost. There are places personnel can't go, jobs they can't do, decisions they can't make unless they have demonstrated specific competencies, both large and small.

Oddly, for a culture that makes education the basis of its reputation, healthcare seems ambivalent and even a little resentful to have technical training imposed on it. In this respect, organizations that depend on fees for revenue may have strikingly different attitudes than those with global budgets. HIT demands a high level of technical support, and cooperation by end users in configuring, operating and troubleshooting systems that are becoming more complex every year. The intern's catchphrase, "See one, do one, teach one" is another of those relics of ancient medical culture that needs to be jettisoned from today's environment. While "operator error" is a contributing factor in the vast majority of adverse EHR events reported today, it is unconstructive—and will misdirect mitigation efforts—if every malfunction is addressed by simply mandating more user training.

Physical Hazards

A thorough safety review must include potential physical hazards of electrical devices including shock hazards, radiofrequency interference, toxic components, radiation exposure and miscellaneous rare risks such as detaching from mountings, dropping, skidding and colliding with people or other devices.

Device Hacking

Both wired and wireless devices in hospitals increasingly connect to networks that are exposed to intrusion by hackers. There are reports of experimental and malicious penetration of the controls of both diagnostic and—most concerning—therapeutic instruments, such as insulin pumps, infusion pumps and ventilators.

Take-Home Message

The foregoing has not emphasized—but it is fitting to say out loud—that information technology is a social force of volcanic proportion that will transform the landscape of medical practice as it has re-shaped so many other facets of society, and will continuously revolutionize the ways doctors, nurses, hospitals and patients interact the more pervasive it becomes. EHRs are a central element of HIT, whose value will be multiplied when they are adopted by a critical mass of providers, and master the problems of data exchange across health information networks. Few human inventions have greater impact upon civilization than information technology, whose upheaving effects proceed at a tempo much faster than the march of generations.

However, *if EHRs were drugs*, *the FDA would have concerns like these*:

A. It is not fully clear what disorders they should be prescribed to treat.
B. There is little objective evidence of their effectiveness, despite many claimed benefits.
C. Their side effects are not well characterized and may be under-appreciated.
D. Some uses may be hazardous.

In many ways, EHRs would be considered "investigational" if the healthcare enterprise were not utterly dependent on information for its every operation. New information tools and channels are not subject to the rules that would slow the adoption of other risky innovations.

Fundamentally, the weaknesses of EHRs are not simply flaws in technology that only await smarter programming. The problem is that EHRs manage information—the underlying material of the universe. Human systems where EHRs are embedded are more complex than technology, and their operating principles and decision rules are beyond our ability to replicate in software. This fact guarantees unintended consequences, which are the law of every natural system. Healthcare's dual personality makes ratcheting progress, jerking irregularly forward with brilliant inventions while regarding each novelty with the suspicion of "*First*, *do no harm*."

References

1. Amarasingham R, Plantinga L, Diener-West M, Gaskin DJ, Powe NR. Clinical information technologies and inpatient outcomes: a multiple hospital study. Arch Intern Med. 2009;169(2):108–14.
2. Bright TJWA, Dhurjati R, et al. Effect of clinical decision-support systems: a systematic review. Ann Intern Med. 2012;157(1):29–43.
3. Dorr D, Bonner LM, Cohen AN, et al. Informatics systems to promote improved care for chronic illness: a literature review. J Am Med Inform Assoc. 2007;14(2):156–63.
4. Garg AX, Adhikari NK, McDonald H, et al. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. JAMA. 2005;293(10):1223–38.
5. Goodman C. Savings in electronic medical record systems? Do it for the quality. Health Aff (Millwood). 2005;24(5):1124–6.
6. Linder JA, Ma J, Bates DW, Middleton B, Stafford RS. Electronic health record use and the quality of ambulatory care in the United States. Arch Intern Med. 2007;167(13):1400–5.

7. Aspden PCJ, Wolcott J, Erickson SM, editors. Patient safety: achieving a new standard for care. Washington, DC: Institute of Medicine, The National Academies Press; 2004.
8. IOM (Institute of Medicine). Health IT and patient safety: building safer systems for better care. Washington, DC: The National Academies Press; 2012.
9. Public Law 111 – 5 – American Recovery and Reinvestment Act of 2009. (Approved 17 Feb 2009)
10. Mark Mansour, JD, partner, Jones Day (Washington, DC). Presentation at Health Information Management Systems Society (Orlando, FL), 23 Feb 2014.
11. U.S. Code of Federal Regulations, Title 45, Subtitle A, Subchapter C, Section 164.308 – Administrative safeguards
12. Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (1996), Codified at 42 U.S.C. § 300gg and 29 U.S.C § 1181 et seq. and 42 USC 1320d et seq.
13. National Institute of Standards and Technology. Information security. NIST special publication 800-30, revision 1, Sept 2012. Washington, DC: U.S. Department of Commerce.
14. Sittig DF, Singh H. A new sociotechnical model for studying health information technology in complex adaptive healthcare systems. Qual Saf Health Care. 2010;19 Suppl 3:i68–74.
15. ECRI Institute, 5200 Butler Pike, Plymouth Meeting, PA 19462-1298, www.ecri.org
16. Magrabi F, Ong M-S, Runciman W, Coiera E. Using FDA reports to inform a classification for health information technology safety problems. J Am Med Inform Assoc. 2012;19(1): 45–53.
17. U.S. Code of Federal Regulations, Title 42, Chapter 6A, Subchapter VII, Part A, Section 299 – Mission and duties [of the Agency for Healthcare Research and Quality]
18. http://www.pso.ahrq.gov/common.
19. Pace WD, Staton EW, Higgins GS, Main DS, West DR, Harris DM. Database design to ensure anonymous study of medical errors: a report from the ASIPS collaborative. J Am Med Inform Assoc. 2003;10:531–40.
20. Smith PC, Araya-Guerra R, Bublitz C, Parnes B, Dickinson LM, Van Vorst R, Westfall JM, Pace WD. Missing clinical information during primary care visits. JAMA. 2005;293:565–71.
21. Smith v. United States, 119 F. Supp. 2d 561 (D.S.C. 2000). Betty C. SMITH and Rudolph Smith, Plaintiffs, v. United States of America, Defendant. United States District Court, D. South Carolina, Beaufort Division. 5 June 2000.
22. Thornton JD, et al. Prevalence of copied information by attendings and residents in critical care progress notes. Crit Care Med. 2013;41:4.
23. Weir CR, Hurdle JF, Felgar MA, Hoffman JM, Roth B, Nebeker JR. Direct text entry in electronic progress notes: an evaluation of input errors. Methods Inf Med. 2003;42(1):61–7.
24. Department of Veterans Affairs, VHA Handbook 1907.01, Health information management and health records. Washington, DC: Veterans Health Administration. 19 Sep 2012. www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2791
25. National Strategy for Trusted Identities in Cyberspace. www.nist.gov/nstic/index.html
26. Health Level Seven International. The HL7 Version 3 Clinical Document Architecture (CDA®)
27. Presentation by William Marella, MBA (Director, Patient Safety Reporting Programs), and Karen Zimmer, MD, MPH (Medical Director), ECRI Institute Patient Safety Organization, 5200 Butler Pike, Plymouth meeting, PA 19462-1298, www.ecri.org at Health Information Management Systems Society (Orlando, FL), 25 Feb 2014
28. Han YY, Carcillo JA, Venkataraman ST, et al. Unexpected increased mortality after implementation of a commercially sold computerized physician order entry system. Pediatrics. 2005;116(6):1506–12.
29. Koppel R, Metlay JP, Cohen A, et al. Role of computerized physician order entry systems in facilitating medication errors. JAMA. 2005;293(10):1197–203.
30. Koppel R, Wetterneck T, Telles JL, Karsh BT. Workarounds to barcode medication administration systems: their occurrences, causes, and threats to patient safety. J Am Med Inform Assoc. 2008;15(4):408–23.
31. U.S. Food and Drug Administration. Safety investigation of CT brain perfusion scans: Update 9 Nov 2010. www.fda.gov/medicaldevices/safety/alertsandnotices/ucm185898.htm

32. Health Information Management Systems Society, (HIMSS), 33 West Monroe Street, Suite 1700, Chicago, IL 60603-5616. www.himss.org
33. Berner ES, Webster GD, Shugerman AA, Jackson JR, Algina J, Baker AL, Ball EV, et al. Performance of four computer-based diagnostic systems. N Engl J Med. 1994;330:1792–6.
34. Massachusetts General Hospital Laboratory of Computer Science. DXplain®. http://lcs.mgh.harvard.edu/projects/dxplain.html
35. Burger C. The use of problem-knowledge couplers in a primary care practice. Perm J. 2010;14:47–50.
36. Edney, Anna. FDA regulators eye medical apps for mobile devices. Bloomberg Businessweek, 26 Sep 2013.

Research and Patient Safety

20

Markus S. Huber-Lang

Pitfalls and Pearls

- Research is the fundament and guarantee for patient safety.
- Surgery and research are often considered as "squaring the circle"— however: surgeons represent researchers for patient safety.
- Research related to patient safety is rather challenging and complex—All research fields have to be engaged to secure patient safety.
- Animal models need to be carefully designed to closely simulate clinical reality and to validly contribute to patient safety.
- Surgical research (in regard to patient safety) has to be performed in accordance with the declaration of Helsinki and needs to fulfill the highest ethical standards.
- High quality research and high quality surgery are bride and groom for future patient safety.

Outline of the Problem

The main problem of research and patient safety in surgery is the surgeon's dissociation between clinical and scientific performance.

Patient "safety" is etiologically related to old French "sauf" and to Latin "salus," meaning "uninjured, healthy, safe." However, no surgical intervention may be performed without some degree of tissue injury and without some exposure to danger.

M.S. Huber-Lang, MD
Department of Orthopaedic Surgery, Center of Musculoskeletal Research, University of Ulm, Albert-Einstein-Allee 23, Ulm 89081, Germany
e-mail: markus.huber-lang@uniklinik-ulm.de

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_20,

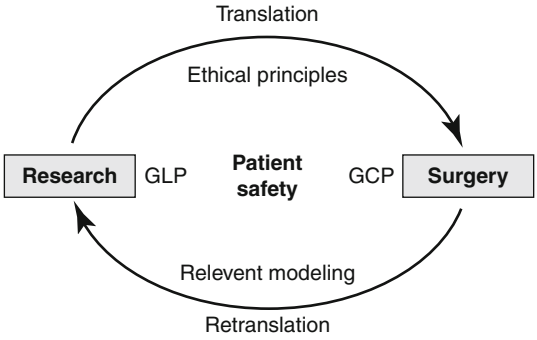


Fig. 20.1 Surgery and research as the best advocates for patient safety. *GCP* good clinical practice, *GLP* good lab practice

Based on this axiomatic fact, "research" (old French "re-cercher") as an "act of searching closely" was in ancient times a constant companion of surgery to limit possible risks and to increase the potential of the healing processes. Thus, valid and reliable research can be considered as a prerequisite of patient safety [1]. Extensive interactions between both research and surgery may generate (via a translational approach) not only innovative better and innovative therapies, but also new knowledge and hypotheses to be reexamined (via a retranslational approach), thereby forming a circuit committed to patient safety (Fig. 20.1). If the quality of the surgical and/or scientific performance is poor, there is subsequently a direct negative impact on patient safety. Thus, there is a necessity to maintain quality standards and mutual understanding at the highest level to develop new concepts for patient care and safety.

Traditional surgical research has covered a vast amount of peri-operative analyses and has used patient safety issues as one read out parameter among many. Often, the 28-day survival rate was vaguely equated to patient safety issues. In this regard, the inherent risks have frequently been well documented, reported and more or less accepted. However, effective means to reduce the risks, such as in cardiac surgery, were rarely developed [2]. The emerging field of specifically investigating patient safety issues commonly focuses on peri-operative management strategies with pre-post-testing, such as after the introduction of operation check-lists [3]. This may be due to the fact, that the majority of adverse events are caused by non-operative management failure rather than by errors in surgical techniques [4].

The regularly very low numbers of patient safety incidences within mono- or oligo-centered studies and within a short study period represent a significant limitation for data recruitment and analysis. Some attempts have been undertaken to analyze larger cohorts (e.g. by multi-center studies or by (inter)national registries and data bases) [5] and/or to use longer time periods of data acquisition [6]. As human time-management is currently becoming ever more compressed, long-term patient safety and long-term quality-of-life (QOL) analyses following a defined surgical procedure appear to be relatively rare [7]. Furthermore, long-term studies are often elaborative and costly, especially when designed in a prospective manner (Table 20.1).

Table 20.1 Current limitations and challenges for surgeons in research on patient safety

Limitations in . . .	Challenges of . . .
Numbers of patient safety incidents	Design and performance of multi-centered studies concerning patient safety; generating a global culture; development of novel statistical evaluation methods
Clinically-relevant, valid and reliable in vitro and in vivo models	Design of worldwide accepted "golden standard" in-vitro and in vivo models
Time and financial resources of surgeons for patient safety research	Establishment of research training requirements during surgical training; improvement of researchers' pay; nationwide/international grant programs
Long-term investigations of safety issues	Long-term investigations of surgical consequences for QOL and patient safety
Mastering of complex study designs and methods	Increasing specialization, clinically and scientifically
Research quality; often confounded with quality management (QM) needs	Innovative research for safety issues; development of innovative analysis methods
The attitude of (academic) surgeons in regard to the dual function as clinicians and researchers	Defining the role of surgeons in research ("surgical researchers" or "research surgeons"). Early training of both, research and operative skills to become an ever-searching advocate for patient safety

For operative procedures, patient safety studies indirectly but strongly depend on valid and reliable *in vitro* and *in vivo* models. However, serious concerns remain as to whether animal models can sufficiently reflect human peri- and intra-operative reality. For example, genomic responses in some trauma models only poorly mimic the inflammatory response found in humans [8]. This is supported by the fact that for instance to date all sepsis trials designed on promising animal data have failed to alter outcome beneficially in humans. In addition, experiments on animals as well as corresponding tissues and cells normally lack many of the clinically most important factors, such as preclinical treatment, co-morbidities, aging processes, genetic and microbiotic variability, and macro- and micro-environmental diversity among others. Thus, animal models have been described as "not close enough" to clinical reality [9]. Consequently, there is still a great demand for well-characterized, valid and reliable animal models simulating the peri- and intra-operative clinical situations as closely as possible to guarantee the transfer to humans with maximal safety.

The design and performance, and thereby the results of safety research in surgery also depend on the economical and cultural background of the study sites and their practical settings. For example, a recent study in the USA involving more than 3,000 peri-operative nurses identified the following ten major safety issues: wrong site/procedure/patient surgery, retained surgical items, medication errors, failures in instrument reprocessing, pressure injuries, specimen-management errors, surgical fires, peri-operative hypothermia, burns from energy devices and difficult intubation/airway emergencies [10]. In contrast, a multi-center study in China recently revealed that more than 50 % of the patients did not know about the existence of medical errors [11].

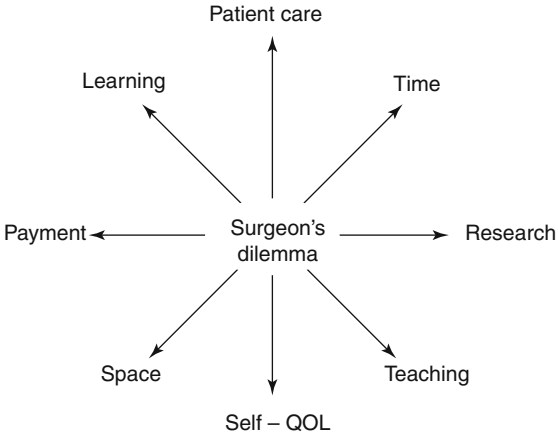


Fig. 20.2 Surgeons' polylemma. *QOL* quality of life

Research in patient safety has clearly indicated that intra-mural miscommunication, especially during complex situations and within complex teams, is a major risk factor for errors and a general priming factor for multiple safety problems. It is well established that, what is "thought is not necessarily said," what is "said is not necessarily done," what is "done is not necessarily done correctly" and to the patient's benefit. Furthermore, in the surgical environment, critical information on the patient appears to diminish with time [12]. In this context, patient safety research may address two objectives: to detect/analyze communication problems and thus teach awareness of pitfalls, and to improve communication skills, knowledge and attitude. Here, simulation-based training is a current domain in teaching communication skills [13]. However, research analysis of standardized simulation of clinically relevant scenarios, such as by videotaping with subsequent blinded expert evaluation, remains elaborative and sometimes rather expensive. In contrast, for training of various surgical skills, particularly minimally invasive surgical procedures, a vast number of electronic- and computer-assisted simulation training programs are offered. These programs are not only designed for the novices in surgery but for all professional levels, and may also efficiently introduce and train novel surgical techniques. Because "the devil is in the detail," simulation programs are often rather rigid and limited, and are thus sometimes maladapted for clinical trainees as well as for manual experience and learning needs [13].

Life-long training, self-criticism, and consistent sharpening and awareness of obvious and hidden risk factors for patient safety may define the major characteristics of excellent surgeons. However, particularly in academia, surgeons are driven ever more into a dilemma, more precisely, into a polylemma, caused by multiple factors (Fig. 20.2). The major axis of care targets is the patient and her/his safety, whereas the opposite direction points to "self-care," meaning quality of life (QOL) balance, and the health of the surgeon and/or researcher. Other factors, such as learning and

teaching, commitment and financial compensation, time- and space-limitation, increasing management demands and so forth, all influence patient care to some extent. In addition, the rapid methodical and technical progress in both research and surgery drives (academic) surgeons towards exclusive clinical or scientific work, and specialization. As a consequence of this polylemma, an increasing dissociation of surgery and research efforts by surgeons can be observed. As a possible consequence, there might be a dangerous reduction in clinic-borne hypothesis. The clinic-research decoupling process reflects the major problem for relevant and valid research in surgery, directly and indirectly affecting patient safety not only currently but also in the future.

Limitations of the Current Practice

Main barriers to effective research in surgery for patient safety:

- Possible communication barriers between surgeons and basic scientists
- Lack of cooperation between surgeons and (university) hospital officials based on personal, career or legal concerns, or cultural background
- Misinterpretation the scientific patient safety readouts as QM-measures, explaining the overall low impact of publications on patient safety issues
- Poor statistical design
- Lack of financial support and specific (inter)national grant programs, probably reflecting a limited degree of public awareness of patient safety issues
- Fear among surgeons and scientists of the "whistle-blower" effect
- Missing or underdeveloped error culture (e.g. crew resource management)
- Impairment of benchmarking and public relations
- Lack of implementation of patient safety research in both scientific and surgical societies (worldwide)

Where Is the "Golden Bullet"?

The "golden bullet" for optimal patient care has been "discovered" several times and presented to medical students and young doctors as principles and values on which good medical practice is founded. Accordingly, the medical or surgical expert is defined as an advocate of health with several key competencies, such as communication and management skills [14]. Strikingly, these definitions rarely include scientific aspects of the desired competencies which should be considered as very critical, because progress in all fields of medicine, particularly in surgery, is strongly dependent on high quality research as an integral part of all University education in the past, present, and future. Furthermore, for valid evaluation and "sharp-minded" assessment of the existing multiple peri-operative parameters determining the final outcome and

patients' QOL, consistent critical investigation using scientific means are necessary not only for the present but also in the future. It is tempting to speculate that future surgical patient care may–based on scientific progress–increasingly include patient-tailored interventions, designed by advanced peri-operative imaging tools, onsite wireless functional monitoring of organ functions and immune system performance to name a few. Performance of surgery will be increasingly less invasive, for example, by using nano-engines, nano-scalpels and other nano-tools, and being more computer-guided. Furthermore, surgical procedures will likely be accompanied by potent regenerative cellular approaches (e.g. stem cell therapies, and *ex vivo* reprogrammed and modulated cells), and innovative molecular materials (e.g. drug-coated ostesynthesis materials, scaffolds and allogenic tissues) and therapies. In addition, peri-operative monitoring of patient safety as well as its online- and post hoc-data-management will become more computer-guided. Establishing these potentially promising opportunities require intensive cross-border ethical discussions and considerations.

As depicted in Fig. 20.3, science and surgery remain the main columns for patient safety and outcome, including QOL improvements and health as the highest aim. Many disrupting factors, such as severe co-morbidities, bad macro- and micro-environmental conditions or the impact of an acute problem, such as severity of trauma or an advanced stage of cancer, will have a negative impact on patient safety and outcome. Therefore, it is even more important and capital for surgical procedures, and thus the underlying scientific justification, to be performed in accordance with good clinical practice (GCP) and good laboratory practice (GLP). The precondition, basis, and justification for any surgical or scientific procedure are of course the operation aim or scientific hypothesis to significantly improve the patients' situation. The platform for surgery and science is represented by the cultural, social, and economic background, and commitment of the present society or nation, respectively. In addition, the extent of the provided platform is dependent on the given personal and material resources, regularly resulting in competition for these resources. Surgical and scientific progress has also to be founded on ethical standards as defined in the Helsinki declaration to protect not only the individual but also society from misguidance and misuse. This includes informed consent before procedures in surgery, and intellectual freedom for the scientist (within the internationally defined ethical framework) in research. To perform both research and surgery at a high level, a constant training and teaching process applying established learning methods [15] on all professional levels is the basis, again accompanied by research analysis to ensure effectiveness and efficiency.

Overall, there are many "bullets" that endanger the structure of the artwork "patient safety" crowned by patient health (Fig. 20.3). Therefore, utmost and consistent care is needed to keep this structure sustainable, not only for patient safety and outcome, but also for human being and mankind as whole. However, one instability and error factor will remain: man!

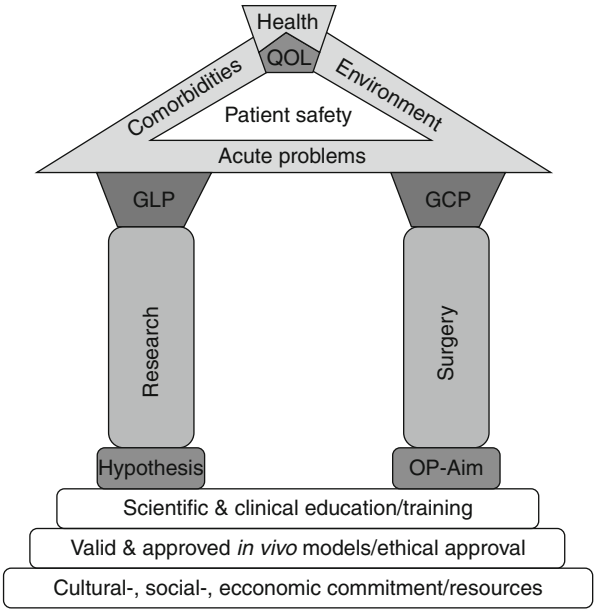


Fig. 20.3 Surgery and research as main columns for patient safety and quality of life. *GCP* good clinical practice, *GLP* good lab practice, *OP* operation, *QOL* quality of life

Take-Home Message

- High quality research on all levels is the future guarantee for patient safety.
- Surgeons are asked to question, as clinicians and scientists, everything potentially affecting patient safety—starting with themselves.
- The surgeon may act as a clinician locally and as a scientist globally.
- Life-long learning and teaching in surgery and research are prerequisites.
- Translational research approaches have to incorporate co-morbidities and real-life conditions.
- More freedom, financial support and time hiatus for clinically relevant and innovative research are needed.
- Association between research and surgery is needed with emphasis on long-term benefits and quality of life.

References

1. Huber-Lang M, Neugebauer E. The dual role of academic surgeons as clinicians and researchers—an attempt to square the circle? Patient Saf Surg. 2011;5:16.
2. Martinez EA. Quality, patient safety, and the cardiac surgical team. Anesthesiol Clin. 2013;31(2):249–68.
3. Lubbeke A, Hovaguimian F, Wickboldt N, Barea C, Clergue F, Hoffmeyer P, et al. Effectiveness of the surgical safety checklist in a high standard care environment. Med Care. 2013;51(5):425–9.

4. Anderson O, Davis R, Hanna GB, Vincent CA. Surgical adverse events: a systematic review. Am J Surg. 2013;206(2):253–62.
5. Chang DC, Handly N, Abdullah F, Efron DT, Haut ER, Haider AH, et al. The occurrence of potential patient safety events among trauma patients: are they random? Ann Surg. 2008;247(2):327–34.
6. Wan W, Le T, Riskin L, Macario A. Improving safety in the operating room: a systematic literature review of retained surgical sponges. Curr Opin Anaesthesiol. 2009;22(2):207–14.
7. Brennan JM, Edwards FH, Zhao Y, O'Brien S, Booth ME, Dokholyan RS, et al. Long-term safety and effectiveness of mechanical versus biologic aortic valve prostheses in older patients: results from the society of thoracic surgeons adult cardiac surgery national database. Circulation. 2013;127(16):1647–55.
8. Seok J, Warren HS, Cuenca AG, Mindrinos MN, Baker HV, Xu W, et al. Genomic responses in mouse models poorly mimic human inflammatory diseases. Proc Natl Acad Sci U S A. 2013;110(9):3507–12.
9. Rice J. Animal models: not close enough. Nature. 2012;484(7393):S9.
10. Steelman VM, Graling PR, Perkhounkova Y. Priority patient safety issues identified by perioperative nurses. AORN J. 2013;97(4):402–18.
11. Zhang Q, Li Y, Li J, Mao X, Zhang L, Ying Q, et al. Patients for patient safety in China: a cross sectional study. J Evid Based Med. 2012;5(1):6–11.
12. Stahl K, Palileo A, Schulman CI, Wilson K, Augenstein J, Kiffin C, et al. Enhancing patient safety in the trauma/surgical intensive care unit. J Trauma. 2009;67(3):430–3.
13. Aggarwal R, Mytton OT, Derbrew M, Hananel D, Heydenburg M, Issenberg B, et al. Training and simulation for patient safety. Qual Saf Health Care. 2010;19 Suppl 2:34–43.
14. Frank JR, Langer B. Collaboration, communication, management, and advocacy: teaching surgeons new skills through the CanMEDS Project. World J Surg. 2003;27(8):972–8.
15. Blackmore CC, Bishop R, Luker S, Williams BL. Applying lean methods to improve quality and safety in surgical sterile instrument processing. Jt Comm J Qual Patient Saf. 2013; 39(3):99–105.

Part II

The Surgeon's Perspective

The Surgery Morbidity and Mortality Conference

21

Gregory J. Jurkovich

Pitfalls and Pearls

- Failure to participate in a 'Morbidity & Mortality' peer-review process will limit payment from federal payers and some third-party payers.
- Failure to participate in a 'Morbidity & Mortality' peer-review process will prevent certification by the various professional Boards of the American Board of Medical Specialties.
- Recognizing that hospitals must report "sentinel events" to the accreditation organizations; and that CMS "never events" result in decreased payments from federal payer.
- Understanding the difference between individual responsibility and system-responsibility for an error.
- Understanding the concepts of 'preventable death'.
- Understanding the concepts of avoidable and unavoidable errors, with opportunities for improvement.

G.J. Jurkovich, MD, FACS
Department of Surgery, Denver Health Medical Center,
777 Bannock Street, Denver 80204, CO, USA
e-mail: jerryj@dhha.org

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_21, © Springer-Verlag London 2014

Outline of the Problem

The 1918 formation of the American College of Surgeons includes this wording: "All hospitals are accountable to the public for the degree of success . . . if the initiative is not taken by the medical profession, it will be taken by the lay public"

The origin of the surgical morbidity and mortality conference perhaps can be traced back to Ernest Emory Codman. Dr. Codman was born in the year that Stanley went to find Livingston (1869) and died as Hitler was overrunning most of Europe (1940). During his lifetime, x-rays were discovered and anesthesia became a reality and he died just as the antibiotic era was born. Dr. Codman was educated at Harvard University and Harvard Medical School, and became a surgeon at the Massachusetts General Hospital (MGH) in Boston at the age of 23. It was there that he likely developed the first surgery morbidity and mortality conference, an outgrowth of his "end results cards," a system in which he kept careful detailed data on surgical outcomes for at least 1 year following treatment [1]. He was known as an advocate of following the patient post-discharge, to determine their overall complications, as he primarily was a fracture surgeon at the time. Codman's "End Result Concept" was what he termed a "common sense notion" that every hospital should follow every patient it treats long enough to determine whether or not the treatment had been successful. Then to inquire, "If not, why not," with a view to preventing similar failures in the future. Dr. Codman's belief in the public scrutiny of outcomes was extremely unpopular with his colleagues, and forced him off the staff at the MGH in 1914. Nonetheless, to support his belief in the value of knowing the "end result," he established his own hospital, and privately published a book entitled "A Study in Hospital Efficiency" which documented 123 errors in the care of 337 patients between 1911 and 1916 [2].

In 1918 under Codman's leadership, the American College of Surgeons founded the Hospital Standardization Program [3]. Of note, the mission statement of the 1918 formation of the American College of Surgeons includes this wording: "All hospitals are accountable to the public for the degree of success . . . if the initiative is not taken by the medical profession, it will be taken by the lay public," which is directly attributable to Dr. Codman's influence. In 1951, a new entity, the Joint Commission on Accreditation of Hospitals was created by merging the Hospital Standardization Program with similar programs run by the American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association. In 1981, the company was renamed the "Joint Commission on Accreditation of Healthcare Organizations" (JCAHO) and in 2007 a major rebranding of this organization lead to the name "The Joint Commission."

Nearly 100 years after Codman's efforts, a sentinel paper by Lucian L Leape was published in 1991 in the New England Journal of Medicine, entitled "The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study" [4]. At the time, Dr. Leape was a professor of surgery at Tufts University and Chief of the Division of Pediatric Surgery at the New England Medical Center, and a member of the Harvard Medical School faculty since 1988. This paper, along with

the body of Dr. Leape's work, lead to an evolving concept that it was not so much the individual physician who was responsible for adverse outcomes (errors, complications) that occurred in patient care, but rather the poor design of the healthcare delivery system itself accounted for almost all the problems that lead to errors, poor quality and unsafe care. In 1994 he co-authored the report "Error in Medicine" [5] and the co-author of the Institution of Medicine 1999 report "To Err is Human" [6] and the 2001 report "Crossing the Quality Chasm" [7]. He is largely considered the father of the modern patient safety movement.

The American College of Surgeons was an outgrowth of the highly successful Clinical Congresses of Surgeons of North America, which took place annually from 1910 in various large surgical centers throughout North America as a means for continuing education of practicing surgeons. The Clinical Congresses were, themselves, an outgrowth of the journal Surgery, Gynecology and Obstetrics (SG&0), another initiative of ACS founder Franklin H. Martin, MD, FACS. SG&O began publishing in 1905 as a vehicle for practicing surgeons to edit their own journal, unlike most other scientific medical journals of the day, with the exception of the Journal of the American Medical Association, which were published by non-medical commercial firms for profit. From the time of its origin, the College has been involved in surgical education and research, patient welfare, hospital standardization, ethics of practice, and collaboration with other medical associations. The twentieth century was a period of increasing government involvement in medical practice, of patient awareness, and interest in care given, and of conflict and collaboration among the various medical societies. The ACS was a leader in hospital standardization practices, and as noted, The Joint Commission finds its origins in the American College of Surgeons.

The early goals of Dr. Codman, and then the American College of Surgeons, and then The Joint Commission, and then nearly 100 years later, Dr. Leape and the Institute of Medicine, were to prevent unnecessary deaths and poor outcomes by overall system improvement. The landmark series of studies in the 1960's on preventable trauma mortality probably best represents the early efforts at a system approach to reducing death. In 1955, Robert Zollinger, then President of the Society of University Surgeons, wrote about the "preventability" of deaths following motor vehicle crashes [8]. Thirty years later Donald Trunkey reviewed 29 studies summarizing the state of the literature on preventable trauma mortalities [9]. The essence of these observations over three decades was that the primary causes of preventative mortality in the trauma patients were failure to adequately evaluate blunt abdominal trauma, delays in initiating appropriate treatment, and critical errors in care management. Preventable death rate around the country approached 70 % at that time, with the developing observation that trauma centers and cities and counties with trauma systems had much better outcomes [10–13].

Limitations of Current Practice

Preventable death studies, however, are limited in their capabilities to define improvement in care. They are not a substitute for continuous quality improvement, and they are not particularly effective at analyzing the root cause of an error; they have no role in assessment morbidity and they lack the ability to assess the affect of

volume on outcome. Additionally they have great difficulty in judging complexities of care, such as the effect of fluid resuscitation on respiratory function, or the timing of blood transfusions on reversing the coagulopathy of trauma. In addition, they were unable to deal with errors in which there was considerable controversy related to care, such as the role of DVT prophylaxis in its prevention of pulmonary embolism. Finally, preventability of death is a moving target, as standards of care change over time. None-the-less, the intra-panel rate of reliability as well as the inter-panel agreement preventable death studies ranges from 66 to 88 % for intra-panel agreement and 86–95 % for inter-panel agreement on non-cerebral vascular deaths [14]. In essence, preventable death studies are good for determining the obvious.

The concept of preventable death studies is also still plagued by the tendency to assign blame to an individual component of the system; whether it is an individual surgeon, a surgical team, or a nursing care unit. This is in contrast to Lucian Leape's precepts, and the more contemporary treatment of all errors as being system-design issues, rather than individual errors with individual responsibility. A quote for the Institute of Medicine "To Err is Human" report emphasizes this change: "One of the report's main conclusions is that the majority of medical errors do not result from individual recklessness or the actions of a particular group—this is not a "bad apple" problem. More commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them." [6] To emphasize this change in the lexicon of patient safety, the American Colleges Committee on Trauma developed new definitions for preventable deaths as listed in Table 21.1. These new definitions emphasize the role of the system in the cause of complications and errors, and also emphasized where there are system opportunities for improvement.

The *Institute of Medicine* in 1999 report "To Err is Human: Building a Safer Healthcare System" attributed over 100,000 preventable deaths to medical error each year [15]. Many surgeons felt that this report was erroneous, and there could not possibly be that many deaths attributable to errors. However, Healy and colleagues reporting in 2002, that in fact this may be an underestimation of preventable death rates. In their single-institution comprehensive review of a total hospital surgical services complication rate revealed that the total complication rate in a University combined vascular service (general, trauma, cardiothoracic, and vascular) had a total complication rate of 32 %. Furthermore, both major and minor complications were nearly 50 % avoidable. And finally, of the 128 deaths that occurred in this study, fully 30 % were felt to be avoidable [16]. These authors concluded that the complication rates in surgical patients are perhaps two to four times greater than those identified in the *Institute of Medicine* report.

Table 21.1 American College of Surgeons Committee on trauma definitions of "preventable death"

Old	New (2011)
Preventable	Unanticipated mortality with opportunity for improvement
Non-Preventable	Mortality without opportunity for improvement
Possibly Preventable	Anticipated mortality with opportunity for improvement

This does not imply there are not events that are so egregious as that they should never be allowed to occur. Two distinct, but overlapping definitions of patient quality and safety events that are felt should never occur, regardless of the health care system are defined by the National Quality Forum (*Never Events*), and The Joint Commission (*Sentinel Events*). The National Quality Forum was originally conceptualized by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry in 1998, with the National Quality Forum established as a nonprofit, public benefit corporation and a unique public-private collaborative venture in 1999; it became operational in February 2000 [17]. The work products of the NQF have largely been adopted by the Centers for Medicare and Medicaid Services (CMS) and the Agency for Healthcare Research and Quality (AHRQ) [18]. *Never Events* were probably first coined by Dr. Ken Kizer, a former CEO of the National Quality Forum in 2001. Dr. Kizer originally called these events "*adverse events*," although this list has subsequently become known as "*never events*." [19] This is a list of adverse outcomes (complications, errors) that are unambiguous (clearly identifiable and measurable), serious (resulting in death or significant disability), and usually preventable. The National Quality Forum additionally identified 27 such events in 2002 and divided these into six categories (see Table 21.2).

The National Quality Forum "*never events*" have been adopted by CMS and AHRQ, but the Joint Commission has developed a similar but separate list of "*sentinel* events." (See Table 21.3) Complications related to *Never Events* result in lack of CMS funding for the care that is directly attributable to that never event complication. *Sentinel Events* require reporting during Joint Commission accreditation visits.

Many continue to question if the error rate in the delivery of medical care is really so high as to warrant all this attention. Healthcare errors typically are not reported in a newspaper, like when a jumbo jet crashes. And many healthcare errors are either intercepted or insignificant in their magnitude, and most errors actually cause little or no harm. For example, a major cause of errors are medication errors which occur in between 2 and 14 % of hospitalized patients, and again, most of these simply do not result in injury, but have the potential to do so. The reality of errors is that while they occur relatively infrequently, they are occurring at over 5,000 healthcare locations

Table 21.2 NQF "never events"

Event	Additional specifications
1. Surgical events	
A. Surgery performed on the wrong body part	Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.
B. Surgery performed on the wrong patient	Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.

(continued)

Table 21.2 (continued)

Event	Additional specifications
C. Wrong surgical procedure performed on a patient	Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery includes endoscopies and other invasive procedures.
D. Retention of a foreign object in a patient after surgery or other procedure	Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.
E. Intraoperative or immediately post-operative death in an ASA Class I patient	Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means within 24 h after induction of anesthesia (if surgery not completed), surgery, or other invasive procedure was completed.
2. Product or device events	
A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility	Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.
B. Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used for functions other than as intended	Includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, and ventilators.
C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility	Excludes deaths associated with neurosurgical procedures known to be a high risk of intravascular air embolism.
3. Patient protection events	
A. Infant discharged to the wrong person	
B. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours	Excludes events involving competent adults.
C. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a health care facility	Defined as events that result from patient actions after admission to a health care facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the health care facility.
4. Care management events	
A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)	Excludes reasonable differences in clinical judgment on drug selection and dose.

Table 21.2 (continued)

Event	Additional specifications
B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products	
C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility	Includes events that occur within 42 days post-delivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a health care facility	
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	Hyperbilirubinemia is defined as bilirubin levels >30 mg/dl. Neonates refers to the first 28 days of life.
F. Stage 3 or 4 pressure ulcers acquired after admission to a health care facility	Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
G. Patient death or serious disability due to spinal manipulative therapy	
5. Environmental events	
A. Patient death or serious disability associated with an electric shock while being cared for in a health care facility	Excludes events involving planned treatments such as electric countershock.
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances	
C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility	
D. Patient death associated with a fall while being cared for in a health care facility	
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility	
6. Criminal events	
A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider	

(continued)

Table 21.2 (continued)

Event	Additional specifications
B. Abduction of a patient of any age	
C. Sexual assault on a patient within or on the grounds of the health care facility	
D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the health care facility	

Table 21.3 The Joint Commission sentinel events

1. Events that have resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition or;
2. Events that include one of the following:
   (a) Suicide of any individual receiving care, treatment, or services in a staffed around-the-clock setting, or within 72 h of discharge;
   (b) Unanticipated death of a full-term infant;
   (c) Abduction of any patient receiving care, treatment, or services;
   (d) Discharge of an infant to the wrong family;
   (e) Rape, assault (leading to death or permanent loss of function), or homicide of any patient receiving care;
   (f) Rape, assault (leading to death or permanent loss of function), or homicide of a staff member, LIP, visitor or vendor while on site;
   (g) Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups);
   (h) Surgical and nonsurgical invasive procedure on the wrong patient, wrong site or wrong procedure;
   (i) Unintended retention of a foreign object in a patient after surgery or other procedure;
   (j) Severe neonatal hyperbilirubinemia (bilirubin >30 mg/dl);
   (k) Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25 % above the planned radiotherapy dose.

across the country, hourly, daily, on hundreds of thousands of patients. Add to this the observation that healthcare providers have difficulty in dealing with their own human error, since the stakes involve the life of another person, and the conflict of error recognition and prevention becomes more apparent.

The difficulty healthcare providers have in dealing with human error is significant. The culture of medicine is one of error-free practice. Mistakes are considered unacceptable, and physicians in particular are unwisely considered to be infallible. Therefore, an error is a failure of their character, leading to the question that drives medical malpractice lawsuits: "How can there be an error without negligence?" Finally, physicians and all healthcare providers have an innate sense of responsibility to the patient and hence, a responsibility for any errors that occur. In the face of this the concept of infallibility, the occurrence of an "error" lead to an attempt to cover up mistakes or to shift or share the blame. Physicians are taught in medical

school and residency to strive for an error free practice and perfection in diagnosis and treatment; in this environment, if an error occurs it occurred because you weren't careful enough, you didn't try hard enough or you didn't know enough.

The paradox then arises since the standard is one of perfection and an error-free practice, yet errors are inevitable. How can we examine and learn from mistakes, and remove the concept of infallibility and the fear of embarrassment and censure, the fear of patient reaction, and the fear of litigation?

The surgical morbidity and mortality conference is one way that surgeons attempts to rectify this paradox. In his 2003 book "Forgive and Remember," Charles L Bosk discusses managing medical failure [20]. The surgical M&M conference has a long-standing legacy in surgical lore. As Dr. Bosk notes, the concept of a surgical M&M process was to identify an error, blame someone for the error, yet forgive them for the error, and move along to the next case, yet trying to instill in all in attendance a deep memory of this event as to never repeat it again. This amounts to the ABC's of The Surgical M&M Conference: Accuse, Blame, and Confess. Alternatively, as Dr. Bosk called it: "Blame, Forgive & Remember." This concept of recognizing human fallibility, acknowledging it, and then providing forgiveness is steeped in Judeo-Christian beliefs and rituals, including the Roman Catholic sacrament of confession with its acknowledgment of sin, the bestowing of forgiveness, and acts of penance.

Unfortunately, the explosion of technologies in the second half of the twentieth Century, and now into the twenty-first Century, the wide availability of different drugs and operations, the super specializations of healthcare providers, and the overall complexity of the healthcare system, coupled with the ever-increasing number of healthcare providers involved in the care of the patient, makes this process of singularly identifying a "bad apple" destined to fail. There simply are too many providers moving through the healthcare system and too many patients moving through an increasingly complicated healthcare system to expect this solution to work.

James Reason has divided the prevention of errors into two distinct conditions, he determined these the *Latent Conditions*, and the *Active Conditions* [21]. The latent conditions are organizational factors, unsafe supervision, and pre-conditions for the performance of unsafe acts. The active conditions are the performance of an unsafe act. Only when all of these align (see Fig. 21.1) will an error or harm occur to the patient. But these failed, or absent defenses can occur without careful attention. In other words, high-risk situations occur in medicine all the time, and high-risk behavior coupled with inadequate preventive mechanisms will result in an error or an adverse event.

Roughly speaking, surgeons will make a mistake once in every 200 times he or she performs surgery, and high-risk activity. A mistake can result in an outcome that ranges from lethal to morbid. Dr. Atul Gawande, a general surgeon practicing at the Brigham and Women's Hospital in Boston has written two best-selling books focusing on the essence of surgical complications and what it means to attempt to practice perfection in an imperfect science [22, 23]. The result of these contemporary discussions reflects the changes in patient safety that is occurring in the twenty-first Century. We no longer refer to complications or bad outcomes as "errors," but rather, as "adverse events." Quality improvement and patient safety tasks are

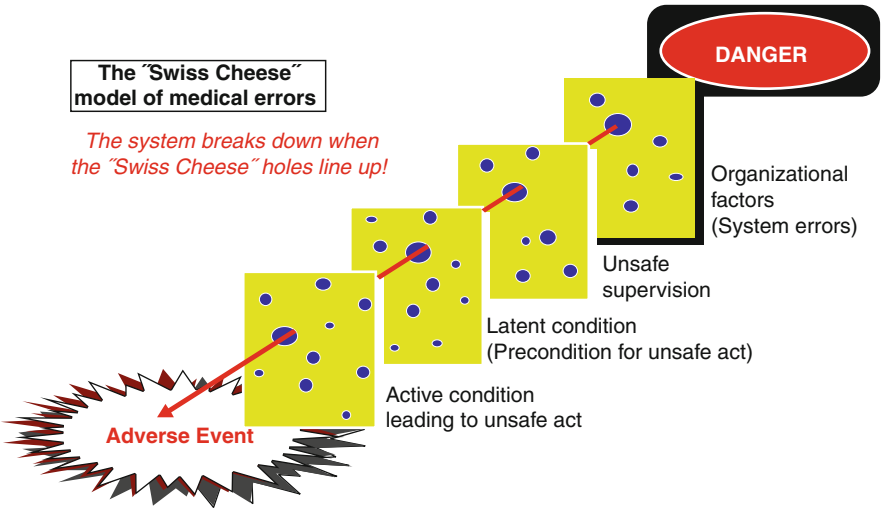


Fig. 21.1 Alignment of factors that allow an error to occur (adapted in modified version from Reason [21])

reviewed not so much to identify the error or the responsible party(s), but as a method of preventing errors from ever occurring. To do so requires enlisting a wide range of stakeholders and healthcare provider's support. To accomplish this task, however, needs the agreement on what interventions are likely to be affective, and uniform and widespread reporting, not just of adverse events that occur, but also as potentially preventable errors, as they occur.

Where Is the Golden Bullet?

A contemporary approach involves improving recognition and reporting, standardizing classifications, and understanding the predisposing factures of structural and system factors, defective information systems, and building safety firewalls rather than assigning blame. Interdisciplinary expertise has been brought to error recognition and reporting, standardizing error classifications, understanding the systemic and psychological associations with errors, and developing effective error mitigating strategies.

Consider this case example. A 69-year-old male sustained a multiple-trauma in a motor vehicle crash, which included a traumatic brain injury and multiple extremity fractures. As a result of a prolonged intensive care unit course he had a tracheostomy placed on hospital day 14 for ventilator weaning. Six hours later, at approximately 9 p.m. at night, a leak was noticed from the freshly placed tracheostomy tube necessitating frequent manipulations by respiratory therapy and bedside nurse. The on-call hospitalist was notified of the problem. What should be done? Should the physician on-call try to trouble-shoot the problem and see the patient? Should

anesthesia be called to orally intubate the patient and remove the tracheostomy? Should a note be made on the chart with plans to verbally notify the intensive care team and morning rounds? Or perhaps should the surgeon who placed the tracheostomy be notified of the problem regardless of the fact the patient was stable and doing fine?

In this example, what actually happened was the patient was seen, a note was made to discuss on morning rounds. However, in the early morning hours prior to morning rounds, the patient coughed the tracheostomy tube out and rapidly desaturated. Bedside attempts to reinsert the tracheostomy tube failed. Endotracheal intubation could not be readily accomplished and the patient ultimately suffered respiratory arrest and died.

As this classic case of preventable death was reviewed, lessons were learned. The classic surgical M&M approach of assign, blame, confess would have been to identify the physicians involved as well as the other healthcare providers, blame them for this occurrence, get them to confess the error, forgive them, and hope they and anyone else in attendance will remember this event forever and never repeat it. Of course a note would be made in their record that this occurred, as a potential lack of diligence in providing good patient care. On the other hand, the contemporary twenty-first Century approach on system prevention of errors would be to write a hospital wide policy for the management of fresh tracheostomies such that judgment calls are not involved and the policy of immediately managing an air leak from a fresh tracheostomy would be revised to include examination by the operating surgeon and replacement of the tracheostomy tube or re-intubation. However this would require intensive effort of tracking the problems, seeing how effective the policy was, and altering the policy as time went on.

One paper has examined the efficacy of such a system-wide approach to common errors and complications in trauma patients. Gruen, Jurkovich and colleagues from Harborview Medical Center in Seattle reviewed lessons learned from a decade of quality improvements analyses of 2,594 trauma deaths at one institution [24]. Two percent of these deaths (n = 53) were attributed to errors in care as identified at a classic surgical M & M process, and 23 % were identified by TRISS probability screening (n = 601). An additional peer review process culled these 654 deaths and identified 64 cases (2.4 % of the total) in which there were errors or "adverse events" that contributed to the mortality. These authors searched for patterns of errors, in both the type of clinical care error that occurred, as well as the location and timing of the error. Figures 21.2 and 21.3 demonstrate these results, clearly emphasizing that treatment errors dominated, primarily because of a failure to follow established care protocols (a system problem), and that the most frequent site of errors was in the intensive care unit, and during the initial resuscitation. The authors further established a wide ranging effort at putting in place policies to address the most common of errors, and found this policy implementation and follow up highly effective for reducing or eliminating some of the errors, but not all. This paper clearly established the efficacy of a system corrective approach to error reduction, but also emphasizes that it is not an easy solution, and not without its own failures.

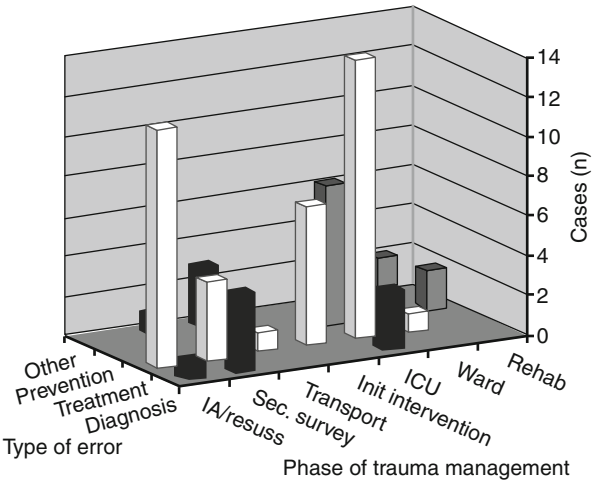


Fig. 21.2 Phase of trauma care in which errors occur. Treatment errors predominate, notably during initial resuscitation (IA), initial intervention and ICU care (From Gruen et al. [24])

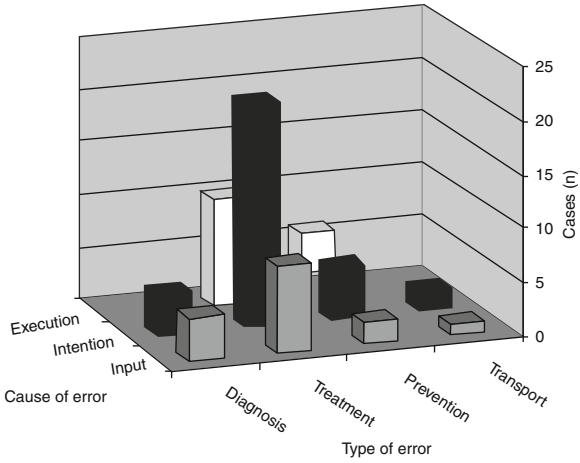


Fig. 21.3 Error by psychological cause (execution = skill, intention = rules; input = knowledge) and type (diagnosis, treatment, prevention, transfer of patient) (From Gruen et al. [24])

Take-Home Message

In conclusion, preventable deaths and preventable errors occur in even the most highly developed healthcare system. Improved communications and eliminating hand-off errors are the latest challenge in professional behavior that affects complications, adverse events, and outcomes. Patterns of errors can be recognized, strategies to mitigate these errors can be developed, and institutional protocols can effectively reduce error occurrence, but reducing medical errors to zero remains a "Shangri-La" of medical care.

References

1. Berwick D. E.A Codman and the rhetoric of battle: a commentary. Milbank Q. 1989; 67(2):262–7.
2. Donabedian A. The end results of health care: Ernest Codman's contribution to quality assessment and beyond. Milbank Q. 1989;67(2):233–56.
3. Roberts JS, Coale JG, Redman RR. A history of the Joint Commission on Accreditation of Hospitals. JAMA. 1987;258(7):936–40. Epub 1987/08/21.
4. Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. N Engl J Med. 1991;324(6):377–84. Epub 1991/02/07.
5. Leape LL. Error in medicine. JAMA. 1994;272(23):1851–7. Epub 1994/12/21.
6. Committee on Quality of Health Care in America. To err is human: building a safer health system. Washington, D.C: National Academy Press; 1999.
7. Committee on Quality of Health Care in America. Crossing the quality chasm: a new health system for the 21st century. Washington, D.C: National Academy Press; 2001.
8. Zollinger RW. Traffic injuries; a surgical problem. AMA Arch Surg. 1955;70(5):694–700. Epub 1955/05/01.
9. Cales RH, Trunkey DD. Preventable trauma deaths. A review of trauma care systems development. JAMA. 1985;254(8):1059–63. Epub 1985/08/23.
10. West JG, Cales RH, Gazzaniga AB. Impact of regionalization. The Orange County experience. Arch Surg. 1983;118(6):740–4. Epub 1983/06/01.
11. Shackford SR, Hollingworth-Fridlund P, Cooper GF, Eastman AB. The effect of regionalization upon the quality of trauma care as assessed by concurrent audit before and after institution of a trauma system: a preliminary report. J Trauma. 1986;26(9):812–20. Epub 1986/09/01.
12. Shackford SR, Hollingsworth-Fridlund P, McArdle M, Eastman AB. Assuring quality in a trauma system–the Medical Audit Committee: composition, cost, and results. J Trauma. 1987;27(8):866–75. Epub 1987/08/01.
13. Guss DA, Meyer FT, Neuman TS, Baxt WG, Dunford Jr JV, Griffith LD, et al. The impact of a regionalized trauma system on trauma care in San Diego County. Ann Emerg Med. 1989;18(11):1141–5. Epub 1989/11/01.
14. MacKenzie EJ, Steinwachs DM, Bone LR, Floccare DJ, Ramzy AI. Inter-rater reliability of preventable death judgments. The Preventable Death Study Group. J Trauma. 1992;33(2):292–302; discussion –3. Epub 1992/08/01.
15. Leape LL. Institute of Medicine medical error figures are not exaggerated. JAMA. 2000;284(1):95–7. Epub 2000/06/29.
16. Healey MA, Shackford SR, Osler TM, Rogers FB, Burns E. Complications in surgical patients. Arch Surg. 2002;137(5):611–7; discussion 7–8; Epub 2002/05/02.
17. Kizer KW. The National Quality Forum seeks to improve health care. Acad Med. 2000;75(4):320–1. Epub 2000/07/13.
18. National Quality Forum. Serious reportable events in healthcare: a consensus report. Washington, DC: National Quality Forum; 2002.
19. Kizer KW. Establishing health care performance standards in an era of consumerism. JAMA. 2001;286(10):1213–7. Epub 2001/09/18.
20. Bosk C. Forgive and remember: managing medical failure. Chicago: University of Chicago Press; 2003. p. 308.
21. Reason J. Human error. Cambridge/New York: Cambridge University Press; 1990. p. 320.
22. Gawande A. Complications: a surgeon's notes on an imperfect science. New York: Picador; 2002.
23. Gawande A. Better: a surgeon's notes on performance. New York: Picador; 2007.
24. Gruen RL, Jurkovich GJ, McIntyre LK, Foy HM, Maier RV. Patterns of errors contributing to trauma mortality: lessons learned from 2,594 deaths. Ann Surg. 2006;244(3):371–80. Epub 2006/08/24.

Reporting of Complications

22

Philip F. Stahel and Nathan Butler

Pitfalls and Pearls

- Surgeons remain inherently reluctant to publicly disclose surgical failures and complications.
- The systematic reporting of medical and surgical errors to other physicians is hampered by fear of condemnation and legal ramifications.
- The written publication of medical or surgical errors, aimed at providing a root cause analysis and future preventability of similar occurrences, can potentially be used against surgeons in a court of law.
- The altruistic willingness to publish case reports on surgical complications is not incentivized by financial or academic merits, and relies purely on the surgeons' good will to "do the right thing."
- Proper regulation and legislative tort reform are needed to avoid penalties for publicly reporting medical or surgical errors, with the ultimate goal of enhancing patient safety and its long-term sustainability.

P.F. Stahel, MD, FACS (✉)
Department of Orthopaedics, Denver Health Medical Center, University of Colorado, School of Medicine, 777 Bannock Street, MC 0188, Denver, CO 80204, USA
e-mail: philip.stahel@dhha.org

N. Butler
West Virginia School of Osteopathic Medicine,
200 North Lee Street, Lewisburg, WV 24901, USA

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_22, © Springer-Verlag London 2014

Outline of the Problem

Disclosure and reporting of surgical complications and medical errors represents an essential "information problem" and dilemma for the surgeon.

From the public perspective, nothing is acceptable short of full disclosure of medical and surgical errors. Nevertheless, surgeons remain inherently reluctant to disclose surgical failures and complications due to fear of medicolegal implications, loss of professional prestige among peers, and the well engrained tenet of non-admission of guilt and fallibility among surgeons ('*culture of blame and shame*') [1]. From an ethical perspective, the concern is that the suppression of data will deprive other health care providers of crucial insights that would prevent similar errors from occurring in the future.

Limitations of the Current Practice

In contrast to other high-risk domains, such as professional aviation safety, where the systematic implementation of error reduction policies has led to an irrefutable drop in fatal accident rates [2], surgeons remain reluctant to recognize, analyze, and publicly report their own errors. Open reporting and peer-review of surgical complications create new dilemmas for the surgeon in practice. Reports of errors negatively affect the provider's and the affiliated institution's official metrics for being perceived as a 'safe' practitioner or practice by customers (patients), payers (insurance companies), and peers (referring providers and other surgeons competing for the same 'market').

Until present, surgeons continue to report their own failures for purely altruistic reasons, as there is no financial incentive or academic merit. A recent landmark article confirmed the notion of the "*wisdom of Solomon*, *the bravery of Achilles*, *and the foolishness of Pan . . .*" for the reporting of medical errors [3]. This allegory is spot on, as it is certainly 'wise' to report lessons learned from previous failures, impressively 'brave' of surgeons to disclose complications, and incomparably 'foolish' to provide a written testimony with the potential to be used as an admission of guilt in the court of law.

Until legislation provides legal protection for full disclosure and reporting of medical errors, we will continue to rely on highly selective anecdotal reports of errors and complications in the peer-reviewed literature.

Where Is the "Golden Bullet"?

Medical journals are in a privileged position to commission and publish articles on controversial topics, including the reporting of surgical failures and complications. Publication ethics makes it extremely difficult, if not impossible, to

publish medical errors anonymously. Authors have to take full accountability for the accuracy of all scientific content in their publications. However, there are recent pilot projects from the open-access publishing arena that have substantiated the feasibility of public reporting of surgical complications. For example, a recently launched open-access online journal, *Patient Safety in Surgery* (*PSS*), was designed to complement traditional journals in surgery by providing a scientific forum for discussion, review, and root-cause analysis of failures in the management of surgical patients [4]. Since there is currently no legal protection for truthful and timely reporting of surgical complications and medical errors, the design and implementation of *PSS* as a new journal in its field was accompanied by multiple challenges and hurdles. For example, surgical colleagues and friends, as well as the publisher's legal advisers, discouraged the founding editors from introducing an article category on 'Case Reports.' The underlying argument was that "*only a fool would agree to publish a case report on preventable surgical complications associated with adverse patient outcomes*."

The ultimate resolution consisted of mandating that submitting authors provide a written consent from patients, or their legal guardians, for any manuscript which provides information on specific identifiable individual patient scenarios. Strikingly, the editors were astonished by the unexpected high submission rate of case reports on surgical complications, preventable sentinel events, and "never events," starting from the first weeks of the journal's launch, until the present day [5–20].

The successful history of this young journal supports the notion that health care providers all over the globe strive for publicly reporting, analyzing, and discussing the root cause analysis of surgical and medical errors. Unequivocally, a global public platform for the reporting of adverse events is needed to provide transparency for other health care providers and the public, and to allow the design of new preventive measures derived from lessons learned.

Within the first 5 years of its inception, *Patient Safety in Surgery* had a spectacular beginning, supported by the following statistical metrics [21]:

- The readers' access to papers published on the PSS website (www.pssjournal.com) has increased from less than 2,000 hits in 2007, to up to 16,000 accesses per month in 2012 (Fig. 22.1).
- The top-25 most accessed articles have been viewed through the PSS website more than 500,000 times to date (www.pssjournal.com/mostviewed/alltime).
- The journal is supported by an internationally renowned editorial board with editors from 17 different countries (www.pssjournal.com/edboard), and is read online in more than 180 countries around the world (Fig. 22.2).

The most accessed article published in *PSS* has been viewed through the journal's webpage more than 10,000 times per year during the first 3 years of its publication [22]. This impressive metric supports the notion that the public is indeed interested in this pertinent topic, and that the theoretical barriers for open reporting outlined above, including legal considerations, do not appear to deter surgeons from publishing complications in an open global forum (Fig. 22.3).

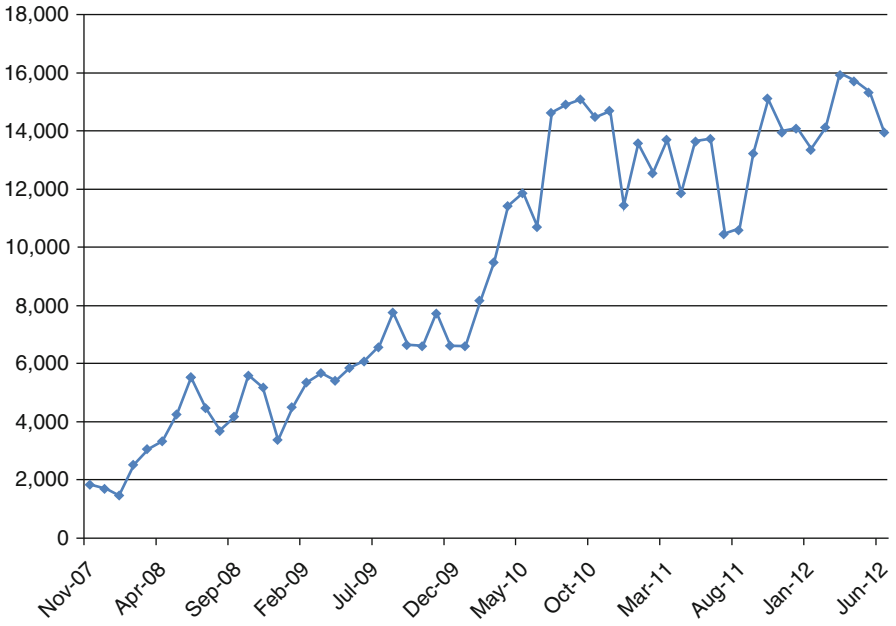


Fig. 22.1 Article accesses to the open-access journal *Patient Safety in Surgery*. The graph shows the growing number of accesses to articles published from the time of the journal's launch in November 2007, until June 2012. The data reflect access statistics to the PSS webpage exclusively, and do not include additional sources of access, including PubMed and other portals and article repositories (Adapted with permission from Stahel et al. [21])

Take-Home Message

The open and transparent global reporting of medical errors and surgical complications represents the "conditio-sine-qua-non" for continuous quality improvement in the care provided to our patients. Reflected by the notion "*You can't fix what you don't know*!" the historic 'veil of secrecy' surrounding medical errors must be replaced by a 'culture of patient safety' aimed at understanding and improving current shortcomings and limitations in the quality of surgical care. Tort reform is needed to relieve surgeons from the fear of litigation—the main deterrent from open disclosure and reporting of surgical complications.

Conflict of Interest Both authors declare that they are editors on the Editorial Board of the open-access journal *Patient Safety in Surgery*.

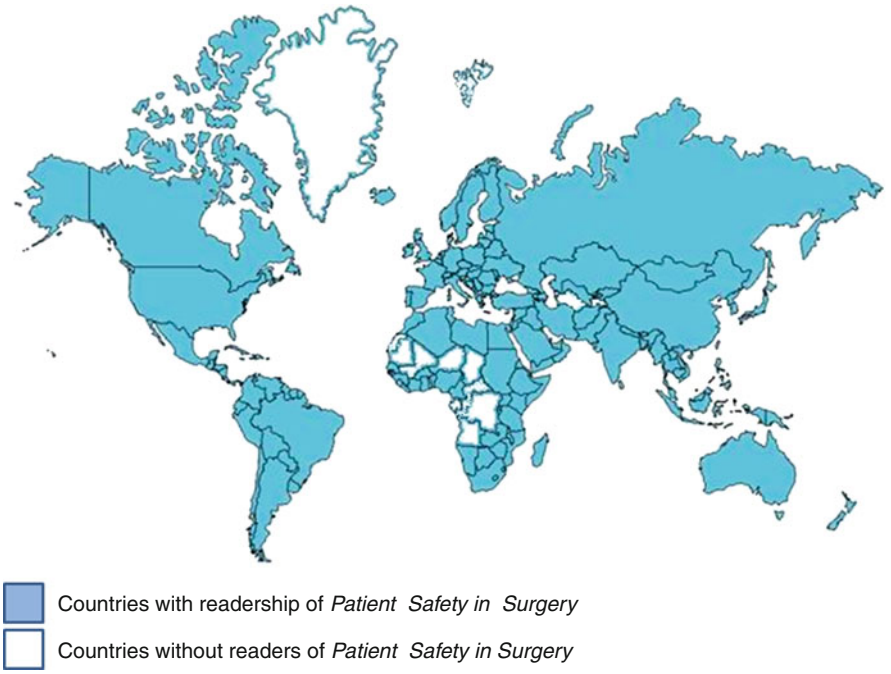


Fig. 22.2 Global readership of *Patient Safety in Surgery*. All countries with previous access to articles published in PSS are marked in blue background. The few unmarked countries do not have a history of access to the journal. These selected states include Greenland, Turkmenistan, Tajikistan, and some countries in West Africa and Central Africa (Adapted with permission from Stahel et al. [21])

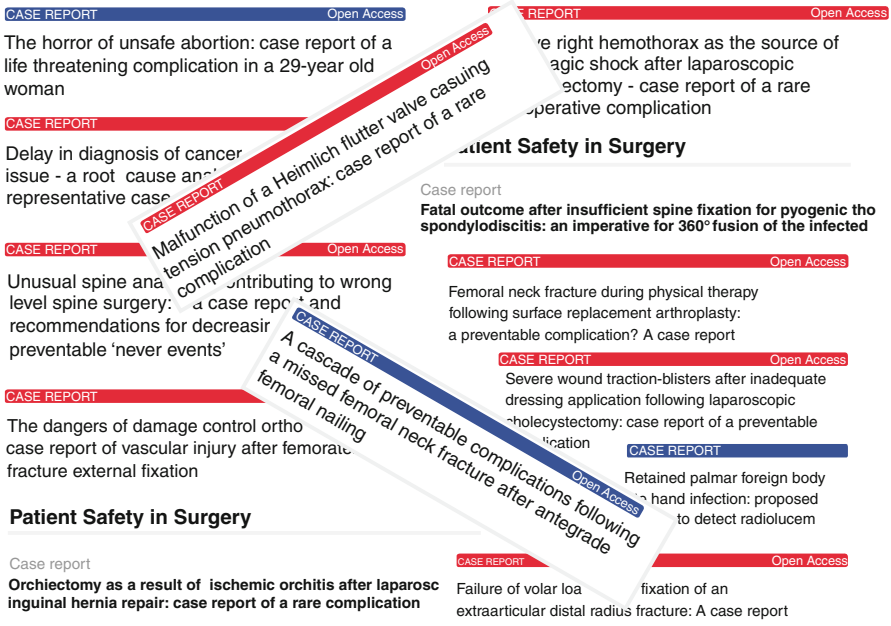


Fig. 22.3 Representative selection of case reports published in *Patient Safety in Surgery* that report surgical complications, medical errors, and other adverse events (Source: www.pssjournal.com)

References

1. Stahel PF, Flierl MA, Smith WR, Morgan SJ, Victoroff MS, Clarke TJ, Sabel AL, Mehler PS. Disclosure of surgical complications: a double-edged sword? Am J Med Qual. 2010;25:398–401.
2. Stahel PF. Learning from aviation safety: a call for formal "readbacks" in surgery. Patient Saf Surg. 2008;2(1):21.
3. Murphy JG, Stee L, McEvoy MT, Oshiro J. Journal reporting of medical errors: the wisdom of Solomon, the bravery of Achilles, and the foolishness of Pan. Chest. 2007;131:890–6.
4. Stahel PF, Clavien PA, Hahnloser D, Smith WR. A new journal devoted to patient safety in surgery: the time is now! Patient Saf Surg. 2007;1(1):1.
5. Moore JB, Hasenboehler EA. Orchiectomy as a result of ischemic orchitis after laparoscopic inguinal hernia repair: case report of a rare complication. Patient Saf Surg. 2007;1(1):3.
6. Weiss HR. Adolescent Idiopathic Scoliosis—case report of a patient with clinical deterioration after surgery. Patient Saf Surg. 2007;1:7.
7. Flierl MA, Beauchamp KM, Bolles GE, Moore EE, Stahel PF. Fatal outcome after insufficient spine fixation for pyogenic thoracic spondylodiscitis: an imperative for 360 degrees fusion of the infected spine. Patient Saf Surg. 2009;3(1):4.
8. Vaidyanathan S, Soni BM, Singh G, Hughes PL, Mansour P, Oo T. Delay in diagnosis of cancer as a patient safety issue—a root cause analysis based on a representative case report. Patient Saf Surg. 2011;5:19.
9. Holzer T, Pellegrinelli G, Morel P, Toso C. Appendectomy during the third trimester of pregnancy in a 27-year old patient: case report of a "near miss" complication. Patient Saf Surg. 2011;5(1):11.

10. Yoshihara H, Vanderheiden TF, Stahel PF. A missed injury leading to delayed diagnosis and postoperative infection of an unstable thoracic spine fracture—case report of a potentially preventable complication. Patient Saf Surg. 2011;5:25.
11. Lindley EM, Botolin S, Burger EL, Patel VV. Unusual spine anatomy contributing to wrong level spine surgery: a case report and recommendations for decreasing the risk of preventable 'never events.'. Patient Saf Surg. 2011;5(1):33.
12. Liporace FA, Yoon RS, Kesani AK. Transient common peroneal nerve palsy following skeletal tibial traction in a morbidly obese patient—case report of a preventable complication. Patient Saf Surg. 2012;6(1):4.
13. Staeheli GR, Fraser Jr MR, Morgan SJ. The dangers of damage control orthopedics: a case report of vascular injury after femoral fracture external fixation. Patient Saf Surg. 2012;6:7.
14. Vaidyanathan S, Selmi F, Soni B, Hughes P, Singh G, Pulya K, Oo T. Pyonephrosis and urosepsis in a 41-year old patient with spina bifida: case report of a preventable death. Patient Saf Surg. 2012;6(1):10.
15. Saini P, Meena S, Malhotra R, Gamanagatti S, Kumar V, Jain V. Pseudoaneurysm of the superior lateral genicular artery: case report of a rare complication after total knee arthroplasty. Patient Saf Surg. 2013;7(1):15.
16. McDonald LS, Tepolt F, Leonardelli D, Hammerberg EM, Stahel PF. A cascade of preventable complications following a missed femoral neck fracture after antegrade femoral nailing. Patient Saf Surg. 2013;7(1):16.
17. Ipaktchi K, Demars A, Park J, Ciarallo C, Livermore M, Banegas R. Retained palmar foreign body presenting as a late hand infection: proposed diagnostic algorithm to detect radiolucent objects. Patient Saf Surg. 2013;7(1):25.
18. Naqvi KZ, Edhi MM. The horror of unsafe abortion: case report of a life threatening complication in a 29-year old woman. Patient Saf Surg. 2013;7(1):33.
19. Patel SH, Moore TA. Motion artifact on computed tomography scan suggesting an unstable 3-column spine injury: case report of a "near miss" root cause of unneeded surgery. Patient Saf Surg. 2013;7(1):35.
20. Vaidyanathan S, Singh G, Soni B, Hughes P, Pulya K. Substandard urological care of elderly patients with spinal cord injury: an unrecognized epidemic? Patient Saf Surg. 2014;8(1):4.
21. Stahel PF, Smith WR, Hahnloser D, Nigri G, Mauffrey C, Clavien PA. The 5th anniversary of "Patient Safety in Surgery"—from the Journal's origin to its future vision. Patient Saf Surg. 2012;6(1):24.
22. Hurlbert SN, Garrett J. Improving operating room safety. Patient Saf Surg. 2009;3(1):25.

Disclosure of Complications

23

Timothy Barlow

Pitfalls and Pearls

- Medical errors are common, with over one million per year in the USA.
- Non-disclosure is estimated to occur in over half the cases of medical error.
- The physician has a fundamental conflict of interest in deciding whether to disclose complications or not: moral courage is a necessity.
- Fear of legal action, loss of reputation, and regulatory action cause a fundamental conflict of interest.
- Varying legal practices mean the offering of an apology may be construed as admission of guilt.
- Different approaches to regulation result in a complex geographical and institutional variations in practice.
- Two systems to increase disclosure are prevalent:
  1. Encourage a culture of open disclosure and decrease the real or perceived cost of disclosure.
  2. Make disclosure a responsibility grounded in statute, with more severe punishment for non-disclosure.

T. Barlow, MD, BSc, MBChB(Hons), MRCS(Glas)
Department of Trauma and Orthopaedics,
University of Warwick, Clifford Bridge Road,
Coventry, Warwickshire CV2 2DX, UK
e-mail: timbarlow@doctors.org.uk

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_23, © Springer-Verlag London 2014

Outline of the Problem

It has been estimated that in the USA doctors disclose less than half of all serious errors.

Disclosure of Complications—After the Fact

The disclosure of complications after surgical procedures has received the attention of various nations' regulatory bodies. These include the General Medical Council in the UK and the American Medical Council in the USA [1, 2].

Some examples of guidance can be found in Table 23.1. The overriding theme is that openness (with patient, relatives, and colleagues), is to be encouraged, and is part of a doctor's ethical code of conduct.

Mounting evidence demonstrates that patients want to have an explanation for adverse events and there is also increasing evidence that physicians want to give an explanation of adverse events [3]: this is consistent with the ethical argument that being open with patients about adverse events is both ethically sound as an action in its own right (deontological), and when considering the possible consequences of that action (consequential). Therefore the current state of affairs is a situation where both patient and physician have the same goal, there is an ethical imperative to support that goal, and this is reflected in recommendations by regulatory bodies. Why then, do we need a chapter on the disclosure of complications?

The reason is twofold: firstly medical errors are common, and they represent an inevitable part of a healthcare service that is delivered by humans. The Institute of Medicine's report *To Err Is Human: Building a Safer health System* [4] in 2000 estimated the number of medical errors that occur in the Health Service in the USA at over one million per annum; 10 % of these (100,000) were considered to cause patients serious harm. The number of deaths attributed to preventable adverse events was estimated at between 44,000 and 98,000. Breast cancer accounted for 42,297 deaths is the same period. Secondly, it has been estimated that in the USA doctors disclose less

Table 23.1 Current guidelines on disclosure of complications

Organisation	Guideline
American Medical Association	*When "a patient suffers significant medical complications that may have resulted from the doctor's mistake . . . the doctor is ethically required to inform the patient of the facts necessary to ensure understanding of what has occurred*" [2]
General Medical Council	"*Patients who complain about the care or treatment they have received have a right to expect a prompt, open, constructive and honest response including an explanation and, if appropriate, an apolog*" [1]
Australian Medical Council	*When adverse events occur, you have a responsibility to be open and honest in your communication with your patient, to review what has occurred and to report appropriately* [13]

than half of all serious errors [5]. Given the number of adverse events, and the proportion of those that are estimated to go undisclosed, we can see that not only is this issue prevalent within the profession, addressing it adequately (with resultant changes to practice and safeguards), could significantly improve health care.

This chapter plans to focus on the balance of factors that feed into a physician's decision to disclose or not disclose complications. We will examine the fundamental issue, which is that physicians have a conflict of interest in disclosing complications.

Limitations of the Current Practice

A complex myriad of factors influence the decision to disclose adverse events. Efforts to provide taxonomy for these factors have been performed: Figs. 23.1 and 23.2 provide taxonomy generated through a literature review of 316 studies, combined with a qualitative methodology [6]. This divided barriers and motivators to disclosure into categories, and is a helpful summary of the complex interplay between different factors. This is by no means the only system for considering these factors, but it provides a useful foundation upon which to build the discussion. The purpose of including it here is to provide a point of reference for the reader. We will now discuss some of these factors in more detail.

Is There a Professional Consensus?

In the introduction, we reviewed the ethical, moral, and professional reasons for full disclosure. The guidance from multiple regulatory bodies encourages full and open disclosure; however, there are two common arguments against such full and open disclosure.

Firstly, protecting the doctor-patient relationship has been cited as a reason against disclosure of complications [7]. This is based on the notion (perceived or real) that the doctor should be seen as being infallible, to engender trust in the doctor and the medical profession as a whole. A mistake can undermine this trust. This argument therefore assumes that a mistake on the part of the medical team may harm the relationship—this may not necessarily be true. This argument also assumes (or, perhaps a better word is *hopes*) that the mistake *will not be discovered* by the patient: non-discovery by the patient, their family, colleagues, the institution, governing bodies etc is a key part in any decision to not disclose a complication, and forms an inherent part in all decisions regarding disclosure—this idea is an important theme, and one which we will refer back to.

Secondly, the moral principle of non-malfeasance has been used to contest full disclosure in certain circumstances: "therapeutic privilege" describes the act of not disclosing something to a patient that may cause the patient harm. This argument therefore requires an assessment that the harm caused to the patient will be sufficient to outweigh the professional and ethical responsibilities on the physician.

Both arguments above are in direct conflict with one of the guiding principles in modern day health care, namely patient autonomy. This principle dictates that a

Attitudinal Barriers	Helplessness
Perpetuating perfectionism, and blaming and humiliating those involved with errors Perpetuating silence about errors, denying errors, or believing others don't need to know about one's errors Being arrogant and proud Placing self-interests before patient-interests Allowing competition with peers to inhibit disclosure Believing disclosure is an optional act of heroism Doubting the benefits of disclosure	Lacking control of what happens to information once it is disclosed Lacking confidentiality or immunity after disclosure Lacking institutional and collegial support after disclosure or a professional forum for discussion Believing error reporting systems penalize those who are honest Lacking feedback after reporting errors or a sense of ownership in the quality improvement process Lacking time to disclose errors Feeling helpless about errors because one cannot control enough of the system of care
Uncertainties	**Fears and Anxieties**
Being uncertain about how to disclose Being uncertain about which errors should be disclosed Being uncertain about the cause of an adverse event Disagreeing with a supervisor or trainee about whether an error occurred	Fearing legal or financial liability Fearing professional discipline, loss of reputation, loss of position, or loss of advancement Fearing patient's or family's anger, anxiety, loss of confidence, or termination of physician-patient relationship Fearing the need to admit actual negligence Fearing the need to disclose an error that cannot be corrected Fearing the possibility of looking foolish in front of junior colleagues or trainees Fearing negative publicity Fearing the possibility of 'fallout' on colleagues Feeling a sense of personal failure, loss of self-esteem, or threat to one's identity as a healer

Fig. 23.1 Barriers to the disclosure of complications (From Kaldjian et al. [6]; used with permission)

Responsibility to Patient	Responsibility to Profession
Desire to communicate honestly with patients or explain the circumstances of an error Desire to show respect for patients or treat patients fairly Desire to facilitate further medical care for harmed patients	Desire to share lessons learned from errors Desire to serve as a role model in disclosing errors or breaking bad news Desire to strengthen inter-professional relationships and build inter-professional trust Desire to change professional culture by accepting medicine's imperfections and lessen the focus on managing malpractice risks
Responsibility to Self	**Responsibility to Community**
Desire to be accountable for one's actions Sense of duty as a physician Desire to be courageous or altruistic Desire to maintain one's integrity Desire to treat others as one would like to be treated Desire to empathize and apologize Desire to alleviate guilt or pursue forgiveness Willingness to accept one's fallibility and limitations, and to be vulnerable Desire to follow one's conscience or 'do the right thing' Desire to follow one's religious/spiritual beliefs	Desire to enhance the health of future patients Desire to sustain patients' trust in the medical profession Desire to foster physician-patient relationships that can absorb the shock of error Desire to help patients be more realistic about medicine's imperfections Desire to help patients understand the complex causes of errors

Fig. 23.2 Motivators to the disclosure of complications (From Kaldjian et al. [6]; used with permission)

patient has the right to make their own choices—not giving patients the relevant information undermines their ability to decide for themselves. Undermining a patient's autonomy to protect the doctor-patient relationship, may be a difficult position to defend. Undermining a patient's autonomy to protect the patient is consistent with current ethical and professional practices, but requires an assessment of the harm that would be caused by disclosure—who, then, conducts that assessment?

There is an inherent conflict of interest in the medical team responsible for the error conducting the assessment, and this theme of conflict of interest is at the very heart of the decision making process.

What Is a Complication?

In order to discuss this aspect of the disclosure process, we will assume that a simplified situation is in place: namely that both patient and physician want complications disclosed.

The definition and classification of a complication was dealt with in a previous chapter in this textbook. However, we need to discuss a specific problem that relates to the disclosure of complications. The fundamental issue is that the physician has to decide what the patient would view as a complication—the "definition" of a complication is subjective. Where one person decides based on what they think another person's subjective assessment is, there is an inevitable disparity, such that some complications will be disclosed that the patient did not feel they needed to know, and others will not be disclosed that the patient would have wanted to know.

For example, if an instrument is dropped during a surgical case, this is unlikely to be called a surgical complication, and the patient is unlikely to come to harm from it. It would be reasonable to assume that the patient does not need to know about this. Indeed, it would present a huge burden on the surgical team if every small mistake had to be disclosed, especially if there was no harm. However, if it was a replacement joint prosthesis that was dropped and sourcing the new, appropriate joint took 10 min, should the patient be told now? Perhaps it took 20 min, 30 min or even an hour.

The patients in this rather contrived example have been exposed to a longer anaesthetic time, with the subsequent increased risks. Therefore the surgical team has to make a judgement as to:

1. The increase in risk that the patient has suffered
2. Does that increase in risk dictate that the patient be told?

In this situation no actual harm has taken place, but there is the *risk* of harm. The level of risk individual patients will be happy with will differ, and therefore the expectations of each patient will differ. Many factors determine what expectations the patients have, including their cultural and religious background, media and previous interaction with healthcare services [8]. The physician is left with a complex task of trying to anticipate what the patient will want to know.

Taking this example further, if the patient now developed a complication associated with a long operative period, would the "threshold" for disclosure of the complication now change? If so, would it now be appropriate to disclose a 10 min delay, whereas before it was not?

This situation is similar to deciding what complications to disclose to a patient *before* an operation. Several bodies have published guidelines on what is reasonable to tell patients for various procedures [1, 2]; however, complication rates such as these are usually well known, and therefore an accurate estimation of risk is possible. The situation after the operation is more complex, as it generally involves less

robust estimates of risk, and therefore more judgement on the part of the surgical team. This is reflected in the published guidelines for both consenting patients to treatment (discussed in Chap. 11), which are more specific that the guidelines for disclosure of complications after the fact.

Uncertainty

The majority of complications are clear cut, and, with patients and physicians both wanting to participate in disclosure over complications, the decision making process should be straightforward, as covered in published guidelines. However, there are a proportion of complications that require the surgical care team to make a judgement call: how much risk a patient can be exposed to before disclosure is required, combined with difficulty in estimating that risk, mean that there is an inevitable disparity. This disparity will unavoidably end with occasions where either the patients are told too much (with the burden on time and resource with no benefit), or the patients are not told enough (with the possibility of dissatisfaction and litigation).

The situation above also applies to event reporting, which is dealt with in a different chapter in this textbook.

Should Disclosure Equal Apology?

Growing evidence suggests that patients do not only want the disclosure of complications, they also want an apology [9]. Apologising is said to decrease the subsequent risk of legal action [9]; however, there are concerns from physicians that apologising apportions blame (increasing the chance that any legal action would be successful). Here a clear distinction has to be made: expressing sympathy and regret over a situation does not assign responsibility for that situation; however, providing an apology has been defined as consisting of the disclosure of the event *and* an assignment of responsibility [7]. This is not a purely semantic argument, as there are practical implications: In the USA, 36 states have laws protecting apologies from physicians from being used in legal proceedings against the physician; however, only 8 of these 36 states protect against any implied or actual admission of fault.

This situation is not limited to the USA. In the UK the Compensation Act of 2006 makes clear that an apology is not equivalent to an admission of liability; however, as we have seen, one of the necessary constituents of an apology is an assignment of responsibility. Similar protective measures exist, or are under development, in other countries [10].

In summary, when conveying a complication, patients would like an apology; however, the assignment of responsibility may be admissible in legal proceedings. Therefore, the reader should be aware of the specific laws that govern their area of practice. What is clear is that there are laws protecting the expression of sympathy when disclosing a complication; however, if no admission of fault is given, disclosure accompanied by expressions of sympathy may not be well received by patients.

Where Is the "Golden Bullet"?

Fear of legal action is an ever-present danger in medicine. This fear is not confined to legal action, as it can encompass regulatory action, reputation, earning potential, and indeed employment. This is the basis of the conflict of interest that all physicians have when deciding whether to disclose a complication or not.

The fundamental question is: does full disclosure increase, or decrease your chances of getting sued? There is some evidence that disclosure decrease malpractice [7]. Several open disclosure programmes have resulted in decreased rates of malpractice suits, decreased time to settlement, and decreased total expenditure on malpractice. This is by no means conclusive evidence; however it is supported by anecdotal evidence:

> *In over 25 years of representing both doctors and patients, it became apparent that a large percentage of patient dissatisfaction was generated by doctor attitude and denial, rather than the negligence itself. In fact, my experience has been that close to half of malpractice cases could have been avoided through disclosure or apology but instead were relegated to litigation. What the majority of patients really wanted was simply an honest explanation of what happened, and if appropriate, an apology. Unfortunately, when they were not only offered neither but were rejected as well, they felt doubly wronged and then sought legal counsel.* [7]

Although the relationship between full disclosure and decreased rates of legal action has not been demonstrated conclusively, there is some evidence that non-disclosure with the patient subsequently finding out, results in a higher chance of legal action [6, 7].

Varying Legal Practices

We have seen that legal practices vary when dealing with the protection offered over apologies. However, there are is a more fundamental legal issue. This revolves around whether it is a statutory duty (i.e. a legal responsibility) to notify patients of adverse events, or if this responsibility is encouraged through a culture of openness, but not through legislations. Each of these two approaches has its benefits, and various states and countries have taken their own approach: In New Zealand the Health and Disability Commissioner Code draws out a statutory duty of disclosure about any adverse event; in the USA, seven states have similar legislation, with a time limit in place for some [11]. This approach provides a legal responsibility to be open, but not for an apology. As we have discussed, such an approach may not lead to patient satisfaction with the interaction. There is also a lack of evidence to support the premise that making the responsibility to disclose a statutory one (as opposed to an ethical and regulatory one), results in a more open culture. One would assume that with a regulatory process that carries a statutory responsibility, the punishment for non-disclosure would have to be more severe.

The second approach, taken in the U.K. and in many states in the USA is to encourage a culture of openness, with no specific legal measures taken. Although regulatory bodies may take action on the basis of a breach of professional ethics,

there remains no *specific* legal obligation to inform patients of some adverse events. If this approach is taken, it stands to reasons that the risks, or the perceived risks, of full disclosure need to be reduced.

Each approach has its relative merits, and each health care worker is encouraged to identify the regulatory and legal obligations that are in place in the organisation and area they work in.

Regulatory Processes

Regulatory processes are discussed in detail in other chapters; however, they require a brief mention here. Regulatory compliance can have several implications beyond the identification and investigation of adverse events. The process can result, or can be felt to result, in a blame culture. Fear of this regulatory process, as much as fear from litigation from the patient or patients involved, can act as a barrier to openness. Conversely, support from the regulatory body (such as advice on the legal stand point of apologising) may encourage openness—some programs have described reductions in malpractice expense; however, they have not enjoyed widespread acceptance [9].

Of note, the Patient Safety and Quality improvement act of 2005 in the United States stipulated that the information passed on to the regulatory body cannot be used in a court of law [12]. The aim of this legislation was to remove one of the barriers to reporting adverse events. However, there was no legal imperative to inform patients of any disclosure or reporting of complications [12].

Should an Assurance That Things Will Improve Accompany a Disclosure?

The primary function of a regulatory process should be to ensure that the situation will improve. Certainly, patients have expressed that, similar to an apology, an assurance that processes are in place to ensure (or at least decrease the chance) of this happening again is wanted. The decision to include this as an integral part of a disclosure of a complication to a patient will revolve around the nature of the complication, and the regulatory processes in place.

Take-Home Message

We have seen that there is an ethical argument towards full disclosure, which is supported by various governing bodies in medicine. However, various blocks to openness have been discussed including the definition of a complication specific to this situation (i.e. the disclosure of increased risk that has not lead to harm), the varying legal obligations and safeguards in place, and if disclosure of complications should equal an apology. A framework for considering these barriers has been introduced.

We have briefly touched upon the some of the regulatory issues inherent in disclosing complications, and have discussed whether openness increases or decreased the chance of litigations.

It may be argued that in order to meet our legal, regulatory, professional, and, not least, ethical obligations, full disclosure of complications is necessary. However, this needs to be balanced against an assessment of what the patient would want to know, and if it the benefits of telling them are outweighed by harm. An appreciation of this situation, combined with knowledge of the legal and regulatory responsibilities, may allow the practice of openness.

Two key themes in the decision over disclosure bear repeating: the belief that a complication will go unnoticed is fundamental to most, if not all, decisions not to disclose; and the medical team has a fundamental conflict of interest in making these decisions. It therefore takes a degree of moral courage to decide to disclose a complication when the chance of getting caught is low, and the cost of disclosure is high. Regulatory processes can either help or hinder this process (see Chap. 11).

The conflict of interest can affect decision making subtly. We have discussed that some complications may not be disclosed as the doctor has to make a judgment call as to what constitutes a complication, and make an assessment of the harm that disclosure will cause a patient: physicians are likely to overstate the input that these two factors have, due to their vested interests. An awareness of this is necessary to be able to make a reasoned decision.

The reader will have to perform a case by case assessment of what constitutes a complication *after the fact* (c.f. a risk of surgery when consenting a patient) and whether to combine disclosure with an apology. It is unclear if this approach will lead to less, or more, litigation. Whatever approach is used, moral courage is required.

In the future, regulatory bodies will have to decide whether to pursue a culture of open disclosure and decrease the real or perceived cost of disclosure or to make disclosure a responsibility grounded in statute, with more severe punishment for non-disclosure. Although these methods are not mutually exclusive, one tends to predominate. Which method is most effective remains open to debate.

The position regarding the disclosure of complications is quite clear—open and full disclosure carries an ethical and professional responsibility. There is a degree of uncertainty over some medical complications, and whether they require disclosure: the fundamental conflict of interest a physician has will likely result in an unrealistic assessment of the issue. Further uncertainty is generated by the necessity of the physician assessing what the patient would want to know, and if it the benefits of telling them are outweighed by harm. An understanding of these issues is required for effective disclosure to occur, along with an understanding of the geographical variances in legal and regulatory practices.

References

1. GMC. Good medical practice. www.gmc-uk.org/guidance. P18, 30–312006. Cited Jan 2013.
2. American Medical Association. Code of medical ethics, annotated current opinions. Chicago: American Medical Association Press; 2008.

3. Gallagher TH, Garbutt JM, Waterman AD, Flum DR, Larson EB, Waterman BM, et al. Choosing your words carefully: how physicians would disclose harmful medical errors to patients. Arch Intern Med. 2006;166(15):1585–93.
4. Kohn L, Corrigan J, Donaldson MS. To err is human: building a safer health system. Washington, DC: National Academy Press; 2000.
5. Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. JAMA. 2003;289(8):1001–7. United States.
6. Kaldjian LC, Jones EW, Rosenthal GE, Tripp-Reimer T, Hillis SL. An empirically derived taxonomy of factors affecting physicians' willingness to disclose medical errors. J Gen Intern Med. 2006;21(9):942–8.
7. Edwin A. Non-disclosure of medical errors an egregious violation of ethical principles. Ghana Med J. 2009;43(1):34–9.
8. Berlinger N, Wu W. Subtracting insult from injury: addressing cultural expectations in the disclosure of medical error. J Med Ethics. 2005;31:106–8.
9. Mastroianni AC, Mello MM, Sommer S, Hardy M, Gallagher TH. The flaws in state 'apology' and 'disclosure' laws dilute their intended impact on malpractice suits. Health Aff (Millwood). 2010;29(9):1611–9.
10. Society MP. Culture of candor vs duty of disclosure. Medical Protection Society Casebook. UK, London: 2010.
11. Gallagher TH, Bell SK, Smith KM, Mello MM, McDonald TB. Disclosing harmful medical errors to patients: tackling three tough cases. Chest. 2009;136(3):897–903.
12. GPO. Patient safety and quality improvement act 2005. http://www.gpo.gov/fdsys/pkg/PLAW-109publ41/pdf/PLAW-109publ41.pdf. US Government; 2005.
13. Medical Board of Australia. Good medical practice: a code of conduct for doctors in Australia. http://www.medicalboard.gov.au/Codes-Guidelines-Policies.aspx2009. Cited Jan 2013.

Surgical Quality Improvement

24

Walter L. Biffl and Susan E. Biffl

Pitfalls and Pearls

- Surgical QI generally focuses on structure, process, and outcomes.
- More recently there has been an emphasis on access, safety, costs, and inpatient experience.
- The process of QI begins with data; it is critical that the data collected by the hospital are shared with the department and the individual surgeons.
- The relationship between structure and process or structure and outcome, is often not well established.
- It is not always clear what are the most relevant outcomes to measure.
- Assessments may be severely limited or misinformed by the source of data.
- Outcomes may not be valid indicators of quality.

Outline of the Problem

In surgery more than in any other specialty, there is a constant striving for perfection, intolerance of carelessness, hostility toward failure, and an inflexible, almost military rigidity concerning performance [1].

W.L. Biffl, MD (✉)
Department of Surgery, Denver Health Medical Center, 777 Bannock St., MC 0206, Denver, CO 80230, USA
e-mail: walter.biffl@dhha.org

S.E. Biffl
Department of Physical Medicine and Rehabilitation, Children's Hospital Colorado, Denver Health Medical Center, 777 Bannock St., MC 0206, Denver, CO 80230, USA

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_24, © Springer-Verlag London 2014

The longstanding culture in surgery has been one of Quality Improvement (QI).

This chapter will provide an overview of the surgical QI program. We will begin with a brief historical overview of surgical quality, and follow with a discussion of the pillars of structure, process, and outcomes on which most QI programs are based. Data sources and interpretation will be discussed, as will the surgical morbidity/mortality conference.

A Brief History of Surgical QI

Contemporary publications on surgical quality point to the 1999 report from the Institute of Medicine (IOM), entitled, *To Err is Human* [2], as the pivotal event in the surgical QI "movement." However, surgical QI is not new. In 1979, at the time of publication of *Forgive and Remember* [1], Eric J. Cassell, MD wrote in the *Wall Street Journal*, "His book is of special interest now, at a time when private citizens and public authorities are growing increasingly concerned about how to control medical costs and medical mistakes." In fact, the American College of Surgeons (ACS) was formed around the issue of quality, and it is embedded in the mission statement of the ACS: "To improve the quality of surgical patient care by setting high standards for surgical education and practice." As Ko [3] points out, by 1917 the ACS had promulgated its first set of quality standards for hospitals, and began conducting inspections under its Hospital Standardization Program. The ACS would later defer this process to the Joint Commission in 1953, which continues to establish and monitor standards of quality. Over the ensuing half-century, external forces began to influence surgical QI in a more tangible manner. In 1965, the Social Security Act created Medicare and Medicaid; "Conditions of Participation" included a requirement to be accredited by the Joint Commission [4]. The Omnibus Budget Reconciliation Act of 1986 enabled Congress, in conjunction with the IOM, to study quality for Medicare – the first notable use of external consensus reporting by the federal government to guide health care QI. The following year, the Department of Health and Human Services followed up by creating the Healthcare Quality Improvement Initiative. This resulted in the creation of the Agency for Healthcare Policy and Research, which later became the Agency for Healthcare Quality and Research (AHRQ) – the creator of the Patient Safety Indicators (PSIs) in 2003. In 2003, the Centers for Medicare and Medicaid Services (CMS) and the Joint Commission joined forces to create the National Hospital Inpatient Quality Measures. These common "core measures sets" include process measures for conditions such as acute myocardial infarction; pneumonia; heart failure; and, most importantly, the National Hospital Inpatient Quality Measures. The Inpatient Quality Measures set includes the Surgical Care Improvement Project (SCIP) measures (Table 24.1) [5].

Donabedian and Surgical QI

Current assessments of quality in healthcare are based in large part on principles described by Donabedian in 1966 [6]. Of note, in his initial work, Donabedian focused on healthcare at the physician-patient interface, and specifically excluded systems issues or issues related to care at the community level; administrative issues related to quality control; and economic (cost-effectiveness) issues. He emphasized three interrelated elements of

Table 24.1 Surgical care improvement project (SCIP) measures, effective 2013 [5]

SCIP-Inf-1	Prophylactic antibiotic received within 1 h prior to surgical incision
SCIP-Inf-2	Prophylactic antibiotic selection for surgical patients
SCIP-Inf-3	Prophylactic antibiotics discontinued within 24 h after surgery end time
SCIP-Inf-4	Cardiac surgery patients with controlled postoperative blood glucose
SCIP-Inf-6	Surgery patients with appropriate hair removal
SCIP-Inf-9	Urinary catheter removed on postoperative day 1 or 2
SCIP-Inf-10	Surgery patients with perioperative temperature management
SCIP-Card-2	Surgery patients on beta-blocker therapy prior to arrival who received a beta-blocker during the perioperative period
SCIP-VTE-2	Surgery patients who received appropriate venous thromboembolism prophylaxis within 24 h prior to surgery to 24 h after surgery

quality. The first category in the Donabedian model is structure. This refers to the settings in which surgical care is delivered, and includes such attributes as material resources (facilities, equipment, funding), human resources (the number as well as the qualifications), and organizational structure. The second is process; this denotes what is actually done in the delivery (and receipt) of care. The third is an assessment of outcomes – that is, effects on the health status. It is assumed that these three factors are interrelated: without resources, processes cannot be implemented, and consequently outcomes suffer. Surgical QI must, therefore, consider all of these factors. In addition, more recently there has been an emphasis on access, safety, costs, and inpatient experience.

Structure

This approach offers the advantage of dealing, at least in part, with fairly concrete and accessible information. Programs run by organizations such as the ACS Committee on Trauma (COT) focus on structures. For example, the ACS COT defines and publishes *Optimal Resources for the Care of the Injured Patient* [7], a manual which serves as the basis for standardized review of the resource availability (and processes) of trauma centers. The review of structure has the major limitation that the relationship between structure and process or structure and outcome, is often not well established.

Processes

The analysis of processes includes the surgeon's processes in delivering care – such as whether "good" care has been delivered. As Donabedian [6] enumerated, judgments may be based on considerations such as the appropriateness, completeness or redundancy of information obtained through clinical history, physical examination and diagnostic testing; justification of diagnosis and treatment plans; technical competence in the performance of diagnostic and therapeutic procedures; application of preventive care; coordination and continuity of care; and acceptability of care to the

patient. The SCIP, which has focused on adherence to process measures as a means of reducing surgical morbidity and mortality, has mandated collection and public reporting of data for the past several years. While compliance has steadily improved over time, it has become apparent that simple adherence to the prescribed measures does not necessarily result in improved outcomes [8]. As Merkow and colleagues [9] note, there are a number of potential explanations for this: (1) there is no relationship between the processes and the outcomes; (2) a level of performance (compliance) has been reached that is high enough – and resulted in outcomes that are good enough – that further improvements are not measurable; (3) relationships between processes and outcomes are not measurable; (4) the most appropriate or sensitive outcomes have not been identified; or (5) the relationships are more complex, with co-factors that may or may not be measured. There is no indication that SCIP is going to end anytime soon, so surgeons are obliged to continue to follow the recommended process measures. Quality improvement science, meanwhile, continues to investigate this area.

The question of whether medicine is "properly practiced" is also a focus of process-driven QI efforts. The current emphasis on delivery of evidence-based care follows from this concept. It may take years for a new care guideline to be inculcated into mainstream practice; a large body of literature has been devoted to the challenges and barriers to implementation of evidence-based practices [10]. On the other hand, just as with SCIP, it is unclear how far "evidence-based" practices can be extrapolated beyond the study populations on whom the evidence is based. Another issue to be cautious about is the fact that many practices make good sense, yet risk being discarded in favor of practices that are supported by a single well-designed study [11].

The patient is an active participant in this dimension, as his or her compliance with prescribed care is also measured. In the performance of surgical QI, it is important to note the patient's behavior. If a surgeon recommended treatment in good faith and the patient failed to follow up, the surgeon should not take the "credit" for an adverse outcome.

Outcomes

The outcome of surgical care – in terms of recovery, functional restoration, or survival – is commonly used as an indicator of quality. There are clear advantages to the assessment of outcomes as a measure of quality: the validity of outcome as a reflection of quality is generally not questioned, nor is the value of outcomes such as survival and functional recovery. But as the science of surgical quality measurement has evolved, many questions have arisen [9].

First, what are the most relevant outcomes to measure? Return to premorbid functional status, including job performance, is a reasonable expectation after hernia surgery, while simply survival with some level of consciousness may be all that can be

asked after emergency craniotomy for trauma. Thus, measures of pain control and time away from work are relevant to one, but not the other. A second consideration is the source of data. It is well-recognized that one would have markedly disparate results from datasets built on physician self-reports, concurrent chart reviews, and hospital billing records. In addition to the accuracy of the data, different systems use different definitions and exclusion/exclusion criteria. An example given by Wick and colleagues is as follows [12]: Consider that there are currently two programs available for colon surgical site infection (SSI) outcome monitoring: the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) and the ACS National Surgical Quality Improvement Program (NSQIP). The NSQIP defines case inclusion by *Current Procedural Terminology* (CPT) coding (surgeon professional fee coding), whereas NHSN inclusion is based on hospital billing coding by *International Classification of Diseases*, *Ninth Revision* (ICD-9). Exclusion criteria vary as well: NSQIP excludes surgical procedures where the wound was not closed, while NHSN does not. Although both systems employ the same CDC definitions to identify SSIs, the approach to follow-up diverges as NSQIP clearly outlines the process for obtaining 30-day follow-up on all patients (medical record review of index admission and all subsequent readmissions to the index hospital as well as other hospitals, clinic notes, and finally telephone calls to patients) but NHSN mandates review of inpatient records within 30 days of the procedure, with additional follow-up at the discretion of the reviewer. A third consideration is whether the outcomes are valid. As Donabedian [6] pointed out, many factors other than the surgical care may influence outcome. Proper risk adjustment of outcomes is currently being debated in many areas. It is difficult to reach consensus on what constitutes valid risk adjustment; moreover, the more risks are adjusted for, the more patients are required to have a sufficient number on which to conclude anything definitive. With all of these considerations, outcomes remain the ultimate measure of quality of medical care.

The Surgical QI Program

The surgical QI program must be equipped to analyze structure, processes, and outcomes, and identify areas for improvement as well as corrective actions. There are a number of different components that are necessary in order to effect a robust QI program.

Data Monitoring/Collection

The process of QI begins with data. Departments of Surgery need to have data on which to base decisions. The provision of resources for data collection is a "Structure" issue; if there is inadequate data collection, there can be no robust QI. There are a number of programs available through the ACS, including the COT

and its National Trauma Data Bank (NTDB); The Commission on Cancer and its National Cancer Data Base; NSQIP; the National Accreditation Program for Breast Centers; the Metabolic and Bariatric Surgery Accreditation and Quality Improvement; and the Nora Institute for Surgical Patient Safety. Participation in these programs costs money, but the Department and institution benefit through better quality data collection and the ability to benchmark their results. Indeed, it has been demonstrated that surgical outcomes improve across all hospitals participating in NSQIP [13]. As participation in these programs is voluntary and costly, there may not be an opportunity to participate. Because there are many measures that require mandatory data collection and reporting, the hospital will generally have invested resources in these initiatives. It is critical that the data collected by the hospital are shared with the department and the individual surgeons.

In planning data collection, it is important to identify processes and outcomes that are important to the institution. Obviously, SCIP and other public-reporting mandates must be followed. Beyond that, it is up to the institution or the department. At our institution, for example, we participate in the NTDB through the COT. The ACS COT encourages individualization of the QI program, so we have implemented our own audit filters such as overtriage and undertriage; time to the operating room for patients in shock or requiring craniotomy; and CT scans in pediatric patients. We also have institution-wide initiatives for which we collect data. One example is compliance with a hospital-wide VTE prophylaxis algorithm, and the occurrence of VTE [14]. An example of a QI tracking/evaluation form is offered in Fig. 24.1.

M&M

Surgical Morbidity and Mortality (M&M) conferences are a historical fixture in departments of surgery. The conference is an opportunity to discuss a case, highlighting decision-making, discussing treatment options, and identifying opportunities for improvement. There is tremendous educational opportunity, and with broad enough participation, structural and process issues can all be addressed, including some outside the department of surgery. Recently, the group from Oregon Health Sciences University reported the results of changes in their M&M conference structure [15]. They implemented a set of M&M best practices, gleaned from an extensive literature review (Table 24.2). In addition, they employed the Situation/Background/Assessment/Recommendations (SBAR) framework for presentations. The authors found that these changes resulted in an improvement in the presentations as well as the educational value of the conference.

A major goal of the M&M conference – particularly in teaching hospitals – is education. The IOM enumerated several "Aims for Improvement." These include the concepts that care should be safe, timely, effective, efficient, equitable, and patient-centered. In 2003, educators at Vanderbilt University Medical Center began using a performance-based diagnostic tool called the *health care matrix*, which guides users to evaluate the care of patients using the IOM aims for improvement and the Accreditation Council for Graduate Medical Education (ACGME) core competencies

PRIVILEGED AND CONFIDENTIAL
PERFORMANCE IMPROVEMENT TRACKING FORM

DEMOGRAPHICS	SOURCE OF INFORMATION	REASON FOR REVIEW
Date of report:	☐ Trauma Program Manager	☐ VTE
Date of service:	☐ Physician	☐ All trauma deaths
Trauma #:	☐ Case Management	☐ All non-surgical admits
ISS:	☐ Medical Record	☐ ISS>15 without trauma activation
MR#	☐ Risk Management	☐ Return visit previously treated at BCH
FIN#	☐ Nursing	☐ Transfer Out
ED Provider:	☐ Conference	☐ Required trauma consultations
Time of arrival:	☐ Registry	☐ Pediatric admissions
Trauma Surgeon:	☐ Other _____	☐ Sentinel Events
Arrival Time:		☐ Unexpected outcomes
Anesthesia:	Vital Signs:_____	☐ Other
Arrival Time:	_____	
Unit: ED	GCS score:_____	
Patient name:	Supp. 02: Y N SaO2:	

Complication, Occurrence, Problem, or Complaint:

STANDARDS OF CARE	PREVENTABILITY	CORRECTIVE ACTION (s)
☐ 1= Routine, acceptable care provided	☐ Unanticipated w/opportunity for improvement	☐ Unnecessary
☐ 2= Acceptable care, minor deviation from practice guidelines	☐ Anticipated w/opportunity for improvement	☐ Trend
☐ 3= Questionable care, practice guidelines not followed	☐ Event/mortality w/o opportunity for improvement	☐ Education
☐ 4= Unacceptable care, inconsistent with practice guidelines/standards of care		☐ Guideline/Protocol
		☐ Counseling
		☐ Peer Review Presentation
		☐ Process Improvement Team
		☐ Privilege/Credentialing Action
		☐ Other:

Comments:	COMPLICATIONS
	☐ Grade 1-Alteration from course, non life-threatening
	☐ Grade 2-Potentially life threatening, no residual disability, requires/ required invasive procedure
	☐ Grade 3-Residual disability, organ resection, persistence of life threatening condition exists
	☐ Grade 4-Death

Signature: Date:

Not a Permanent Part of the Medical Record

Fig. 24.1 Example of trauma QI evaluation/tracking form

(Table 24.3) [16]. As a case is reviewed, each box in the grid is filled in with pertinent findings; the ultimate assessment of whether the aim was met is recorded in the "Patient Care" row; QI action items are recorded under "Practice-Based Learning and Improvement." An individual case will have its own matrix; over time, patterns in deficits may be identified that will lead to change and improvement.

Another important element of the quality assessment is to determine whether an issue is preventable, nonpreventable, or potentially preventable; and whether

Table 24.2 Key elements of a successful M&M conference [15]

Mandatory attendance by residents and faculty
Decreasing environment of blame or defensiveness
Improving the efficacy of case presentations
Use of slides
Use of radiologic images
Focused analysis of error
Integration of evidence-based literature into the discussion
Provision of pertinent educational points
Audience participation in the process
Allowing for consensus to be met regarding analysis of the cases
Facilitation of the conference by a moderator

Table 24.3 Health care matrix [16]

Aims *Competencies*	Safe	Timely	Effective	Efficient	Equitable	Patient-centered
Patient care (overall assessment)						
Medical knowledge						
Interpersonal and communication skills						
Professionalism						
System-based practice						
Practice-based learning and improvement						

outcomes were anticipated or not. Near-misses are also important to identify, in the interest of avoiding future events.

Feedback to clinicians is critical to improvement. Physicians are, by their nature, interested in optimizing the outcomes of their patients. If they are aware of deficiencies in outcomes or processes, they will be more likely to engage and foster improvement.

Where Is the "Golden Bullet"?

The golden bullet in surgical QI is data. The data must be accurate, reliable, complete, and shared with providers.

Take-Home Message

Data collection, and the methodology of doing so, is critical to surgical QI. The data must be accurate and reliable or else everything that follows may be misguided. Data must be complete enough to allow an assessment of whether an event was

expected or preventable, and to allow appropriate risk adjustment for benchmarking/comparison purposes. Finally, data must be shared with providers. It is much easier to motivate surgeons to improve if they are aware of the opportunity for improvement. Rigorous data collection and analysis is important but also expensive. Departments and institutions must commit resources to this. As the science of QI evolves, so will our methodologies of data collection and assessment.

References

1. Bosk CL. Forgive and remember: managing medical failure. Chicago: The University of Chicago Press; 1979.
2. Committee on Quality Health Care in America Institute of Medicine. In: Kohn L, Corrigan J, Donaldson M, editors. To err is human: building a safer health care system. Washington, DC: Washington National Academy Press; 1999.
3. Ko CY. ACS quality programs. In American College of Surgeons- Remembering milestones and achievements in surgery: inspiring quality for a hundred years 1913–2012. Tampa: Faircount Media Group; 2013.
4. McIntyre RC. Improving quality improvement. Am J Surg. 2012;204:815–25.
5. The Joint Commission Specifications Manual for National Hospital Inpatient Quality Measures, Applicable 1/1/2013–12/31/2013 http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx Accessed December 17, 2013
6. Donabedian A. Evaluating the quality of medical care. Milbank Mem Fund Q. 1966;44(3 Suppl):166–206.
7. American College of Surgeons Committee on Trauma. Optimal resources for the care of the injured patient. Chicago: American College of Surgeons; 2006.
8. Stulberg JJ, Delaney CP, Neuhauser DV, Aron DC, Fu P, et al. Adherence to surgical care improvement project measures and the association with postoperative infections. JAMA. 2010;303:2479–85.
9. Merkow RP, Bilimoria KY, Ko CY. Surgical quality measurement: an evolving science. JAMA Surg. 2013;148:586–7.
10. Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH, et al. Why don't physicians follow clinical practice guidelines? A framework for improvement. JAMA. 1999;282:1458–65.
11. Smith GCS, Pill JP. Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomized controlled trials. BMJ. 2003;327:1459–61.
12. Wick EC, Hicks C, Bosk CL. Surgical site infection monitoring: are 2 systems better than 1? JAMA Surg. 2013;148(12):1085–6.
13. Hall BL, Hamilton BH, Richards K, Bilimoria KY, Cohen ME, et al. Does surgical quality improve in the American College of Surgeons National Surgical Quality Improvement Program: an evaluation of all participating hospitals. Ann Surg. 2009;250:363–76.
14. Biffl WL, Beno M, Goodman P, Bahia A, Sabel A, et al. "Leaning" the process of venous thromboembolism prophylaxis. Jt Comm J Qual Patient Saf. 2011;37:99–109.
15. Mitchell EL, Lee DY, Arora S, Kenney-Moore P, Liem TK, et al. Improving the quality of the surgical morbidity and mortality conference: a prospective intervention study. Acad Med. 2013;88:824–30.
16. Bingham JW, Quinn DC, Richardson MG, Miles PV, Gabbe SG. Using a healthcare matrix to assess patient care in terms of aims for improvement and core competencies. Jt Comm J Qual Patient Saf. 2005;31:98–105.

Surgical Safety Checklists

25

Marja A. Boermeester

Pitfalls and Pearls

- The incidence of preventable adverse events in surgical patients is still too high.
- Many incidents occur in the perioperative phase of the surgical pathway, outside the operation room.
- Cause and effect of adverse events are not closely related in time and space.
- A surgical checklist formalizes and coordinates individual responsibilities and shared responsibilities within a team during the surgical process of a patient, and the tasks that go with it.
- System thinking teaches us that the essence of a system or organization is not the sum of its parts, but the process of interactions between those parts.
- A surgical checklist can compensate for lapses in our awareness and memory.
- "*The harder you push, the harder the system pushes back*."
- "*The easy way out usually leads back in*."
- Focusing on a mere operation room checklist as a safety intervention limits the potential safety improvement that can be accomplishes by a *surgical checklist*.
- Promote 'evidence-based' surgical safety in stead of 'rule-driven' safety.
- A process/pathway checklist is one of the most successful ways to link individual health care professionals or teams in a process chain. This way coherence between different steps in the chain is secured.
- A team can perform its tasks within a process by using a checklist.
- Checklist use structures essential team factors such as communication and coordination and improves situational awareness.
- A checklist breaks through hierarchy and stimulates situational leadership.

M.A. Boermeester
Professor of Surgery, Department of Surgery (Suite G4–132.1),
Academic Medical Center, 22660, Amsterdam 1100 DD, The Netherlands
e-mail: m.a.boermeester@amc.uva.nl

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_25, © Springer-Verlag London 2014

Outline of the Problem

Patient safety is getting more and more attention. Despite the high quality level of health care in the Western world, too many patients experience preventable adverse events during their hospital stay. Patient safety can be defined as the (almost) lack of (the chance of) physical and/or emotional damage to a patient, that is caused by health care professionals who do not act according to professional standards and/or by deficits in the health care system.

In 1999 the publication of the Institute of Medicine's (IOM) report, "To Err is Human: Building a Safer Health System," concluded that damage during hospital admission caused more deaths than breast cancer or car accidents [1]. This damage is termed 'adverse event' or 'undesired outcome of care.' Adverse events are damage or complications other than directly related to the underlying disease of the patient and caused by the actions or lack thereof of a health care professional and/or the health care system. The damage or complications are sufficiently severe to lengthen hospital stay, cause temporary or permanent disability, or death. Adverse event should be distinguished from incident or error, which terms are predominantly used for all deviations of a process, irrespective of their outcome. An adverse event is not always the consequence of a medical error or incident and vice versa does not every error or incident lead to an adverse event (Fig. 25.1).

Every undesired outcome of care is a complication, irrespective of its cause. Not every complication is an adverse event, because complications can be related to the underlying disease or comorbidity. Of all adverse events almost half is preventable [2]. Besides the physical and emotional damage adverse events generate considerable health care costs.

The landmark report in patient safety awareness suggests that 44–98 thousand deaths every year resulted directly from medical errors that could, and should have

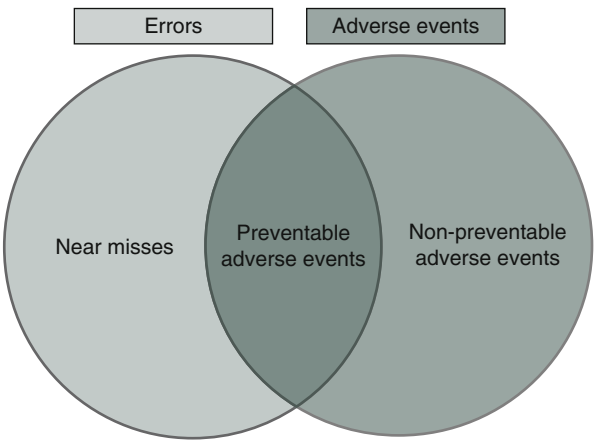


Fig. 25.1 Errors (incidents) are not the same as adverse events. Only a part of all adverse events are preventable

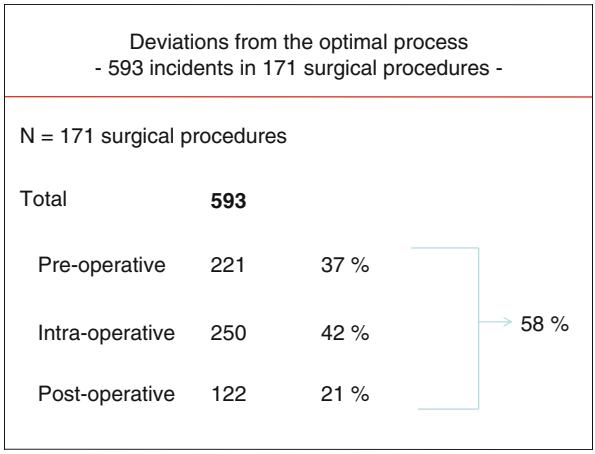


Fig. 25.2 Observed deviations from the optimal surgical process

been prevented [1]. According to a systematic review of eight studies covering nearly 75,000 medical records in various high income countries, an adverse event (AE) occurs in 1 out of 11 patients (9.2 %) in hospital. More than half of AEs are associated with surgery. Many adverse events take place in the operating room and on the ward. Complex environments such as the Emergency Room and the Intensive Care Unit contribute less to adverse events (3.0 % and 3.1 %, respectively) [2] Medication related events are relatively frequent with 15.1 % of all in-hospital adverse events.

In the decade since the IOM report, thousands of scientific articles have been written about this subject, illustrating the raised awareness regarding preventable medical errors and patient harm [3]. Patient safety publications increased from 59 to 164 articles per 100,000 on MEDLINE [4]. Not only has awareness increased, but there has been a change in safety culture. The way we think about surgical safety has changed for the better, and promising interventions such as the use of operative checklists, have been studied extensively, and are routine in daily practice in many hospitals.

Errors and adverse events are not always easily to distinguish from risks inherent to medical treatment. This causes confusion and incomparability of published data with different underlying definitions. Risks of interventions or surgical procedures can never be eliminated completely. Doctor and patient together must discuss and weigh expected effects of a procedure against its risks.

Process deviations involving a surgical patient are seen more outside than inside the operating room [5]. A surgical patient goes through an admission pathway with different locations: from the ward (or admission unit or daycare facility) to the holding area, to the operating room, to the recovery room (or ICU), to the surgical ward until discharge. From observations of the entire surgical pathway of 170 patients is became apparent that over 50 % of process deviations occur outside the operating room, in the pre- and postoperative phase of the pathway (Fig. 25.2) [5].

Many of these deviations can and must be corrected before the patient enters the operating room, and not just before start of surgery. When essential checks are performed in the operating room at first, this can lead to unnecessary risks. A patient who was already under anesthesia when at team time-out in the operating room it was discovered that a prosthetic knee implant was not available in her size.

She had to return to the ward without being operated. Indeed the problem had been discovered before the surgical incision was made, but the patient underwent needless anesthesia, because the problem was not intercepted earlier. This case must be judged as a preventable error, leading to needless anesthesia and postponement of surgery. This postponement is associated with extra costs and a considerable psychological burden for the patient. Moreover, in similar situations there is a considerable risk of the alternative: one decides to go through with another prosthesis size, as the first step (going into surgery) has been made, leading potentially to suboptimal results for the patient. These risks can be prevented by early intervention, for example by a check of necessary equipment and materials on the day before surgery or the morning of surgery. The patient is not safe even after leaving the operating room, as many adverse events happen in the postoperative phase. Previous observational data have found that in 22 % of patients the postoperative instructions are incomplete. Moreover, 11 % of patients are discharged without home medication prescriptions [5].

A process is a sequence of coherent activities. If a process takes place in a complex environment, memory and situational awareness can be aided by the use of a checklist (see Box 25.1). The surgical process comprises the sequence of coherent activities of a patient undergoing surgery, from (pre)admission to discharge. It is counterproductive to have separate checklists, each covering an isolated part of the same process. This creates a checklists' jungle with different checklists used side by side: at start of anesthesia equipment, maintenance of medical devices, use of laparoscopic equipment, sterilization of instruments, counting of sponges, needles and instruments, preparation and use of medication, communication at transfer moments, and so on. General overview of the process, of what needs to be done at what time and who is responsible, is subsequently lost.

Box 25.1. Underlying Rationale for Surgical Checklists

- The steps of any procedure can be summed up in a checklist. The question is whether that is always efficient and effective.
- A patient safety checklist must be more than a collection of tick boxes. A tick box list is useless bureaucracy, while a checklist is a lifesaving genius.
- An effective safety checklist in healthcare should cover only complex procedures with an inherent risk hazard, being performed in a complex environment, where memory and situational awareness of a team or multiple individuals that form links within the process chain can be channeled by checklist use.
- A surgical pathway checklist is needed for optimal safety. When we focus on checks just before to the execution of an intervention (i.e., in the operating room) and not on all steps prior to that intervention, the consequences of errors may be more severe. There is only a short time frame in which we can recognize and correct a human error or a chain of (near) misses.

In this chapter we learn about adequate and integrated use of a checklist. A team can work together with a checklist in hand and perform necessary process checks as a team. This chapter however focuses on the role of checklist use in situations where there is not clearly a team present, but multiple individuals have a role within the process chain and are thereby links in the chain. Background knowledge is needed to understand why checklist use is necessary in situations where multiple individual tasks are part of the surgical process chain. That knowledge is discussed.

Limitations of the Current Practice

Safety Culture (or Lack Thereof)

Twenty years ago it was a common belief that bad doctors or nurses were the main cause of poor quality healthcare and medical errors [6]. In that 'blame, name and shame' culture, people sought the guilty health care professional. This led to a situation in which caregivers were afraid to report near miss incidents. An accurate overview of the cause of safety issues was lacking, and solutions could not be aimed at the root of the problem.

Now the extent of the problem slow but sure penetrates the minds of health care professionals. We see a change in the way the medical community handles medical errors. A hospital is an unsafe environment, inherent to the fact that patients are admitted to a hospital for a disease that needs diagnostics and/or treatment. Add this to the fact that health care professionals make mistakes, because making mistakes in human. Being perfectly flawless is simply impossible because of our limitations as humans. Perfection does not exist. While being imperfect we need help: by systems that intercept errors and near-misses, by training, by specialisation, by team work.

Health care workers evidently make mistakes, despite their tremendous dedication and effort not to. The only way to effectively improve safety is to develop systems that intercept errors and mistakes before adverse events take place. The recent shift to a system approach and a more open culture has paved the way for changes in patient safety policy; safety is seldom related to the actions of an individual; errors and unsafe situations occur due to failing systems. The focus is now on changing systems in a way to prevent individuals making mistakes [3, 7, 8]. Complications, errors and performance are better recorded, and this information can be being used to identify problem areas and improve systems.

This system approach builds on the concept of layers of defense mechanisms against the consequences of errors that can occur in any layer of the system [9]. As long as errors are not in a straight line so they can cross over to the next layer of the system, errors usually do not lead to adverse events. When weaknesses in the system can be in a straight line (serial) from layer to layer, then a series of incidents can

accumulate to an adverse event (Reason's 'Swiss cheese' model) [9]. A safety system must be targeted at interception of errors in each layer of the system to prevent a series of incidents across layers.

Why We Make Mistakes: Human Factors

The relationships between people, the instruments and equipment they use in their working environment determine safety. These are the man-machine interactions and man-man interactions such as communication, teamwork and organizational culture. We must strive for the best combination of man and the world they live and work in. This environment must be designed and organized in a way that minimizes the chance of errors but also the impact of errors once they occur. We cannot eliminate human error, but we can reduce error risk. Furthermore, we must take into account individual differences and differences in skill.

Adverse events in health care occur when we do not understand these principles or take them into account. When we know how human factors as fatigue, stress, inadequate communication, prestige and inferior knowledge and skill affect the professional, we understand the circumstances that predispose to errors and adverse events. We receive information from the world around us, we interpret, we try to understand and react subsequently. Fatigue and stress have the greatest impact on information processing. There is ample evidence for the relationship between fatigue and diminished functioning, which makes fatigue an important risk factor for patient safety. Working long hours diminishes functioning level, comparable to a blood alcohol level that forbids driving a motor vehicle. Also the relationship between stress and functioning is confirmed in research. This applies to a high stress level, but also a low stress level is counterproductive as this leads to boredom and inattention.

Hospital processes should be designed in a way that different layers can influence the risk of harmful events, helping intercept errors and minimise their impact [7]. Understanding human factors has lead to reductions in working hours for doctors in several countries. Fatigue, stress, hunger and illness impair information handling and, according to human factors science, affect judgment and actions [10–12]. Other important contributing risk factors include dangerous behavior due to inexperience, insufficient supervision or inadequate execution of a procedure as a result of lack of preparation or attention. High stress levels and lack of time lead to shortcuts, contributing to errors. Obvious factors such as language and cultural differences lead to complicated communication.

Human memory is neither endless nor flawless. Interventions such as checklists prevent dependence on memory. Prestige and hierarchy define the relationships between surgical teams. It is imperative that all team members, without restrictions due to hierarchy, feel free to address issues that can adversely influence patient outcome.

Root Causes of Medical Errors

Inexperience

When the health care professional is not familiar with the task he or she has to perform, the risk of making an error is high. The necessary tasks must be learned under supervision and initially as much as possible in a dummy situation (test dummy, scenario training, serious gaming, virtual reality). Trainees are in the privileged position that patients do not expect them to know everything. Therefore, it is important not to pretend to know more than one really does.

Lack of Time

Under time pressure people are inclined to take shortcuts that are not wise nor allowed. Shallowly washing hands prior to surgery is an example of the effect of time pressure.

Insufficient Checks

Medication checks, dose, route, and patient identification are of the essence.

Inadequate Execution of a Procedure

This can be caused by insufficient preparation, attention or supervision.

Limited Memory Capacity

This is the most important health care professional related cause of preventable adverse events. It is of the utmost importance to recognize one's limitations. To learn to ask for help in time is an important quality that improves safety. Many students think that recalling medical information from a textbook that makes them good doctors. First, the human brain has limited capacity to store information in every detail. Secondly, functioning has more impact than information storage. Guidelines, protocols and checklists are designed to support this human factor. You must have a healthy disbelieve in your own capacity to remember everything you need to remember.

Fatigue

Memory is affected by fatigue. Recognition of this problem has lead to restriction of working hours for doctors in many countries. The relation between medical

errors and sleep deprivation caused by shifts of more than 24 h has been demonstrated in 2004 for interns [11]. Recently, however, no association has been found between death and complications in over 4,000 cardiac surgery procedures and the number of sleeping hours of consultants before surgery [12].

Stress, Hunger, Illness

It is important to monitor your own wellbeing and be conscious that feelings of stress and illness increase error risk.

Language Barriers and Cultural Factors

The risk of errors in communication caused by differences in language and culture is obvious. Also between doctor and patient communication errors can be detrimental.

Supervision

Doctors can be so preoccupied when performing a task in a training setting, sometimes even without supervision, that they have not enough awareness of the patient's wellbeing.

Prestige

The health care system has a hierarchic organization: the professor is superior to the consultant, who is superior to the registrars, who are in turn superior to the interns; the nurse is seen as someone who has predominantly a caring task and is depended on instructions from the doctor. Time and again these traditional relationships are not based on knowledge and expertise, and different situations ask for different types of knowledge. Errors are sometimes made because health care professionals position their opinion above the opinion of other simply because of their position in hierarchy and prestige and let that prevail over patient interest.

System Thinking

System thinking during analyses of incidents and accidents started in the nineties. It is the cornerstone of a learning society. System thinking is about the capacity to see the bigger picture, to look at inter-individual relationships instead of simple cause-effect sequences. This thinking teaches us that the essence of a system or organization is not the sum of its parts but the process of interactions between those parts (Box 25.2) [13].

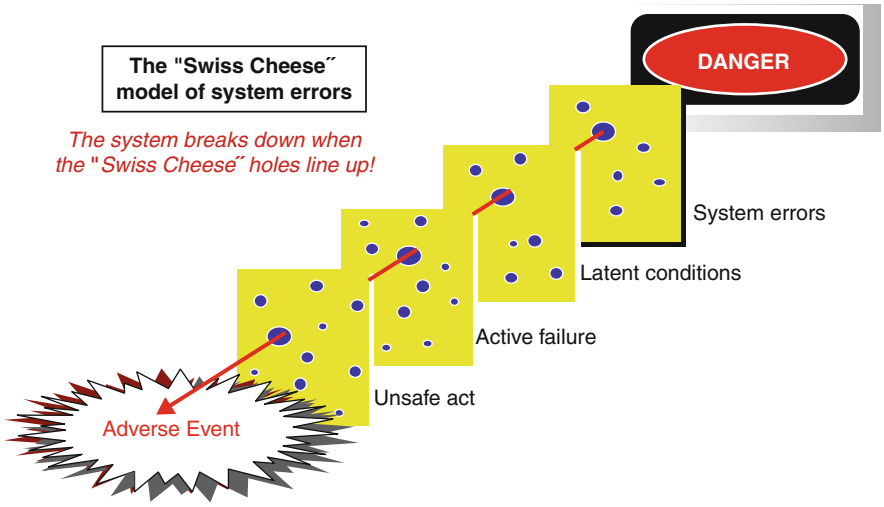


Fig. 25.3 'Swiss cheese model' of errors in health care

Some holes are due to active failures ('sharp end of the knife' being an altogether clear error made by a person); other holes are due to latent conditions ('the knife handle' being failure of the system or the organization or the design, thus usually not immediately evident) (Fig. 25.3) [9].

There are a number of categories within system thinking:

- *Patient and health care professional factors*. These are characteristics of involved individuals, including the patient. Professionals, medical students and patients are part of the system. With respect to health care professional related factors training and certification are very important; for the patient co-morbidity and age play an essential role.
- *Task factors*. These are the characteristics of the tasks and assignments health care professionals execute. Moreover the characteristics of the work flow, time pressure, job control (control of multiple tasks, in part related to resources), and work load.
- *Technology and instrument factors*. These factors refer to quality and quantity of the technology within the organization. Such factors are about the number and types of technology and their availability. The design of instruments and technology, their integration with other technology, the sensitivity of defects, the power to react are important in this respect.
- *Team factors*. Health care is characterized by multidisciplinary care (multiple medical specialties). Also multifunctional care plays a major role (nurses, nurse practitioners, physician assistants, paramedics, medics). Team communication, clear division of roles and function, and team management are important factors.
- *Environmental factors*. These factors comprise lighting, sound, physical space and use of space.
- *Organisational factors*. These are structural, cultural and rule related characteristics of an organization, and comprise leadership characteristics, culture, rules and regulations, level of hierarchy, and span of control.

Box 25.2. Laws of 'System Thinking' [13]

1. *The harder you push, the harder the system pushes back*. Well intended solutions or interventions that worsen the problem in the end, because they are not targeted at the system.
2. *Behavior grows better before it grows worse*. The short-term gains of 'quick wins' are followed by long-term losses.
3. *The easy way out usually leads back in*. Well-known (obvious) solutions that are easy to implement usually do not solve the problem.
4. *The cure can be worse than the disease*. Well-known solutions can not only be ineffective, but also addictive and dangerous.
5. *Cause and effect are not closely related in time and space*. The part of the system that causes the problem is usually distant from the part of the system that shows the symptoms.
6. *Dividing an elephant in half does not produce two small elephants*. The qualities of a system are dependent on the entire system. Many organizations try to address problems and issues by isolating them. It prevents them from seeing the whole issue. Every part of the system affects every other part.
7. *There is no blame*. Individuals and the causes of their problems are part of one single system.

Safe organizations are characterized by:

- Much attention for the possibility of failure, inherent to high-risk activities.
- The capacity to develop and grow, despite difficult circumstances (*resilience*).
- Attention for performance and work circumstances.
- Safety culture where coworkers can report potentially unsafe situations and actual incidents safely and without risk of blame.

Team Factors and Checklists

To only formalize responsibilities in a process is not enough. Fundamental aspects of team functioning, such as awareness of one's own fallibility and mutual respect and trust, must be structurally developed in health care professionals. Moreover, the team player must communicate and work together very well ('non-technical skills'). The factors that determine a successful 'operating' team are clear division of roles, task liability, competence, unity, communication and leadership. It is important that team members communicate, support each other, solve problems, and take decisions in a straight predictable line. A team can perform its process tasks by use of a checklist to enhance this predictability (standardization). The big advantage is that certain team factors such as division of roles, communication and leadership are structured by checklist use, and vise versa good team work can improve checklist

use. Herewith situational awareness of the team is enhanced. The features and advantages of a checklist, for individual as well as for team use, are explained below.

As said, human error is inevitable. Functioning is predominantly affected by fatigue and performance of complex tasks under pressure. A checklist is an important instrument to prevent human error. A checklist can serve different goals: to assist human memory, to standardize processes and methods, as a basis for evaluation, or as a diagnostic instrument. Apart from their specific goal to reduce human error, checklists promote adherence to protocols and guidelines. In comparison with for example aviation, checklists in health care are more difficult to standardize because of the large variation in patient population. Introduction of checklists is not without risk. Abundant checks can cause checklist fatigue. Also the quality of the process can be affected negatively when the process is delayed by superfluous and redundant checks. A checklist must function within a context and not be a 'loose cannon' at random in a process. Care professionals can become dependent on checklists and lose their objectivity and clinical judgment.

A good checklist takes chronology and logistics of a process into account, and an abundance of details and redundancy to prevent checklist fatigue. An effective, well-balanced, goal directed implementation strategy prevents that a checklist is incongruent with the care process. A checklist of the surgical process fulfills the basic checklist preconditions: a. an operation is a high risk process; b. the perioperative checklist in embedded in the work flow of a surgical intervention; and c. the checklist enhances situational awareness during a complex process in a complex environment (Box 25.3).

As part of the World Health Organization's campaign 'Safe Surgery Saves Lives,' a structured surgical checklist emerged in 2009 (Box 25.4). This extended time-out procedure is a perioperative checklist consisting of three parts: the 'sign in' right before induction of anaesthesia, 'time out' after anaesthesia and before the skin incision, and 'sign out' once the surgery is complete and before the patient is transported to recovery. Its effect has been studied in four hospitals in low-middle-income and four high-income countries with a 4 % absolute reduction in perioperative complications. Overall, mortality decreased by 0.7 %, while in high income countries in-hospital mortality fell by 0.3 % [14]. The year these results were published, use of the check list became mandatory in the UK [15].

A more comprehensive checklist, the SURgical PAtient Safety System (SURPASS), has been developed and validated in the Netherlands (Fig. 25.4) [5]. This checklist is customized for the surgical patient, is multidisciplinary, focuses on transfer moments, and follows the surgical pathway from (pre)admission to discharge (Table 25.1). An effectiveness study conducted in 11 high quality hospitals in the Netherlands showed mortality was reduced by half (from 1.5 to 0.8 %; 0.7 % absolute risk reduction) and the number of complications decreased by a third (from 27.3 to 16.7 %; 10.6 % absolute risk reduction) (Table 25.2) [16]. The digital SURPASS application connects with hospital information systems

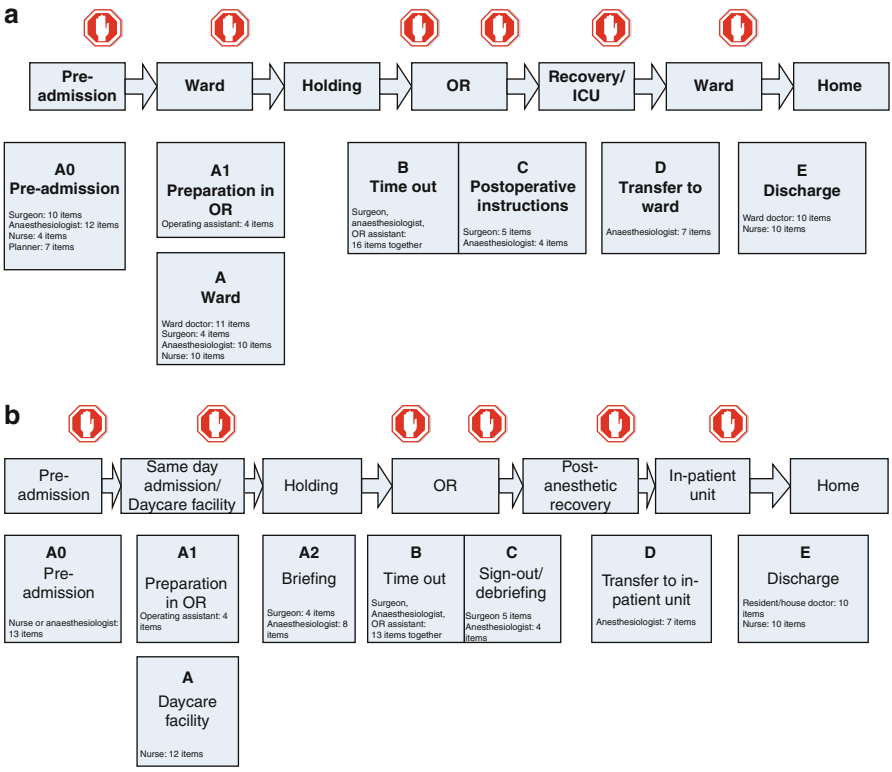


Fig. 25.4 Structure of the Surgical Patient Safety System (SURPASS) checklist along the backbone of the surgical process [15]. (**a**) Original SURPASS; (**b**) Adapted for use in Canada

Table 25.1 Comparison of who and surpass checklist characteristics

	WHO	SURPASS
Location	Operating room	Ward, holding, operating room, recovery
Timing	Directly pre- and postoperatively	From (pre-)admission until discharge
Involved disciplines	Surgeon, anesthesiologist, scrub nurse	Ward doctor, ward nurse, surgeon, anesthesiologist, scrub nurse, recovery nurse
Implementation	Relatively easy	Relatively difficult
Range	Limited	Extensive

and further simplifies its use and implementation. Moreover, timing and compliance with antibiotic prophylaxis in het operating room has improved with use of the SURPASS checklist [17]. It's use also theoretically prevents 29 % of accepted surgical malpractice claims, paid by insurance companies for medical liability [18]. In six participating hospitals, 6,313 checklists have been collected. One or more incidents are intercepted in 2,562 checklists (40.6 %). In total, 6,312

Table 25.2 Complications per 100 patients [16]

	Intervention			Control		
	Pre	Post	p	Pre	Post	p
Respiratory	3.3	2.1	0.004	3.7	3.8	0.91
Cardiac	2.3	1.3	0.001	1.6	1.4	0.72
Abdominal	3.5	2.4	0.04	3.1	3.1	0.56
Infectious	4.8	3.3	0.006	6.8	6.3	0.22
Wound	1.5	0.8	0.008	1.0	1.2	0.56
Bleeding	2.0	0.9	0.001	2.0	2.7	0.12
Urological	2.6	1.7	0.007	3.3	2.8	0.28
Neurological	2.1	1.2	0.005	2.2	2.6	0.43
Technical	1.2	0.8	0.08	1.2	1.7	0.25
Organizational	0.9	0.4	0.007	0.4	0.3	0.77
Disturbed function	1.4	0.7	0.002	1.3	1.4	0.90
Other	1.7	1.2	0.15	3.7	3.9	0.89
Total	**27.3**	**16.7**	**<0.001**	**30.4**	**31.2**	**0.81**
	ARR 10.6 (95 % CI 8.5–12.8)			**ARR –0.8 (95 % CI –3.2–1.7)**		

Complications per 100 patients in 6 SURPASS intervention hospitals compared with 5 control hospitals, in total and per type of complication
ARR absolute risk reduction, *CI* confidence interval

incidents have been intercepted. After correction for the number of items and the extent of adherence in each part of the checklist, the number of intercepted incidents is highest in the preoperative and postoperative stages. Of the 6,312 intercepted incidents, 54.8 % occur preoperatively, 14.2 % operatively and 31.0 % postoperatively. The numbers of intercepted incidents during the three phases differ significantly with 17.02 (95 %CI 16.47–17.60), 10.71 (95 %CI 10.03–11.44) and 15.79 (95 %CI 15.10–16.50) per 1,000 fully completed checklists, respectively [19].

The two checklist studies have received a lot of international attention. When Health Care Inspectorates and national guidelines demanded hospitals all over the world use a surgical checklist, implementation received a boost, however, some hospitals customized their own checklist. It is essential to identify the parts that make a surgical checklist effective. Some redundancy in checks must be allowed, but an overload probably makes checklists less effective. The majority of preventable incidents occur preoperatively, before the patient is admitted or taken to theatre. The hospital setting and established surgical pathways restrict which items can be checked on or before admission. Ideally the checks should occur long before anaesthesia induction. Important determinants of success or failure of checklists include the safety culture in a hospital, the level of system thinking and awareness of human factors.

A surgical pathway checklist is needed for optimal safety. When we focus on checks just before to the execution of an intervention (i.e., in the operating room) and not on all steps prior to that intervention, the consequences or errors may be

more severe. There is only a short time frame in which we can recognize and correct a human error or a chain of (near) misses. And when we take our lapses in observation capacity into account it is likely that we see the error too late, and there is no time left to correct the error.

A comparison with aviation is often made: cockpit versus operating room. In the heart of the matter the comparability between aviation and surgery is limited. One plane crash takes many lives at the same time and is very visible. One medical error can cause one fatality at the most and is less visible because of underlying disease. The analyses of errors in aviation, however, are much more advanced than in the medical world, and we can learn from that. Many small deviations from the optimal process can accumulate into an emergency situation with a much higher safety risk and more severe consequences than would have been the case with an isolated problem. When focus is on the operating room—where the most visible high-risk activity takes place—and not on the entire surgical process, the majority of errors is not intercepted.

A time-out procedure in the operating room is however important as part of a pathway checklist, as this is the first time the operating team comes together as a team and the last moment before anesthesia. Now also verbal transfer of medical information is possible, the briefing. Details of the operation are discussed with the team members. Herewith the situational awareness of the team is optimized before start of surgery. The team also discusses perioperative risks and action that needs to be taken in case of an emergency.

We can conclude with respect to a time-out procedure as single checklist moment and check location compared to a surgical pathway checklist:

- More than half of observed incidents take place outside the operating room, in the pre- and postoperative phase. Merely a time-out procedure in the operating room is not enough and too late in the surgical pathway (five-minutes-to-twelve‘ check) with the risk of fake safety and inefficient use of location and resources.
- The risks of a surgical patient are spread over all phases and locations of the surgical pathway from (pre)admission to discharge. Checks demand a multidisciplinary approach that covers the entire surgical pathway.
- A time-out procedure including briefing and debriefing is however an essential part of a surgical pathway checklist. The SURgical PAtient Safety System checklist is an example of a surgical pathway checklist from preadmission to discharge, with proven effect on in-hospital mortality and morbidity even in hospitals with an already high quality level.
- The SURgical PAtient Safety System checklist intercepts many potentially harmful incidents across all stages of the surgical patient pathway. The majority of incidents were intercepted in the preoperative and postoperative stages of the pathway (58 %, see above). The degree to which these incidents would have been intercepted by a single checklist in the operating room only, compared with a checklist for the entire surgical pathway, remains a subject for future study. [19]

Box 25.3. Checklist Preconditions and Subsequent Effects

Preconditions

- should be used only in a complex process with potential safety risks
- should function within a context; should be embedded within the process (work flow), not as a separate action but integrated in the process actions or in parallel to that process.
- should avoid too much redundancy in checks
- should be congruent and in chronology with the care process
- should not contain actual information nor document information, but merely sum up checks in a generic way
- should enhance situational awareness

Effects

- standardizes the surgical process, predominantly in situations when there is no clear team present at one moment, but a series of team members who work together in a sequential process.
- avoids reliability on human memory
- formalizes and coordinates individual responsibilities and shared responsibilities within a team, and the tasks that go with it
- integrates process steps and related checks
- standardizes en structures transfer of information
- improves team communication
- breaks through hierarchy and stimulates shared situational awareness and team work

Box 25.4. Ten Essential Objectives of the Who 'Safe Surgery Saves Lives' Checklist (2009)

1. The team will operate on the correct patient at the correct site/side.
2. The team will use methods known to prevent harm from administration of anaesthetics, while protecting the patient from pain
3. The team will recognize and effectively prepare for life-threatening loss of airway or respiratory function.
4. The team will recognize and effectively prepare for risk of high blood loss
5. The team will avoid inducing an allergic or adverse drug reaction for which the patient is known to be at significant risk
6. The team will consistently use methods known to minimize the risk for surgical site infection
7. The team will prevent inadvertent retention of instruments and sponges in surgical wounds
8. The team will secure and accurately identify all surgical specimens
9. The team will effectively communicate and exchange critical information for the safe conduct of the operation
10. Hospitals and public health systems will establish routine surveillance of surgical capacity, volume and results

Compliance

Insufficient compliance with standards and guidelines is no exception in health care, even in hospitals that deliver the most complex care. A good example is hand hygiene. Despite all efforts in educational programs and system analyses, most hospitals have a hand hygiene score of 30–70 %. It becomes more and more apparent that for safe behavior the 'no blame'-approach, that focuses on system improvement and education, has reached its limits. Just like in any other high-risk industry health care professionals should be held personally responsible for unsafe behavior and disregard of safety rules.

In their article 'Balancing "no-blame" with accountability in patient safety' Wachter and Pronovost extent this idea to time-out procedures before surgery [20]. They state that doctors who fail to comply with safety procedures are hard to correct when institutes tolerate such behavior. Regular audits and feedback of compliance can resolve this problem. Department heads should take responsibility and give individual feedback on compliance with safety rules. Reinforcement of safety rules is essential to reach and maintain adequate compliance.

Checklist and Crew Resource Management

In a high-risk and complex environment a checklist can increase situational awareness and thereby increase safety. A powerful way to ensure situational awareness is to create mental aids. A checklist is the most commonly used method to focus the attention of a team. By working through a checklist shared situational awareness is increased, which in turn improves team work. A process (pathway) checklist is one of the most successful ways to link individual health care professionals or teams in a process (chain). This way coherence between different steps in the chain is secured.

Make every team member read each item out loud. Make sure that that the entire team acknowledges, even when it seems repetitious or unnecessary to call this item. Each and every one will eventually miss something, and methodical use of a checklist as a tool to focus a team can prevent this. A checklist must not be seen as a means to everything; a checklist cannot think and is not meant for every situation. A checklist is not a cookbook nor a shopping list but a memory aid to properly execute a procedure that should have been okay from start.

Where Is the "Golden Bullet"?

Several interventions can improve skills and promote safe action. Training by simulation or serious gaming increases experience. Guidelines and protocols increase knowledge and reduce practice variance. Additionally, clustering of low volume/high risk operations performed by differentiated super specialists improves outcome. Knowledge and experience among team members can be optimally utilized by improvement of communication and teamwork with crew resource management

training. Accurate and available patient information is a key safety feature. Digital patient records make critical information available for all involved caregivers from different workstations and safe practice. Since sleep deprivation and a combination of fatigue and high workload are recognized as risk factors for medical errors, self-evaluation and fatigue management should be stimulated. In parallel with the maximum driving time of truck driver, enforced for traffic safety reasons, we are not that far away from a maximum 'cutting time.'

Periodical evaluation and effect measurements of interventions are essential for feedback information, to make necessary adjustments and to keep up with changing times and demands. An intervention may take up much time and man power without accomplishing the desired effect. For evaluation of surgical performance a prospective, digitalized complication registration system is needed. Such a system is also very helpful in determining the objective and not merely perceived effect of a safety intervention.

Adherence to safety principles starts with awareness of the problem, but it is still a giant leap from awareness to behavioral and attitude changes that improve surgical safety. Preventable errors comprise almost half of all in-hospitals medical errors, and about one in 150 patients dies from a medical error [2]. This means that there is ample room for improvement. In the last decade much has been accomplished, but preventable errors still happen.

Patient safety management is in need of more data to guide and prioritize the choices made; evidence-based surgical safety instead of rule-driven safety. Not every enthusiastic, seemingly logic, new safety initiative should be adopted [21] before ample evidence exists that it really works in terms of patient outcome. The extent of its effect ranks a safety intervention and prioritizes the need for implementation. Surgeons and not the government or inspectorates should be in the lead steering necessary changes to improve surgical safety.

Take-Home Message

- It is important to recognize our own fallibility: we do not observe nor remember perfectly.
- A checklist can cope with lapses in our observation and memory.
- System thinking learns us that the essence of a system or organization is not the sum of its parts but the process of interactions between those parts.
- A surgical checklist formalizes and coordinates individual responsibilities and shared responsibilities within a team during the surgical process of a patient, and the tasks that go with it.
- It standardizes the surgical process, predominantly in situations when there is no clear team present at one moment, but a series of team members who work together in a sequential process.
- A process (pathway) checklist is one of the most successful ways to link individual health care professionals or teams in a process (chain). This way coherence between different steps in the chain is secured.

- A team can perform its tasks within a process by using a checklist. Checklist use structures essential team factors such as communication and coordination, and improves situational awareness.
- A surgical checklist integrates process steps and related checks.
- A surgical checklist breaks through hierarchy, and stimulates shared situational awareness and team work.
- More than half of observed incidents take place outside the operating room, in the pre- and postoperative phase. Merely a time-out procedure in the operating room is not enough and too late in the surgical pathway.
- We should promote evidence-based surgical safety instead of rule-driven safety.

References

1. Kohn LT, Corrigan JM, Donaldson MSE. To err is human: building a safer health system. Washington, DC: National Academy Press; 1999.
2. de Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. Qual Saf Health Care. 2008;17(3):216–23.
3. Longo DR, Hewett JE, Ge B, Schubert S. The long road to patient safety: a status report on patient safety systems. JAMA. 2005;294(22):2858–65.
4. Stelfox HT, Palmisani S, Scurlock C, Orav EJ, Bates DW. The "To Err is Human" report and the patient safety literature. Qual Saf Health Care. 2006;15(3):174–8.
5. de Vries EN, Hollmann MW, Smorenburg SM, Gouma DJ, Boermeester MA. Development and validation of the SURgical PAtient Safety System (SURPASS) checklist. Qual Saf Health Care. 2009;18(2):121–6.
6. Berwick D. Continuous improvement as an ideal in health care. N Engl J Med. 1989;320: 53–6.
7. Reason J. Human error: models and management. West J Med. 2000;172(6):393–6.
8. Leape L, Berwick D. Five years after to err is human. J JAMA. 2005;293(19):2384–90.
9. Reason J. Human errors: models and management. BMJ. 2000;320:768–70.
10. Dawson D, Reid K. Fatigue, alcohol and performance impairment. Nature. 1997;388(6639):235.
11. Landrigan CP, Rothschild JM, Cronin JW, Kaushal R, Burdick E, Katz JT, et al. Effect of reducing interns' work hours on serious medical errors in intensive care units. N Engl J Med. 2004;351(18):1838–48.
12. Chu MW, Stitt LW, Fox SA, Kiaii B, Quantz M, Guo L, et al. Prospective evaluation of consultant surgeon sleep deprivation and outcomes in more than 4000 consecutive cardiac surgical procedures. Arch Surg. 2011;146(9):1080–5.
13. Senge PM. The fifth discipline: the art and practice of the learning organization. New York: Random House; 1990.
14. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat A-HS, Dellinger EP, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med. 2009;360(5):491–9.
15. McConnell DJ, Fargen KM, Mocco J. Surgical checklists: a detailed review of their emergence, development, and relevance to neurosurgical practice. Surg Neurol Int. 2012;3:2.
16. De Vries EN, Prins HA, Crolla RMPH, Den Outer AJ, Van Andel G, Van Helden SH, et al. Effect of a comprehensive surgical safety system on patient outcomes. N Engl J Med. 2010; 363(20):1928–37.
17. De Vries EN, Dijkstra L, Smorenburg SM, Meijer RP, Boermeester MA. The SURgical PAtient Safety System (SURPASS) checklist optimizes timing of antibiotic prophylaxis. Patient Saf Surg. 2010;4(1):6.

18. De Vries EN, Eikens-Jansen MP, Hamersma AM, Smorenburg SM, Gouma DJ, Boermeester MA. Prevention of surgical malpractice claims by use of a surgical safety checklist. Ann Surg. 2011;253(3):624–8.
19. De Vries EN, Prins HA, Bennink MC, Neijenhuis P, van Stijn I, van Helden SH, van Putten MA, Smorenburg SM, Gouma DJ, Boermeester MA. Nature and timing of incidents intercepted by the SURPASS checklist in surgical patients. BMJ Qual Saf. 2012;21(6):503–8.
20. Wachter RM, Pronovost PJ. Balancing "no blame" with accountability in patient safety. N Engl J Med. 2009;361(14):1401–6.
21. Shekelle PG, Pronovost PJ, Wachter RM, McDonald KM, Schoelles K, Dy SM, Shojania K, Reston JT, Adams AS, Angood PB, Bates DW, Bickman L, Carayon P, Donaldson L, Duan N, Farley DO, Greenhalgh T, Haughom JL, Lake E, Lilford R, Lohr KN, Meyer GS, Miller MR, Neuhauser DV, Ryan G, Saint S, Shortell SM, Stevens DP, Walshe K. The top patient safety strategies that can be encouraged for adoption now. Ann Intern Med. 2013;158(5 Pt 2):365–8.

Part III

Other Perspectives

The Anesthesia Perspective

26

Kirk J. Hogan

Pitfalls and Pearls

- Anesthesia-related mortality and morbidity are difficult to measure and analyze.
- Anesthesia-related mortality and morbidity are more common than patients and caregivers assume.
- Post-operative cognitive dysfunction, delirium and dementia are prevalent, poorly understood, worsen with age, and are not avoidable at present.
- Inhalational and intravenous general anesthetics cause neuronal apoptosis and impaired learning and behavior in infant laboratory animals, with ominous but inconclusive evidence in humans.
- Sterile drug shortages disrupt the supply of most injectable anesthetic induction, maintenance and resuscitation drugs in a burgeoning crisis.
- Digital information technology in the operating room will attract heightened levels of regulatory scrutiny as harms and means for their prevention are identified.

Outline of the Problem

The chief cause of problems is solutions.
Eric Severeid

Less than 3 months after James Young Simpson introduced chloroform anesthesia on November 8, 1847, Hannah Greener became the first person known to die from an anesthetic during removal of a toenail. The immediate and

K.J. Hogan, MD, JD
Department of Anaesthesiology, University of Wisconsin School of Medicine,
600 Highland Avenue, Madison, WI 53792, USA
e-mail: khogan@wisc.edu

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_26,

profound lessons of her death reverberate to this day. With the introduction of ether and chloroform, physicians were for the first time able to provide an agent that *always* works for its intended purpose (the number needed to treat is one) but that often kills, and by a wide diversity of means. It was soon learned that to achieve conditions satisfactory for anything other than superficial procedures, anesthetics must be delivered at a dose with an inverted therapeutic ratio i.e., the effective dose of volatile anesthetics (those with an odor) for most surgeries is two times or greater than the lethal dose if ventilation and circulation are not assured. Early caregivers recognized that anesthesia-related mortality and morbidity arise from the interplay of patient specific susceptibilities, inherent properties of drugs, sophistication of equipment, and the experience and judgment of the caregiver. In turn, seeking the safest possible use of ether, chloroform, and their progeny gave birth to the merger of science and medicine in deciding who gets what, when, where, and how. Many of the major sources of anesthesia-related mortality and morbidity were identified and harnessed over the ensuing century and a half, only to have new hazards emerge from increasingly complex surgeries, severe co-morbidities, patients at the extremes of age, and tectonic shifts in health care delivery systems. The aims of this chapter are to take stock of where we stand now in view of anesthesia-related contributions to patient safety in the perioperative interval, to survey a handful of important but unresolved issues which presently occupy our attention, and to consider how far we have yet to go "ensure that no patient shall be harmed by anesthesia" [1].

Anesthesia-Related Mortality

Anesthesia caregivers often quote a tenfold decline in the incidence of anesthesia-related mortality from 10 to 30 deaths per 100,000 anesthetics in 1980, to 1–3 deaths per 100,000 anesthetics over the intervening three decades [2–5]. The purported fall in anesthesia-related deaths is variously ascribed to improved risk assessment and patient preparation, to practice protocols and guidelines, and to the introduction of monitoring technologies able to range far beyond human senses (e.g., analysis of transcutaneous oxygen saturation, end-tidal carbon dioxide, and inhaled gases), safer drugs, and management technologies (e.g., fiberoptic bronchoscopy, the laryngeal mask airway, ultrasound-guided anatomy) that overcome the challenges of ever-sicker patients and novel surgical interventions. As a corollary, the specialty of anesthesiology has been cited as "the only system in health care that begins to approach the vaunted 'six sigma' level of perfection" [6]. Evidence to the contrary suggests that the profession still falls far short of this performance standard. In a survey of death certificates from 1999, Lienhart et al. [7] confirm an incidence of anesthesia-related deaths to be 0.69/100,000. However, closer analysis of risk factors associated with mortality identified numerous potentially correctable team factors (e.g., communication and supervision), caregiver factors (e.g., experience,

judgment, competence) and work environment factors (availability and use of equipment, staffing, managerial support) that contributed to 62, 51 and 44 % of deaths, respectively.

Other authorities contend that the cited 1–3/100,000 risk of anesthesia-related death may be unintentionally misleading [8–12]. Disparities in the definitions and taxonomy of "anesthesia-related mortality" distinguished from "partial" or "anesthesia-associated mortality," in which events under the control of anesthesia caregivers contribute to death but are not the primary cause, and from events in which anesthesia is not a contributor, remain fundamental issues. Methods used to resolve these distinctions are not objective, vary widely between published accounts, and are typically confounded by poor inter-rater reliability and absent proof of causation. Most deaths in which anesthetic management plays a role originate in complex chains of acts of omission and commission, in keeping with a fivefold greater risk of deaths that are "partially" rather than "totally" related to anesthetic care [7]. Early reports focused on deaths in the first 24–48 h after surgery, in contrast to more recent recognition of anesthetic predictors of mortality lasting up to 30 days after surgery and beyond. Because anesthesia-related mortality is uncommon, databases from multiple centers are usually examined at the cost of added heterogeneity in patient status, and variation arising from differences in surgeon, anesthesiologist, institutional and system-wide practices, and in reporting systems that undergo rapid evolution. Further uncertainties in the numerator of mortality ratios arise from a lack of standardized methods of data reporting, archiving, sampling, and data sources comprising death certificates, coded data in administrative databases collected for other purposes (e.g., billing), and malpractice litigation, and are paired with imprecise and inconsistent estimates of a relevant denominator.

Accordingly, inconsistencies in methods of data acquisition and analysis generate widely disparate estimates of anesthetic mortality. Using data derived from peer-review of deaths in a single hospital network over two decades, Lagasse reports an all-cause perioperative mortality rate of 1/500, with human error by an anesthesiologist (e.g., improper technique, misuse of equipment, disregard of available data, failure to seek appropriate data, inadequate knowledge) contributing to 1/15,000 deaths within 48 h after surgery, a rate observed to be stable over the last 20 years [11]. Thiele et al. [13] argue on the other hand that "By adhering to the six sigma approach, the anesthesia community has reduced the mortality attributable directly to anesthesia so significantly that it is now almost impossible to measure."

All anesthesia-related mortality risk estimates must be further tempered by two overriding factors. First, anesthetic deaths escalate rapidly with poor pre-operative physical status, with a tenfold or greater increase in mortality observed between American Society of Anesthesiologists status I and status IV patients [7]. Failure to analyze and report appropriate risk stratification substantially impairs interpretation of summary death statistics. Second, perioperative and anesthesia-related mortality vary enormously by locale. The World Health Organization (WHO) reports that of 230 million anesthetics for major surgery worldwide each year, 7 million patients

develop severe complications, and 1 million die [14, 15]. This burden is not evenly distributed between developed and developing nations. Schlack and Boermeester [16] describe a death rate of 5–10 %, and major complications in up to 17 % of patients having major surgery with anesthesia in developing countries, with anesthesia-related mortality falling between 1/150 to 1/3,000 surgeries. These values have motivated the WHO to organize the World Alliance for Patient Safety, and to issue WHO Guidelines for Safe Surgery comprising 10 objectives, validated checklists, and recommendations for implementation [17]. Similarly, the World Federation of Societies of Anaesthesiologists (WFSA) has adopted International Standards for a Safe Practice of Anesthesia, and is a co-founder of Lifebox, a non-profit organization established to provide pulse oximetry and training to anesthesia caregivers in low-resource countries at low cost [18, 19].

All investigators agree that the accuracy of anesthesia-related mortality estimates depends on factors that vary widely between published investigations. A further point of consensus is that despite inconsistent definitions, methods, analysis and interpretation between authorities, anesthesia-related mortality alone is a poor index of patient safety in anesthesia care. A "six sigma" performance standard indicates work product that is 99.99966 % free of defects [4]. When the risk of anesthesia-related mortality is tethered to the risk of anesthesia-related morbidity, few practitioners can reasonably argue that contemporary anesthesia care is anywhere close to this "level of perfection."

Anesthesia-Related Morbidity

While most patients and many practitioners consider the modern practice of anesthesia to be generally free of complications, two large surveys paint a different picture. With closely parallel findings, Bothner et al. [20] and Fasting et al. [21] identify severe and permanent damage arising from major errors in anesthetic management in 0.2–0.5 % of surgeries, intermediate severity outcomes including unplanned postoperative intensive care in 0.5–1.5 % of procedures, and an incidence of minor anesthetic morbidities in 22 % of patients, many of which comprise "near-miss" events wherein immediate attention is required to forestall far more deleterious outcomes [20–22]. Loss of airway control, management of hemorrhage and dysrhythmia, complications of central line placement, and anaphylaxis are common causes of intermediate and high severity outcomes. Anesthetic induction, intubation and emergence from anesthesia are intervals of particular susceptibility, although lapses in pre-operative and post-operative care contribute to unfavorable sequelae in 40 % or more of severe adverse outcomes. Of note, anesthesia-related morbidity risk estimates further reflect conditions encountered in regional anesthesia that infrequently cause death, but often engender substantial harm e.g., neuropathy (3 %), circulatory consequences of regional anesthesia and vascular injection, epidural abscess and hematoma, and paraplegia (1/100,000). Investigators acknowledge that the rigor and reliability of estimates of anesthesia-related morbidity share

most of the deficiencies of estimates of anesthesia-related mortality [4]. Based on the best available data it may further be concluded that the high risk of anesthesia-related morbidity in a setting of a relatively low risk of anesthesia–related mortality points to a culture of intense vigilance and rescue in protecting patients from harm, rather than to drugs, technologies and regimens of intrinsic safety.

Adoption of pulse oximetry and end-tidal capnography in the middle 1980s heightened the anesthesia profession's awareness of its proximity to the edge of catastrophe in daily care, and underscored how widely the margin of safety could be augmented by routine use of non-invasive, low cost instruments. Suspecting that still further reductions in anesthesia-related morbidity and mortality were achievable, Dr. Ellison C, Pierce Jr. and colleagues inaugurated the Anesthesia Patient Safety Foundation (APSF) (http://www.apsf.org) which has recently celebrated its 25th anniversary [1]. As the first organization of its kind, the APSF established patient safety as a discrete aspiration and discipline, and has been instrumental in triggering the worldwide patient safety movement of the present day. The Board of the APSF is composed of representatives from physician and nursing anesthesia communities, attorneys, regulatory agencies, and pharmaceutical and medical device manufacturers. The Board oversees research and educational support, safety programs and campaigns, publishes a freely available newsletter, and participates in national and international exchanges of information and alliances with the American College of Surgeons and the WFSA among many others.

Under the guidance of Dr. Pierce, the American Society of Anesthesiologists (ASA) established the Closed Claim Project in 1984 wherein hospital and medical records, narrative statements from personnel involved, expert and peer reviews, deposition summaries, outcome reports, costs of settlement and jury awards made available from personal injury insurance carriers are reviewed after litigation is resolved (i.e., "closed") by practicing anesthesiologists [23]. As an incident reporting system aimed at detecting rare events, the Closed Claims Project seeks to identify anesthesia-related complications, and to issue best practice recommendations. Despite limited carrier participation, under-reporting, geographic variation, lack of control groups, reviewer subjectivity, and inability to test hypotheses of causality, the Closed Claim Project has been instrumental in reducing morbidity from oversedation in monitored anesthesia care (MAC), perioperative burns, hazards of anesthesia in remote locations, analgesic medication in chronic pain management, delay in establishing a surgical airway in management of difficult intubation, and numerous other mishaps. A general trend from inception of the Closed Claims Project to the present has been a decline in claims associated with general anesthesia during surgery, and increasing claims after monitored anesthesia care (MAC), regional anesthesia, and the management of acute and chronic pain.

Apart from lessons learned over the past 25 years with regard to specific anesthesia-related morbidities, aggregate principles of perioperative safety have recently come into sharpened relief. A first insight is that most anesthesia-related morbidity has many sources including patient co-morbidities and inter-current medications, caregivers, technology, the operating room environment, the perioperative care team and its communication practices, the institution and its locale, delivery

system traits, and payer resources. A second is that perioperative care is itself a complex system that requires the organization of highly heterogeneous tasks taking place in a rapidly evolving environment. Complex systems are inherently unsafe with accidents caused both by breakdowns in existing processes and procedures, and as a consequence of the *normal* and *expected* function of a complex system. As noted by Arfanis et al. "Automation will increase reliability and improve performance but make the operation more rigid. As long as humans are kept in the system, automation will also make their environment more complex, and create new problems in man-machine interaction" [24]. Perioperative safety comprises many stakeholders, with providers, managers, and payers focused on costs as well as internal and external benchmarking [25]. Optimal anesthesia safety is expensive and may not be compensated, particularly in the absence of well-established sentinel event and surrogate indicators of work safety and work quality [26]. These facts dictate that perioperative safety must balance trade-offs between irreconcilable goals, for example, optimal safety versus the restrictions of efficiency and cost, and standardization versus caregiver autonomy [27].

Multiple target initiatives have been introduced to address these challenges. As a predicate to provide shared definitions and taxonomy, Haller et al. have recently conducted a comprehensive review of published clinical markers of patient quality and safety, together with appraisals of the level of evidence for each predictor and methods of their use [28]. Promulgation of strict checklists and protocols has had, and will continue to have, clear cut beneficial effects, although recognition is growing that pushback in caregiver implementation, complacency, fading compliance, and guideline fatigue sets an upper threshold of diminishing returns for standardization as a panacea. Training and high fidelity manikin simulation, particularly in inter-professional team (i.e., surgery, anesthesiology and nursing) performance, crisis response management (CRM), identification of latent threats to safety, and non-technical skills remain nascent at present, but with a bright future apparently assured.

In seeking international improvement in anesthesia-related morbidity and mortality, the European Board of Anesthesiology, the European Society of Anesthesiology, the European Union of Medical Specialists, the European Patients Federation, and WHO have recently endorsed the Helsinki Declaration on Patient Safety in Anaesthesiology with the laudable aim to "do the right thing to every patient all of the time" [15, 29]. Signatories of the Helsinki Declaration agree to adopt minimal standards of monitoring, to employ 10 practical management protocols and WHO checklists, to commit to provide a standardized annual report of anesthesia outcomes, and to participate in multi-center research and educational agendas. Further sources of high-quality educational content are available to all stakeholders including the "National Patient Safety Goals Effective January 1, 2013 Office-Based Surgery Accreditation Program" at www.jointcommission.org/assets/1/18/NPSG_Chapter_Jan2013_OBS.pdf and "Fundamentals of Patient Safety," composed of an Introduction and 4 modules of online continuing medical education available from the American Society of Anesthesiologists at http://education.asah1.org.FPS.

Expert opinion is divided with regard to the possibility of identification of new anesthesia-related morbidities and mortalities and their solutions. Some share the beliefs of Von Aken et al. [30], that "There will obviously be a few technical improvements in very specialized aspects in the future as well, but new technology or new medications will probably not be responsible for major improvements in the global aspects of safety in anesthesiology." Others seek to harness integrated information sources, multifunctional display, and digital support to bring findings derived from large clinical databases directly to individual patient management [31]. With mortality and major complication data, coded co-morbidities for risk adjustment, and structural measures (e.g., physician training and certification, hospital and delivery system descriptors), the National Anesthesia Clinical Outcomes Registry (NACOR) serves as the infrastructure to provide practitioners with benchmarking information, and with information on best practices to be disseminated by the Anesthesia Quality Institute (AQI) to the anesthesiology and surgery communities [32]. The Multicenter Perioperative Outcomes Group (MPOG) houses anesthesia-specific data elements collected from the centrally-linked anesthesia information management systems (AIMs) of 30 participating institutions to leverage larger sample sizes necessary to detect rare outcomes, and small effects of substantial significance to predisposed patients and their caregivers [27].

Limitations of the Current Practice

The following sections discuss contemporary barriers in anesthesia-related patient safety that share novelty, severity, global impact, and wide gaps in resolution.

Post-operative Cognitive Dysfunction (POCD) in Adults

For over 150 years after the introduction of surgical anesthesia caregivers and patients shared the belief that the experience leaves no enduring neurologic marks other than that observed after surgery on the central nervous system (CNS) itself. Although persistent cognitive deficits in the absence of structural lesions in patients undergoing open heart surgery raised first doubts, new onset post-operative mental decline was blamed on the technology and techniques of cardiopulmonary bypass (e.g. bubble vs. membrane oxygenators) rather than on anesthesia and surgery per se [33]. Early reports of post-operative cognitive dysfunction (POCD) made apparent by comparison of pre- and post-operative psychometric testing in 10–30 % of patients 60 years and older at 3 months, and up to 10 % of patients at 12 months met with initial skepticism, only to be confirmed by other investigators at other institutions [34–40]. In vitro data showing amyloid and tau aggregation with anesthesia exposure, animal studies describing Alzheimer's disease-like histologic and performance changes after anesthesia and surgery [41], and decreased regional volumes of CNS structures measured by magnetic resonance imaging (MRI) after elective surgery in healthy subjects [42, 43], spurs current research aimed at

identifying risk factors, biomarkers, possible causes, and the relationship between post-operative cognitive dysfunction (POCD) and the syndromes of post-operative delirium and dementia.

POCD is not a condition codified by the Diagnostic Standards Manual (DSM). Nor do case reports of severe or even moderate POCD in individuals or families appear in the anesthesiology literature. Investigations of POCD exclude patients who are unhealthy or otherwise at risk, and define POCD by statistically significant changes in components of psychometric test batteries that are not standardized and are often idiosyncratic. The few available peer-review imaging publications are provocative but early in their development with manuscripts comprising retrospective or preliminary analysis. Risk factors other than age, physical status and education level have not been validated. Investigations of cerebrospinal fluid biomarkers including amyloid and tau levels before and after surgery are underway but not disseminated at present. Genomic predictors of POCD have been investigated with intensity, but no genotypes have been identified that correlate with susceptibility to persistent POCD [44]. Informed consent for anesthesia and surgery will most likely incorporate risks for delirium, POCD and possible effects on dementia onset and progression in the near future in view of a large and growing literature, but current consent practice does not contemplate CNS complications.

A first priority is to encourage peer-reviewed publication and registry of case reports of patients and families experiencing new onset cognitive changes after surgery and anesthesia that are not otherwise explained. To sort out disproportionate risks between patients, a focus on severe cognitive decrements in memory and executive function (i.e., reasoning, planning, problem solving) lasting 3 months and longer will be more productive than seeking subtle differences with minimal impact on the quality of life. A second priority is standardization of POCD terminology, experimental designs, test panels, inclusion and exclusion criteria for selection of control participants, re-test intervals, analytic methods, composite scores and thresholds for clinically significant changes [45–50]. A third priority is the addition of anesthesia and surgical variables available from standardized perioperative care records to longitudinal dementia investigations, and to randomized clinical trials (RCTs) of drugs targeting dementia, both of which employ serial psychometric evaluations. Supplementation of existing databases in this fashion is high in yield, low in cost, low in risk to enrolled research participants, and will be as informative to primary dementia investigators as to their anesthesia and surgical colleagues. Analysis of administrative databases assembled for quality assurance, caregiver and institution compensation, and to meet medico-legal requirements with novel statistical methods (e.g. propensity score matching) [51] may comprise independent surgical and anesthetic variables that are otherwise ethically precluded from RCT experimental designs i.e., age of dementia onset after surgical vs. medical management of a given condition, or alternate surgical and anesthetic management for the same disorder. Patients with cognitive decline after other insults including traumatic brain injury [52], chemotherapy [53], and acute and critical care illness [54] often have coincident surgery. Predictors and

prognoses of cognitive loss may direct research teams who participate in the care of shared patients to closer ties. Introduction of innovative technologies that measure baseline and serial psychometric performance in all patients coming to surgery is long overdue [55–57]. Routine psychometric testing that is quick, affordable, precise, easy to administer and interpret, and modeled on technologies developed for evaluation of athletic and combat-related head injury will be a critical step forward to improved patient safety in surgery.

Where Is the "Golden Bullet"? (1)

Emergence from anesthesia has not been considered a subject worthy of coordinated investigation or even review to date. A new focus on identifying and quantifying the molecular, cellular and tissue events that underlie emergence from anesthesia in health and disease is motivated by those whose cognitive emergence may be incomplete. In the setting of patients who may never fully emerge after anesthesia, a more profound understanding of anesthetic emergence and its disruption is both compelling and feasible.

Anesthetic Neurotoxicity in the Developing Brain

First reports of widespread neuroapoptosis after administration of ketamine [58], and isoflurane, midazolam and nitrous oxide [59] to neonatal rats have been followed by numerous published investigations in tissue culture and animal models that confirm widespread neuronal degeneration and persistent neurobehavorial deficits in many species, including sheep and primates [60, 61]. Nitrous oxide may be particularly deleterious [62]. Most animal experimental protocols do not add surgery or other painful models in their design. Those with CNS stimulation report increased neuroapoptosis and behavorial changes in response to inflammation [63]. Corresponding human data is sparse but foreboding [64, 65]. Increased domain-specific disabilities in receptive and expressive language, and in abstract reasoning, are observed in children after anesthetic exposure before age 3 compared to unexposed children [66]. A meta-analysis of seven studies reports a twofold increase in the likelihood for an adverse behavorial or developmental outcomes after anesthesia and surgery in early life [67].

Downstream mechanisms of cognitive changes after anesthetic exposure in childhood are poorly understood. Higher cognitive performance decrements in animals incompletely correspond to human conditions and disorders. No risk factors or biomarkers have been identified that segregate exposed children with subsequent deficits from those without. Post-operative diminution in intelligence, learning, memory, emotional health and fine motor skills is subtle, fluctuating, and may take years to manifest. Differences in outcomes derived from school testing, administrative databases, teacher referrals and standardized testing highlight the need for prospective comparisons between neuropsychological profiles performed at serial intervals in children who have been exposed to one or more

anesthetics and surgeries with those who have not. Human retrospective data is conflicting and insufficient to separate the effects of anesthetic drugs from other potential influences on post-operative cognition such as surgery, inflammation, co-existing diseases, inter-current medications, and socioeconomic, nutritional and heritable factors.

Where Is the "Golden Bullet"? (2)

A major step forward over the past decade has been the elimination of nitrous oxide for anesthetic maintenance in pediatric anesthesia in most centers [68–70]. Multiple prospective investigations of other anesthetic drugs and regimens are now well underway. In the multicenter, international General Anesthesia Spinal Anesthesia (GAS) study, 660 infants 60 weeks of age or younger undergoing inguinal hernia repair are randomized to general anesthesia with sevoflurane, or to spinal anesthesia with bupivacaine, with serial neuropsychological testing at 2 and 5 years thereafter [71]. The Pediatric Anesthesia Neurodevelopment Assessment Project (PANDA) is a multicenter prospective investigation that compares psychometric indices in children less than 3 years of age having a single anesthetic for hernia repair to their unexposed sibs [72]. Multi-domain cognitive tests will be administered between the ages of 8 and 15 with a target sample size of 500 sibling pairs. The Mayo Anesthetic Safety in Kids (MASK) study compares a retrospective-prospective matched birth cohort comprising children who have been exposed once, and more than once, to anesthesia and surgery [73]. Data from these human trials are expected to be published by 2106. In 2010 the FDA, the International Anesthesia Research Society, the Society for Pediatric Anesthesia and the American Academy of Pediatrics founded the public-private partnership "SmartTots" with a mission to raise resources and fund research that targets anesthetic safety in children 4 years old and under. (See http://www.smarttots.org/) [74].

Surgery in childhood is essential to well-being, with immediate and substantial benefits. No evidence supports postponement of a needed procedure to an older age in hope of reduced risks of anesthetic neurotoxicity [75]. Nor is there firm evidence at present to guide drug or regimen selection. Family concerns over possible neurotoxicity are best met with a tailored, open-ended approach [73]. Investigations of novel neuroprotective agents, and of regimens to better prepare the infant CNS for surgery and to hasten its recovery from anesthesia, stand at the frontier of patient safety in pediatric surgery.

Sterile Injectable Anesthesia Drug Shortages

Anesthesia caregivers are confronted on a daily basis with new, recurring and longer duration shortages of their preferred sterile, injectable medications. The astonishing list comprises virtually the entire anesthesia drug drawer including induction and maintenance agents (propofol, thiopental, ketamine), analgesics (fentanyl, morphine, hydromorphone), muscle relaxants (succinylcholine, vecuronium, pancuronim, atracurium), local anesthetics (lidocaine, bupivacaine), anti-emetics

(droperidol), resuscitation drugs (atropine, naloxone, epinephrine, ephedrine, phenylephrine, vasopressin), sedatives (midazolam), neuromuscular blockade reversal agents (neostigmine, glycopyrrolate) [76] and, most recently, normal saline and Lactated Ringer's solution. Most sterile injectable drugs require specialized equipment and complex synthetic pathways to manufacture that are predisposed to quality control failures. Profit margins for off-patent, tort-liable anesthesia drugs and formulations may not offset high risks for mishap inherent to potent agents that target the nervous system. Substitute regimens combine older drugs with less attractive risk-benefit profiles. Sterile injectable drug shortages in anesthesia comprise a clear cut fall off in patient safety beyond the awareness of most patients and other caregivers, with patient harms arising from prolonged operating and recovery room times, increased complication rates (e.g. nausea and vomiting, aspiration), increased costs, medical errors with second-rate, "work-around" alternatives (i.e., with altered and unfamiliar concentrations, packaging, dosages, volume, preservatives), and delayed or cancelled procedures.

Current practices essential to ongoing availability of injectable drugs used by anesthesia caregivers are susceptible to disruption at a multitude of steps that may occur alone or in combination with one another, including [76]:

1. Raw material supplies may be interrupted at the point of origin by contamination of plant, microbe or animal sources, weather and industrial accidents (hurricanes, tsunamis, fire), labor unrest and trade sanctions, transportation breakdowns, and bankruptcy.
2. Manufacturer slowdowns and stoppages may arise from business method pressures (mergers, shifts of production to other materials, departure from the market, "just-in-time" raw material management, investment greater than projected return to correct manufacturing glitches, voluntary recalls, labeling changes, loss of staff due to mergers, subcontractor breaches), and bricks and mortar constraint, i.e., costs of re-configuring and re-building aging infrastructure, expense of manufacturing and compounding facilities in compliance with Good Manufacturing Practices (GMP). Taken together, quality assurance during manufacture is the commonest cited cause of sterile injectable drug shortages (56 %) [77].
3. Regulatory and legislative impediments include U.S. Food and Drug Administration (FDA) violations, delayed reporting by manufacturers of shortages to the FDA, withdrawal of FDA approval of compliance with GMP, insufficient FDA resources and staffing for post-market surveillance, and failure of federal agencies to anticipate injectable drug shortages with effective systems of early detection and amelioration.
4. End-user factors that contribute to injectable drug shortages are ascribed to hoarding between institutions competing in the healthcare marketplace, maintenance of minimal pharmacy stocks, group purchasing, secondary shortages of substitutes, and increased demand with new or off-label indications.

The causes of sterile injectable anesthesia drug shortages are multi-factorial, therefore no single solution will be adequate standing alone. From the top down, in October, 2011 the U.S. President issued Executive Order #13588 requiring the FDA to broaden its reports of potential drug shortages, to expedite its reviews of

applications to initiate or resume drug production, and to seek evidence for collusion and price-gouging. (available at http://www.whitehouse.gov/the-press-office/2011/10/31/executive-order-reducing-prescription-drug-shortages) In July, 2012 the U.S. Congress passed the FDA Safety and Innovation Act (FDASIA) that mandates increased Drug Enforcement Agency (DEA) manufacturing quotas for scheduled drugs, advanced notification and reporting to Congress of drug shortages, establishing a task force for agency responsiveness, and requiring the FDA to prepare a "Strategic Plan for Preventing and Mitigating Drug Shortages" comprising best practices (see: www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf).

In February, 2014 the Government Accountability Office released "Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability," that delineates risks of rationing of care and reliance on less effective drugs as potential consequences of drug scarcity (see: www.gao.gov/products/GAO-14–194). The ASA professional organization lobbies federal lawmakers and regulators for relief from drug shortages with tangible steps, for example, improved web-based mechanisms to report impending shortages directly to caregivers, support for repackaging of drugs in short supply to smaller vials, and standards for custom on-site compounding to conserve limited stocks. The AQI (above) provides an on-line Anesthesia Incident Reporting System (AIRS) (see: www.aqihq.org/airsIntro.aspx) to collate caregivers' de-identified accounts of deleterious outcomes caused by missing medications in support of ASA lobbying efforts.

Where Is the "Golden Bullet"? (3)

Recommendations for perioperative providers to address drug shortages in daily practice include: identification of institutional and departmental drug shortage managers responsible for alert systems, education in the use of substitutes (e.g., in-services, simulation paradigms with unfamiliar substitute drugs), reporting systems, public advocacy and professional solidarity (i.e., between anesthesia caregivers, surgeons, pharmacists, administrators, payers) at the local level; communication about drug shortage problems and alternatives with patients and other caregivers before surgery; division of single-use ampules into pre-filled syringes in compliance with Center for Disease Control (CDC) guidelines for sterility, labeling, and expiration; and preparedness (i.e., ethical stockpiling vs. hoarding). Despite these measures, shortages of sterile injectable drugs in anesthesia practice deepen further into a patient safety crisis. Many factors are beyond the influence of single caregivers and institutions, and even single governments, for example, breaks in the raw material supply chain, and regulation of international corporate behavior. For factors that are within reach, Dutton and Cohen [78] affirm:

> *In carrying on despite the lack of desired medications, we should recognize the risks to which we are exposing our patients, and the danger of co-enabling an intolerable situation. We must not continue to expose patients to these risks, when we know that proper action on the part of industry, our policy makers, and ourselves, can reduce it.*

Electronic Recording Devices in the Operating Room

The two greatest changes in anesthesia practice in the twenty-first century have been the cessation of nitrous oxide for anesthetic maintenance in adults and children, and the introduction of electronic recording devices for use during surgery. The first was evidence-based. The second was not. Contraction in nitrous oxide use has taken place despite strict FDA regulation. Imposition of electronic recording devices into the operating room has taken place without FDA review [79]. The Institute of Medicine's (IOM) 2011 call for greater scrutiny of the electronic health record (EHR) based on limited data showing improved patient safety, and accumulating reports of health information technology (HIT)–related unsafe conditions, serious injuries and deaths were subdued by White House Office of National Coordinator (ONC) initiatives, and subsidies in the Affordable Care (ACA) Act, the Health Information Technology for Economic and Clinical Health (HITECH) Act, and the Electronic Health Records Incentive Program of the American Recovery and Reinvestment Act aimed at EHR implementation without regulatory delays [80, 81]. As noted by the National Research Council, objective data to assess the safety of health information systems is lacking [82]. Data integrity failure in EHRs (i.e., "e-iatrogenesis") is the Emergency Care Research Institute's (ECRI) fourth ranked health technology hazard of 2014. (see: www.ecri.org/Press/Pages/2014_Top_Ten_Hazards.aspx) In the absence of regulatory scrutiny, EHR vendors side-stepped FDA purview of manufacturing processes, design controls and evidence that systems perform as claimed, asserting that their products merely automate administrative tasks and paperwork [83]. The Epic Systems Vice President Carl Dvorak notes: "The policing of design by a third party or agency, however well intended, will likely stifle innovation and inhibit the growth and development of electronic health records in the future," (see: www.arma.org/r1/news/washington-policy-brief/2011/01/04/electronic-medical-records-prompt-patient-safety-concerns)

Shortcomings of electronic recording devices in general medical practice are amplified during anesthesia and surgery. A partial listing includes: privacy and security disrupted work flow with data entry; errors from "doctoring while distracted"; charting on the wrong patient in the electronic system (COWPIES) (see: www.aqihq.org/files/airscases/CASE_2012_09_Garbage_In.pdf); user interface and display design flaws; inadequate or faulty recording and transmission of data; data loss; alert fatigue; software upgrade fatigue; information overload; refractory documentation errors; practice blindness during implementation; documentation discontinuities at paper and electronic interfaces; and vigilance reduced by passive record making. In view of these harms, Limitation of Liability provisions in software licenses signed by representatives of caregivers and facilities that shield vendors from damages may appear onerous. Few patients and families are aware of EHR risks. EHR risks do not appear in preoperative informed consent documents, nor are patients given a choice. Similarly, risks inherent to electronic recording devices during surgery are not components of informed consent for clinical research using data acquired with their use. Institutional Review Boards and journal editorial boards have not addressed data sources comprising EHR risks despite attention to

potential harms of much smaller magnitude. Electronic recording devices used during anesthesia and surgery require substantial and ongoing costs paid by third parties, patients and taxpayers. Caregivers are not compensated for repetitive training, credentialing and compliance monitoring.

Where Is the "Golden Bullet"? (4)

Electronic recording devices and digital AIMs offer many opportunities for enhanced patient safety during surgery and anesthesia with immediate access to patient records, improved communication with primary caregivers and consultants, automatic data entry that assures legibility and consistency, and clinical decision support e.g., alerts and warnings in real-time [84, 85]. HIT data supports coding, billing, practice standardization, compliance monitoring and reporting, and construction of databases able to detect trends, rare events, and novel safety associations. To ensure that the benefits of electronic recording devices in the operating room offset risks, caregivers and their professional organizations must demand finished digital recording hardware and software, with safety and quality documentation before deployment that meets cross-vendor standards. Providers and facilities must weigh the patient safety ramifications of concessions to liability waivers in order to secure federal subsidies. While incentives may be time-limited, caregiver waivers that cushion the HIT industry from making needed changes may take years to terminate. Despite inter-agency conflicts within the Executive Branch i.e., between the FDA and ONC, intense FDA scrutiny of EHRs and related technologies appears probable, with classification of physical embodiments as medical devices under the FDA's Center for Device and Radiological Health (CDRH), and oversight of software parallel to Federal Aviation Administration (FAA) regulation of cockpit algorithms. Electronic recording device vendors will replace market processes, incremental changes, and non-binding regulatory suggestions with formal registration as drivers of product development to include pre-market approval processes, and mandatory post-market reporting and surveillance. The FDASIA (above) requires the FDA to issue a report on its EHR regulatory intentions in 2014 to comprise recommendations for a risk-based framework for HIT that protects patient safety, promotes innovation, and avoids administrative duplication.

Take-Home Message

The four patient safety issues considered above provide a brief sampling that belies complacency in presumptions of acceptable anesthesia-related mortality and morbidity [30]. Current anesthesia caregiver preoccupations also address adverse consequences of productivity pressure, the interplay of patient safety and the quality directives [86], structured hand-offs, the role of aging caregivers, persistent drug errors [87], effects of anesthesia care on long-term outcomes e.g., wound infection and cancer recurrence [88], latent risk factors [89], improvements in the safety of pain management, palliative care and other anesthesia sub-specialties [90],

anesthesia caregiver safety, and care for the "second victim" i.e., the provider after untoward events. Investigations of the effects of anesthetics on tissue healing and regeneration, perioperative genomics [91] and epigenomics, and introduction of crew resource management (CRM) and acquisition of non-technical skills (NOTECs) [92–96] serve to frame the patient safety problems and their solutions of the near future. As novel sensors, transducers, processors, storage and transmission media, and executive and analytical protocols are developed, safe caregivers will require a solid foundation in biostatistics to craft questions, to judge contributions, and to determine when changes in practice are premature, timely, or overdue.

The greatest single threat to sustained and improving patient safety in surgery is allocation of scarce resources without caregiver participation early on. Perverse scenarios are certain to arise when end-users stand last in line to learn the mandates of stakeholders outside the doctor-patient relationship, as the introduction of unregulated digital information technologies that record the timing and dose of antiquated, second- or third-in class drugs during surgery demonstrates. What price will caregivers, patients and their families pay for failing to heed Dr. Pierce's decades-old warning? [97]

> *Patient safety is not a fad. It is not a preoccupation of the past. It is not an objective that has been fulfilled or a reflection of a problem that has been solved. Patient safety is an ongoing necessity. It must be sustained by research, training, and daily application in the workplace. I fear that we may be entering an era that could easily undo many of the gains that we cherish so highly. This is the era of cost-containment, production-pressure, and bottom-line decision-making by corporate deal-makers. The forces underlying this new era are driving us to be leaner, faster, and cheaper. To some extent, these changes may bring a measure of immediate health and vigor to the practice of medicine; they also pose a worrisome threat. If we try to meet financial challenges by short-cutting our daily attention to patient safety or by minimizing our long-term commitments to education and research, we may not be able to carry forward the gains of the immediate past or pursue the exciting insights and innovations that are just emerging. Patient safety is truly the framework of modern anesthetic practice, and we must redouble efforts to keep it strong and growing.*

References

1. Eichhorn JH. The Anesthesia Patient Safety Foundation at 25: a pioneering success in safety, 25th anniversary provokes reflection, anticipation. Anesth Analg. 2012;114(4):791–800.
2. Li G, Warner M, Lang BH, Huang L, Sun LS. Epidemiology of anesthesia related mortality in the United States, 1999–2005. Anesthesiology. 2009;110(4):759–65.
3. Gottschalk A, Van Aken H, Zenz M, Standl T. Is anesthesia dangerous? Dtsch Arztebl Int. 2011;108(27):469–74.
4. Haller G, Laroche T, Clergue F. Morbidity in anaesthesia: today and tomorrow. Best Pract Res Clin Anaesthesiol. 2011;25(2):123–32.
5. Bainbridge D, Martin J, Arango M, Cheng D. Perioperative and anaesthetic-related mortality in developed and developing countries: a systematic review and meta-analysis. Lancet. 2012;380(9847):1075–81.
6. Leape LLO, Berwick DM, Bates DW. What practices will most improve safety? Evidence-based medicine meets patient safety. JAMA. 2002;288(4):501–7.

7. Lienhart A, Auroy Y, Péquignot F, Benhamou D, Warszawski J, Bovet M, Jougla E. Survey of anesthesia-related mortality in France. Anesthesiology. 2006;105(6):1087–97.
8. Gaba DM. Anaesthesiology as a model for patient safety in health care. BMJ. 2000; 320(7237):785–8.
9. Lagasse RS. Anesthesia safety: model or myth? A review of the published literature and analysis of current original data. Anesthesiology. 2002;97(6):1609–17.
10. Cooper JB, Gaba DM. No myth: anesthesia is a model for addressing patient safety. Anesthesiology. 2002;97(6):1335–7.
11. Lagasse RS. Innocent prattle. Anesthesiology. 2009;110(4):698–9.
12. Eichhorn JH. Review article: practical current issues in perioperative patient safety. Can J Anaesth. 2013;60(2):111–8.
13. Thiele RH, Huffmyer JL, Raphael J. Perioperative morbidity: lessons from recent clinical trials. Curr Opin Crit Care. 2012;18(4):358–65.
14. Weiser TG, Regenbogen SE, Thompson KD, Haynes AB, Lipsitz SR, Berry WR, Gawande AA. An estimation of the global volume of surgery: a modelling strategy based on available data. Lancet. 2008;372(9633):139–44.
15. Whitaker DK, Brattbo G, Smith AF, Staender SEA. The Helsinki Declaration on Patient Safety in Anaesthesiology: putting words into practice. Best Pract Res Clin Anaesthesiol. 2011;25(2):277–90.
16. Schlack WS, Boermeester MA. Patient safety during anaesthesia: incorporation of the WHO safe surgery guidelines into clinical practice. Curr Opin Anaesthesiol. 2010;23(6):754–8.
17. Gawande A, Weiser T, editors. WHO guidelines for safe surgery 2009—safe surgery saves life. Geneva: WH Press; 2009.
18. Merry AF, Cooper JB, Soyannwo O, Wilson IH, Eichhorn JH. International Standards for Safe Practice of Anesthesia 2010. Can J Anaesth. 2010;57(11):1027–34.
19. Enright A. Review article: safety aspects of anesthesia in under-resourced locations. Can J Anaesth. 2013;60(2):152–8.
20. Bothner U, Georgieff M, Schwilk B. Building a large-scale perioperative anaesthesia outcome-tracking database: methodology, implementation, and experiences from one provider within the German quality project. Br J Anaesth. 2000;85(2):271–80.
21. Fasting S, Gisvold SE. Statistical process control methods allow the analysis and improvement of anesthesia care. Can J Anaesth. 2003;50(8):767–74.
22. Staender SEQ, Mahajan RP. Anesthesia and patient safety: have we reached our limits? Curr Opin Anaesthesiol. 2011;24(3):349–53.
23. Metzner J, Posner KL, Lam MS, Domino KB. Closed claims' analysis. Best Pract Res Clin Anaesthesiol. 2011;25(2):263–76.
24. Arfanis K, Fioratou E, Smith A. Safety culture in anaesthesiology: basic concepts and practical application. Best Pract Res Clin Anaesthesiol. 2011;25(2):229–38.
25. Weiser TG, Porter MP, Maier RV. Safety in the operating theatre—a transition to systems-based care. Nat Rev Urol. 2013;10(3):161–73.
26. Gisvold SE, Fasting S. How do we know we are doing a good job—can we measure the quality of our work? Best Pract Res Clin Anaesthesiol. 2011;25(2):109–22.
27. Kheterpal S, Woodrum DT, Tremper KK. Too much of a good thing is wonderful observational data for perioperative research. Anesthesiology. 2009;111(6):1183–4.
28. Haller G, Stoelwinder J, Myles P, McNeil J. Quality and safety indicators in anesthesia. Anesthesiology. 2009;110(5):1158–75.
29. Mellin-Olsen J, Staender S, Whitaker DK, Smith AF. The Helsinki Declaration on Patient Safety in Anaesthesiology. Eur J Anaesthesiol. 2010;27(7):592–7.
30. Von Aken H, Staender S, Mellin-Olson J, Pelosi P. Patient safety in anaesthesiology. Best Pract Res Clin Anaesthesiol. 2011;25(2):ix–x.
31. Tremper KK. Anesthesiology: from patient safety to population outcomes: the 49th Annual Rovenstine Lecture. Anesthesiology. 2011;114(4):755–70.
32. Glance LG, Neuman M, Martinez EA, Pauker KY, Dutton RP. Performance measurement at a tipping point. Anesth Analg. 2011;112(4):958–66.

33. Bartels K, McDoinagh DL, Newman MF, Mathew JP. Neurocognitive outcomes after cardiac surgery. Curr Opin Anaesthesiol. 2013;26(1):91–7.
34. Moller JT, Cluitmans P, Rasmussen LS, Houx P, Rasmussen H, Canet J, Rabbitt P, Jolles J, Larsen K, Hanning CD, Langeron O, Johnson T, Lauven PM, Kristensen PA, Biedler A, van Beem H, Fraidakis O, Silverstein JH, Beneken JE, Gravenstein JS. Long-term postoperative cognitive dysfunction in the elderly ISPOCD1 study. ISPOCD investigators International Study of Post-Operative Cognitive Dysfunction. Lancet. 1998;351(9106):857–61.
35. Abildstrom H, Rasmussen LS, Rentowl P, Hanning CD, Rasmussen H, Kristensen PA, Moller JT. Cognitive dysfunction 1–2 years after non-cardiac surgery in the elderly. ISPOCD group International Study of Post-Operative Cognitive Dysfunction. Acta Anaesthesiol Scand. 2000;44(10):1246–51.
36. Johnson T, Monk T, Rasmussen LS, Abildstrom H, Houx P, Korttila K, Kuipers HM, Hanning CD, Siersma VD, Kristensen D, Canet J, Ibañaz MT, Moller JT. ISPOCD2 Investigators. Postoperative cognitive dysfunction in middle-aged patients. Anesthesiology. 2002;96(6): 1351–7.
37. Rasmussen LS, Johnson T, Kuipers HM, Kristensen D, Siersma VD, Vila P, Jolles J, Papaioannou A, Abildstrom H, Silverstein JH, Bonal JA, Raeder J, Nielsen IK, Korttila K, Munoz L, Dodds C, Hanning CD, Moller JT. ISPOCD2 (International Study of Postoperative Cognitive Dysfunction) Investigators. Does anaesthesia cause postoperative cognitive dysfunction? A randomised study of regional versus general anaesthesia in 438 elderly patients. Acta Anaesthesiol Scand. 2003;47(3):260–6.
38. Price CC, Garvan CW, Monk TG. Type and severity of cognitive decline in older adults after noncardiac surgery. Anesthesiology. 2008;108(1):8–17.
39. Steinmetz J, Christensen KB, Lund T, Lohse N, Rasmussen LS, ISPOCD Group. Long-term consequences of postoperative cognitive dysfunction. Anesthesiology. 2009;110(3):548–55.
40. McDonagh DL, Mathew JP, White WD, Phillips-Bute B, Laskowitz DT, Podgoreanu MV, Newman MF, Neurologic Outcome Research Group. Cognitive function after major noncardiac surgery, apolipoprotein E4 genotype, and biomarkers of brain injury. Anesthesiology. 2010;112(4):852–9.
41. Eckenhoff RG, Laudansky KF. Anesthesia, surgery and Alzheimer's disease. Prog Neuropsychopharmacol Biol Psychiatry. 2013;47:162–6.
42. Kline RP, Pirraglia E, Cheng H, De Santi S, Li Y, Haile M, de Leon MJ, Bekker A, Alzheimer's Disease Neuroimaging Initiative. Surgery and brain atrophy in cognitively normal elderly subjects and subjects diagnosed with mild cognitive impairment. Anesthesiology. 2012;116(3): 603–12.
43. Price CC, Tanner JJ, Schmalfuss I, Garvan CW, Gearen P, Dickey D, Heliman K, McDongah DL, Libon DJ, Leonard C, Bowers D, Monk TG. A pilot study evaluating presurgery neuroanatomical biomarkers for postoperative cognitive decline after total knee arthroplasty in older adults. Anesthesiology. 2014;120(3):601–13.
44. Hogan KJ. Hereditary vulnerabilities to post-operative cognitive dysfunction and dementia. Prog Neuropsychopharmacol Biol Psychiatry. 2013;47:128–34.
45. Rasmussen LS, Larsen K, Houx P, Skovgaard LT, Hanning CD, Moller JT, ISPOCD group. The International Study of Postoperative Cognitive Dysfunction. The assessment of postoperative cognitive function. Acta Anaesthesiol Scand. 2001;45(3):275–89.
46. Lewis M, Maruff P, Silbert B. Statistical and conceptual issues in defining post-operative cognitive dysfunction. Neurosci Biobehav Rev. 2004;28(4):433–40.
47. Funder KS, Steinmetz J, Rasmussen LS. Methodological issues of postoperative cognitive dysfunction research. Semin Cardiothorac Vasc Anesth. 2010;14(2):119–22.
48. Rudolph JL, Schreiber KA, Culley DJ, McGlinchey RE, Crosby G, Levitsky S, Marcantonio ER. Measurement of post-operative cognitive dysfunction after cardiac surgery: a systematic review. Acta Anaesthesiol Scand. 2010;54(6):663–77.
49. Terrando N, Brzezinski M, Degos V, Eriksson LI, Kramer JH, Leung JM, Miller BL, Seeley WW, Vacas S, Weiner MW, Yaffe K, Young WL, Xie Z, Maze M. Perioperative cognitive decline in the aging population. Mayo Clin Proc. 2011;86(9):885–93.

50. Hovens IB, Schoemaker RG, van der Zee EA, Heineman E, Izaks GJ, van Leeuwen BL. Thinking through postoperative cognitive dysfunction: how to bridge the gap between clinical and pre-clinical perspectives. Brain Behav Immun. 2012;26(7):1169–79.
51. Rosenbaum P. Design of observational studies. New York: Springer; 2010.
52. Sharma R, Laskowitz DT. Biomarkers in traumatic brain injury. Curr Neurol Neurosci Rep. 2012;12(5):560–9.
53. Ahles TA. Brain vulnerability to chemotherapy toxicities. Psychooncology. 2012;21(11):1141–8.
54. Ehlenbach WJ, Hough CL, Crane PK, Haneuse SJ, Carson SS, Curtis JR, Larson EB. Association between acute care and critical illness hospitalization and cognitive function in older adults. JAMA. 2010;303(8):763–70.
55. Hogue CW, Selnes OA, McKhann G. Should all patients undergoing cardiac surgery have preoperative psychometric testing: a brain stress test? Anesth Analg. 2007;104(5):1012–4.
56. Crosby G, Culley DJ, Hyman BT. Preoperative cognitive assessment of the elderly surgical patient: a call for action. Anesthesiology. 2011;114(6):1265–8.
57. Long LS, Shapiro WA, Leung JM. A brief review of practical preoperative cognitive screening tools. Can J Anaesth. 2012;59(8):798–804.
58. Ikonomidou C, Bosch F, Miksa M, Bittigau P, Vöckler J, Dikranian K, Tenkova TI, Stefovska V, Turski L, Olney JW. Blockade of NMDA receptors and apoptotic neurodegeneration in the developing brain. Science. 1999;283(5398):70–4.
59. Jevtovic-Todorovic V, Hartman RE, Izumi Y, Benshoff ND, Dikranian K, Zorumski CF, Olney JW, Wozniak DF. Early exposure to common anesthetic agents causes widespread neurodegeneration in the developing rat brain and persistent learning deficits. J Neurosci. 2003;23(3):876–82.
60. Paule MG, Li M, Allen RR, Liu F, Zou X, Hotchkiss C, Hanig JP, Patterson TA, Slikker Jr W, Wang C. Ketamine anesthesia during the first week of life can cause long-lasting cognitive deficits in rhesus monkeys. Neurotoxicol Teratol. 2011;33(2):220–30.
61. Creeley CE, Dikranian KT, Dissen GA, Back SA, Olney JW, Brambrink AM. Isoflurane-induced apoptosis of neurons and oligodendrocytes in the fetal rhesus Macaque brain. Anesthesiology. 2014;120(3):626–38.
62. Sanders RD, Weimann J, Maze M. Biologic effects of nitrous oxide. Anesthesiology. 2008;109(4):707–22.
63. Shu Y. Nociceptive stimuli enhance anesthetic-induced neuroapoptosis in the rat developing brain. Neurobiol Dis. 2012;45(2):743–50.
64. Jevtovic-Todorovic V. Functional Implications of an early exposure to general anesthesia: are we changing the behavior of our children? Mol Neurobiol. 2013;48(2):288–93.
65. Sanders RD, Hassell J, Davidson AJ, Robertson NJ, Ma D. Impact of anaesthetics and surgery on neurodevelopment: an update. Br J Anaesth. 2013;110 Suppl 1:i53–72.
66. Ing C, DiMaggio C, Whitehouse A, Hegarty MK, Brady J, von Ungern-Sternberg BS, Davidson A, Wood AJ, Li G, Sun LS. Long-term differences in language and cognitive function after childhood exposure to anesthesia. Pediatrics. 2012;130(3):e476–85.
67. DiMaggio C, Sun LS, Ing C, Li G. Pediatric anesthesia and neurodevelopmental impairments: a Bayesian meta-analysis. J Neurosurg Anesthesiol. 2012;24(4):376–81.
68. Selzer RR, Rosenblatt DS, Laxova R, Hogan K. Adverse effect of nitrous oxide in a child with 5,10-methylenetetrahydrofolate reductase deficiency. N Engl J Med. 2003;349(1):45–50.
69. Baum VC, Willschke H, Marciniak B. Is nitrous oxide necessary in the future? Paediatr Anaesth. 2012;22(10):981–7.
70. Hogan KJ. Nitrous oxide genotoxicity. Anesthesiology. 2013;118(6):1258–60.
71. Sun L. Early childhood general anaesthesia exposure and neurocognitive development. Br J Anaesth. 2010;105 Suppl 1:i61–8.
72. Sun LS, Li G, DiMaggion CJ, Byrne MW, Ing C, Miller TL, Bellinger DC, Han S, McGowan FX. Feasibility and pilot study of the Pediatric Anesthesia NeuroDevelopment Assessment (PANDA) Project. J Neurosurg Anesthesiol. 2012;24(4):382–8.
73. Nemergut ME, Aganga D, Flick RP. Anesthetic neurotoxicity: what to tell the parents? Paediatr Anaesth. 2014;24(1):120–6.

74. Ramsay JG, Roizen M. SmartTots: a public-private partnership between the United States Food and Drug Administration (FDA) and the International Research Society (IARS). Paediatr Anaesth. 2012;22(10):969–72.
75. Byrne MW, Ascherman JA, Casale P, Cowles RA, Gallin PF, Maxwell LG. Elective procedures and anesthesia in children: pediatric surgeons enter the dialogue on neurotoxicity questions, surgical options, and parental concerns. J Neurosurg Anesthesiol. 2012;24(4):396–400.
76. De Oliveira GS, Jr TLS, McCarthy RJ. Shortage of perioperative drugs: implications for anesthesia practice and patient safety. Anesth Analg. 2011;113(6):1429–35.
77. Kweder SL, Dill S. Drug shortages: the cycle of quantity and quality. Clin Pharmacol Ther. 2013;93(3):245–51.
78. Dutton RP, Cohen JA. Medication shortages: are we the Iron Chefs or our own worst enemies? Anesth Analg. 2011;113(6):1298–9.
79. Gee T. The case for regulating EMRs. Patient Safety and Quality Health Care. 2011. Available from: http://www.psqh.com/januaryfebruary-2011/738-the-case-for-regulating-emrs.html.
80. Mitka M. IOM: health IT needs better oversight. JAMA. 2011;306(24):2659.
81. Koppel R. Demanding utility from health information technology. Ann Intern Med. 2013;158(11):845–6.
82. National Research Council. Health IT and patient safety: building safer systems for better care. Washington, DC: The National Academies Press; 2012.
83. Sittig DF, Singh H. Electronic health records and national patient-safety goals. N Engl J Med. 2012;367(19):1854–60.
84. Peterfreund RA, Driscoll WD, Walsh JL, Subramanian A, Anupama S, Weaver M, Morris T, Arnholz S, Zheng H, Pierce ET, Spring SF. Evaluation of a mandatory quality assurance data capture in anesthesia: a secure electronic system to capture quality assurance information linked to an automated anesthesia record. Anesth Analg. 2011;112(5):1218–25.
85. Stabile M, Cooper L. The evolving role of information technology in perioperative patient safety. Can J Anaesth. 2013;60(2):119–26.
86. Merry AF. An overview of quality and safety in health care. Can J Anaesth. 2013;60(2): 101–4.
87. Orser BA, Hyland S, U D, Sheppard I, Wilson CR. Review article: improving drug safety for patients undergoing anesthesia and surgery. Can J Anaesth. 2013;60(2):127–35.
88. Snyder GL, Greenberg S. Effect of anaesthetic technique and other perioperative factors on cancer recurrence. Br J Anaesth. 2010;105(2):106–15.
89. van Beuzekom M, Boer F, Akerboom S, Hudson P. Patient safety: latent risk factors. Br J Anaesth. 2010;105(1):52–9.
90. Butwick A. What's new in obstetric anesthesia in 2011? Reducing maternal adverse outcomes and improving obstetric quality of care. Anesth Analg. 2012;115(5):1137–45.
91. Hogan KJ, Burmester JK, Caldwell MD, Hogan QH, Coursin DB, Green DN, Selzer RM, Broderick TP, Rusy DA, Poroli M, Lutz AL, Sanders AM, Oldenburg MC, Koelbl JA, de Arruda-Indig M, Halsey JL, Day SP, Domanico MJ. Perioperative genomic profiles using structure-specific oligonucleotide probes. Clin Med Res. 2009;7(3):69–84.
92. Flin R, Patey R, Glavin R, Maran N. Anaesthetists' non-technical skills. Br J Anaesth. 2010;105(1):38–44.
93. Smith AF, Arfanis K. 'Sixth sense' for patient safety. Br J Anaesth. 2013;110(2):167–9.
94. Stiegler MP, Neelankavil JP, Canales C, Dhillon A. Cognitive errors detected in anaesthesiology: a literature review and pilot study. Br J Anaesth. 2012;108(2):229–35.
95. Stiegler MP, Tung A. Cognitive decision processes in anesthesiology decision making. Anesthesiology. 2014;120(1):204–17.
96. Schulz CM, Endsley MR, Kochs EF, Gelb AW, Wagner KJ. Situation awareness in anesthesia: concept and research. Anesthesiology. 2013;118(3):729–42.
97. Pierce Jr EC. The 34th Rovenstine Lecture: 40 years behind the mask—safety revisited. Anesthesiology. 1996;84(4):965–75.

The Nursing Perspective

27

Seleem R. Choudhury

Pitfalls and Pearls

- Nurses have the closest and most frequent contact with patients.
- Regular interaction with patients' families gives nurses a different perspective on the day to day issues that physicians may not be familiar with.
- Patient safety culture must remain a priority in the nursing profession.
- A reduction of nurse to patient ratio driven by cost saving measures may have a negative impact on the goal to establish a culture of safety.
- Critical thinking and communication are constant 'check points' that complement algorithms and guidelines.

Outline of the Problem

The cultivation of a safe care environment requires a system dedicated to refining the standard of clinical practice through robust multidisciplinary alignment that engages all staff.

A ubiquitous culture of patient safety is a quintessential component of good care, good hospital operation, and expected by the community the hospital serves. If operational procedures are not standardized to ensure patient safety, variations in practice will ultimately lead to bad outcomes.

Hospitals have built entire teams focused on case review and measuring patient safety. The best learning often comes from asking the question: *"Could this have*

S.R. Choudhury, MSN, MBA, RN, CEN
Chief Nursing Officer, Northeastern Vermont Regional Hospital,
1315 Hospital Drive, St. Johnsbury, VT 05819, USA
e-mail: s.choudhury@nvrh.org

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_27,

been avoided?" Today managing risk is as much a skill as clinical acumen. Physicians and nurses are inextricably linked in the journey toward improved patient safety. The nurse helps set the standard with understanding clinical risk, error mitigation, and quality review.

This chapter explores the importance of learning from past experiences, the nursing role in patient safety which will include adequate staffing, how the nurse thinks, putting the patient first, nurse-physician communication, dealing with a patients pain, and how understanding these critical elements leads to creating a philosophy of acting rather than reacting to safety concerns.

Limitations of the Current Practice

Nurses provide the largest portion of direct patient care and nearly always have the closest relationship with patients therefore it is vital to prevent errors during these encounters [1]. The nurse during these encounters will often have a different perspective from other clinical providers. This perspective will be built from a blend of interactions with the patient and other allied disciplines together with the nurses education which typically involves both a holistic perspective and regulatory compliance as set forth either by the hospital or a government agency. Although all disciplines share the common goals of compassion and safety, nurses will often spend significantly more time with the patient and family. As such, nurses build different type of relationship through day to day decisions such as changing the patient's position in bed or deciding on the need for as-necessary medications. Constant bedside assessments put nurses in unique position to not only know if a patient understands their management, but also recognize when a patient is deteriorating. With the most direct frequent patient contact and the main responsibility for monitoring and interpreting the patients' vital signs, nurses are often in the best position to detect patients' physiological changes, playing a crucial role in the safety of patients [2]. It's important to emphasize that objectives changes in the patient condition are often the easiest to convince other medical team members that the patient's condition is deteriorating after all its easy for the nurse to report an increase or decrease in heart rate or blood pressure however due to the relationship with the patient and with experience nurses often observe subtle changes in conditions [3] which are not objective findings. It's important for the nurse physician relationship to understand and respect these subtle findings.

Hospitals must balance patient safety with fiscal responsibility, whilst maintaining quality care—administrators constantly have to maintain a delicate balance between the three. If staffing is too lean, then safety may be impacted, typically correlating with poor outcomes. Conversely, a surplus of staff may become unaffordable for both the hospital and the community. Quality care cannot exist without quality nursing [4]. Achieving safe, effective and ethical nursing requires a sufficient number and appropriate mix of competent nurses [5]. Optimal nursing will safeguard the baseline of care desired by both physicians and patients [6].

Recent studies reveal pervasive concerns over suboptimal patient to nurse ratios, with a greater likelihood of poor outcomes (mortality, nosocomial infections and

patient complaints) when nurses care for a greater number of patients. These studies have prompted related research which has demonstrated not only poor patient outcomes, but also degraded nurse job satisfaction, leading to increased absenteeism, burn out, and dissatisfaction, resulting in compassion fatigue [7]. The perception so often in healthcare today is that hospital administrators or productivity (efficiency) consultants are constantly challenging what is deemed as optimal and sadly some of these decisions are often made in a vacuum away from the units and away from discussions with frontline staff. A balance most be sought to ensure safe staffing and it is in the physician best interest to be involved in these discussions. Barriers to provide appropriate direct patient care can leave nurses feeling helpless to perform their desired level of care [8]. Ultimately, the nurse is left feeling helpless and resigned to their fate, resulting in burnout or resignation from an already understaffed unit, thus perpetuating the cycle of inadequate staffing, poor outcomes and patient dissatisfaction. Successfully breaking this cycle requires engaged unit leadership, including medical directors and nurse leaders.

Where Is the "Golden Bullet"?

The entire medical/surgical team must engage in ongoing advocacy for positive change. By working across disciplines, an individual caregiver's belief of belonging to something bigger, a team dedicated to optimal care, can often counter these stressful challenges [9].

Good nursing care requires critical thought processes, including clinical judgment, reflection and decision-making skills [10]. To those outside nursing, this may be misperceived as questioning authority or knowing better than the provider. However, as part of the team, these skills help contribute desirable outcomes of safe clinical care—a back-up system to ensure optimal post-operative care is provided.

Nurses employ "nursing process" in clinical practice to assess, plan, implement, and evaluate their patient care (Fig. 27.1). It is this systematic approach that Turner described as "resulting in safe, competent practice and improved decision making, clinical judgments, and problem solving" [11]. The Nursing process is an important aspect of critical thinking; it is a systematic and analytical way of thinking which is taught in nursing school and continues throughout a nurse's career. The application of critical thinking skills is encouraged by managers, educators, nursing peers, and physicians, and long been considered essential to the provision of safe and effective nursing care; it allows the nurse to conceptualize and articulate care provided and anticipate the care coveted by the medical and surgical team. The author knows from experience that praise toward nurses from medical and surgical teams is often based upon the nurse who can not only communicate past and current care, but also anticipate the appropriate next steps in care. This navigation may start with advocating for pain medication or recommending needed steps in patient evaluation.

To strengthen the medical and surgical team, each nurse must feel valued for their skills and knowledge. This recognition is a powerful driver of continued

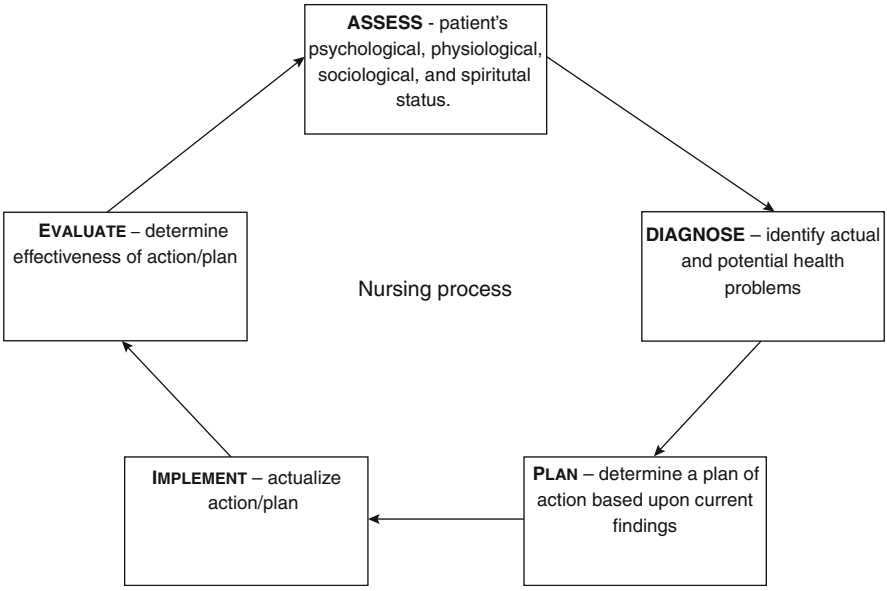


Fig. 27.1 The nursing process. The five phases demonstrate a systematic approach the nurse utilizes in providing care. All nurses are taught this process and alignment with the nursing process in everyday nursing is encouraged from nursing school to the clinical environment

quality nursing care, increased job satisfaction, and nurse retention. Ideally, the medical/surgical team should feel empowered to invest in the nursing team by listening, challenging and educating, thereby strengthening the quality of the team as well as the level of care delivered to the patients.

A good clinical team will learn to adopt a patient-family centered model which enthusiastically embraces the patient's relationship with their support system [12]. A challenge to this status quo is the *person*-centered approach. A person-centered approach recognizes the individual over their diagnosis (e.g. "the leg injury patient" becomes "Mr. Smith with a leg injury") and can drive a personalized patient-care approach, thereby reinforcing a humanistic culture of care. A person-centered approach can improve patient satisfaction scores that focus on the perception of care as it relates to listening, respect, explanation and viewing the patient as an individual. A distant second reason for providing this humanistic approach is that it can also be fiscally advantageous as patient satisfaction scores now impacts reimbursement.

The cultivation of a safe care environment requires a system dedicated to refining the standard of clinical practice through robust multidisciplinary alignment that engages all staff. According to Spears et al. [13], sustained high quality nursing care engages and integrates multidisciplinary teams to work more effectively and safely; this integration should involve both frontline and nurse leaders. Physicians may be reluctant to involve nursing leadership, nurse leadership involvement starting from the unit leadership to hospital nurse. Efforts to engage often pays dividends by building the relationship, helping to drive change and add another layer of accountability for

sustainable quality care. McSherry and Douglas [14] assert that nurse managers play a substantial role in facilitating frontline nurses to innovate and dispense high-quality compassionate people-centered nursing care. While physician input to on nursing performance is essential, good nursing leaders will reciprocate with physician feedback, fostering an open relationship built on improving the level of care delivered.

According to The Joint Commission [15], approximately 60 % of medical errors are a direct result of communication failures. Effective communication can prevent these errors and deliver the desired care by a cohesive team. Collaboration between nurses and physicians is vital for improving patient care quality indicators as well as patient satisfaction. The advantages of effectual nurse/physician relationships include decreased errors with decreased cost, better patient care, and decreased patient morbidity and mortality [16]. Like any relationship, success requires effort from both parties, along with trust that both share common goals good patient care, clinical excellence, and patient/family satisfaction.

Studies have repeatedly shown that Nurses who work closely with physicians and contribute in shared decision making encounter less burnout. Conversely, disruptive physician behavior has been cited as a contributor to the national nursing shortage [17]. The first step to develop a good nurse-physician relationship is to personally know and value the other, fostering respect, trust, and open honest communication. The nurse perspective is typically systematic in approach and often elaborate in day to day details, whereas the physician is in broader strokes about general disease progression; however, both have the same objective of improving the patient's condition and can use this foundation to strengthen their team.

Pain management following surgical procedures is an imperative matter when appraising the effectiveness of the nurse-medical team interventions [18]; effective pain control is an essential component of safe care. Nurses often try many methods for pain control, some dictated by standard unit practices, some from their clinical knowledge and sometimes intuition of what will help the patient [19]. Continual assessment by skilled trusted nurses ensures that pain is constantly being adequately addressed. Moreover, both Joint Commission as well as state agencies require that pain is not only measured, but that pain management is commensurate with the level of pain experienced. For example, while one medication may be sufficient for moderate pain, a more powerful medication could be needed as the level of pain escalates a robust system that scores pain level on a 1–10 scale can guide management, providing alternatives for breakthrough pain.

Nurse willingness to advocate for better pain management can be influenced by baseline rapport with physicians [9]. Poor nurse-physician relationships can lead to unsuccessful pain management and subsequently bad outcomes and unnecessary cost from prolonged hospital stays to readmissions. Thus, it is vital that a partnership is quickly established and sustained between the surgical team and the nurse responsible for unit-based care. Dynamic and open communication between team members as well as between the patient and the medical team helps facilitate optimal care. The effective team has trust, holds each member accountable, and participates in open communication that recognizes the common goal serving the patient. Although the nurse may fail to pick up on pain cues or the physician may be hesitant

to give opioid medication, the other team member can give the other constructive feedback on perceived gaps and openly discuss how to best serve the patient [20].

Take-Home Message

Patient safety is an essential component of high quality care, yet healthcare facilities struggle to prevent errors. Safe health care is a constant of controversy and politics, with government agencies using financial incentives and penalties to compel heath care providers to improve outcomes. Regardless of technology advance or financial investment, healthcare errors often stem from poor human-to-human communication or lack thereof. Safety is a continuum and the very nature of risk means prohibits total safety, but integration of nursing into an effective team, ensuring that all have fair opportunity to verbalize input into the care of the patient and fundamentally understanding the role and perspective of the nurse in patient safety can improve the odds [21].

References

1. Farquhar M, Collins Sharp B, Clancy CM. Patient safety in nursing practice. AORN J. 2007;86(3):455–7.
2. Liaw S, Scherpbier A, Klainin-Yobas P, Rethans J. A review of educational strategies to improve nurses' roles in recognizing and responding to deteriorating patients. Int Nurs Rev. 2011;58(3):296–303.
3. Oermann M, Truesdell S, Ziolkowski L. Strategy to assess, develop, and evaluate critical thinking. J Contin Educ Nurs. 2000;31(4):155–60.
4. Wunderlich G, Sloan F, Davis C. Nursing staff in hospitals and nursing homes: is it adequate. Washington, DC: National Academy Press; 1996.
5. MacPhee M, Ellis J, Sanchez A. Nurse staffing and patient safety. Can Nurse. 2006; 102(8):19–23.
6. Aiken L, Clarke S, Sloane D. Hospital staffing, organizational support, and quality of care: cross-national findings. Int J Qual Health Care. 2002;14(1):5–13.
7. Person S, Allison J, Kiefe C, Weaver M, Williams O, Centor R, et al. Nurse staffing and mortality for medicare patients with acute myocardial infarction. Med Care. 2004;42(1): 4–12.
8. Hall D. Work-related stress of registered nurses in a hospital setting. J Nurses Staff Dev. 2004;20(1):6–14.
9. Yoder E. Compassion fatigue in nurses. Appl Nurs Res. 2010;23(4):191–7.
10. Tanner C. Thinking like a nurse: a research-based model of clinical judgment in nursing. J Nurs Educ. 2006;45(6):204–11.
11. Turner P. Critical thinking in nursing education and practice as defined in the literature. Nurs Educ Perspect. 2005;26(5):272–7.
12. Mead N, Bower P. Patient-centeredness: a conceptual framework and review of empirical literature. Soc Sci Med. 2000;51:1087–110.
13. Spears P, Thornton D, Long L. Journey to nursing excellence: building partnerships for success nurse leader. Nurse Leader. 2008;6(3):59–66.
14. McSherry R, Douglas M. Innovation in nursing practice: a means to tackling the global challenges facing nurses, midwives and nurse leaders and managers in the future. Editor J Nurs Manag. 2011;19(2):165–9.

15. Woods M. How communication complicates the patient safety movement. Patient Safety and Quality Healthcare. http://www.psqh.com/mayjun06/dun.html. 2006.
16. Nelson G, King M, Brodine S. Nurse-physician collaboration on medical-surgical units. Medsurg Nurs. 2008;7(1):35–40.
17. Maysoon A, Sawsan M, Ingegerd B. Jordanian surgical nurses' experiences in caring for patients with postoperative pain. Appl Nurs Res. 2010;23(3):164–70.
18. Söderhamn O, Idval E. Nurses' influence on quality of care in postoperative pain management: a phenomenological study. Int J Nurs Pract. 2003;9:26–32.
19. Manias E, Bucknall T, Botti M. Nurses' strategies for managing pain in the postoperative setting. Pain Manag Nurs. 2005;2005(6):18–29.
20. McCaughan E, Parahoo K. Medical and surgical nurses' perceptions of their level of competence and educational needs in caring for patients with cancer. J Clin Nurs. 2000;9:420–8.
21. Currie L, Lecko C. The importance of applying human factors to nursing practice. Nurs Stand. 2012;26(32):36–40.

The Patient's and Patient Family's Perspective

28

Patty J. Skolnik and Nathan Butler

Pitfalls and Pearls

- Patients don't know what they don't know.
- The first conversation between the patient and physician/provider 'sets the stage' for the quality of the future relationship.
- Signing the informed consent is an opportunity for discussion, questions and for '*readbacks*' ensuring a full understanding by the patient and confirming the treatment plans align with the patient's values, needs and beliefs.
- Nothing can replace a full, open and honest discussion about realistic outcomes and expectations.
- Shared decision-making and informed consent are processes, not isolated events, which allows the physician to continually manage the patient's expectations and understanding.
- Safe healthcare is a team effort with the physician responsible for not only building the team but also acting as the team leader and building a stable structure.
- Patriarchal medical culture where "the doctor knows best, don't question it" is detrimental to communication.
- Patients and physicians alike have fears, some of them shared: fear of asking a question, fear of questioning a decision made, fear of requesting a second opinion, fear of dying, fear of being sued, fear of being humiliated, fear of looking stupid or bothering someone.

P.J. Skolnik, BASW (✉)
Citizens for Patient Safety, 801 Yosemite St, Denver, CO 80230, USA
e-mail: pjskolnik3@msn.com

N. Butler
West Virginia School of Osteopathic Medicine,
200 North Lee Street, Lewisburg, WV 24901, USA

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_28, © Springer-Verlag London 2014

Outline of the Problem

> *There are at least two bodies of knowledge that are relevant to the exchanges between doctor and patient – the doctor's and the patient's. Both are experts in their own fields…Caring for a patient requires both parties to recognize and respect the other's area of expertise.* [1]

During training physicians are taught to be scientific and analytical, having discussions and making decisions among peers and specialists before developing the best plan for a patient's care. Historically little training and thought was given to the patient-physician interaction or involving them in the decision process. In 1999 a landmark report by the Institute of Medicine, "*To Err Is Human*," brought awareness to errors and problems associated with the healthcare system. In part thanks to the report, patients are no longer holding physicians on the pedestal once bestowed to them, nor are they blindly accepting advice just because it comes from a doctor. In this information age patients are highly informed and knowledgeable, questioning that which is not understood to the fullest extent. People have come to expect instant access to information, and that includes information from their doctors. Patients can search on the Internet and find out specific Ph.D. level information with a click of a mouse. With this power comes an expectation to be told every possible outcome and full explanation of why a particular treatment is recommended over another. Over the years, a number of papers have been published identifying expectation patients have of their surgeons and they conclude that effective communication would address the vast majority of complaints [2–7]. There are often many obstacles in the path to developing a good patient-physician relationship. Time, legalities, patient loads, arrogance, and culture are all constraints that may impede a physician's positive, interactive relationships with a patient, and they are constraints that desperately need to be addressed.

A full understanding of all the options, risks, and expectations is essential for patient comfort and trust. Uninhibited, transparent, open and honest communication between the physician and patient is the cornerstone in building a healthy and safe healthcare relationship.

As physicians, one must always attempt to envision how a patient feels when explaining that surgery is needed. "*Our minds wander into the future… we will be in an unfamiliar environment where we will be isolated from everything we know. We are frightened. You are paramount in helping us to get past this by partnering with our families and encouraging us to be part of our own healthcare team.*" (Patient testimony)

The first conversation between patient and/or their advocate/family member, and the physician is critical to laying the groundwork for the remainder of the patient's visit. Open and honest communication with the patient or family members starts the ties of trust and begins to build an understanding of the patient's beliefs, feelings and wishes. The wishes of the patient are paramount and often dictate the next step

in a treatment plan. If a patient, for example, has a belief that prohibits blood product, this may dramatically alter the treatment plan.

Safe healthcare is a team effort with the physician responsible for not only building the team but also acting as the team leader. Like spinning a web that catches inadvertent oversight before it becomes a medical error, the physician will design and build a structure which encompasses a multitude of care-critical issues. Safe healthcare requires that the physician be an actively engaged leader guided by knowledge, intelligence, empathy, compassion and self-awareness. The physician must realize his or her limitations and communicate any possible complication to the patient. If there is a limitation it is up to the physician to refer the patient to another physician capable of doing a procedure.

Signing the informed consent is an opportunity for an open discussion, questions and '*readbacks*' (or '*teachbacks*') to ensure full understanding of the course of treatment by the patient. This will also provide an opportunity to assure all treatment plans aligned with the patient's values, needs, preferences and beliefs. Informed consent and shared decision-making are the keystones in building a strong bridge between the patient and the physician (Box 28.1).

The Informed Consent

Informed consent is defined by the Merriam-Webster dictionary as: "a formal agreement that a patient signs to give permission for a medical procedure (such as surgery) after been told about the risks, benefits, etc." The informed consent form is becoming a legal "catch-all" for the protection of the physician from litigation. The informed consent form should provide an opportunity for the physician to explain potential

Box 28.1. Checklist for Preoperative Conversations with Patients and Informed Consent

- Does your patient understand why they need surgery, what condition you hope it will improve and all alternatives? Including doing nothing at all.
- Have you discussed the success rate of the surgery in general as well as your rate of success and experience in correcting the problem?
- Does the patient understand your individual experience with the recommended procedure, including annual 'case load' and complication rate?
- Is this a new/experimental surgery or performed often? Is the surgeon embarking on a new 'learning curve' with this procedure?
- The short and long-term risks associated with the procedure including side effects?
- Is the patient aware of what to expect during the recovery period?
- Who is going to do the surgery and will there be others assisting?
- Tell the patient and family who will be talking to your family in the waiting room.

complications to the patient and an opportunity to make sure the physician and patient have the same realistic expectations for the outcome. The physician will best ensure reasonable patient and family expectations by explaining his or her own expectations for the outcome in plain, non-medical language, and ask the patient to repeat back the key points in their own words—describe the potential and likely outcomes as he or she understands them. The physician is then able to identify and correct misunderstandings immediately and ask the patient again to describe potential and likely outcomes in their own words ('*readbacks*' or '*teachbacks*') to ensure that misunderstandings have been corrected. Before informed consent can be given that is truly informed, the physician must identify the patient's needs, preferences, values, goals, uncertainties, experience, costs, expectations and make sure there is a two-way conversation. Patients don't know, what they don't know: sometimes you will have to walk them through the important information they do not know to ask.

Shared Decision-Making

Shared decision-making is a process, not an event, which allows the physician to continually manage expectations regarding outcomes with the patient's full knowledge and understanding. Once physician competence has been determined, there must be an accurate description of the proposed treatment or procedure, and disclosure of who will be performing the steps. This is extremely important in a teaching hospital and complete transparency must be given to the patient and family.

The importance of shared decision-making cannot be understated. Shared decision-making, like informed consent, begins with the first conversation between doctor and patient. An important and often valuable component to shared decision-making is the inclusion of family members or friends during the informed consent if the patient wishes to have such others present. The patient and physician alike must understand that the patient's care is a process and not an event, requiring modifications and updates that may necessitate a resetting of expectations. If done properly there will be well communicated, transparent, patient-centered care, improving outcomes and reducing medical liability.

Bedside Rounding

Communication breakdowns continue to rank in the top three of primary causes of sentinel events [7–9]. Bedside rounding, where a multidisciplinary team conducts daily rounds with the patient and family at the patient's bedside has been shown to reduce medical errors, increase patient satisfaction and impact health outcomes [10–13]. Bedside rounding provides the perfect venue for the patient and family to correct any misunderstanding regarding information about medical history, medications, allergies and care plans. Staff is able to hear their expectations and share their progress. Bedside rounds need to be conducted with patient involvement, which

does not appear to be happening in some academic environments [12, 14]. This denies a key opportunity for ensuring the ongoing sharing (and understanding) of information and shared decision-making discussed in this chapter. A crucial role of medical professionals is to push for this culture change in institutions and practice. A good motto is: "*Never about me, without me*." It stresses the importance of patient involvement in their care.

Limitations of the Current Practice

Current practice for patient communication is getting better over the last decade but there are still mountains of work ahead. Rounds are still being conducted outside the patients' room without the involvement of the patient. As the hospital rounds begin, think "never about the patient without the patient."

When informed consent is obtained, often the patient is given a form to sign and told to ask if they have any questions. This act of getting a signature is defeating the purpose of the informed consent. The time spent with the patient should be thought of as an opportunity to practice the shared decision-making process allowing the patient to interject their beliefs and wishes.

Where Is the "Golden Bullet"?

The most influential reason for anger and medical litigation is the patient or family getting surprised by a procedural outcome. With everyone's full understanding of the procedures and realistic outcome possibilities, a healthy physician-patient relationship will grow.

Selected 'tips and tricks' for building a successful physician-patient relationship include:

- Trust which you must have for true partnership between patients and providers begins with the truth
- Give information continually, not just at the beginning of a plan of care, test, procedure
- Provide a real two-way communication
- Teach patients how to ask questions (see small discussion group below)
- Encourage other opinions
- Take the time to adequately explain whatever treatment, medication, surgery in everyday language
- Use patient aids and informational CDs/DVDs designed for specific procedures or diagnoses
- Use Teach-back for all explanations
- Keep patient/families in the loop as new health data becomes available
- Let the patient know they are part of the health care team
- If they are unable who do they want to be included in all diagnosis and treatment discussions you encourage them to have a patient advocate 24/7

Take-Home Message

Open, honest and transparent communication is the cornerstone for a safe and engaged healthcare team. They set the stage for better patient outcomes, reduced costs and constructive responses in the face of errors with a decrease in litigation. Understanding the difference between informed consent and shared decision-making is paramount when fostering an active discussion with the patient or family members.

References

1. Kennedy I. Patients are experts in their own field. BMJ. 2003;326:1276–7.
2. Huntington B, Kuhn N. Communication gaffes: a root cause of malpractice claims. Proc (Bayl Univ Med Cent). 2003;16(2):157–61.
3. Pichert JW, Miller CS, Hollo AH, Gauld-Jaeger J, Federspiel CF, Hickson GB. What health professionals can do to identify and resolve patient dissatisfaction. Jt Comm J Qual Improv. 1998;24(6):303–12.
4. Vincent C, Young M, Phillips A. Why do people sue doctors? A study of patients and relatives taking legal action. Lancet. 1994;343(8913):1609–13.
5. Beckman HB, Markakis KM, Suchman AL, Frankel RM. The doctor-patient relationship and malpractice. Lessons from plaintiff depositions. Arch Intern Med. 1994;154(12):1365–70.
6. Hickson GB, Clayton EW, Githens PB, Sloan FA. Factors that prompted families to file medical malpractice claims following perinatal injuries. JAMA. 1992;267(10):1359–63.
7. Sheppard F, Williams M, Klein VR. TeamSTEPPS and patient safety in healthcare. J Healthc Risk Manag. 2013;32(3):5–10.
8. Wall Y, Kautz DD. Preventing sentinel events caused by family members. Dimens Crit Care Nurs. 2011;30(1):25–7.
9. Lamontagne C. Intimidation: a concept analysis. Nurs Forum. 2010;45(1):54–65.
10. Lyons KJ, Giordano C, Speakman E, Isenberg G, Antony R, et al. Jefferson interprofessional clinical rounding project: an innovative approach to patient care. J Allied Health. 2013;42(4):197–201.
11. Mittal VS, Sigrest T, Ottolini MC, Rauch D, Lin H, et al. Family-centered rounds on pediatric wards: a PRIS network survey of US and Canadian hospitalists. Pediatrics. 2010;126(1):37–43.
12. Gonzalo JD, Chuang CH, Huang G, Smith C. The return of bedside rounds: an educational intervention. J Gen Intern Med. 2010;25(8):792–8.
13. Sisterhen LL, Blaszak RT, Woods MB, Smith CE. Defining family-centered rounds. Teach Learn Med. 2007;19(3):319–22.
14. Stickrath C, Noble M, Prochazka A, Anderson M, Griffiths M, et al. Attending rounds in the current era: what is and is not happening. JAMA Intern Med. 2013;173(12):1084–9.

The Ethical Perspective

29

Emily P. Caldes

Pitfalls and Pearls

- Ethical norms and moral virtues play a significant role for motivation and justification in both a fiduciary and public health approach to patient safety in surgery.
- The ability to create a culture of patient safety is dependent upon both systems and individuals working together to fulfill the ethical obligation to "*do no harm*" to our patients.
- Honest and transparent disclosure, apology and amends, are key to minimizing patient harm and medicolegal implications after an error has occurred.
- Lack of transparency is a significant barrier to establishing a "culture of accountability" for patient safety in surgery.
- Surgeons and surgical teams would benefit from the integration of ethics education and communication skills training into existing practices.

Outline of the Problem

Patient safety in surgery represents an ethical obligation placed upon health care professionals and the system as a whole.

Existing efforts to improve patient safety focus on micro and macro level systems within healthcare that can be enacted or acted upon to improve patient safety. This approach envisions patient safety as a preventable threat to public health. Thus

E.P. Caldes, MA
Office of Research and Sponsored Programs,
University of Denver, 2199 S., Denver, CO 80208, USA
e-mail: emily.caldes@gmail.com

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_29, © Springer-Verlag London 2014

policy efforts to improve patient safety treat it primarily as a public health problem. *To Err is Human: Building a Safer Health System*, the Institute of Medicine's (IOM) 1999 report on Patient Safety [1], set forth a comprehensive set of public policy recommendations that aim to create a culture of safety through standardization, accountability, training and education, engagement of stakeholders, incentives, and abandoning the blame culture. The IOM report and numerous subsequent public policy efforts have served as a significant catalyst for change in how patient safety is approached by the health community.

"*Do no harm*," a cornerstone in the foundation of the patient safety movement, is an ethical norm derived from the principle of nonmaleficence. Yet somehow the discussion of ethics remains largely implicit in the public dialogue about patient safety. Further, a pure systems-based approach to fostering change that is sustainable discounts the importance of individual buy-in and personal motivation in the process of organizational change. The ability to create a culture which cultivates patient safety is dependent upon both systems and individuals working together to fulfill the ethical obligation to patients to "*do no harm*." This chapter will directly address patient safety, specifically as it relates to surgery, as an ethical obligation placed upon health care professionals and the system as a whole.

An Integrated Approach to Patient Safety

It is important to make the explicit the often implicit values and moral norms that guide public policy related to patient safety. There are various reasons to caution against setting aside the moral basis for patient safety at either the systems or individual level. A systems approach to patient safety will not supplant the value of virtuous organizations and moral health care professionals. The existing approach to creating a culture of patient safety draws upon the assertion that systems must be in place to protect patients, because virtue and individual moral norms have proven an insufficient means to ensuring patient safety [1, 2]. The prescribed "cure" is a public health approach that sets aside individual moral arguments and motives [2]. However, as there is an inherent moral imperative in public health to ensure and protect the health of the population and the individual, ethics plays a significant role both as moral motivation and justification for public policy. Further, a moral system of patient care is dependent upon moral individuals caring for the patients. Efforts to improve patient safety will ultimately fail if they do not include systems that help internalize strong moral code and encourage members of the community to act on their moral code [2]. As such, in order to reduce surgical errors, individuals and systems must reinforce each other in the pursuit of the good each purports to serve [3].

Edmund Pellegrino, a prominent Bioethicist, posits that: "*1) properly organized organizational and systematic context is essential to reduce the prevalence of medical error; 2) its effectiveness and efficient working depend on parallel information of the moral duty and accountability of each professional in the system; 3) each individual health professional must possess the competence and character crucial to the performance of his or her particular function as well as those the system as a whole; 4) the major function of the system is to reinforce and sustain these individual competencies and virtues*." [3]

Table 29.1 Surgical ethics

"When patients die in other areas of medicine the question is 'what happened?' However, when a patient dies during or after surgery, the question is, 'what did you do?'"—Peter Angelos 2009
Surgical ethics: Traditionally, surgeons received informal, "on the job" training in medical ethics via mentoring and role modeling by senior surgeons. Surgeons have relied on virtue ethics, professionalism, and the field of medical ethics to inform ethical practice and decision making. In recent years, "surgical ethics" has started to attract more attention as a sub-discipline of medical ethics. Intuitively, surgical ethics involves the application of moral norms or principles to the practice of surgery
In the discussion of patient safety there are elements of the surgeon patient relationship that inform the discussion of patient safety in such a way that it would be inappropriate not to explicitly address surgical ethics as requiring distinct attention
Elements of surgery that make patient safety in surgery unique:
Increased trust in surgeon because of vulnerability
Intimacy
Direct relationship between surgical action and patient outcome
Measurable outcomes
More emphasis on documentation of consent
Intensity of the time frame that surgeons spend with patients in comparison to other specialties
Inability of patient to be actively involved once surgery begins
Some harm is inevitable
The presence of, and dependence upon, a team at the time of treatment

From an ethics perspective, the role of individual moral reasoning and motivation in patient safety in medicine is well recognized. However, despite the fact that increased attention has been paid to ethics in surgery over the past 10 years, there is still a documented gap in the ethics literature between medicine and surgery [4–7], which is especially evident in review of the literature pertaining to patient safety in surgery. The exact reason for this disparity is unclear [4]. Although increased attention has been paid to ethics in surgery over the past 10 years, there is still a relative dearth of discussion within the ethics community about the unique aspects of the surgeon-patient relationship, the potential impact this has on surgical ethics and in turn the ethics perspective on patient safety in surgery.

While the normative focus of public health is the population, in aggregate, the health and safety of individuals is the normative focus of the surgeon's obligation. Physicians in general have a moral obligation to their patients based on the fiduciary nature of the relationship. A fiduciary, a concept barrowed from the legal field, is generally a person with an obligation to act in another's best interest under circumstances that require complete trust and confidence. Typically, the fiduciary is someone who possesses expertise and is more knowledgeable about the matters at hand [8]. It is well established that in his or her capacity as moral fiduciary, physicians must prioritize the protection and promotion of the patient's interests above his or her own [8]. This is especially valuable is surgical specialties, compared to non-surgical specialties, because surgery involves a unique proximity [9] that allows for increased intimacy and vulnerability, and a more direct connection between a surgeon's actions and patient outcomes (Table 29.1). Failure to fulfill this obligation is a breach of moral contract that is the foundation of the patient-surgeon relationship.

This chapter will address the following questions as they relate to both individual and systems roles in protecting patient safety:

- How do moral norms relate to patient safety in surgery?
- What are the best practices for ethical prevention of and ethical response to surgical adverse events?
- What are the barriers to ethical prevention of and ethical response to surgical adverse events?
- What are the appropriate next steps and areas of future research to help meet the ethical obligations related to patient safety in surgery?

Moral Virtues and Ethical Norms

Various approaches may be taken to ethical analysis. Descriptive ethics poses the question, "what is right and good?" through factual investigation of actual moral beliefs and conduct. General normative ethics, or theoretical ethics, attempts to identify provide philosophical justification for moral norms. Applied ethics is a form of normative ethics that employs general norms and theory to particular circumstances [10]. In this case, virtues and common morality theory are moral norms that can be applied in the context of patient safety in surgery. In context of surgery, virtues reflect the moral character of a surgeon, while principles reflect the moral nature of surgeon's actions. Virtue and common morality, or principlism, are not the only norms or theories that may be applied to patient safety in surgery; however, they are widely accepted and commonly applied in most medical settings.

Virtue

Many argue that moral character, or "being good," leads to moral action, or "doing the right thing." This is particularly true among surgeons. However, it is possible to do the right thing for a bad reason, and vice versa. Rather, the motive for taking a specific action speaks more to character, or virtue, than the action itself. Doing "what is right" may not be easy or widely supported. This is especially true when the "right thing" for the patient may bring about a negative consequence for the surgeon or institution. Surgeons may be deterred by a particularly difficult conversation with a patient or family member about surgical error, or the fear that an admitting to an error will lead to litigation. Reluctance to face these situations is understandable. Such cases are likely to trigger the instinct for self-preservation; however, when this instinct arises, virtuous motives and good moral character reinforce the decision to act in a way that is consistent with moral norms.

Some virtues serve surgeons particularly well in matters of patient safety. A small sample of noteworthy examples includes trustworthiness, truthfulness, respectfulness, discernment, courage, conscientiousness and humility (Table 29.2). However, just as "the road to hell is paved with good intentions"; virtuous motives are often not enough. This is especially the case when faced with complex moral

Table 29.2 Moral virtues

Conscientiousness	Being thorough, careful, or vigilant
Trustworthiness	Able to be trusted or depended on
Truthfulness	Accurately conveys what is real
Respectfulness	Regard for the worth and dignity of others
Courage	The courage to take action for moral reasons despite the risk of adverse consequences
Discernment	The ability to distinguish or judge
Humility	Respect for one's own limitations

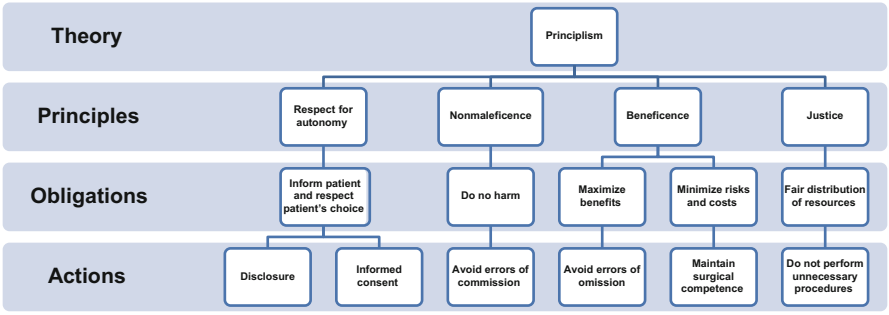


Fig. 29.1 Visualizing the relationship between principles, obligations, and actions

dilemmas in which there is no satisfactory solution, let alone a clear right or wrong. When these cases arise, it may be preferable to use a defined framework to help evaluate the various options and come to a decision. For this, the field of medical ethics often employs a framework that has come to be known as principlism.

Principles

Moral norms, specifically principles, are commonly employed to inform moral conduct. In their book, *Principles of Biomedical Ethics*, bioethicists Tom Beauchamp and James Childress, present an ethical framework for medical decision-making based in common morality theory, or principlism [10]. This framework is known today as the four principle approach to biomedical ethics, and is a common normative tool to "identify and reflect on moral problems" in biomedical ethics. The four principles—respect for autonomy, beneficence, nonmaleficence, and justice—and their general implications for patient safety in surgery are briefly introduced in this section [10]. The ethical application of these principles to patient safety in surgery is expanded upon later in this chapter. The relationship between theory, principle, and practice as it relates here is illustrated in Fig. 29.1.

Respect for Autonomy

Respect for autonomy recognizes the patient as the decision maker and facilitates action in accordance with patient choice [10]. This places the onus on the surgeon to provide patients with sufficient knowledge to enable reasonably informed medical decisions. As such, "while the surgeon is the authority, the patient has the authority" [8]. Respect for autonomy acknowledges the fact that patient decisions are informed by personal values, opinions, beliefs, and experiences. As a result, objective assessments of a "medical benefit" may not align with the patient's subjective benefit assessment [11]. The classic example is that of the exsanguinating patient who requires urgent transfusion in order to survive. An objective assessment of medical benefit points clearly towards administering blood to the patient in order to preserve life. However, if the patient is a Jehovah's Witness who adheres to the belief that it is not permissible to accept blood products, regardless of the possibility of death [8]. For the patient, receiving blood products may lead to excommunication from their community and fear of eternal damnation. From this patient's perspective, benefit is not a question of the physical outcome, but the spiritual one. In patient safety, both prospective informed consent and full disclosure of all medical errors are obligatory to respect for autonomy. A decision to withhold information based on what the surgeon thinks the patient should do, or not to disclose information about the cause of an error, is paternalistic and violates patient trust.

Nonmaleficence and Beneficence

Derived from the principle of nonmaleficence, the maxim to **"***Do no harm*," is inextricably linked to patient safety. The principle of nonmaleficence denotes an obligation not to impose harm or the risk of harm [10]. Nonmaleficence relates closely to the principle of beneficence, the ethical obligation to maximize benefits and minimize risks and costs. In this context, harms are defined as adverse outcomes that occur as a direct or indirect result of medical error. Nonmaleficence refers primarily to errors of commission [2], such as surgical slips or wrong site surgeries; however, its application is both active and preventative. Conscientiousness is a particularly valuable virtue in surgeons as both meticulousness and thoroughness are traits that lend themselves to prevention of surgical harms.

In patient safety, beneficence presumes an obligation to avoid errors of omission [2], such as incorrect diagnosis, failure to perform a necessary surgery, or failure to utilize evidence based practices. To maximize benefits, the surgeon and members of a patient's care team have an obligation to execute procedures and provide quality post-op treatment to ensure the best possible outcome from surgery. To minimize risks and costs, there is an obligation to minimize the potential adverse consequences of error. This applies to psychological, financial and physical harms. Should an error of any scale occur, a timely, carefully executed apology and description of plans for follow up or future prevention will often minimize the harms experienced by victims after the event. Further, doing so allows individuals and organizations to

learn from errors in order to prevent future harms. The ability to learn from adverse incidents when they occur is a function of both beneficence and nonmaleficence.

Justice

Justice asserts that equals ought to be treated equally, and "unequals" should be treated unequally. In healthcare, the principle of justice insists on fair distribution as well as fair, equitable, and appropriate treatment in light of what is due or owed to individuals and groups [10]. Justice-based obligations related to patient safety in surgery are closely connected to the principles of nonmaleficence and beneficence.

First, there is an obligation to provide an appropriate (i.e. adequate) standard of surgical care to patients. Similar to beneficence, surgeons who believe they are putting patients at undue risk of surgical harm must address the problem [12, 13]. Further, all members of the surgical team have a duty to take action if he or she recognizes a problem in a colleague that may introduce undue risk. If a team member notices a pattern of carelessness or error, or believes a colleague may be impaired and says nothing, then he or she is morally complicit to subsequent harms. When faced with the obligation to approach a colleague or superior to report suspected negligence, moral virtues such as truthfulness, courage serve surgeons and other personnel well. Second, there is an obligation to ensure that surgical resources are distributed fairly among all patients who need them [14]. Efficiency is implicit to the concept of fair distribution. Efficient care is care that both meets patient needs and is not wasteful. Preventable adverse events that result in harm to the patient do not meet either standard. Nor do unnecessary surgeries. Finally, patients or their loved ones ought to be able to seek compensation for harms when they do occur [2, 12].

"Prima Facia" Obligation

According to Beauchamp and Childress, these principles present a "prima facia" obligation that "*must be fulfilled unless it conflicts on a particular occasion with an equal or stronger obligation*." An obligation related to the four principles is always binding unless it conflict with another obligation of equal weight. When this happens, the optimal solution is that which finds the greatest balance between the two in the specific circumstances [10].

A simple example is the conflict between autonomy and nonmaleficence in cases involving disclosure of near miss medical errors. On one hand, there is a duty to disclose based in autonomy and the patient's right to know. On the other, there is the concern that telling a patient about the near miss error will do more harm than good. There is also the possibility that not disclosing may do equal or worse damage if the patient finds out. Given the fact that the patient's response to disclosure can be affected positively by employing communication skills that help with disclosure, it is possible to respect autonomy and do so without inflicting additional harms. If the surgeon decides not to disclose, then autonomy is not respected in any regard.

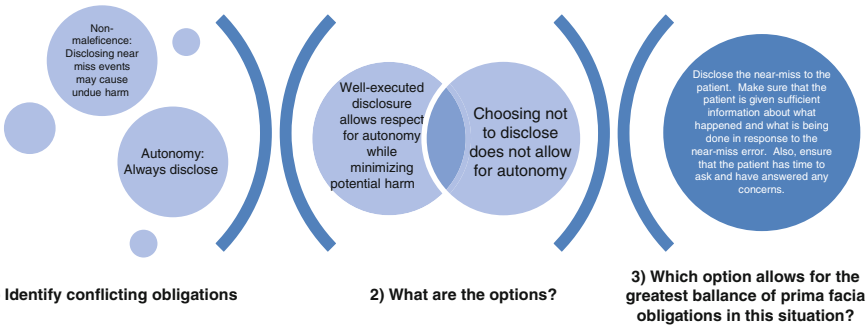


Fig. 29.2 Applying *prima facia* obligations to decision making. Should surgeon disclose a near-miss medical error to patient?

Therefore, the option that provides the greatest balance between the autonomy and nonmaleficence is well-executed disclosure (Fig. 29.2).

Public Health Ethics

Public health ethics is the systematic analysis of moral problems that arise in public health and preventive medicine. The ethical act in public health is one that aims to improve or preserve the health of the public. Thus, there are different principles that emerge as paramount to decision making and policy development. Besides the principles associated with "*do no harm*," utility and fairness (or social justice) are central to the systems approach to patient safety.

One view of public health ethics involves the balance of individual liberties with the advancement of good health outcomes for the population, or autonomy with utility [14]. The principle of utility promotes maximal balance of benefit over harm or other costs [10], and is a concept that is paramount to public health ethics. In this context, utility asserts a duty to promote action that will do the most good for the most people as opposed to what is in the best interest of an individual patient. The principle of utility is apparent throughout current patient safety policy recommendations as both a justification for action and a consideration in weighing options for specific policy. The principal measure of utility in this context is health, but economic utility is also a significant motivator. In other words, money will motivate when nothing else will. However, if financial concern is the primary motivation, then significant conflicts arise when doing the right thing for safety are actually costs more to implement than to allow errors to continue.

Fairness is also integral to understanding the public health approach to patient safety. The principle of fairness technically falls under the principle of justice; however, as with "*do no harm*," it applies slightly differently in this context. Fairness not only encompasses fair distribution of resources, but also calls for policies of action that preserve human dignity and show equal respect for the interests of all members of the community [15].

Current Best Practices

Admittedly, philosophical appraisal of the moral motivations and obligations related to patient safety in surgery has limited value here, unless it includes some assessment of the practical application of these virtues and norms to the practice of medicine.

Informed Consent

While informed consent is discussed in depth in a previous chapter, it is important to stress that the informed consent process is principally an ethical tool for respecting persons, rather than a legal formality. The informed consent process, as a function of respect for autonomy, is founded in the patient's right to be adequately informed about the risks and benefits of his or her treatment, and his or her right to decide whether to accept treatment under given conditions. Respect for autonomy is especially crucial in surgery due to the invasiveness, short term harm, and "temporary unconscious state of the patient" [12]. With respect to patient safety, the informed consent process should include an honest discussion of the potential complications of a proposed surgery.

Surgeons must recognize and avoid personal bias, and must not allow personal opinion about what "should" be done to impact the content or quality of the information that is provided to the patient during the consent process. The surgeon is charged with disclosing all information pertinent to the patient's participation in the fiduciary relationship. The extent of the disclosure ought to depend on severity of the potential complication, the likelihood of occurrence, and the patient's preferences to be informed [12]. This is also referred to as the "reasonable person standard"; the surgeon should provide the amount of information that a reasonable person in the patient's circumstances would want to know.

What a reasonable person would want to know in order to make a decision is not the same as deciding what a reasonable person would decide. If misinterpreted this way, the surgeon may not provide information tailored to the specific patient. The patient will influence the extent and content of disclosure. Information about patients, such as activity level, profession and other interests, may help surgeons better assess what information he or she should include during the consent process.

Response to Medical Error

After errors occur, patients want incidents to be acknowledged, information about what happened, an apology, a plan for prevention of future errors [16, 17], and access to financial reparations and legal action [17]. Virtues that aid disclosure include courage to do the right thing, humility to admit to making an error, and truthfulness.

Disclosure

Any argument against full and transparent disclosure of surgical errors lacks ethical standing. Patients have a right to be informed about their medical care. To withhold knowledge of a near miss event denies the patient the right to make medical decisions given all of the potentially relevant information, and violates trust. In addition, failing to report knowledge of a near miss or other type of error committed by a colleague violates beneficence, by impeding the ability to learn from near miss incidents.

There is discrepancy between the number of practicing physicians who agree that all medical errors should be disclosed to patients, and those that actually practice full disclosure [16–18]. Some of the reasons doctors do not disclose include: the belief that harm is trivial or that patient will not find out; the belief that the patient would not want to know or would not understand; personal psychological reasons, such as self-preservation or denial; and fear of litigation [16, 19]. Not surprisingly, those who believed that litigation may be reduced by disclosure, were more likely to disclose. The research shows that surgeons are less likely to explicitly disclose medical errors than other medical specialists [16].

Apology

Disclosure alone is an insufficient tool for minimizing the harms that occur as a result of medical error. It is evident that the simple act of saying "sorry" does not meet the needs of patients or family members. Without proper training and execution, apologies may be perceived as disingenuous and may cause additional harm. Patients want apologies to include an assumption of responsibility [20]. An apology should include: (1) information about what happened and what will happen in response; (2) sincerity; and (3) appreciation for those involved and how they will be impacted not only financially but emotionally [16, 20, 21]. Communications researchers have also indicated that the non-verbal cues play an important role [20]. In western cultures, well executed apology is associated with positive response and reduced likelihood that a patient will change physicians [21]. In response to concerns about liability, apology laws have been enacted by two thirds of the states, some of which disallow use of statements made during an apology to be used in future litigation. However, the structure of these laws has been criticized for impeding full apology.

Financial Reparations and Legal Support

The legal perspective on patient safety in surgery is addressed elsewhere in this text. The ethical perspective pertains primarily to personal accountability for wrongdoing and relieving undue financial harms. Tort liability is a fault-based system of compensation for those who sustain iatrogenic injury. To qualify for payment, the injured party must prove negligence was present. The intended purpose of tort liability is both accountability and deterrence. However, the system benefits relatively

few patient victims; disproportionately excludes the poor and elderly from access; creates incentives against full and honest disclosure; and impedes safety improvement [2]. The system is clearly inefficient in maximizing benefits and minimizing harms and does not facilitate respect for autonomy. Further it is inefficient in the supposed delivery of justice.

Both institutional and private sector disclosure and compensation programs have received significant attention from the ethics community as potential alternatives to tort liability. The University of Michigan Health Systems' institutional disclosure program requires immediate error review and determination about appropriateness of events. If care was "inappropriate" a thorough explanation and apology are required. Over 7 years litigation costs were cut in half, new claims reduced by 50 %, and processing time by 60 % [18]. An example from the private sector, the Colorado liability insurer, COPIC, has the 3Rs program. The goal of 3Rs, Recognize Respond, and Resolve Patient Injury, is transparent communication through no-fault claims. The average compensation is $5,400. Compensation is not based on finding of fault and patients are not required to waive their right to sue. It should be noted that COPIC's program exists in a state where there has been broad tort reform. Similar programs may not work in other states. Ultimately, the impact of disclosure programs is unknown. Some tout their positive effect on reduced legal action, but it is likely that the only meaningful solution to legal climate is tort reform [16, 18].

Mechanisms for Patient Support

When medical errors occur, the effect on patients is two-fold. Patients must not only endure the effects of the injury itself, but also the after effects when the injury or error is mishandled. Research shows that patients want to be informed regarding virtually all unexpected events that occur during the course of treatment. However, they also recognize that being told may raise more questions or make them uneasy. As such, patient education is vital to minimize undue harms during the disclosure process [22].

When caring for patients after a patient safety incident, it is important for healthcare professionals, particularly surgeons, to believe them, listen to them, and inquire regarding the emotional trauma and psychological impact [23]. Family members and support persons may benefit from emotional support, as they often report feelings of guilt [17]. It should be noted that patients define medical errors more broadly that the medical profession does. Specifically, patients define patient safety as access to care; responsiveness and empathy; good communication; clarity of the information provided; appropriate treatment; relief of symptoms; improved health status; and freedom from medical injury [22].

Error Prevention

There are various obligations related to prevention that stem from beneficence and nonmaleficence. Surgeons must be willing to recognize and admit when his or her

ability to operate is impaired. This applies to both transient and non-transient circumstances; for example lack of sleep or reduced ability to execute certain procedures due to worsening eyesight or loss of fine motor skills. Surgeons also have an obligation to innovate and contribute to research and quality improvement when possible; publish case studies or editorials so that others may learn from their experiences; keep up to date on research; attend professional conferences; and generally strive to practice self-care [12, 13]. Further, due to rapid advances in medicine, surgeons must always exercise discernment to determine whether ability to operate means that surgery is appropriate or justified under the circumstances [7, 12].

Systematic Tracking and Reporting of Adverse Events

Reporting requirements aim to (1) use data to acknowledge trends and prevent future errors; (2) collect information about errors to help patient victims after the error occurs; and (3) act as a deterrent that will inspire institutions to prevent injury in order to avoid reporting. The principles of utility and fairness, nonmaleficence and beneficence, convey an obligation to implement systematic tracking and reporting measures. Truthfulness and conscientiousness are especially pertinent to the ethical surgeon in reporting and tracking.

The increase in pay-for-performance programs in the US has led to mandated reporting of quality and safety measures [24]. In the current patient safety climate, there are various reporting mandates which apply depending on the state or oversight agency. However, reporting generally depends on provider self-report to institutions [24]. Compliance with safe practice guidelines is voluntary and data is not externally validated [18, 25]. This stands contrary to the best practice among quality assurance professionals is dependent upon validated self-reports or implement quality improvement audits that utilize patient records and administrative reports to collect or confirm primary data.

Mandated external reporting has obvious value, but these tend to include only serious events, which is ethically unjust. By treating serious errors as more important than non-serious errors, an individual must be exposed to harm in order for reporting to trigger an investigation into the cause for future prevention. Whereas, reporting everything is neither feasible, nor does it facilitate the meaningful use of data. Pronovost et al suggest that progress in patient safety should be measured by the following questions [24]:

1. How often do we harm patients?
2. How often do surgeons provide appropriate, evidence-based interventions?
3. Have clinicians learned from mistakes?
4. How successful are clinicians and healthcare organizations at improving and maintaining a culture of safety?

Most reports sent to external agencies are protected on an institutional level [25]. The next step for accountability must be to improve transparency of the reports. The

culture of non-transparency is counterintuitive to safety culture. In addition, institutions should be using general data and tracking to measures to identify concerning trends.

Evaluation of System Failures Beyond the "Culture of Blame"

A major conclusion of the IOM Report was that the blame culture surrounding medical error, hinders activities that help minimize and prevent harm. The report asserts that even when there is a clear connection between individual actions and adverse outcomes, errors are ultimately caused by complex causation, rather than individual failures. Errors are evidence of larger systematic failures. When institutions focus on systematic circumstances that lead to errors, they not only avoid individual assertions of blame, but also, appropriately direct attention to valuable conversations about the root cause of errors and broad prevention efforts. Removing individual blame eliminates individual incentives to hide or minimize errors and represents a more realistic approach to assessing what led to failures and implementing realistic solutions.

Use of systematic analysis to identify root causes of error is well accepted. Findings from systematic analysis have led to widespread acceptance of patient safety checklists to prevent medical error and increased focus on cultivation of a safety culture that encourages members of the surgical team to speak up. At the same time, some argue that employing top-down tactics to dictate 'correct' actions will have the unintended consequence of apathy essentially allowing individuals to become morally disengaged [3]. While the intention of a systems approach is not to allow medical professionals to pass off responsibility for error, but to adopt a system that facilitates rather than inhibits proactivity and accountability [2], it is clear that some degree of personal responsibility is required.

Recent attitudes towards medical error are more consistent with a traditional ethics understanding of error which distinguishes between technical and normative errors [3, 10]. Technical errors may occur as a result of execution failures or poor judgments [3, 10]. These errors do not necessarily speak to the moral character of individuals or team members. Occasional "honest errors" of either sort are to be expected [10]. However, when errors do occur, the conscientious surgeon or team attempts to identify the root cause and seeks additional guidance, education, or training as needed before returning to the operating room or under similar circumstances or attempting the same surgery again. A pattern of technical or judgment errors committed by an individual or group of individuals should raise concerns about competence or negligence. Normative errors are moral errors that violate norms of conduct [3, 10].

For example, if a surgeon fails to be discerning, and therefore performs numerous unnecessary operations which introduce unnecessary risks to patients with little or no benefit and wastes valuable institutional resources in the process, this surgeon would be guilty of committing a normative error and should obviously be held personally responsible. However, a root cause analysis should still be performed to identify ways in which institutional failures may have also contributed, and action items should be identified to prevent reoccurrence.

Limitations of the Current Practice

- Mandatory and voluntary reporting of limited error data has not led to a major breakthrough in patient safety. The focus on mandatory reporting of serious surgical events limits institutional focus on minor events that may inform large scale prevention and a reduction in the number of serious events. Mandatory external reports to various oversight entities are piecemeal and do not paint the whole picture. Also, reports are not validated. Hospitals and surgery centers have a wealth of patient data at hand. Most of that data is now entirely electronic. There is frequent discussion about the ethical implications related to access to this data for research or marketing purposes; however, it seems the most ethically justifiable reason to access and use the data is to track and identify indicators of both technical and normative errors.
- Institutions continue to insist on confidential reporting. Focus on protecting the hospital rather than the patient sends the wrong message to surgeons and other personnel and is an impediment to safety culture. Further, these types of competing interests, financial or otherwise, erode patient trust.
- It is ethically imperative for surgeons to engage in QI, research, and innovation. However, current research ethics regulation is a barrier to conducting low risk patient safety research. This is partially due to continued segregation of clinical and research care and failure on the part of research ethics and research regulations to adapt to evolving best practices. Further, innovation introduces safety concerns that patients do not understand.
- Shaming and burnout among medical professionals, especially surgeons, limits their ability to function within systems and increases the likelihood of errors. Errors do not only effect patients, surgeons and team members also experience psychological effects after the fact. It is likely, that when this happens, errors beget more errors. Further, a common finding in error analysis is that underlying communication failures are a contributing factor [26], and a lack of communication skills is often cited as reason for non-disclosure and as barrier to well executed consent process.

Where Is the "Golden Bullet"?

Quality Improvement, Research, and Innovation

The surgical profession as a whole has an obligation to improve surgical outcomes and reduce complications. These goals are typically achieved through innovation and by conducting research and participating in systematic of quality improvement (QI) protocols. Pronovost et al provide a framework for patient safety research proposes five domains: "(1) evaluating progress in patient safety; (2) translating evidence into practice; (3) measuring and improving culture; (4) identifying and mitigating hazards; and (5) evaluating the association between organizational characteristics and outcomes" [24]. Translating evidence into practice is perhaps the most challenging of these to realize, but must be a focus for researchers from the beginning as failure to disseminate

results and use them to improve patient safety means that resources were wasted and risks associated, if any, are not justified [25]. The benefit of research is dependent upon the availability and application of the information gained through completing the research; however, research, innovation, and to a lesser degree, QI raise ethical concerns about exposing patients to undue risks and respect for autonomy.

As a result, research in the US is conducted under strict regulatory oversight. Major tenants of the US regulations include review and oversight by an IRB, voluntary prospective informed consent, a determination that the potential benefits outweigh risks, and protection of vulnerable populations. However, there are many who feel that IRB oversight is a significant barrier to conducting low risk research that produces meaningful results.

In many cases, surgical innovation does not lend itself well to systematic evaluation or scientific methods This is usually because of inherent methodological or ethical issues unique to surgery (i.e. sham surgery, likelihood of complications that require intervention). When innovation is neither systematic nor generalizable—both current standards for "research" in the US institutional review and oversight is not required. Nevertheless, innovation introduces a number of safety concerns. Peter Angelos, the Chief of Endocrine Surgery at the University of Chicago and the Associate Director of the MacLean Center for Clinical Medical Ethics, has written a number of articles on the ethics of innovation in which he provides a nice overview of the concerns related to innovation which include: obtaining informed consent despite limited knowledge of the potential risks and complications associated with new procedures or techniques; potential optimism bias; the inherent learning curve as new surgeons adapt new techniques and the related safety and training issues, and potential conflicts of interest when surgeons stand to benefit from the innovation rather than innovating for altruistic purposes. Finally, Angelos stresses the difficulty but importance of collecting and scrutinizing patient outcomes [27].

Systematic Tracking and Reporting of Patient Safety Data

Efforts to track and report patient safety data ought be employed to help institutions and surgeons fulfill their ethical obligation to minimize risks and prevent future harms. It is imperative that reporting methods are efficient and effective, so as not to be waste limited time and financial resources, and that information is shared in a way that ensures respect for patient autonomy.

Current reporting requirements are compulsory and not well thought out. As a result, resources dedicated to meeting reporting centers are not well spent. Further, the wealth of data related to safety, quality, processes, prices, costs and outcomes of care that is available to institutions may be used for marketing or research purposes, but is often not employed to inform patient safety monitoring. For example, as more cases come to light involving surgeons who perform numerous unnecessary surgeries for financial gain, it should not be acceptable for institutions to claim that they had no previous knowledge of this abuse. Even if there is a complete breakdown at the institutional level, there must be a process in place to identify indicators that something is amiss.

A 2012 IOM report entitled "*Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*" proposes that healthcare leadership ought to transform health care centers into "Learning Health Care Systems" [28], and calls for tracking and reporting systems which "continuously and reliably capture, curate and deliver the best available evidence to guide and improve clinical decision-making and healthcare safety and quality." This aim reflects the importance of not only the ability to capture data but also the quality of the data and the ability to access and use that data to inform practice. The ability to demonstrate how data informs practice should be a standard to which all institutions are held.

Transparency

Systematic tracking has limited value unless it is shared in a way that informs decision-making by clinicians, patients and their families. Lack of transparency is a major barrier to patient trust and sustainable safety culture. The public has a right to quality healthcare and to be informed by unsafe conditions. Any arrangement that fails to hold healthcare systems to this standard, fails at the most fundamental level. Healthcare systems ought to be held accountable to the patients it serves, and the gold standard of accountability is transparency. This is true in every other field besides medicine.

Patients that want to use measures of quality to inform health care decisions have limited option. They can access patient satisfaction surveys published by hospitals, visit physician rating websites, or check Hospital Safety Scores published by the Leap Frog Group. However, patient satisfaction and overall hospital scores based solely on reported incidents, do not tell the whole story. A surgeon may have great bedside manner and horrible surgical technique or even poor professional character. Similarly, a surgeon with exquisite technique may lack the social skills to instill confidence at the bedside. This is not news to healthcare professionals. Martin Makary, a renowned surgeon at Harvard, suggests that the best indicator of hospital or physician safety is to ask someone who works there, i.e. an OR nurse, whether or not he or she would want to be operated on by said surgeon or at the hospital itself [26]. This information should be made available to patients when they decide where to go to get help. There is also significant variation across the US about what is reported and how information is made available to the public.

Systems for reporting medical errors and making them available to the public are improving but have not begun to meet the mark. Transparency should not only be expected in the individual physician patient relationship, but should also be practiced by health care organizations in reporting patient safety findings, provided said reporting does not violate privacy or confidentiality at the patient level.

Towards an Integrated Research Culture

QI allows healthcare systems to make systematic changes that can be measured and used to inform and shape medical practices in a particular setting. Research, the

systematic analysis that informs the profession in general about what works and what does not, is an important tool in evidence based medicine. QI and research facilitate improvement and innovation in surgery, which in turn ensures that harms are minimized and potential benefits are maximized.

One of the most significant developments of the past few years is the use of checklists to "bundle" an all or nothing approach to implementing safety procedures. To test the efficiency of checklists in reducing hospital infections, Johns Hopkins University engaged 67 Michigan hospitals, with a total of 103 ICUs. The results were dramatic. The successful use of checklists for catheter infections led to more widespread use of checklists, most notably the preoperative checklist. However, when results of the initial study by JHU were published, the Office for Human Research Protections sounded the alarm. The research being conducted by JHU was approved as Exempt, inappropriately, allowing the study to essentially be conducted without IRB oversight and without individual consent [29].

Requiring consent for each participant in this study would have been unwieldy. It is likely the study investigators would have been able to obtain a waiver of consent, but the IRB process itself is sometimes slow and scares many people off. However, IRB approval is needed in order to publish data and share results that are generalizable. In order to avoid having to obtain IRB approval, institutions may decide to design studies for internal QI purposes, instead of generate generalizable research results. In the case, the research may not be shared internally, but is that ethical? Probably not; the results may not be shared with other institutions, or published or presented at conferences. This means that the ability to share valuable experiences with other institutions is limited and institutions may have to repeat the same QI measures again and again while meanwhile, conducting the study one time using proper scientific measures and publishing that data could get the message out to everyone at once. Both QI and traditional surgical innovation are best served by systematic evaluation. However, the current system for conducting these measures is difficult to practice [28–31].

There is a growing movement in the bioethics community towards a more integrated model of clinical and research care [28, 30, 31]. Although discussions about integration of research and clinical care are principally intended to address logistical issues facing the entire clinical research enterprise, the ethical implications of this movement cannot be ignored. In an article published by the bioethics thank tank, The Hastings Center, the authors address some of the ethical issues that may be anticipated by integrating research with clinical care by presenting a hypothetical model for integrating research and care [31]. This does not suggest an intention to abandon IRB oversight or respect for autonomy. It should be possible for the existing system to evolve away for lengthy consent process for individual research interventions in favor of prospective permission from patients to be involved in low risk research or QI without expressed consent. Education about research participation and its purpose should be integrated into patient education and culture so that even when patients are approached about specific studies, they have an established understanding of the differences between the goals of research compared to the goals of clinical care and whether or not they

in interested in being a research participant. Ultimately, integration of clinical research and clinical care may benefit current and future patients without sacrificing the ethical integrity of either research or clinical medicine. Disposing of IRB oversight for patient safety research is neither realistic nor responsible. However, incorporating a culture of research that facilitates understanding and participation has the potential to create meaningful change and, if done well, would be consistent with the true spirit of autonomy while still allowing for efficient use of resources and improved healthcare than minimized harm to patients.

Surgeons' Support

It has been established that there is an ethical mandate for surgeons to pursue continuing education, keep up in the field, and be honest with self and others about their ability to operate. In addition to ensuring that technical ability and knowledge is intact and consistent with current best practices, there may be additional factors that deserve attention and that aide in assuring patient safety and competent patient care in preventing and responding to medical error.

The discourse on patient safety ethics and response to adverse surgical events focuses primarily on disclosure, minimizing harms to patients, and justice. Discussions pertaining to medical professionals involved with adverse events are generally limited to removing individual blame and the safety culture. In doing so, ethicists tend to disregard the impact that medical error has on clinicians, and perhaps more so on surgeons and the surgical teams. Studies conducted on the psychological and emotional impact of medical errors suggest that many surgeons do experience a negative psychological impact after errors occur. This impact is seen more in younger and less experienced surgeons; however, personality also appears to influence ability to cope with errors [32]. In another study, increases in QOL score on items related to emotional exhaustion and mental health are associated with higher likelihood of reporting recent medical errors [33]. Efforts to avoid burnout have focused primarily on reduced work hours. The causal relationship between the surgeon's distress and increase in reported safety incidents is unclear.

Further, abandoning the deeply ingrained blame culture has proven more difficult, especially in surgery. In a 2008 survey of surgeons in the US, over 70 % of surgeons questioned attributed errors to self rather than to the system [33]. Another study comparing surgical and non-surgical residents found that surgical residents are less likely than their counterparts to express concerns about medical errors to other members of the team and both surgical and nonsurgical residents believe that disclosure will have a negative impact on their careers as well as on the physician patient relationship [32]. Surgeons also report more frequent instances of colleagues receiving punishment, verbal abuse or negative consequences in response to mistakes and a general expectation to compromise their own values in response to medical errors [34].

In an effort to minimize the harms to both the surgeon, and potentially to future patients, every effort should be made to ensure that surgeons and members of

surgical teams receive sufficient support after medical injury occurs. In addition to training, surgeons require mentoring, morbidity and mortality meetings (that do not include a blame culture), focus on teamwork, and psychological interventions [32]. Surgeons may also benefit from breaks from surgery and structured debriefing after serious medical errors [32]. Removing institutional or legal blame does not equate with removing a culture of blame among colleagues or personal blame [33]. Regardless of whether the system is to blame in these cases, the system is certainly critical to finding and implementing solutions.

Communication skills play a significant role in both safe surgical practice and response to medical error. Lack of communication skills may lead to surgical errors occurring, prevents meaningful consent discussions that facilitate patient understanding of risks, and prevents surgeons from appropriate response to error when they occur. Not only is there evidence to suggest that practitioners with error disclosure training are more willing to disclose medical errors to their patients [14], but also when error disclosure does occur, but is poorly executed, there is a risk of inflicting additional, unnecessary harm. Institutions must continue to find ways to incorporate communication skills training into continuing education for all personnel, especially those who work in the surgery setting. Future research ought to include means for assessing consent and disclosure skills so that standards may exist and improvement may be tracked.

Take-Home Message

The focus on systems is a poor excuse not to reinforce the important role ethics plays in a safety culture. The result of this is a culture of safety in which self-preservation is a barrier to disclosure; lack of ownership within systems leads to lack of buy-in and is barrier to meaningful function of systems; increased focus on checklist rather than process and purpose. Incentivizing patient safety is certainly not a bad thing, but it is not sufficient replacement for the moral incentive to do the right thing.

The ethics perspective on patient safety in surgery is that both systems and individuals have an obligation to work together to ensure that:

1. Patient autonomy is respected throughout all phases of patient care;
2. When errors do occur, institutions support the surgeon's fiduciary obligation to the patient above all else, and that patients are treated with dignity and respect;
3. Patients have access to sufficient institutional information in order to enable informed healthcare choices;
4. Surgeons have access to necessary tools to maintain and improve upon both technical and non-technical knowledge, and dedicated time to devote to continuing education and self-care;
5. Institutions support and empower an "if you see something say something" approach to patient safety that encourages respectful communication about concerns related to both technical and normative errors;
6. Emotional support is available to surgeons and team members after errors occur;

7. Institutions are held accountable through reporting of patient safety incidents
8. Patient data is collected in a way that is both meaningful and efficient in order to ensure that institutional resources are not wasted;
9. Research, QI, and safe innovation methods are employed to help maximize the benefits and minimize the risks and costs of surgical care; and
10. Barriers to conducting meaningful research and QI are identified and regulatory conflicts are resolved ethically.

As these are ethical obligations, the motivation to act accordingly is best grounded in both internal moral beliefs and a culture of institutional ethics, rather than external incentives. A system is only as safe, and as ethical, as it's least ethical part. Norms, beliefs, attitudes, and values define safety culture. All of these relate to common morals and a shared code of ethics. Faced with rapid changes to healthcare systems, advances in technology, and increases in patient volume, among numerous other factors, ethical dilemmas faced by surgeons are too complex to continue to rely on an antiquated model [5]. Formalizing and integrating ethics education and discussion is essential to sustainable patient safety programs [5]. Conversations about ethics should be integrated into rounds, morbidity and mortality conferences, one on one mentoring, and continuing education. The concerted effort among surgeons to internalize a culture of providing ethical care in surgery is indispensable in order to improve patient safety.

References

1. Kohn LT, Corrigan JM, Donaldson MS, editors. To err is human: building a safer health system. Washington, DC: National Academy Press, Institute of Medicine; 1999.
2. Sharpe VA. Accountability: patient safety and policy reform. In: Sharpe VA, editor. Accountability: patient safety and policy reform. Washington, DC: Georgetown University Press; 2004.
3. Pellegrino ED. Prevention of medical error: where professional and organizational ethics meet. In: Sharpe VA, editor. Accountability: patient safety and policy reform. Washington, DC: Georgetown University Press; 2004.
4. Paola F, Barton SS. An 'ethics gap' in writing about bioethics: a quantitative comparison of the medical and surgical literature. J Med Ethics. 1995;21(2):84–8.
5. Sade RM, Williams TH, Perlman DJ, Haney CL, Stroud MR. Ethics gap in surgery. Ann Thorac Surg. 2000;69(2):326–9.
6. Hanlon CR. Surgical ethics. Am J Surg. 2004;187(1):1–2.
7. Wall A, Angelos P, Brown D, Kodner IJ, Keune JD. Ethics in surgery. Curr Probl Surg. 2013;50(3):99–134.
8. McCullough L, Jones J, Brody B. Principles and practice of surgical ethics. In: McCullough L, Jones J, Brody B, editors. Surgical ethics. New York: Oxford University Press; 1998. p. 3–15.
9. Little M. The fivefold root of an ethics of surgery. Bioethics. 2002;16(3):183–201.
10. Beauchamp TL, Childress JF. Principles of biomedical ethics. Oxford: Oxford University Press; 2012.
11. Angelos P. Orlo Clark and the rise of surgical ethics. World J Surg. 2009;33(3):372–4.
12. Adedeji S, Sokol DK, Palser T, McKneally M. Ethics of surgical complications. World J Surg. 2009;33(4):732–7.
13. Angelos P. Complications, errors, and surgical ethics. World J Surg. 2009;33(4):609–11.

14. Childress JF, Faden RR, Gaare RD, Gostin LO, Kahn J, Bonnie RJ, Kass NE, Mastroianni AC, Moreno JD, Nieburg P. Public health ethics: mapping the terrain. J Law Med Ethics. 2002; 30(2):170–8.
15. Hannawa AF. Principles of medical ethics: implications for the disclosure of medical errors. Medicolegal Bioeth. 2012;2:1–11.
16. O'connor E, Coates HM, Yardley IE, Wu AW. Disclosure of patient safety incidents: a comprehensive review. Int J Qual Health Care. 2012;22(5):371–9.
17. Wu AW, Boyle DJ, Wallace G, Mazor KM. Disclosure of adverse events in the United States and Canada: an update, and a proposed framework for improvement. J Publ Health Res. 2013; 2(3):186–93.
18. Gallagher TH, Studdert D, Levinson W. Disclosing harmful medical errors to patients. N Engl J Med. 2007;356(26):2713–9.
19. Stahel PF, Flierl MA, Smith WR, Morgan SJ, Victoroff MS, Clarke TJ, Sabel AL, Mehler PS. Disclosure and reporting of surgical complications: a double-edged sword? Am J Med Qual. 2010;25(5):398–401.
20. Hannawa AF, Beckman H, Mazor KM, Paul N, Ramsey JV. Building bridges: future directions for medical error disclosure research. Patient Educ Couns. 2013;92(3):319–27.
21. Mazor KM, Reed GW, Yood RA, Fischer MA, Baril J, Gurwitz JH. Disclosure of medical errors: what factors influence how patients respond? J Gen Intern Med. 2006;21(7):704–10.
22. Vincent C, Coulter A. Patient safety: what about the patient? Qual Saf Health Care. 2002; 11(1):76–80.
23. Chamberlain CJ, Koniaris LG, Wu AW, Pawlik TM. Disclosure of "nonharmful" medical errors and other events: duty to disclose. Arch Surg. 2012;147(3):282–6.
24. Pronovost PJ, Goeschel CA, Marsteller JA, Sexton JB, Pham JC, Berenholtz SM. Framework for patient safety research and improvement. Circulation. 2009;119(2):330–7.
25. Wachter RM. Patient safety at ten: unmistakable progress, troubling gaps. Health Aff. 2010; 29(1):165–73.
26. Makary M. Unaccountable: what hospitals won't tell you and how transparency can revolutionize health care. New York: Bloomsbury Publishing; 2012.
27. Angelos P. Ethics and surgical innovation: challenges to the professionalism of surgeons. Int J Surg. 2013;11:S2–5.
28. Smith M, Saunders R, Stuckhardt L, McGinnis JM, editors. Best care at lower cost: the path to continuously learning health care in America. Washington, DC: National Academies Press; 2013.
29. Miller FG, Emanuel EJ. Quality-improvement research and informed consent. N Engl J Med. 2008;358(8):765–7.
30. Brody H, Miller FG. The research-clinical practice distinction, learning health systems, and relationships. Hastings Cent Rep. 2013;43(5):41–7.
31. Largent EA, Joffe S, Miller FG. Can research and care be ethically integrated? Hastings Cent Rep. 2011;41(4):37–46.
32. Pinto A, Faiz O, Bicknell C, Vincent C. Surgical complications and their implications for surgeons' well-being. Br J Surg. 2013;100(13):1748–55.
33. Shanafelt TD, Balch CM, Bechamps G, Russell T, Dyrbye L, Satele D, et al. Burnout and medical errors among American surgeons. Ann Surg. 2010;251(6):995–1000.
34. Martinez W, Lehmann LS. The "Hidden Curriculum" and residents' attitudes about medical error disclosure: comparison of surgical and nonsurgical residents. J Am Coll Surg. 2013; 217(6):1145–50.

Patient Safety: A Perspective from the Developing World

30

Ashok N. Johari, Shalin K. Maheshwari, and Ratna S. Maheshwari

Pitfalls and Pearls

- Developing countries have recently adopted internationally recognized protocols and strategies aimed at increasing patient safety in surgery and reducing the incidence of adverse events in the perioperative setting.
- Adoption of a uniform institutional practice for antibiotic administration can decrease variations in performance, in both developed and developing countries.
- Prophylactic administration of antibiotics is not the only means for reducing infections at surgical sites: other means are antisepsis, optimal surgical technique, patient temperature maintenance, glucose control and the use of clippers instead of razors.
- Prophylaxis against venous thromboembolism remains the most appropriate strategy for reducing the sequelae described above, and primary thromboprophylaxis reduces the rates of deep-vein thrombosis, pulmonary embolism and fatal pulmonary embolism.
- Virtual consultations could improve patient safety by widespread dissemination and access to expert medical and surgical care.
- Routine intra-operative radiographic screening in selected, high-risk categories of procedures has been proposed for detecting retained foreign bodies.
- A positive, non-punitive reporting culture could build the basis for assessing the incidence and scope of surgical errors and allow the design of further measures to decrease the rate.

A.N. Johari, MS, MCh, FRCS, FAMS, FCPS, DNB (✉)
S.K. Maheshwari, MBBS, Dip(SICOT),M.S(Ortho)
R.S. Maheshwari, MBBS, Dip(SICOT),M.S(Ortho)
Department of Paediatric Orthopaedics, Children's Orthopaedic Centre,
Bobby Apartments, Lady Jamshedji Road, Mahim, Mumbai, Maharashtra 400 016, India
e-mail: drashokjohari@hotmail.com

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_30,

- A systems approach should also emphasize team training and improved communication.
- Integrating patient safety and error reduction into the curriculum of medical education, postgraduate medical education, board certification, re-certification and continuing medical education could raise awareness about these issues and perhaps modify the practice of clinical care.

Outline of the Problem

Greater longevity of population has created a greater need for essential surgical services worldwide. Health systems in all countries are now massively increasing the number of surgical procedures performed. As a result, the safety and quality of care has become a major issue everywhere.

Surgical patients remain highly susceptible to preventable perioperative complications, despite the nationwide implementation of standardized patient safety protocols in recent years. Preventable adverse occurrences include so-called "never events," such as wrong-patient and wrong-site surgery [1]. Recent publications emphasize the fact that our current patient safety protocols are indeed not safe in protecting our patients from suffering unintended and preventable harm [2]. We have inculcated a great deal of knowledge, nevertheless it is often unmanageable. The volume and complexity of what we know has exceeded our individual ability to deliver the benefits correctly, safely or reliably. Medicine has become the art of managing extreme complexity. New strategies to improve patient safety in surgery include the implementation of defined surgical safety checklists, standardized "readbacks" to improve communication in perioperative services, and medical team training programs [3, 4].

Limitations of the Current Practice

Surgical Site Infections

Infections at surgical sites make a heavy contribution to patient injury and mortality and to health-care costs. Their prevalence in the United States is more than 2 % [5]. Mortality rates, length of stay, readmission rates, use of health-care services and the total cost of care are all substantially higher for patients with infections at surgical sites than for uninfected patients [6]. Reports from developing countries indicate an even higher incidence of infections at surgical sites than in developed countries, two studies showing rates of 12 and 26.7 % [7, 8]. Overall, infection control practices were considered to be poor as a result of deficient facilities, inadequate surgical instruments and lack of proper supplies

for wound care and personal hygiene. While records of surgical site infections are rare and few studies are available, rates of 40–70 % have been reported [9]. Lack of adequate decontamination, non-functioning sterilization equipment, reuse of limited sets of equipment and improperly reprocessed surgical drapes pose threats to hygiene [10]. The more pressing issue in healthcare systems in developing countries, however, is ensuring a constant supply of antibiotics for prophylaxis. Because of different hygiene and disinfection procedures and potentially different infectious disease profiles, the needs for specific types and classes of antibiotics might be different from that in developed countries. Research is needed to evaluate feasible supply channels and cost-effective application and distributions, taking into account the local culture and needs. The focus should be on establishing efficient, cost-effective, sustainable strategies for financing and implementation.

Venous Thromboembolism

Postoperative thromboembolic events are among the main causes of morbidity and mortality after surgery [11]. Patients undergoing certain types of surgery, such as orthopaedic and abdominal operations, are at highest risk [12, 13]; postoperative pulmonary embolism is the single most important cause of death after surgery such as hip replacement. The extent of this type of complication in resource-poor settings is unknown and might be difficult to assess because of lack of consensus on diagnosis and because a substantial number of incidents occur after discharge from the hospital and are therefore not recorded. Even though most countries might not have access to advanced surgical interventions such as joint replacement, the preventable nature of venous thromboembolism as a post-surgical complication underlines the importance of raising awareness of prophylactic measures.

Most hospitalized patients have one or more risk factors for venous thromboembolism, which are usually cumulative [14]. Without prophylaxis, the incidence of objectively confirmed, hospital acquired deep-vein thrombosis is 10–40 % among medical and general surgical patients and 40–60 % after major Orthopaedic surgery [15]. In many of these patient groups, venous thromboembolism is the commonest serious complication [16] and about 10 % of hospital deaths are attributed to pulmonary embolism [17], making it the commonest preventable cause of hospital death. Although better patient care might attenuate some of the risk factors for venous thromboembolism, hospitalized patients might now be at greater risk than those studied in the past because of more advanced age, a greater prevalence of cancer and intensive cancer therapy, more extensive surgical procedures and prolonged stays in critical care units.

While groups at high risk for venous thromboembolism can be identified, it is not possible to predict which patients in a given risk group will have a clinically important thromboembolic event. Furthermore, massive pulmonary embolism usually occurs without warning, and patients with this complication often cannot be resuscitated. Routine screening of patients for asymptomatic deep-vein thrombosis is

logistically difficult and is neither effective in preventing clinically important venous thromboembolism nor cost-effective [18, 19].

The objective of thromboprophylaxis is not only to prevent fatal pulmonary embolism but also to prevent symptomatic deep-vein thrombosis and pulmonary embolism, which are associated with considerable short- and long-term morbidity and use of resources [20].

Most cases of symptomatic venous thromboembolism associated with hospital admission occur after hospital discharge. When symptomatic hospital-acquired venous thromboembolism is suspected, extensive diagnostic testing is necessary. If the condition is confirmed, therapeutic anticoagulation therapy, with its potential for serious bleeding complications, must be initiated, resulting in a longer hospital stay or readmission. In resource-poor settings, early mobilization of patients and cheaper alternatives, such as intermittent pneumatic calf compression, might also be useful.

Infrastructure

In many developing countries, the quality of surgical care is often constrained by lack of trained staff, poor facilities, inadequate technology and limited supplies of drugs and other essential materials. Basic supplies for preoperative disinfection at standards considered acceptable in developed countries are often lacking, probably resulting in higher rates of preventable infection. In order to formulate sustainable, feasible approaches to these issues, it is important to understand the local infrastructure. The different levels of infrastructure in developing countries also affect use of newer surgical techniques with potentially better outcomes, lower complication rates and lower use of resources in the long run. Aside from the initial investment in equipment and training for these techniques, a new infrastructure for care support might be required for successful implementation. The resistance from local surgeons might be substantial barriers to safer patient treatment and care. Use of some techniques, however, might be feasible even in settings lacking the optimal infrastructure [21].

Adequate infrastructure includes not only equipment and facilities but also qualified medical personnel and specialists, who are lacking in vast regions of developing countries, representing a major cause of morbidity and mortality in those areas. The impossibility of being seen by a qualified surgeon in a timely manner almost surely contributes to death and disability across the world. Improved training and more surgeons are the solution but are costly.

Wrong-Site Surgery

Although rare, cases of surgery at the wrong site receive wide media coverage when they occur. Surgery at the wrong site can be defined as surgery on the wrong person, on the wrong organ or limb or at the wrong vertebral level [22]. The incidence of such errors has been difficult to assess. In a review of 10 years of data from medical

malpractice insurers, claims related to surgery at the wrong site comprised 1.8 % of all orthopaedic surgical claims. In an analysis of the causes of 126 cases by the Joint Commission on Accreditation of Healthcare Organizations in the United States, surgery on the wrong patient accounted for 13 % of cases, use of the wrong procedure for 11 % and surgery on the wrong body part or site for 76 % [23].

Possible risk factors include emergency operations, unusual time pressures to start or complete a procedure and the involvement of many surgeons or procedures at a single surgical visit. Surgery at the wrong site is unacceptable but rare, and serious injury attributable to it is even rarer. No single protocol will prevent all cases. An optimal reduction in the number of cases requires safe, simple, efficient, pragmatic measures, and various systematic approaches to prevention have been proposed [24]. Communication failure has been identified as a leading cause of operations at the wrong site [25]. Teamwork is central to a culture of effective communication in the operating room and is a surrogate marker for patient safety [26]. A number of team-based approaches have been proposed over the past few years, which could be used in tackling this and other sources of surgical errors [27]. Effective team communication can provide an additional safeguard against surgery at the wrong site. Even if multiple layers of checks and controls are in place in a coordinated health-care team, however, the ultimate responsibility for ensuring the correct site of operation in every case is that of the surgeon.

Unintentionally Retained Foreign Objects

Like surgery at the wrong site, leaving sponges or instruments inside patients is rare but can result in major injury [28] and often results in wide media coverage and lawsuits. The incidence of these errors has not been determined, but estimates suggest that they comprise one case out of every 1,000–1,500 intra-abdominal operations [29]. It is unclear why these incidents occur and how to prevent them. As is the case in wrong-site surgery, the lack of information on this error makes it difficult to assess the prevalence of this error in resource poor settings accurately. The possible catastrophic consequences and readily preventable nature of this error merit an evaluation. The established standards require that only sponges detectable on radiography be used for surgery; they should be counted once at the start and twice at the end of surgery. Instruments should be counted in all cases involving open cavities. If the count is incorrect, radiography or a manual search should be performed. Some reported incidents appear to have resulted from failure to adhere to these standards [30]. In most cases, however, foreign bodies go undetected, despite proper procedures. Even if counts are done properly, one-third of the time they are not documented because of the emergency nature of an operation or an unexpected change in procedure. It has been proposed that hospitals should monitor compliance with the existing standard of counting sponges and counting instruments in every operation involving an open cavity. Radiographic screening of high-risk patients before they leave the operating room should be considered even when the counts are documented as correct.

Communication Breakdown

Surgery at the wrong site or with the wrong procedure, retained sponges, unchecked blood transfusions, mismatched organ transplants and overlooked allergies are all potentially catastrophic events, which, in certain circumstances, can be prevented by improved communication and safer hospital systems. In the analysis of causes submitted to the Joint Commission on Accreditation of Healthcare Organizations in the United States, communication was identified as the commonest cause of sentinel events [26]. Creating a culture of safety is therefore a high priority for surgeons and hospitals. Several interventions to improve patient safety in surgery have been introduced, including additional checks to confirm procedures and new policies for operating rooms. In addition, many hospitals are investing in safety training programs for their staff. System factors have been identified that change the expected course of care and compromise patient safety. Some relate to communication and information flow, particularly in the context of handover of patients, competing tasks and a high workload. Like other complex systems, operating rooms rely on information: performance and safety depend on how information is forwarded between phases, physical locations and providers.

Team instability—for example, different scrub nurses—can result in inferior outcomes in terms of care, indicating the importance of human resource management to ensure good team work, where members know and understand each other well. Organizational and team policies for communication are also important [9]. A policy that disallows distraction in the operating room appears to be beneficial, probably because of the inevitable effects on communication.

Another systemic cause, which is often ignored by researchers, is resources. If there is more than minimal staffing—known in highly reliable organizations as 'redundancy'—people have time to communicate properly. Communication is not simply transmitting but also receiving, including confirmation that the transmission has been understood in the way intended. Team meetings can engender rapport and improve communication [31]. Personality may also be a factor: leaders should foster active communication among team members even when it results in constructive criticism of the leader.

Where Is the "Golden Bullet"?

Indeed, many complications and errors in surgery can be prevented. A study in the United States in 1999 showed that 54 % of surgical errors were preventable. The Harvard Medical Practice Study showed that adverse events in the operating room accounted for 48 % of all adverse events, occurred in about 2 % of all hospitalized patients and were preventable 74 % of the time [32]. The most effective strategy might be to plan interventions for the operations most likely to result in adverse events: the study of surgical adverse events in the United States in 1992 showed that 15 types of operations accounted for 58 % of surgical adverse events and for 37 % of all hospital adverse events [33]. Guidelines for the prevention of surgical site infections such as those established by the United States Centers for

Disease Control and Prevention might be useful. These issues should be addressed in conjunction with adequate perioperative antibiotic prophylaxis. The effectiveness of preoperative administration of antimicrobial agents to prevent infection has been established and confirmed [34]. Therapeutic levels of antibiotics must be present at the time of the incision to achieve effective prophylaxis, and the timing of administration is critical. Despite the existence of guidelines, however, adherence is frequently inadequate as evident in inadequate timing of antimicrobial administration, inappropriate choice of antibiotics and inadequate duration of prophylaxis [35]. Few studies have been reported on prophylaxis for infections at surgical sites in developing countries, and a quality improvement program to reduce the incidence of these infections in low- and middle-income countries has been proposed [36]. Although an estimated 40–60 % of infections at surgical sites could be prevented by administration of proper prophylactic antibiotics, over-use, under-use and misuse of antibiotics have been estimated to occur in 20–50 % of operations [6]. The timing of administration is critical, and both early and late administration is associated with increased rates of infection.

Improving adherence to evidence-based practice, as determined by national experts and representatives of major surgical professional organizations, can reduce the incidence of surgical infections. The guidelines include three main performance measures for antibiotic administration: selection of appropriate drugs, administration 60 min before incision to achieve therapeutic levels, and discontinuation within 24 h of surgery. In one study, anesthetists were identified as the practitioners most likely to administer antibiotics within 60 min of the incision. Changes were made accordingly in ordering, documentation and antibiotic preparation, and education sessions were held with all operating-room staff at meetings and grand-round presentations. The results of these changes were prominently displayed, and feedback was provided. The surgical site infection rate was significantly reduced [37]. For a lasting reduction in the rate of infections at surgical sites, the process of antibiotic prophylaxis administration must be analyzed, and all departments providing care must participate in implementing change [38]. Appropriate use and administration of prophylactic antibiotics can also be improved by standing orders, computerized reminders, defined location of antibiotic administration, proper documentation and identification of accountable providers [39]. A local response to restricted supplies of standard preparations from developed countries can be to use cheaper, locally available preparations that are equally effective. This would be a cost-effective option, and the funds saved could be used to improve preoperative antibiotic administration or hospital infrastructure [40].

Prophylaxis against venous thromboembolism remains the most appropriate strategy for reducing the sequelae described above, and primary thromboprophylaxis reduces the rates of deep-vein thrombosis, pulmonary embolism and fatal pulmonary embolism [41]. In a systematic review by the Agency for Healthcare Research and Quality in the United States, in which interventions for patient safety were ranked on the basis of the strength of the evidence [42], the safety practice with the highest rank was appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk. The recommendation was based on

overwhelming evidence that thromboprophylaxis reduces adverse patient outcomes, while, at the same time, decreasing overall costs [43]. Prevention of thromboembolic events with anticoagulants, early mobilization and mechanical devices (i.e. compression stockings) are also known to be effective. Many of these treatments, such as warfarin and compression devices, are known to be cost-effective in high-income countries. Whether they are readily available, cost-effective and likely to be used in middle- or low-income countries is not known. The limited publications available for review indicated that the rate of postoperative thromboembolic complications is higher in developing than in developed countries. As in developed countries, there appears to be no clear consensus about prevention strategies [44]. The same issues and barriers as those described above with regard to a sustainable supply of antibiotics apply to pharmaceutical thromboprophylaxis.

Modifiable risk factors for surgical and anesthesia errors should be identified in order to design targeted interventions to improve patient safety. The focus of the challenge is the WHO Safe Surgery Checklist. The checklist identifies three phases of an operation, each corresponding to a specific period in the normal flow of work: Before the induction of anesthesia ("sign in"), before the incision of the skin ("time out") and before the patient leaves the operating room ("sign out"). In each phase, a checklist coordinator must confirm that the surgery team has completed the listed tasks before it proceeds with the operation. The WHO safe surgical checklist was first employed in eight hospitals across the globe as a pilot study [5]. The final results of the study showed that the rate of major complications fell by 36 % after introduction of the checklist. Deaths fell 47 % by following a few critical steps; health care professionals can minimize the most common and avoidable risks endangering the lives and well being of surgical patients.

Advances in communication and information technology might extend specialist coverage to underserved rural regions, and telemedicine can provide local medical personnel with specialist advice on diagnosis, management and monitoring of treatment [45]. This concept could also be extended to include the participation of international experts.

The encouragement of open communication and constructive criticism has been used in aviation safety and could be applied to surgical teams as well. Miscommunication can also arise from the power relationships that exist in health care as a result of the traditionally different status of different professional groups. Effective teamwork is an asset in the operation theater. "Team briefing" before the surgery, wherein the team members including the surgeons, nurses, anesthesiologist are supposed to stop and take a moment simply to talk with one another before proceeding- about whether the patient has any risk factors or concerns that the team needs to be prepared for, how much blood loss is expected etc, can help the operating room be a safer place. Each one in the OR must not only perform their set of tasks but also help the team get the best possible results. Teamwork remains a critical component of success in surgery.

Reducing surgical errors and improving patient safety are essential for improving health care and should be included in research and implementation in this area.

Ideally, safe standards of care with a focus on better outcomes should be founded on the principles of evidence-based medicine. Implementation of and adherence to safety guidelines should be monitored, possibly with financial incentives.

Take-Home Message

- A systems approach to reducing surgical errors must take into account the highly complex, interdisciplinary, high-pressure environment of surgery.
- Adoption of a uniform institutional practice for antibiotic administration can decrease variations in performance, in both developed and developing countries.
- Prophylactic administration of antibiotics is not the only means for reducing infections at surgical sites: other means are antisepsis, optimal surgical technique, patient temperature maintenance, glucose control and the use of clippers instead of razors.
- Routine intra-operative radiographic screening in selected, high-risk categories of procedures has been proposed for detecting retained foreign bodies.
- One aim would be to modify the professional culture prevalent in surgery, addressing the leadership style of surgeons.
- A positive, non-punitive reporting culture could build the basis for assessing the incidence and scope of surgical errors and allow the design of further measures to decrease the rate.
- A systems approach should also emphasize team training and improved communication.
- Methods used in industry, aviation and the military could be applied to surgery, including human factor engineering, crew resource management and simulation training. Experience in improving reliability could be applied as well.
- Integrating patient safety and error reduction into the curriculum of medical education, postgraduate medical education, board certification, re-certification and continuing medical education could raise awareness about these issues and perhaps modify the practice of clinical care.
- Virtual consultations could improve patient safety by widespread dissemination and access to expert medical and surgical care.

References

1. Stahel PF, Sabel AL, Victoroff MS, Varnell J, Lembitz A, Boyle DJ, Clarke TJ, Smith WR, Mehler PS. Wrong-site and wrong-patient procedures in the universal protocol era: analysis of a prospective database of physician self-reported occurrences. Arch Surg. 2010;145:978–84.
2. Landrigan CP, Parry GJ, Bones CB. Temporal trends in rates of patient harm resulting from medical care. N Engl J Med. 2010;363:2124–34.
3. de Vries EN, Prins HA, Crolla RM, den Outer AJ, van Andel G, van Helden SH, Schlack WS, van Putten MA, Gouma DJ, Dijkgraaf MG, Smorenburg SM, Boermeester MA. SURPASS Collaborative Group: effect of a comprehensive surgical safety system on patient outcomes. N Engl J Med. 2010;363:1928–37.

4. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med. 2009;360:491–9.
5. Bratzler DW. Use of antimicrobial prophylaxis for major surgery: baseline results from the National Surgical Infection Prevention Project. Arch Surg. 2005;140:174–82.
6. Astagneau P. Morbidity and mortality associated with surgical site infections: results from the 1997–1999 INCISO surveillance. J Hosp Infect. 2001;48:267–74.
7. Hernandez K. Incidence of and risk factors for surgical-site infections in a Peruvian hospital. Infect Control Hosp Epidemiol. 2005;26:473–7.
8. Soleto L, et al. Incidence of surgical-site infections and the validity of the National Nosocomial Infections Surveillance System risk index in a general surgical ward in Santa Cruz, Bolivia. Infect Control Hosp Epidemiol. 2003;24:26–30.
9. Reggiori A. Randomized study of antibiotic prophylaxis for general and gynaecological surgery from a single centre in rural Africa. Br J Surg. 1996;83:356–9.
10. Fehr J. Risk factors for surgical site infection in a Tanzanian district hospital: a challenge for the traditional national nosocomial infection surveillance system index. Infect Control Hosp Epidemiol. 2006;27:1401–4.
11. Howlie C, Hughes H, Watts AC. Venous thromboembolism associated with hip and knee replacement over a ten-year period: a population based study. J Bone Joint Surg Br. 2005;87:1675–80.
12. Colwell Jr CW. Thromboprophylaxis in orthopedic surgery. Am J Orthop. 2006;Suppl:1–11.
13. Bergqvist D. Venous thromboembolism: a review of risk and prevention in colorectal surgery patients. Dis Colon Rectum. 2006;49:1620–8.
14. Kearon C, Salzman EW, Hirsh J. Epidemiology, pathogenesis, and natural history of venous thrombosis. In: Colman RW, editor. Hemostasis and thrombosis: basic principles and clinical practice. Philadelphia: JB Lippincott; 2001. p. 1153–77.
15. Anderson Jr FA. A population-based perspective of the hospital incidence and case fatality rates of deep vein thrombosis and pulmonary embolism. The Worcester DVT Study. Arch Int Med. 1991;151:933–8.
16. Fender D. Mortality and fatal pulmonary embolism after primary total hip replacement Results from a regional hip register. J Bone Joint Surg Br. 1997;79:896–9.
17. Lindblad B, Eriksson A, Bergqvist D. Autopsy-verified pulmonary embolism in a surgical department: analysis of the period from 1951 to 1988. Br J Surg. 1991;78:849–52.
18. Paiement GD, Wessinger SJ, Harris WH. Cost effectiveness of prophylaxis in total hip replacement. Am J Surg. 1991;161:519–24.
19. Meyer CS. Surveillance venous scans for deep venous thrombosis in multiple trauma patients. Ann Vasc Surg. 1995;9:109–14.
20. Sullivan SD. Measuring the outcomes and pharmacoeconomic consequences of venous thromboembolism prophylaxis in major orthopaedic surgery. Pharmacoeconomics. 2003;21:477–96.
21. Chauhan A. Day care laparoscopic cholecystectomy: a feasibility study in a public health service hospital in a developing country. World J Surg. 2006;30:1690–5.
22. Kwaan MR. Incidence, patterns, and prevention of wrong-site surgery. Arch Surg. 2006; 141:353–8.
23. Joint Commission on Accreditation of Healthcare Organizations. A follow-up review of wrong site surgery. Sentinel Event Alert. 2001;24:1–3.
24. Seiden SC, Barach P. Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events: are they preventable? Arch Surg. 2006;141:931–9.
25. Joint Commission on Accreditation of Healthcare Organizations. Sentinel events: evaluating cause and planning improvement. Oakbrook Terrace: Joint Commission on Accreditation of Healthcare Organizations; 1998.
26. Saufl NM. Universal protocol for preventing wrong site, wrong procedure, wrong person surgery. J Perianesth Nurs. 2004;19:348–51.
27. Healey A, Undre S, Vincent C, Healey AN. Developing observational measures of performance in surgical teams. Qual Saf Health Care. 2004;13 Suppl 1:i33–40.
28. Gonzalez-Ojeda A. Retained foreign bodies following intra-abdominal surgery. Hepatogastroenterology. 1999;46:808–12.

29. Hyslop JW, Maull KI. Natural history of the retained surgical sponge. South Med J. 1982;75: 657–60.
30. Kaiser CW. The retained surgical sponge. Ann Surg. 1996;224:79–84.
31. Firth-Cozens J. Why communication fails in the operating room. Qual Saf Health Care. 2004;13:327.
32. Brennan TA. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. N Engl J Med. 1991;324:370–6.
33. Gawande AA. The incidence and nature of surgical adverse events in Colorado and Utah in 1992. Surgery. 1999;126:66–75.
34. Classen DC. The timing of prophylactic administration of antibiotics and the risk of surgical wound infection. N Engl J Med. 1992;326:281–6.
35. Silver A. Timeliness and use of antibiotic prophylaxis in selected inpatient surgical procedures. Am J Surg. 1996;171:548–52.
36. Huskins W. Risk-adjusted infection rates in surgery: a model for outcome measurement in hospitals developing new quality improvement programmes. J Hosp Infect. 2000;44(1):43–52.
37. Kanter G, Connelly NR, Fitzgerald J. A system and process redesign to improve perioperative antibiotic administration. Anesth Analg. 2006;103:1517–21.
38. Hawn MT. Timely administration of prophylactic antibiotics for major surgical procedures. J Am Coll Surg. 2006;203:803–11.
39. St Jacques P. Improving timely surgical antibiotic prophylaxis redosing administration using computerized record prompts. Surg Infect (Larchmt). 2005;6:215–21.
40. Meier D. Prospective randomized comparison of two preoperative skin preparation techniques in a developing world country. World J Surg. 2001;25:441–3.
41. Collins R. Reduction in fatal pulmonary embolism and venous thrombosis by perioperative administration of subcutaneous heparin. Overview of results of randomized trials in general, orthopedic, and urologic surgery. N Engl J Med. 1988;318:1162–73.
42. Shojania KG. Making health care safer: a critical analysis of patient safety practices. Evidence report/technology assessment no. 43. Rockville: Agency for Healthcare Research and Quality; 2001.
43. Bick RL. Proficient and cost-effective approaches for the prevention and treatment of venous thrombosis and thromboembolism. Drugs. 2000;60:575–95.
44. Prasannan S, Chin L, Gul Y. Venous thromboembolic disease prophylaxis among general surgeons in Malaysia. Asian J Surg. 2005;28:125–30.
45. Ganapathy K. Telemedicine and neurosciences in developing countries. Surg Neurol. 2002; 58:388–94.

Recommended Further Reading

Weiser TG. An estimation of the global volume of surgery: a modeling strategy based on available data. Lancet. 2008;372:139–44.
Donabedian A. Evaluating the quality of medical care. Milbank Meml Fund Q. 1966;44: 166–206.
Gawande AA. Analysis of errors reported by surgeons at three teaching hospitals. Surgery. 2003;133:614–21.
Luft HS, Bunker JP, Enthoven AC. Should operations be regionalized? The empirical relation between surgical volume and mortality. N Engl J Med. 1979;301:1364–9.
Sosa JA. The importance of surgeon experience for clinical and economic outcomes from thyroidectomy. Ann Surg. 1998;228:320–30.
Keyes C. Every defect is a treasure. Int J Qual Health Care. 1997;9:391–2.
Taffinder NJ. Effect of sleep deprivation on surgeons' dexterity on laparoscopy simulator. Lancet. 1998;352:1191.
Leape LL. Error in medicine. JAMA. 1994;272:1851–7.
Lingard L. Communication failures in the operating room: an observational classification of recurrent types and effects. Qual Saf Health Care. 2004;13:330–4.

Part IV

Case Scenarios

Improving Operating Room Safety: A Success Story

31

Scott N. Hurlbert

Background

Memorial Health System is a community health care organization located in Colorado Springs, Colorado. It is comprised of 650 beds located across 2 campuses. There are 14 operating rooms located in the central campus and 6 operating rooms at the north campus. An ambulatory surgical center is also associated with the system and has 6 operating rooms. Approximately 18,000 surgeries are performed in the system in a single year.

A Journey for Patient Safety

Despite the implementation of standardized surgical safety checklists, ensuring patient safety remains a daily challenge in the operating room. This case study describes one community health system's efforts to improve operating room safety through a dedicated, leadership-driven approach.

Our journey towards improved operating room safety started in June 2005. At that time we applied for and obtained a $50,000 grant sponsored by the Association of Perioperative Registered Nurses (AORN) with funding provided by Kimberly-Clark to introduce human factors training in the operating room. AORN was responsible for approving and administering the grant. Human factors training is based on the Crew Resource Management (CRM) programs championed by the airline industry.

S.N. Hurlbert, MD
Department of Surgery, Memorial Health System, 1400 E. Boulder St., Colorado Springs, CO 80909, USA
e-mail: scott.hurlbert@uchealth.org

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_31,

In the 1970s the airline industry was plagued by multiple high profile accidents that were a direct result of a toxic culture in the cockpit. Many of the same attitudes that were present during these dark days of the airline industry are currently present in the operating rooms of today. Before CRM the flight team was often afraid to challenge the captain even in the face of critical errors. Today in most operating rooms the staff also find it hard to question decisions made by the surgeon even though the decision may lead to patient harm. The working environment in both of these industries are characterized by significant on-time pressures, high workloads, dependence on properly working equipment, a rigid hierarchy, and a potential for catastrophic results if errors occur. Effective communication is critical for safety in both industries. The goal of these programs was to reduce the errors that occur from well-intentioned, highly skilled professionals working in a stressful environment.

The money from the grant was used to subsidize human factors training for the OR staff and surgeons of our operating rooms. We used the company Safer Healthcare to provide the training. Throughout November and December of 2005 training sessions were held. Each of these training sessions lasted 4 h. Physicians and operating room staff members were trained together to emphasize the team concept. The training was mandatory for the operating room staff, but voluntary for the surgeons. Two-hundred perioperative staff and 60 physicians participated in the training. At the core of the human factors training was a preoperative briefing by the attending surgeon. The briefing was very similar to the checklists initially proposed by the World Health Organization (WHO) [1]. The preoperative briefing sets expectations as to how the conduct of the case will proceed. It informs the operating room staff as to what equipment will be needed and if any difficulties are expected. More importantly the preoperative briefing also opens the lines of communication and helps to break down the hierarchy of the operating room. Under conditions of great stress it is easy to lose situational awareness and become focused on only one aspect of the case. Often there are other people in the room who recognize that an error is being made, but are too afraid to speak up. The preoperative briefing should encourage anyone in the room to speak up if an error is being made. A postoperative debriefing was also encouraged to help critique the conduct of the case. We measured two outcomes.

The first outcome we looked at was if the preoperative briefing resulted in any change in operating room culture. We used a survey from the Agency for Health Care Research and Quality (AHRQ) to measure the change. The other outcome was whether or not operating room efficiency and miscommunication events were improved with a preoperative briefing. Essentially we stationed an observer in an operating room throughout the day. They kept track of the number of times the circulating nurse had to leave the room to get equipment that had not been planned for. They also looked at miscommunication events and how that impacted on the conduct of the case. Specifically questions were asked how these events affected the dynamics of the team, whether the events adversely affected the conduct of the case, whether the events impacted what equipment was available, and whether or not the patient was adversely affected by the events. We compared surgeons who did briefings with surgeons who did not do briefings.

Program Implementation

The initial human factors training was open to all of the surgeons who practiced at our hospital. The surgeons who participated in the initial training represented all of the major surgical fields. There was some concentration in general surgery, orthopedic surgery and vascular surgery just from the number of these physicians who practice these specialties at our hospital. Almost all of the surgeons were independent practitioners and not hospital employees. There were 60 surgeons who underwent the training.

At the beginning of the program there were two physicians who routinely did preoperative briefings. The human factors training resulted in another 20 physicians who routinely conducted the briefings. Most of the surgeons involved in the training saw the value in the briefing but didn't change their operative routine. The most common reason given by the surgeons as to why they didn't change was the perception that a briefing would slow down the progress of the case. Over the next 2 years the number of physicians remained relatively stable. The program remained completely voluntary on the part of the physicians. There were no other training classes provided. Instead we focused on peer to peer efforts to spread the message. The operating room staff was also encouraged to ask for briefings from the attending surgeons. Initially the major barrier to participation was that the physicians did not believe that doing a preoperative briefing would enhance their practice or patient care to any measurable amount. We also ran into some resistance from surgeons who felt that the whole human factors training was just another way for the hospital to try and control them.

By the beginning of 2008 it became evident that we needed to be more aggressive in our efforts to recruit doctors to do briefings. We invited Dr. Thoralf Sundt, a cardiothoracic surgeon at the Mayo Clinic to give a single presentation on how preoperative briefings have affected his practice. We also started a study in our operating room looking at miscommunication events and operating room efficiency. The results of this study are provided in Fig. 31.1. We found that there was a positive difference in the rooms that had a preoperative briefing. The briefings decreased the number of times the circulating nurse left the operating room. There was a rough correlation with the duration of the operation and the number of times the nurse had to leave the room. Patient issues were defined as any questions about the patient that should have been known ahead of time. For example if the patient was a diabetic did the anesthesiologist know this ahead of time. Team issues were defined as any miscommunication between the members of the operating room staff that resulted in a delay or adverse event. Equipment issues were defined as any time the appropriate instrument or device was not available at the time it was needed. A procedural event was any adverse event that affected the patient's care. This event did not necessarily need to be clinically significant. We did not specifically isolate how much time each issue cost the patient in terms of efficiency as this was extremely variable. Efficiency was measured indirectly as it was assumed that an operating room with fewer disruptions was more efficient. It is difficult to compare operating room times across different specialties and procedures. Since we had data on a local level we could show surgeons how a change in their behavior can positively affect the conduct of the operating room.

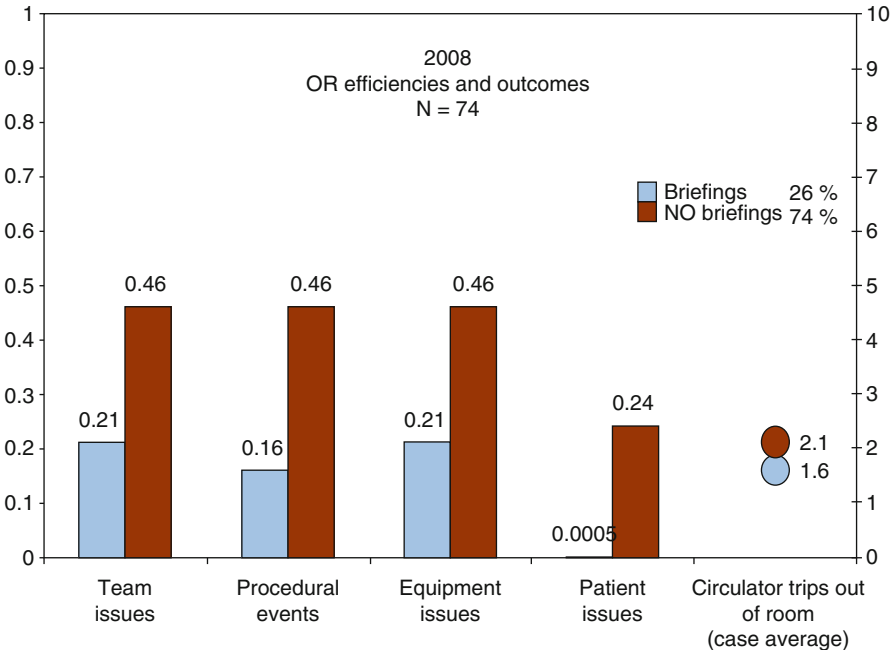


Fig. 31.1 Operating room efficiencies study. These are the results of our local operating room efficiency study. The *x* axis is the issues studied. The *y* axis is the frequency of the issues expressed as a factor of 1. The *light color* represents the efficiency of the operating rooms that performed a preoperative briefing and the *dark color* represents the operating room that did not have a preoperative briefing

In February of 2008 a retired pediatric surgeon was hired to help coach surgeons on how to do a briefing. This surgeon would circulate among the rooms observing cases. She interacted with surgeons on a one-to-one basis providing guidance and advice on the best way to do a briefing. Her presence also was a reminder to do a briefing. She was present for approximately 3 months.

The combination of a single conference devoted to preoperative briefings, a local study demonstrating increased OR efficiency, and hiring a physician coach resulted in an increase in the number of surgeons doing briefings. Once we could show surgeons how care is improved with the briefings, it removed some of the skepticism over the process. By the end of 2008 48 surgeons were doing preoperative briefings. Throughout this time we were also conducting periodic cultural surveys. Over time the use of briefings has made our operating rooms a less hostile environment although we still have significant work to do. Figure 31.2 documents the improvement in operating room culture from before training and preoperative briefings to the present time. Specifically we found that as more and more surgeons did briefings the operating room staff felt that there was more teamwork and openness in communications than previous. We also found that the staff felt that there was less of a punitive reaction to errors. Overall the staff thought that the operating room was less

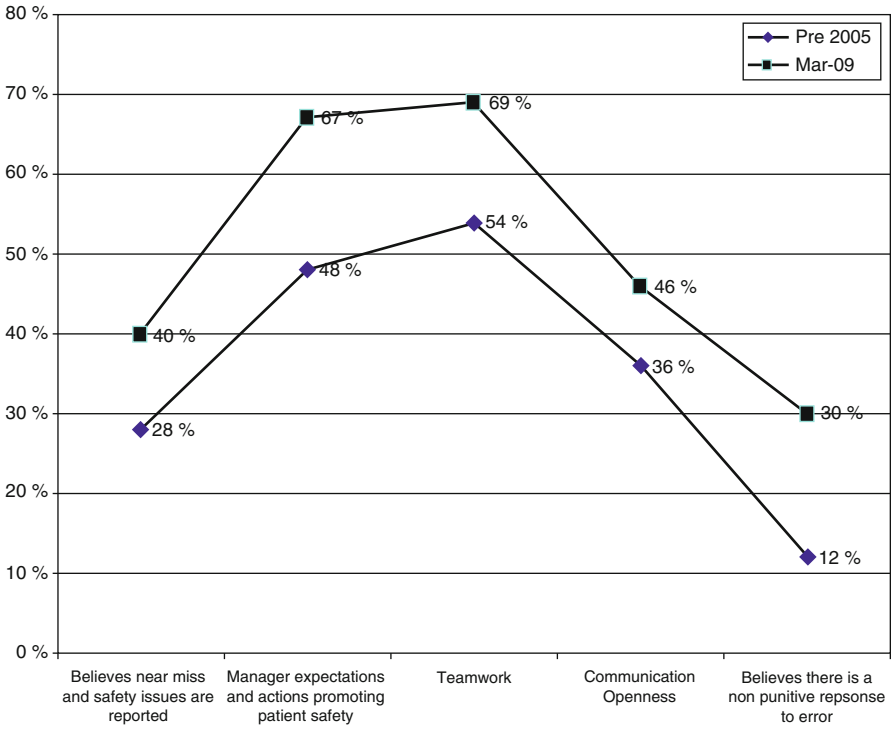


Fig. 31.2 Agency for Health Care Research and Quality (AHRQ) Survey results for operating room safety before and after human factors training. These are the Agency for Health Care Research and Quality Survey results of operating room culture before and after human factors training. The *x* axis is the specific questions asked. The *y* axis is the frequency of a positive answer expressed as a percentage. The *dark line with the triangular data points* represents the results of the survey done before human factors training. The *dark line with the square data points* represents our most recent results

hostile because of the briefings. In May 2009 54 % of the over 6,000 cases done at our system have had a preoperative briefing.

At the beginning of 2009 the World Health Organization endorsed the implementation of a surgical checklist to help improve the safety of operating room. Using the lessons that we learned from the preoperative briefing process we developed our own checklist and incorporated that into the briefing process. The development of the checklist was entirely physician led and took us about a year to fully implement. The checklist was initially rolled out to a few physicians who tried it and then provided feedback on how to make it better. We had to balance having a process that was quick and easy to use with one that had all the elements to insure patient safety. The WHO checklist was used as a template and then modified to our circumstances. For example we have had a problem with the core measure of perioperative beta blocker administration so we added that to our checklist. The surgeon briefing was also an integral part of our checklist. Once the initial feedback was obtained the form was modified and rolled out to all of the surgical sections for their

use and input. It was only after the entire physician staff got a chance to use the checklist that we came up with the final edition. We understood this process would take longer than forcing physicians to use the checklist but we felt it was important to have the physicians involved in the development of the checklist. In 2010 our Board of Trustees mandated that the checklist be used in all of the operating rooms.

Overcoming Challenges

Our struggle since the implementation of the checklist has been to maintain our success. Once the initial effort with human factors training and development of the checklist were over it was easy to lose focus as other issues arose. We also had a problem as staff and physicians left our system and new people came on. The culture of safety wasn't as ingrained as we would have liked. As a result we saw a decrease in the use of the checklist. In 2012 we rededicated ourselves to the briefing and the checklist. In order to mitigate the effects of staff turnover, we incorporated the lessons we learned into the orientation for all new employees to the operating room. Our system has a perioperative education program for staff who have no experience in the operating room. The checklist and briefing are part of the perioperative communications module for these students. For the experienced OR staff the checklist is part of the orientation done by our Perioperative Clinical Educator. The educator is in routine contact with the new employee throughout the orientation process to assess their experience with the checklist. A part of the program for both students and experienced staff is to give positive feedback to the surgeons when the checklist is performed properly. The idea is to empower the staff to insist on a culture of safety.

The physicians presented a different problem. Since most of our medical staff are independent, we don't have as much leverage as with employees. We had to develop a different process for physicians. All new surgeons meet with a member of physician leadership where we discuss the culture in the operating room and the Board of Trustees expectation that all cases include the use of the checklist. We also have a DVD of an actual case where the checklist is being used and have the physician sign off that they have viewed the DVD. Intraoperatively the circulating nurse is responsible for documenting if the checklist was used. Since we have implemented these changes, use of the checklist has improved to 98–100 % across all operating rooms. Our next challenge is to determine if the checklist is being used in a way that actually improves patient care.

A Success Story

Our journey to improving the safety of our operating rooms has been enlightening. The most important lesson that we learned is that initiatives for cultural change within the operating room have to be physician led. Without a core group of physician champions to lead the change the process becomes much more difficult. This is particularly true in a setting where a majority of the medical staff is independent. It

was also important to avoid the perception that a preoperative briefing was something imposed by the hospital administration. In the current environment of increasing regulation physicians are becoming very sensitive to anything that is perceived as restraining their practice of medicine. In spite of having physician leadership we still were met with resistance to this change. We had about a year where not much progress was made. Peer to peer interaction was not enough.

Formal training to include all members of the operating room team was also essential. Doctors, nurses, and other operating room staff overall trained as a combined group to help foster a team approach. This also helped to break down some of the hierarchy present in the operating room. The nurses and other operating room staff became more comfortable in questioning the physician if they felt that something was going wrong. This was further strengthened in the operating rooms that had preoperative briefings. Because of funding limitations, only one formal training session occurred. More training may have increased participation.

Persistent and frequent reinforcement of the concepts that we learn with the human factors training was also important. Our number of briefings increased once we had a physician mentor in the operating room to help facilitate the briefing process. The physician mentor was a constant presence in the operating room to remind surgeons to do the briefing as well as to help the surgeon figure out the most efficient use of the briefing. Finding a surgeon to fill this role can be difficult and our experience lasted only 3 months. Once we no longer had a physician mentor this role fell to the clinical staff. While not as effective as a physician we found that having someone give persistent positive reinforcement of a culture of safety is key.

Besides formal training sessions, periodic guest speakers also keep the concepts fresh in everybody's mind and reinforce the importance of doing the briefings. These also allow physicians to see how outside facilities manage the briefings. We only had one outside speaker come and talk to us during the program. In the future having speakers present on a quarterly basis would be extremely helpful.

Finally having our own data to show physicians the actual benefits in safety and efficiency was crucial. These data were able to show the 'real world' affects of preoperative briefings. A common complaint that we hear from surgeons is that data obtained at other institutions are not valid for our own because of regional variation. Having a study done on the premises that shows a positive correlation with the preoperative briefing is very powerful in refuting this concern.

The program started out as voluntary. There are both strengths and weaknesses to this. The major downside to having a voluntary process is that cultural change is very slow. The fastest way to achieve 100 % compliance is to mandate it throughout the entire operating room. This can engender a considerable amount of resentment from the medical staff. Passive and active resistance would be significant. We felt that imposing a set of guidelines on surgeons would actually hamper us from affecting any meaningful cultural change. The fact that the preoperative briefing was voluntary allowed the surgeon to make the process their own. While overall acceptance was slower we believed that adherence to the principles behind the briefing would be more robust if every surgeon claimed ownership. Once we shifted to mandatory use of the checklist our challenge was to continue this sense of physician

ownership. Having strong physician leadership has been crucial. We have a core group of physicians doing the checklist well who serve as role models for other surgeons. Positive feedback from the clinical staff has also been beneficial.

We still have a considerable way to go on our journey to improve operating room safety. The work we have done has laid a good foundation for our further efforts. We will use the lessons learned from this project to continue to grow our culture of safety. Fortunately others have also embarked on this journey and we can use their examples to help guide us [2–14].

Take-Home Message

Operating room safety has a significant influence on patient care. We found that we needed multiple approaches over time to advance a culture of patient safety. Ultimately the best process occurs when physicians and clinical staff take ownership of the cultural change. We recommend that whatever approach systems take to implementing a culture of safety in the operating room that physicians and clinical staff are intimately involved in the process. The other point is to not give up. The ultimate goal of improved patient safety in the operating room is worth all the effort.

References

1. World Alliance for Patient Safety. WHO guidelines for safe surgery. Geneva: World Health Organization; 2009.
2. Awad S, Fagan S, Bellows C, Albo D, Green-Rashad B, De La Garza M, Berger D. Bridging the communication gap in the operating room with medical team training. Am J Surg. 2005;190:770–4.
3. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AHS, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MCM, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med. 2009;360:491–9.
4. Henrickson SE, Wadhera RK, ElBardissi AW, Wiegmann DA, Sundt TM. Development and pilot evaluation of a preoperative briefing protocol for cardiovascular surgery. J Am Coll Surg. 2009;208:1115–23.
5. Kao LS, Thomas EJ. Navigating towards improved surgical safety using aviation-based strategies. J Surg Res. 2008;145:327–35.
6. Lingard L, Espin S, Rubin B, Whyte S, Colmenares M, Baker GR, Doran D, Grober E, Orser B, Bohnen J, Reznick R. Getting teams to talk: development and pilot implementation of a checklist to promote interprofessional communication in the OR. Qual Saf Health Care. 2005;14:340–6.
7. Lingard L, Espin S, Whyte S, Regehr G, Baker GR, Reznick R, Bohnen J, Orser B, Doran D, Grober E. Communication failures in the operating room: an observational classification of recurrent types and effects. Qual Saf Health Care. 2004;13:330–4.
8. Lingard L, Regehr G, Orser B, Reznick R, Baker GR, Doran D, Espin S, Bohnen J, Whyte S. Evaluation of a preoperative checklist and team briefing among surgeons, nurses, and anesthesiologists to reduce failures in communication. Arch Surg. 2008;143:12–8.
9. Makary MA, Holzmueller CG, Thompson D, Rowen L, Heitmiller ES, Maley WR, Black JH, Stegner K, Freischlag JA, Ulatowski JA, Pronovost PJ. Operating room briefings: working on the same page. Jt Comm J Qual Patient Saf. 2006;32:351–5.

10. Makary MA, Mukherjee A, Sexton JB, Syin D, Goodrich E, Hartmann E, Rowen L, Behrens DC, Marohn M, Pronovost PJ. Operating room briefings and wrong-site surgery. J Am Coll Surg. 2007;204:236–43.
11. Makary MA, Sexton JB, Freischlag JA, Holzmueller CG, Millman EA, Rowen L, Pronovost PJ. Operating room teamwork among physicians and nurses: teamwork in the eye of the beholder. J Am Coll Surg. 2006;202:746–52.
12. Sexton JB, Makary MA, Tersigni AR, Pryor D, Hendrich A, Thomas EJ, Holzmueller CG, Knight AP, Wu Y, Pronovost PJ. Teamwork in the operating room: frontline perspectives among hospitals and operating room personnel. Anesthesiology. 2006;105:877–84.
13. Soar J, Peyton J, Leonard M, Pullyblank AM. Surgical safety checklists. BMJ. 2009;338:b220.
14. Undre S, Healey A, Darzi A, Vincent C. Observational assessment of surgical teamwork: a feasibility study. World J Surg. 2006;30:1774–83.

Management of Unanticipated Outcomes: A Case Scenario

32

Jeffrey L. Varnell

Outline of the Problem

As providers we strive very hard to assure the best outcomes for our patients. Despite our best efforts, however, occasionally our patients may suffer harm through an unanticipated outcome. At that point it is part of our duty to our patients to work with them to mitigate the effects of that outcome and help them on the road to the best physical, emotional, and financial recovery possible. We will discuss in this chapter, with the use of an illustrative case, a template that can be used to address the needs of our patients, their families, and ourselves at that critical time, and also to make use of the opportunity to minimize the risk of a similar event occurring again. We will look at the importance of reporting untoward events (even those at do not cause harm), going through the disclosure process with patients and their families, and working to return them to health. We will also review how to analyze and address the nature of the medical error if present, assure authority to actualize the process changes identified, and reconcile the affected providers with what happened. Note that these discussions should be taken as guidelines only, and that as each situation is unique (given patient, family, provider, and clinical variables), no single approach is ideal. We have found, however, that it has been helpful to have a paradigm by which to have an intentioned approach, so that each party can feel that the most was made out of each unfortunate situation.

J.L. Varnell, MD, FACS
Department of Patient Safety and Risk Management,
COPIC Insurance Cos, Denver, CO, USA

Department of Surgery,
University of Colorado School of Medicine,
Denver, CO, USA
e-mail: jvarnell@copic.com

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_32, © Springer-Verlag London 2014

Case Scenario

John Doe and his wife have been managing their ranch together for 40 years. Their sons have moved to the city, and they hope to sell within 5 or so years to retire. One afternoon while on the tractor John notices the gradual onset of right upper quadrant pain. He completes his chores and takes ibuprofen that night to control the pain. By the next day, however, the pain has increased to the point that he feels he needs to go to the emergency room. His wife Verna drives him there where he is checked in and seen by the ER physician. After an IV is started and pain medicine is given, blood work is ordered and an ultrasound performed, which reveals acute cholecystitis and cholelithiasis. He is admitted to the hospital after the surgeon is notified. John has a significant past medical history: he has hypertension and a history of mitral valve replacement for which he takes warfarin, as well as diabetes controlled with oral hypoglycemic agents. The surgeon, Dr. Brown, sees John that evening and recommends laparoscopic cholecystectomy the next morning; he agrees and the surgery is scheduled for 7:30 the next day. Informed consent is obtained and antibiotics are started and pain medicine continued. The following day the patient was taken to the preoperative holding area where he met the anesthesiologist and the circulating nurse; after review of the chart the patient was taken to the operating room. Laparoscopic cholecystectomy was begun, however soon after the trocars were placed it became apparent that the patient was bleeding heavily. Dr. Brown made the decision to convert to an open approach, after which the bleeding was successfully controlled and the gall bladder was removed. The patient was returned to the recovery room, and as Dr. Brown was writing his postoperative orders he was handed a laboratory report which revealed that the preoperative INR was above normal (3.2), as the patient was on warfarin (Box 32.1).

Box 32.1. Open Questions

Several questions are raised:

1. What should Dr. Brown do next? In addition to telling Mrs. Doe of the need for open surgery, should he tell her about the lab report which was not addressed before surgery? Should he take personal responsibility for the error or blame the system?
2. Should anyone else accompany him for this discussion? What would their role be?
3. Who else should be informed about this event? What is expected to happen as a result?

Recognition and Reporting of Medical Errors

Although the patient did require open surgery, he recovered well and this could be considered a ‘near-miss’ event. Unfortunately these near-miss opportunities are often overlooked due to lack of error recognition, either because providers are used to “workarounds” or relief that there is no significant patient harm. It is crucial that

the event be acknowledged as a latent threat to other patients and then reported, so that appropriate corrective actions can be taken. There is now good evidence that incidents are under-reported, and opportunities to avoid patient harm are accordingly lost [1]. Also, when patients are not informed about these events we lose credibility should anything else go awry later on, and we miss an opportunity to show patients that we will be honest and transparent about their health care. Patients have told us in safety forums that they expect to be informed when their health is affected or could have been affected by an error, and that an appropriate apology is anticipated [2, 3]. Given the nature of this miscue, wherein several providers had the opportunity to perceive the risk and take corrective action, it would be appropriate for the anesthesiologist and an operating room representative to attend the conversation with Velma and the surgeon. This should not be delayed past when the patient is stabilized in the recovery room; after this risk management can be notified so investigation can begin as to the nature of the problem and how it can be corrected. Now let's move on to what really happened in this de-identified case.

In fact, when the surgery began, Mr. Doe's bleeding was excessive. After laparotomy was performed, the bleeding continued; despite all efforts to get it under control, and despite transfusions and fresh frozen plasma, the patient exsanguinated on the table. At this point the INR value of 4.4 is returned from the lab. Obviously now the providers have a very different scenario to address. This will be emotionally charged for all involved, and planning ahead of time will hopefully have allowed everyone to prepare for what will be a very difficult series of actions. One tendency might be to rush into the waiting area to begin the disclosure conversation immediately; this would not serve Mrs. Doe or the medical team well. While extensive delay is also not appropriate, taking a few minutes to review the situation can be very helpful. It should be decided who should be involved in this initial conversation, and how much can be divulged at this point in the event analysis. A brief role-playing involving the anesthesiologist and head OR nurse or risk manager (presumably, unless others have been designated) of the anticipated conversation would be helpful; this can help ensure that all are on board as to how to proceed. The intent here is not to decide how to 'spin' the presentation, but to ensure what is known for sure and what remains to be determined, as well as which roles each participant will play.

Disclosure and Reconciliation with Patient and Family

What do patients and/or their families want and need to hear in these circumstances? First and foremost they want to hear expressions of sincere empathy, with appropriate demonstrations of apology. A determination needs to be made as to whether responsibility for the error can yet be assigned; if such is delayed, or taken prematurely, trust will be eroded between the team and the family. For example, if a surgeon operates on the wrong side, he needs to take personal responsibility: "*I am sorry that I. . . .*" On the other hand, if the root cause of the error is still unclear, it may be more appropriate at the time to say "*I am sorry that you have had to have had to go through this. . . .*" Later on it may be necessary to be more explicit if the error can be attributed to a specific agent, whether personal or institutional. Many

states have enacted apology laws which allow in varying degrees expressions of empathy, regret, and even acceptance of responsibility; these expressions cannot be used subsequently in any litigation, though the facts discussed in the apology process can be asserted. Even without this legislative support, however, empathizing with the patient's plight is the right approach. Secondly, patients and families desire an affirmation of honesty and transparency. "*I would like to be completely open and honest with you; we do not know everything that happened as yet, but we will keep you apprised as we continue our investigation*." We may assume that our statements will be seen as transparent, but commitments to those principles on an ongoing basis help the aggrieved parties move forward. Thirdly, a commitment to perform a thorough investigation and institute changes to prevent recurrence demonstrate to families that we are committed to quality medical care, and reassure them that their loved ones did not suffer in vain. Finally, we should personally commit to continue to be involved in the process, which shows that our concerns are authentic. It should be emphasized that disclosure is a process, not a single event, so future communication is to be expected. It is reassuring and relieving to families to arrange for the next meeting at this point, so they do not have to worry about missing critical phone calls or catching us at random. These conversations require our best communication techniques and non-verbal skills, such as sitting at eye level, using open body language, listening patiently, and turning off communication devices. It can be acknowledged that emotions will be high, and ours may not match those of the patient or family. We should give the family room to process those feelings before moving on to what we will be doing next, which is our natural tendency. We may also need to repeat key pieces of information, and give the families the opportunity to ask any questions. Even if patients have passed on, it is reassuring to other family members to have subsequent contact with provider; ongoing expressions of sympathy and further insights as to the error analysis are appropriate days and weeks later [2]. Ultimately it may be reasonable offer the patient or family compensation under the auspices of an existing disclosure-and-offer, or disclosure-and-reimbursement, program, to address the financial burdens which accompany the physical and emotional losses that errors can bring [4–6]. This can be accomplished without increasing, in fact likely decreasing, the risk of subsequent litigation.

Having begun the disclosure process, what is the next step that needs to be taken? If the institution has not been advised yet, it should be at this point. Certainly whenever a death or serious adverse outcome occurs, a sentinel event analysis will ensue. However we should not restrict reporting of unexpected outcomes to cases of severe patient harm; as noted above the opportunity to prevent harm arises from recognizing near misses and latent threats and acting proactively. Discussions with residents and attending reveals that many have never reported an adverse event in their careers, despite their knowledge that errors occur to patients as many as one per day in the hospital, and many more if they are in the ICU [3]. What are the barriers to effective reporting? Firstly, to many it is viewed as shameful or punitive; no one wants to draw attention to an error, especially if it may result in loss of professional reputation or job security. Secondly, usually it is a tedious and obscure process, taking many minutes out of a busy day. Thirdly, any feedback on the results of the report is usually absent;

the report seems to go into a "black box" with no reward for the effort that went into identifying and reporting the threat to patient safety. Finally, since so little reporting does go on there is no modeling of that behavior and the trend continues with each wave of new practitioners. From a legal perspective this delay in reporting leads to a rupture of communication with patients and their families, with development of distrust and suspicion; often they will seek legal recourse and establish an adversarial relationship before we can work proactively with them to address their concerns. These barriers to reporting can be overcome by creating a culture that celebrates the identification of threats to patient safety, by developing a system that simplifies the process and ensures feedback to everyone as to the results of the investigations, and by encouraging medical staff leaders to model the ideal of frequent reporting [7, 8].

What Went Wrong? A Root Cause Analysis

Once the threat is recognized, the analysis must be thorough and the remedies persistent. As in the case presented above, the causes are usually multifactorial and involve several providers. We must resist the temptation to blame individuals and instead look for systemic factors that could put anyone at risk. Several individuals had the opportunity to check the INR for this patient, yet there was no system in place to ensure that it would be seen. One system that has recently been instituted is the use of preoperative briefings, wherein the surgeon, the anesthesiologist, and the OR nurse meet prior to the surgery to review the patient's case. The current medication list, laboratory values, specific surgical needs, and surgical plan can be reviewed so that everyone is prepared. This process has been shown in multiple studies to reduce mortality and morbidity in a variety of settings [9]. It has also been shown, however, that this behavior has been implemented with varying degrees of commitment across different institutions. This brings us to the next important step in the management of adverse outcomes: ensuring that the opportunities identified by the event analysis actually are acted upon. Too often we have seen that potential changes identified as the result of an event analysis are not acted on, or are gradually abandoned. It is critical that processes are put into place to ensure that systems are still working and effective communication is still occurring. This may necessitate direct observation of behaviors that make these measures effective; chart review is often not useful in detecting compliance with known safe behaviors. Here strong leaders are needed to model effective actions and hold peers accountable for enacting those measures which have been shown to reduce errors and improve teamwork. Thus system analysis is an important aspect of evaluating untoward events. It should be recognized that systems will fail if their effectiveness is not continually evaluated, and if each participant is not accountable for his role in the system. It has also recently been recognized that effective communication plays an important role in avoiding patient harm; as many as 70 % of sentinel events may primarily derive from failures in communication. In the surgical arena this would include not only peer-to-peer interactions but also communication with other providers and with patients and family members. Surgeons substantially increase the risk of errors in the operating suite if all members of the surgical do not feel comfortable and

empowered in speaking up. This also applies in offices and wards, and can be readily remedied with specific invitations to participate and actions that demonstrate that their input is indeed valued. Specific communication techniques, such as SBAR, can facilitate these exchanges in critical situations, as will team training involving all members of the team [10]. We can also recognize the risks associated with personal conditions that may affect our situational awareness, such as fatigue, excessive workload, hostile environments (which we can decide whether to create or ameliorate), or individual stressors. Finally, critical documentation of information is important not only for defense of appropriate care in case of litigation but also for continuity of care over time. This is all part of the continuous quality improvement cycle which allows for personal and institutional error reduction, and the personal satisfaction which results from advocating for our patients (Box 32.2).

Box 32.2. Elements to Evaluate Surgical Complications

1. Informed consent process
2. Appropriate Indications
3. Preoperative measures taken
4. Technical performance
5. Timely recognition and rescue

Care for the Caregiver

Lastly, the effects of these events on the providers should be given equal weight. As professionals we often underestimate the toll that is taken on our emotional and cognitive states in dealing with these often tragic outcomes. "Care for the Caregiver," in various forms, should be given direct attention in an intentional manner, and carried out throughout the process of resolving these occurrences [11]. Several programs have been successfully promulgated, and have in common the idea of reaching out to the affected practitioner in a proactive manner, and not waiting until they feel the need to ask for assistance. This can be accomplished by peers or trained counselors (or ideally, trained peers) in a non-confrontative manner. Often the tendencies we have learned in our training to react to these situations must be counteracted. For example, it is not helpful to work harder to avoid errors, nor to self-medicate if we are not able to sleep, nor to withdraw from colleagues or friends. What is important is to put more importance on self-care, such as scheduling time alone, taking actual vacations, and continuing family and friendly relationships. Continue or resume your workout schedule, and invest in community and faith-based activities. See your personal physician, and work with her to maximize your health. This may be an opportunity to re-examine priorities, and to learn to say no to some of the time-consuming commitments. Our mutual goal is for the provider to continue to practice in a manner that is both safe and fulfilling, and to continue to experience the rewards of a medical practice [11].

Take-Home Message

In summary, though adverse outcomes from medical care can be devastating to patients, families, and providers alike, they can be seen as opportunities to improve overall patient care, to re-affirm our fulfillment from our chosen profession, and to help our patients deal with the consequences of disease. A principled and institutional approach offers the best chance for successful management of these unfortunate circumstances, and we owe it to our patients and ourselves to institute these processes proactively (Box 32.3).

Box 32.3. Guidelines for the Management of Unanticipated Outcomes

1. Recognition of Threat.
2. Disclosure to patient/family.
3. Reporting to team/facility.
4. Analysis of event.
5. Corrective steps taken.
6. Care for the caregiver.

References

1. Levinson DR. Hospital incident reporting systems do not capture most patient harm. Office of Inspector General; 2012.
2. Gallagher TH, Denham CR, Leape LL, Amori G, Levinson W. Disclosing unanticipated outcomes to patients: the art and practice. J Patient Saf. 2007;3(3):158–65.
3. Boyle DB, O'Connell D, Platt FW, Albert RK. Disclosing errors and adverse events in the intensive care unit. Crit Care Med. 2006;34(5):1–5.
4. Boothman R, Hoyler MM. The University of Michigan's early disclosure and offer program. Bull Am Coll Surg. 2013;98:21–5.
5. Studdert DM, Mello MM, Gawande AA, Brennan TA, Wang YC. Disclosure of medical injury to patients: an improbable risk management strategy. Health Aff. 2007;26(1):215–26.
6. Murtagh L, Gallagher TH, Andrew P, Mello MM. Disclosure-and-resolution programs that include generous compensation may prompt a complex patient response. Health Aff. 2012; 31(12):2681–8.
7. Bilimoria KY, Kmiecik TE. Development of an online morbidity, mortality, and near-miss reporting system to identify patterns of adverse events in surgical patients. Arch Surg. 2007; 144(4):305–11.
8. Schuerer DJE, Nast PA. A new safety event reporting system improves physician reporting in the surgical intensive care unit. J Am Coll Surg. 2006;202(6):881–7.
9. Haynes AB, Weiser TJ, Berry WR, Lipsitz SR, Breizat AS, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry FC, Moorthy K, Reznick RK, Taylor B, Gawande AA. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med. 2009;360:491–9.
10. Armour FR, Bramble JD, McQuillan R. Team training can improve operating room performance. Surgery. 2011;150(4):771–8.
11. White AA, Waterman AD, McCotter P, Boyle DJ, Gallagher TH. Supporting Health Care workers after medical error; considerations for health care leaders. J Clin Outcomes Manage. 2008;15(5):240–5.

The Preventable Death of Michael Skolnik: An Imperative for Shared Decision-Making

33

Patty J. Skolnik, David M. Skolnik, and Nathan Butler

Outline of the Problem

This case study describes the 'nightmarish experience' of a young family related to inappropriate and potentially unneeded surgical care which resulted in the horrendous suffering and the unnecessary death of Michael Skolnik, their only son.

The root cause analysis of contributing factors leading to Michael Skolnik's death include poor communication, lack of experience, improper monitoring, negligent medical care, and absence of a formal 'shared decision-making process' with the patient and the patient's family. Most importantly, from the beginning, there was an apparent lack of open, honest communication among the healthcare team with all negative implications and potential risks excluded from every conversation between the patient's family and the surgeon in charge. By trying to understand the detailed plan of care, Michael's mother was labeled as a 'problem' on his chart. Informed consent was obtained when Michael was under heavy sedation, and the family was not present and involved as part of a 'shared decision-making' process. When asked about indication, risks and benefits of the surgical procedure, the neurosurgeon misrepresented his abilities and

P.J. Skolnik, BASW
Citizens for Patient Safety, 801 Yosemite St., Denver, CO 80230, USA

D.M. Skolnik (✉)
Citizens for Patient Safety, 5226 E. Weaver Ave, Centennial, CO 80121, USA
e-mail: dskolnik1@msn.com

N. Butler
West Virginia School of Osteopathic Medicine,
200 North Lee Street, Lewisburg, WV 24901, USA

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_33,

grossly overstated his experience. The surgeon claimed that the neurosurgical procedure would be like *"a walk in the park."* The opinion of the family physician who knew Michael well, and was extremely knowledgeable about his history, was arrogantly dismissed and minimized. Discussion of nonsurgical options or alternative treatment methods were blatantly dismissed by the surgeon, and according requests and inquiries were ignored during the preoperative decision-making process.

Case Report

On September 17, 2001, Michael Skolnik was taken to the emergency room after a losing consciousness at home. Michael was 22 years old at the time. He was on medication with Bupropion (Wellbutrin™) for smoking cessation, and had a history of a previous collapse without further consequences. A craniocerebral CT scan was obtained and interpreted by the radiologist as an incidental *"(. . .) tiny round hyperdensity which may represent a very small colloid cyst, which does not appear to create any ventricular obstruction at this time. Recommend further evaluation with MRI."*

The next day, a craniocerebral MRI was obtained and interpreted with similar findings: *"Again noted and without change is a small 4.2 mm area, most likely represents a colloid cyst, which is causing no ventricular obstruction."*

On September 19, 2001, the consulting neurosurgeon explained that the cyst was apparently causing elevated pressure in Michael's brain, and he recommended to insert a ventricular drain immediately, followed by further 'brain surgery.'

The neurosurgeon's statement to Michael's parents was: *"I need to operate in the next 48 hours, or Michael will die."* The neurosurgical procedure was scheduled for 3 h, and ended up lasting 6 1/2 h due to serious intraoperative complications.

As Michael was transferred to a rehabilitation hospital after 5 months, it was revealed to his parents that there had been an intraoperative *"heavy manipulation of the brain"* during the initial procedure, which culminated in a partial frontal lobotomy and part of the hypothalamus being removed (Box 33.1).

Box 33.1. Michael Skolnik's Postoperative Complications During the First 5 Months

Michael's estimated hospital length of stay of less than 1 week for a 'minor cyst extraction' turned into 5 months of intensive care unit stay due to multiple life-threatening complications, including intracerebral hemorrhage, recurring brain abscesses, hydrocephalus, pulmonary embolism, recurring MRSA infection and sepsis, intracerebral yeast infection, and respiratory arrest. None of these potential risks and complications were discussed with the patient and family prior to surgery.

The long-term impairment of Michael's condition at the time of transfer to rehabilitation consisted of:

- Hemi paralysis
- 50 % blindness and left eye neglect
- Severe seizure disorder
- Thalamic chronic pain syndrome
- Loss of short-term memory
- Severe immune system compromise
- Hallucination and psychosis

Neither the intra-/ and postoperative complications, nor Michael's expected chronic impairment were disclosed to the family during the 5 months hospital stay. Instead, Michael's parents learned these shocking details from the receiving rehabilitation center.

Michael spent the subsequent 22 months in rehabilitation hospitals, interspersed with readmissions to multiple centers, including escalation of care in stepdown units and intensive care units. He was stable for discharge home for a very short period of time, and subsequently went into multiple organ failure. After this episode, Michael would never walk, talk, laugh, eat, or hug and embrace his parents again. Michael was finally brought home to the family house, which had been transformed into a 'home intensive care unit.' Michael's parents had installed a medical bed, Gulman lifts, stairway chairs, shower chair, bowel program, wheelchairs, ramps, and purchased a medically equipped wheelchair-accessible van for transport.

At the same time, Patty and David Skolnik continued pleading and fighting with insurance companies for coverage and support of quality home health care, in light of the exploding costs associated with Michael's extensive care requirements. Michael's continuous care included a tracheostomy (tube in the windpipe), a gastrostomy (a feeding tube inserted in the stomach through a hole in the skin) and a suprapubic catheter (a tube inserted in the bladder through a hole in the skin). Aside from daily injections, a total of 27 medications had to be ground up every day by Michael's mother to go into his feeding tube. Michael suffered from excruciating neuropathic pain that could only be soothed by continuous sedation. With the cognitive ability reduced to the level of a third grader, Michael's suffering was cruel and immeasurable. He was able to spastically raise his right hand to his head and imitate pulling the trigger of a gun to imply his desire to die, a restricted action which Michael repeated throughout each day during the last 6 months of his life. Michael Skolnik's final agony was initiated one night when he had an acute grand-mal seizure which went unobserved by his 'night sitter'—a Licensed Practical Nurse (LPN)—who had fallen asleep at the bedside. Michael aspirated and developed a pneumonia, requiring a re-hospitalization to an intensive care unit.

Over long agonizing hours, Michael shared his wish to die comfortably by squeezing his parents' hands and letting them know that he was ready to go. Patty and David Skolnik witnessed what no parent should ever have to witness—morphine flowing into their only child's veins, drop by drop. With Michael's eyes opened, he mouthed the words "I love you," and drew his last breath.

What Went Wrong? A Root Cause Analysis

Discussion—The Parents' Perspective

Figures 33.1, 33.2, 33.3, and 33.4 depict images of Michael from our family album. At the age of 22, our only son Michael was a vet tech and an Emergency Medical Technician (EMT) who was embarking on an educational track to become a pediatric nurse. Why did Michael want to become a nurse? Probably for the same reasons that have brought you into medicine, to help people. He believed in the healing power and noble practice of medicine and was ready to further dedicate his life to serving others. This came to an abrupt halt the day Michael was admitted to the hospital after collapsing at home.

"I need to operate in the next 48 hours or Michael will die." The weight of those words. The life-altering power behind them coupled with the trust and faith we had in the surgeon made deciding to act easy. We could not have seen it at the time, but those words irrevocably changed our family's path. Those words set events in motion that resulted in horrible suffering for our only son Michael. Those words left us questioning absolutely everything about what is right and ethical in medicine. Since Michael's passing, we have thought long and hard about how we allowed words like these to remove our choices and our voices. And you are reading this now in the hopes that understanding can enable every patient, family member and physician to know their role in preventing the unthinkable.

This 'worst-case' scenario turned into the longest day of Michael's life, lasting 32 months (Figs. 33.5 and 33.6). What set the stage for the catastrophic events that ultimately took our son's life was that we believed those words. We believed this neurosurgeon, because he was the neurosurgeon. When he told us that there was a colloid cyst in Michael's brain and that it was life threatening, we believed him. When he told us it was a "*walk in the park*," we believed him. When he told us he had performed this procedure many times, we believed him (Table 33.1).

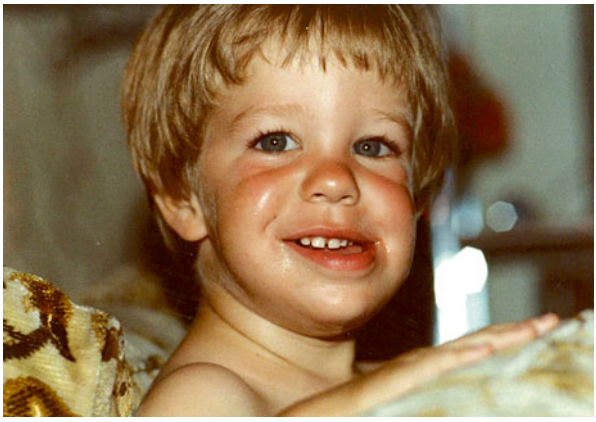


Fig. 33.1 Michael 20 months old, always smiling

Fig. 33.2 Michael at age 2 ½ years, being his 'silly self'

Fig. 33.3 Michael 11 years old, with his younger cousin and first 'crush' on a visiting young lady from Russia

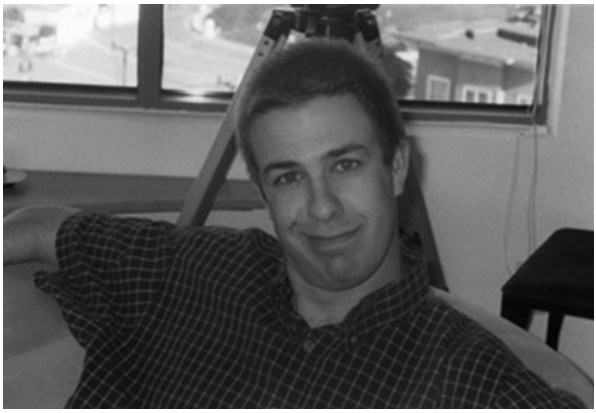


Fig. 33.4 Michael at age 22 years visiting family in San Francisco. This is his last picture before undergoing brain surgery 1 month later

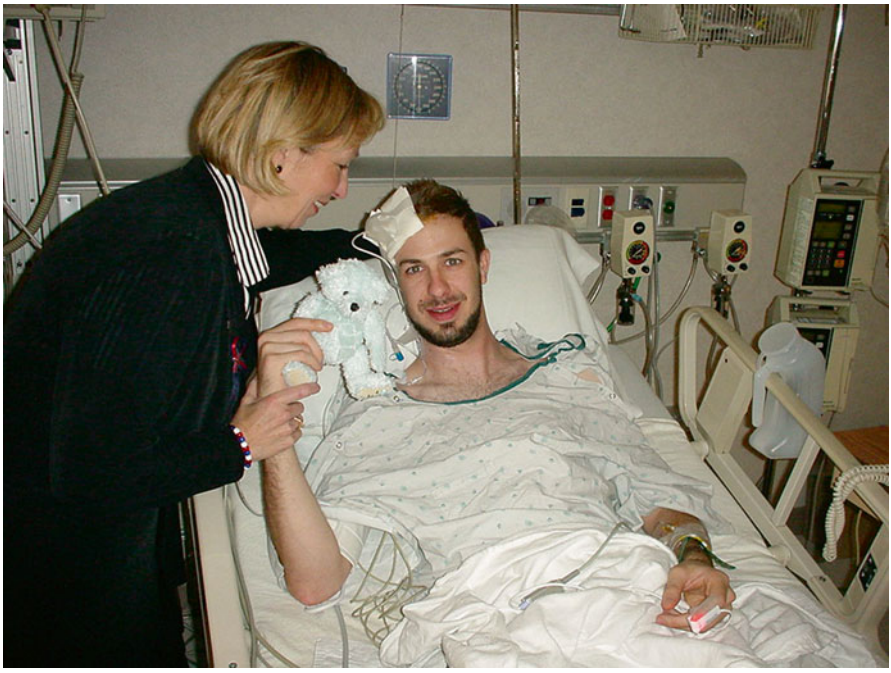


Fig. 33.5 Michael with his mother Patty at the bedside—the first postoperative night in ICU, after the ventricular drain had been placed

An investigation by a group of medical experts found that the standard of care related to informed consent was not met in this case. None of us were ever provided surgical and non-surgical options for treatment. And that the risks associated with the neurosurgeon's planned procedure, in particular his lack of experience and expertise in performing the surgery, were never discussed. They also concluded that

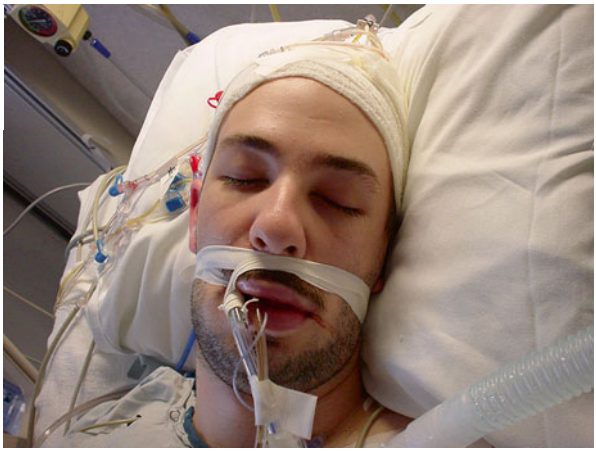


Fig. 33.6 Michael in intensive care after multiple repeated surgeries, with ventricular and intracerebral drains in place

the small cyst was not the cause of Michael's symptoms. It is 2013 and this doctor is practicing medicine, but now patients have a resource to research their physicians in Colorado.

Our work today is guided by the promise that we made to Michael when he passed. We promised to leave the medical profession better than he found it. Sadly, the expertise and knowledge that has been gained through our family's ordeal was not realized in time to save our son. Our hope is for future healthcare team members to learn the responsibilities your patients and their families deserve. Our goal is that you or your colleagues never have to sit across from a family devastated by broken trust and poor communication, a family facing a lifetime affected by a tragic, yet preventable loss.

The skills that serve you as a person and a human being will further serve you as a surgeon and keep your self-knowledge, compassion and empathy intact. Attempt to recognize your own life and the lives of those that you hold most dear, in each and every patient that seeks your professional services. Remember that each patient in your care is someone who is loved and cherished, who has dreams, ideas, feelings and who needs you on their side at every step of their treatment. Honest communication delivered with compassion and enveloped with empathy, should be the most valued currency in your relationship with every patient.

Checklists, informed consent, shared decision-making, patient-centered approaches, health literacy, patient engagement and empowerment—these are all the titles of books, journal articles, chapters and white papers. They are all important ideas and worthy beliefs, but only if they are implemented. Are you able to teach and empower your patients so that they are comfortable asking questions and possibly challenging you?

Our hope is that this 'worst-case' scenario will inspire you to set your own best practices for the safety of your patients. Engaged, as the leader of the healthcare team, you are able to celebrate the triumphs of great outcomes as well as face challenges in

Table 33.1 Critical lapses in 'shared decision-making' and the process of informed consent during Michael Skolnik's surgical care

Information presented to the Skolniks	Information withheld from the Skolniks
The surgeon interpreted a 'possible' colloid cyst on CT scan as acutely life-threatening.	By nature, colloid cysts are slowly growing and are typically only problematic at a larger threshold which may lead to cerebrospinal fluid obstruction.
The intraventricular drain placement took place in Michael's hospital room, by the use of a hand drill, not in an operating room under formal sterile conditions. The Skolniks were not informed of any potential complications from this bedside procedure.	During the bedside procedure, Michael stopped breathing due to overmedication from the conscious sedation. A nurse who aided during the resuscitation was later censured from telling the Skolniks about this occurrence. As Mr. Skolnik inquired from the doctor "Did Michael arrest?" the surgeon replied "Who told you that?"
With the intraventricular drain in place, the neurosurgeon told the Skolniks that he must "operate within 48 h or Michael will die." With pinpoint accuracy and microscopic point of entry, he will extract the cyst.	The scope and destructive nature of this procedure would not be fully revealed to the Skolniks for months. Again, no complications during the surgery were discussed and disclosed.
For the surgery, Michael's signature on the informed consent was obtained in Patty and David's absence, while he was sleeping in his room. Michael had to be woken, up due to heavy sedation, to sign the consent.	Michael had received 10 doses of morphine, 2 doses of hydrocodone and 1 dose of Droperidol in the previous 10 h prior to the surgeon obtaining consent.
The Skolniks conducted online research about the surgeon who claimed to have done many of these procedures and found no negative information.	The surgeon had performed this procedure exactly one other time and had multiple malpractice suits against him in other states. This information was unavailable to the patient and parents. After Michael's preventable death, legislation in the State of Colorado adopted the "Michael Skolnik Medical Transparency Act" mandating full disclosure by licensed physicians regarding current and past occurrences related to licensure, conflicts of interest, etc.
Four people, including the surgeon, were present for Michael's 6.5 h surgery.	Another surgeon refused to scrub in believing there was no good reason to perform surgery. Again, this was not shared with the Skolniks.
A planned 3 h surgery turned into a 6.5 h probe of Michael's brain—no cyst was found and the surgeon described that during the procedure there was "heavy manipulation of the brain."	At the time, there was a medically preferred, noninvasive, alternative to the procedure the surgeon performed. Part of the hypothalamus removed and during one of the later procedures for bleed to the brain part of the frontal lobe removed.

difficult situations—all from a patient-centered mindset. We feel Michael flaps his angel wings every time a positive step forward for patient safety is made, each time an open and honest conversation takes place. Keep him busy up there.

> *The blind trust is the blind trust of the public. It's not their fault. They have no choice but to walk into an emergency room and get treated by the first doctor on call. But the treatment is too often based on that individual doctor's practice rather than what's the best evidence. I'm convinced that the government is not going to fix health care. And doctors are not going to fix health care. It's going to be the patients* [1].

Reference

1. Makary M. Why patient harm is one of the leading causes of death in America. Interview with Marshall Allen of ProPublica, 9–18–12. http://www.propublica.org/article/qa-marty-makary-m.d.-author-of-unaccountable

Further Reading

Makary M. Unaccountable: what hospitals won't tell you and how transparency can revolutionize health care. New York: Bloomsbury Press; 2012.
Mauffrey C, Stahel PF. Shared decision making—the importance of open communication with our patients. Bone Joint J; Feb 2013.
Mayer DB, McDonald T. The faces of medical error—from tears to transparency. The Story of Michael Skolnik. DVD, Solid Line Media; 2010.
National Patient Advocate Foundation. (www.npaf.org).
Patient Advocate Foundation. (www.patientadvocate.org).
To err is human: building a safer health system. Institute of Medicine; 1999.
Wen L, Kosowsky J. When doctors don't listen: How to avoid misdiagnoses and unnecessary tests. New York: St. Martin's Press; 2013.

Would You Defend This Complication? 34

Jeffrey L. Varnell

Outline of the Problem

The risk of complications is an unfortunate but unavoidable accompaniment of surgical procedures. While no surgeon's complication rate will be zero, it is our duty to our patients to do whatever we can to keep the rate as low as possible.

From a legal perspective, the occurrence of a complication should not be inherently negligent. It should be evident, however, that everything was done to avoid the unanticipated outcome, and that the effects of the misadventure were mitigated as much as possible. We would like to present several case histories, and use the lessons from those cases to present a paradigm by which we can evaluate whether appropriate measures were taken to minimize the complication risk, and whether the event could be defended in the case of a lawsuit being brought (Table 34.1). In brief we will look at: (1) the adequacy of the informed consent process, (2) whether the procedure performed was indicated, (3) whether all known preventative measures were taken preoperatively, (4) how the procedure was performed technically, and (5) whether the complication was recognized in a timely manner and rescue initiated.

Case Scenario #1

John Doe is a 58 year old who presented to his internist with a recent history of swelling in the left leg. Concerned about a possible DVT, Dr. Smith ordered an ultrasound that revealed no evidence of thrombosis. When the swelling persisted, a CT of the abdomen

J.L. Varnell, MD, FACS
Department of Patient Safety and Risk Management, COPIC Insurance Cos, Denver, CO, USA

Department of Surgery, University of Colorado School of Medicine, Denver, CO, USA
e-mail: jvarnell@copic.com

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7_34, © Springer-Verlag London 2014

Table 34.1 Five elements to evaluate procedural complications

1. Informed consent process
2. Appropriate indications
3. Preoperative measures taken
4. Technical performance
5. Timely recognition and rescue

was performed, again showing no evidence of a thrombosis but incidentally demonstrating a 6 cm solid lesion in the lower pole of the left kidney. The patient was referred to a urologist who recommended nephrectomy due to the high likelihood of malignancy. It was noted that the patient had multiple co-morbidities including morbid obesity (BMI 32), bipolar disorder, and hypertension. After appropriate informed consent was obtained, which included the risks of infection, bleeding, blood clots, injury to surrounding organs and death; the patient was scheduled for left radical nephrectomy. Surgery was performed the following week and was largely uneventful; final pathology confirmed the presence of a confined renal cell carcinoma. Postoperative pain was managed with a combination of epidural catheter using bupivicaine and short acting opioids and intravenous demand opioids. On the first postoperative night the patient was found by the nurse to be short of breath when his oxygen cannula came out; oxygen saturation at that time was 47 % but returned to 91 % when the cannula was replaced at 2 l per minute. The following day a consultation was obtained with the internist for management of his medications; the episode during the night was noted, and preoperative medications were continued, including a sleep medicine. That night, when the nurse visited the patient's roommate, the patient was noted to be "snoring loudly"; she did not awaken him. One hour later the patient was found with his oxygen cannula on the floor, and he was unresponsive with pupils fixed and dilated. Resuscitative efforts were unsuccessful, and he was pronounced dead. Subsequent autopsy revealed cause of death to be acute right heart failure due to hypoventilation syndrome. Mrs. Smith subsequently brought a lawsuit against the surgeon, the internist, and the hospital.

What Went Wrong?

Let us apply the above-noted paradigm to determine if this unfortunate outcome could have been avoided and if the lawsuit should be defended.

1. Upon review there was good evidence that the surgeon had spent considerable time with the patient going over the indication for the procedure, the risks inherent to it, the risks of not proceeding, the nature of the procedure itself, and the expected outcome. It was clear that the patient was adequately informed and no allegation was made about lack of consent. Of course informing a patient about the risk of a procedure does not protect from liability if it occurs, but it removes the separate allegation regarding lack of informed consent. In addition, it has been shown that patients who are adequately informed about the nature of their procedures have improved outcomes from the perspectives of shorter hospital stays, decreased pain medicine usage, and overall satisfaction.

2. Certainly there was no concern about the indication for this surgery, as confirmed by the final pathology. In cases where the indications are marginal, or non-existent, however, patients are not well-served, particularly when they do suffer complications. The unique circumstances of each individual patient must be taken into consideration, and a recommendation for intervention must be tailored to the individual, especially when the circumstances are elective. Allegations of unnecessary surgery are unfortunately not infrequent, but can be defended when there is good documentation that the patient's unique situation and needs were given full consideration and the diagnosis of their condition was accurate.
3. As advances in patient safety have proceeded, we have become increasingly aware that much can be done preoperatively to reduce the risk of postoperative complications. Whether it may be appropriate administration of preoperative antibiotics to screening for underlying conditions such as hypercoagulability and obstructive sleep apnea, it is incumbent upon all providers caring for surgical patients to take all measures necessary to reduce their risk of complications prior to taking them to the operating room. Numerous resources are available to ensure adequate preoperative assessment is performed, including a guideline from NSQIP [1]. In this case, the allegation in the lawsuit was that the patient was not monitored carefully enough. While this was certainly accurate, in truth the failure was in not recognizing that the patient had obstructive sleep apnea, so that appropriate preoperative interventions were not taken. In addition to more careful monitoring (such as continuous pulse oximetry and/or telemetry or recovery in the ICU), adjustments in pain medicine administration and use of CPAP would likely have reduced the likelihood of this event. Each patient must be evaluated for risky conditions or pre-conditions that might increase their risk of a complication; in many cases this can be accomplished by the operating surgeon, however sometimes the judicious approach might include referral to a specialist or to a preoperative clinic. As always documentation in the medical record of the thought process that led to actions taken (or those not felt necessary) helps in the defense of a lawsuit should it result from that complication occurring.
4. The proper technical performance of a procedure is a source of great pride to all surgeons; it requires judgment, learned dexterity, experienced decision making, and extensive knowledge of anatomy, physiology, and pathology. We join with our patients in desiring perfect outcomes, and suffer with them when that ideal is not reached despite our best efforts. Whether those "best efforts" were sufficient from a legal perspective is determined by a jury after evidence is presented by experts in a court of law; in most cases those experts were not present at the time of surgery, and they need to rely on the medical record to determine what happened. Thus the documentation of the operative report is key to making such a determination, and should reflect not only the actions of the surgeon but also something of the thought processes that led to those actions. In addition, many of the actions that can affect the success of the procedure are not commonly reflected in the record, such as participation in preoperative briefings and time-out processes, which have also been shown to correlate with outcomes and risks of complications. In these areas it is important that surgeons show leadership in

promoting patient safety by adhering to and encouraging in others behaviors that are known to reduce complication rates.

5. No surgeon wishes to believe that a complication has occurred to his patient. Nonetheless the likelihood that a patient can recover from a complication depends directly on the speed of recognition of that complication and subsequent rescue. In addition the most frequent cause for indefensibility of a known complication in legal actions is delay in recognition and rescue. The reasons for these failures are manifold, and include denial by the surgeon, failure to communicate with partners and other providers such as specialists and nurses, and system failures which can lead to lack of critical information [2, 3]. Surgeons must be cognizant of the complications which can occur, willing to investigate at the first sign of trouble, and able to act quickly to mitigate the effects when they occur. This includes keeping an open approach to communication with other providers, so that nurses and others feel comfortable in contacting them when they have concerns, even if they are ultimately not confirmed. We will discuss in another chapter how a surgeon can be proactive in helping their patient through these events from emotional and financial perspectives as well as the physical recovery, once the complication has been addressed. Certainly in this case an opportunity was lost in at least two instances when the patient became hypoxic and no further measures were taken to prevent recurrence; part of that would be education of providers that snoring does not necessarily mean that the patient is safely resting, and that physicians were not notified on the occasions when the hypoxia off oxygen was dangerously low.

Case Scenario #2

John Doe is an established patient of Dr. Smith, having previously undergone ACDF for disc problems in the cervical spine. He presented with a recent history of thoracic back pain without focal neurological deficit. An MRI was obtained which revealed an epidural mass at the T8–9 level; the radiologist could not definitively determine the nature of the lesion but could not rule out neoplasm. The patient met with Dr. Smith who recommended thoracic exploration and possible excision. The clinic notes reflect that the meeting occurred and informed consent was obtained. Surgery was scheduled for the next week. Open thoracotomy was performed and exploration with mass excision performed. Initially the patient did well, however, on the second postoperative day he developed weakness and paresthesias in both lower extremities. Despite prompt workup and re-exploration he went on to complete paralysis below the waist. Final pathology report on the surgical specimen revealed an inflammatory lesion with no evidence of malignancy. The patient and his spouse subsequently filed a lawsuit against Dr. Smith for failure to obtain informed consent and unnecessary surgery. During the discovery process pre-trial, the written permit was found in the hospital records. The pre-printed portion noted the risks of infection, bleeding, nerve injury, and death; the specific risks portion, however, showed that the physician had written “there are no guarantees,

anything can happen". During the subsequent jury trial this was shown in court; after both sides had presented their cases the jury deliberated before returning a verdict in favor of the plaintiff for in excess of $5 M. Following the case, interviews of the jurors revealed that in their opinion, the patient had not been adequately consented as to the risks of the surgery and that surgery may have been unnecessary.

What Went Wrong?

1. This case highlights a rather flagrant example of disregard by the physician towards the informed consent process,and as a consequence poor care that is challenging to defend. Paralysis is a recognized risk of spinal surgery, and patients have the right to understand that risk and the others specific to their operations so they can make an informed decision. Patients who have undergone a thorough informed consent process have been shown to have improved clinical outcomes, in the form of reduced requirement for pain medicine, reduced hospital stays, and reduced recovery times. Note that we have used the term "process" in this discussion, for it is not a single event but rather ongoing education throughout the care of the patient [4]. The documentation should include the conversations that are held with the patient, any drawings or pictures that are shared, and any other materials including videos that are used during the process. Performance of this process protects to some degree the physician from litigation being filed should a complication occur. Documentation of the process, including the written permit, is most effective in defending the physician against allegations of negligent informed consent once a lawsuit is filed. We should also keep in mind that many patients may not understand some of the aspects of their care due to literacy challenges, and can be afraid to speak up when meeting with their physician. It is appropriate to ask directed questions during the discussion to assess their understanding, further explain as needed, and to document that effort. The discussion should be tailored to the patient's particular concerns and interests, for example how a complication might affect their specific livelihood. A paternalistic approach should be avoided, and efforts should be made to achieve shared decision-making.
2. In addition, expert review of this case questioned the indications of surgery without prior efforts to determine the nature of the lesion. In retrospect, lack of progression or development of neurological compromise should have stopped the surgeon from performing this highly invasive procedure.
3. No preoperative measures were identified which would have altered the course of care and outcome in this case.
4. The surgery appeared to have been performed in a technically competent fashion.
5. Rescue efforts were undertaken in a thorough and timely manner, but the patient suffered a devastating complication and his care, as a whole was not defensible.

Case Scenario #3

Jane Smith presented to the emergency room with a recent history of sudden onset of right upper quadrant pain with nausea and vomiting. She was otherwise in good health without previous history of abdominal surgery. Ultrasound examination revealed the presence of acute cholecystitis and cholelithiasis and surgical consultation was obtained. After admission to the hospital and administration of antibiotics and pain medicatioin, Mrs. Smith was recommended to have laparoscopic cholecystectomy. The surgeon explained the indications for the surgery, risks (including risk of bile duct injury), alternatives, and risks of not proceeding; the patient agreed to proceed and surgical permit was signed. The patient was taken to surgery the following day and underwent laparoscopic cholecystectomy with intraoperative cholangiograms. The patient did well overnight but the following morning complained of increasing pain and nausea; liver function studies were obtained and were elevated. A HIDA scan was performed which demonstrated absence of flow into the duodenum. Subsequent ERCP revealed that the common bile duct had been clipped and transected. She was transferred to the University hospital where she underwent Roux-en-Y choledochojejunostomy. Despite several complications the patient eventually recovered. A lawsuit was brought against the surgeon for negligent performance of laparoscopic cholecystectomy.

What Went Wrong?

1. Analysis of this case revealed that the consent process was appropriate, and that the indications for surgery were sound.
2. As the patient was otherwise healthy no preoperative measures other than antibiotics were indicated.
3. Although the complication was not recognized intraoperatively, the surgeon did act decisively the following day and appropriately transferred her to a tertiary care facility with experience in bile duct reconstruction. The main consideration was if the procedure had been performed in a technically sound manner through expert review of the operative report. In this case the surgeon noted that “a long structure going right into the gall bladder . . . however despite multiple attempts to free this it did not free up . . . a clip was placed on it distally”. It was then cut into, and a cholangiocatheter was placed and cholangiograms taken. These revealed “free flow of contrast into the duodenum, but only the distal portion of the common duct was seen”. The gall bladder was then removed in a retrograde fashion after the ductal structure had been doubly clipped and transected. Clearly and in retrospect, there were several opportunities for obtaining a different outcome in this case. As the surgeon was unable to obtain a clear picture of the anatomy towards the beginning of the dissection, it was inappropriate to place a clip on a structure that had not yet been definitively identified. Adequate decision at that point may have been to perform the cholangiogram without clipping a duct, or alternatively to proceedi to open surgery.

Once the cholangiogram was taken, absence of flow into the proximal ductal system should have been a sufficient warning sign to proceed with open surgery at that point without placing further clips or transecting a structure that has not yet been clearly identified. The threshold for changing the operative approach based on the patient's safety should be lower, and is a matter of surgical judgment and mindset before beginning the procedure, rather than persisting when danger signs present themselves. Thus it was not felt that an adequate defense of the allegation was not feasible, and the case was settled out of court. Had the surgeon heeded the signals noted above and altered his approach, a different clinical and legal outcome may have occurred. In general, surgeons are not expected to follow a "cookie-cutter" approach to operative technique, and some variation based on preference and unique situations is considered within the standard of care. However, there should be evidence of a sound thought process and consideration of surgical principles and available information that is documented in the operative record and any subsequent discussions. It should be noted as well, however, that many of the behaviors that have been correlated with risk reduction may not show up in the operative record at all. Recent research has shown that adherence to protocols such as the surgical timeout and the preoperative briefing have been correlated with reduction in mortality and morbidity in multiple settings; the degree to which this is taken seriously can rarely be inferred from the operative records [3]. Implementation of the preoperative timeout and surgical checklist has been shown to reduce morbidity and mortality [5] and yet reductions in wrong site/wrong patient and other surgical events have been elusive [6, 7]. Successful use of these strategies requires strong leadership, commitment to the process by all team members, and thoughtful system design, or the benefits will not be realized [8, 9]. All members of the surgical team must be empowered to feel that they can offer significant input into the safety of the patient, and the surgeon explicitly asking for team contributions encourages and enables team members. It should be noted that the majority of errors leading to patient injury occur in routine operations performed by experienced surgeons, such that increasing attention should be given to decision-making processes and system analysis, which can be anticipated to an extent by adherence to preoperative briefings [10].

4. The complication was recognized in a timely fashion and appropriate rescue efforts initiated.

Case Scenario #4

John Doe presented to his primary care physician after repeated bouts of left lower quadrant pain with fever and constipation; he had been hospitalized three times for treatment of diverticulitis with intravenous antibiotics, twice within the last 3 months. He was concerned that these episodes were becoming more frequent and severe, and was worried about having a complication or losing his job. He was then referred to a surgeon for consideration of elective colectomy. Barium enema was

performed which revealed that the diverticulitis was limited to the sigmoid and lower descending colon. After appropriate examination the patient and the surgeon discussed elective laparoscopic colectomy, including the risks of anastamotic leak and injury to nearby structures. They also discussed alternatives of open surgery, watchful waiting, or prophylactic antibiotics, and that his risk of complications such as abscess or fistula was getting higher. The patient decided to proceed with the laparoscopic approach and signed the surgical permit. He was anxious to have the surgery done before the end of the year, so a date was selected just prior to the surgeon leaving town; he was made aware that the surgeon's partners would be assuming care in the postoperative period. The patient had a history of insulin-dependent diabetes, and consultation was obtained from the primary care physician for management in the perioperative period. Prior to the surgery the patient was given low molecular weight heparin for prophylaxis. The surgery was performed on a Wednesday and went well, though there was moderate adhesion formation from the repeated episodes of diverticulitis. The patient was seen by a covering partner surgeon on the first two postoperative days and remained stable, though on day 2 he developed a low-grade fever which was attributed to atelactasis and increased pulmonary hygiene was instituted. The patient was seen over the weekend by two on call partners, one in the mornings and one in the evening. On Sunday afternoon, the patient became agitated and complained of increasing pain, and requiring more oxygen.

Consultation with the hospitalist service was obtained and the patient was started on antibiotics for pneumonia. During this time he was also becoming more distended and stopped passing flatus; he was seen by the evening on call surgeon on Sunday evening and an abdominal CT scan was obtained which showed free intra-abdominal air and fluid near the anastamosis. This was presumed due to the recent surgery but a leak could not be ruled out. The patient was seen early the next morning by the assistant surgeon and a gastrograffin enema was ordered. The radiology reports became available at midday, showing an anastamotic leak. The on call surgeon was in surgery, so the assistant surgeon came up and saw the patient and scheduled him for exploration that evening with the on call surgeon. Finally the patient was taken to surgery and diverted with a colostomy, but continued to deteriorate and succumbed to sepsis the following day. Autopsy revealed peritonitis and sepsis as the cause of death. A lawsuit was brought against all three surgeons and the hospital for wrongful death following negligent care and treatment.

What Went Wrong?

1. Review of the medical records showed that the informed consent process was appropriate, including discussions on the risk of anastamotic leak.
2. The indications for the procedure were appropriate in retrospect.
3. The patient's diabetes and DVT prophylaxis were managed appropriately in the perioperative period.

4. Review of the operative note and relevant records showed that the procedure was performed in accordance with accepted standards for laparoscopic resection of the sigmoid and descending colon.
5. Clearly, there were concerns with the postoperative management of the patient. There were sufficient signs of deterioration many hours prior to his re-exploration, and although we cannot extrapolate that the patient would have survived had there been an earlier intervention, his chances would have been greater. The lack of communication between surgical providers was obvious and may have caused the delay in decision making to bring the patient back to the operating room. An adequate process of signing out should have been done prior to the transfer of care. Concerns relating to understaffing were raised. The surgeon involved should scrutinize early possible system errors, breakdown in communication both of these having been shown to have a delayed recognition [2].

Case Scenario #5

Jane Smith is a 50-year-old female who presented to her local emergency department with a history of lower abdominal pain and nausea. A CT scan of the abdomen revealed a 3.5-cm soft tissue mass in the right lower quadrant in proximity to the tip of the cecum. Further tests including tumor markers, ultrasound, and colonoscopy did not further delineate the nature of the mass, though it became apparent that it was not the cause of the pain experienced by the patient. The surgeon recommended a diagnostic laparoscopy with biopsy and possible resection. The patient gave her informed consent to the proposed procedure although it was later alleged that she was expecting a laparoscopic biopsy but not an excision of the lesion. The surgical consent did not mention resection specifically but it did note the possible need for additional procedures. In his operative report the surgeon documented that the mass extended under the ilioinguinal nerve. The nerve was mobilized and the mass was resected. In the recovery room the patient quickly realized that she could not move her right leg, and subsequent evaluation revealed paresis of the femoral nerve. The surgeon later corrected his operative note to replace the name femoral nerve instead of ilioinguinal nerve. Final pathology report confirmed a diagnosis of benign Schwannoma. The patient eventually brought suit against the surgeon for negligence in removing the mass, lack of informed consent and possibly unnecessary surgery.

What Went Wrong?

1. Several concerns were raised during the expert review. The deficiency in the informed consent process was identified. The patient was able to successfully allege, in the absence of documentation that she was not fully informed about the possibility of having her tumor excised and that the femoral nerve could be damaged. .

2. The inadequate workup of the patient's condition and consequent indications for surgery were highlighted. Having recognized that the soft tissue lesion was not the source of the patient's pain, further workup, including an MRI should have been done preoperatively to, characterize the extent of the lesion. This investigation would have enabled the surgeon to warn the patient about the risk of injury to the femoral nerve,
3. Expert review did not raise any concerns regarding the performance of the procedure per se, but altering the medical record casted doubts on the credibility of the surgeon. The surgeon should have dictated an addendum rather than attempting to modify the original dictation,
4. The complication was recognized in a timely manner but could not materially impact the final outcome.

Take-Home Message

Using these elements of informed consent, appropriate indications for surgery, taking all known preventative measures, performing surgeries in a technically sound manner, and recognizing and rescuing complications in a timely manner, we can not only evaluate whether we have done everything possible to reduce the hazards of complications for our patients, but also whether the occurrence of the complication could be defended in the event of an ensuing lawsuit.

References

1. Chow WB, Rosenthal RA, Merkow RP, Ko CY, Esnaola NF. Optimal preoperative assessment of the geriatric surgical patient. J Am Coll Surg. 2012;215(4):453–66.
2. Symons NR, Almoudaris AM, Nagpal K, Vincent CA, Moorthy K. An observational study of the frequency, severity, and etiology of failures in postoperative care after major elective general surgery. Ann Surg. 2013;257(1):1–5.
3. Hu YY, Arriaga A, Roth ER, Peyre SE, Swanson RS, Osteen RT, Schmidt P, Bader AM, Zinner MJ, Greenberg CC. Protecting patients from an unsafe system. J Am Coll Surg. 2011;213(3):S111.
4. Brenner LH, Brenner AT. Beyond informed consent: educating the patient. Clin Orthop Relat Res. 2009;467:348–51.
5. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA, Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global polulation. N Engl J Med. 2009;360:491–9.
6. Stahel PF, Sabel AF, Victoroff MS, Varnell JL, Lembitz AL, Boyle DJ, Clarke TJ, Smith WR, Mehler PS. Wrong-site and wrong patient procedures in the universal protocol era: analysis of a prospective database of physician self-reported occurrences. Arch Surg. 2010;145(10):978–84.
7. Mehtsun WT, Ibrahim AM, Diener-West M, Pronovost PJ, Makary MA. Surgical never events in the United States. Surgery. 2013;153(4):465–72.
8. Conley DM, Singer SJ, Edmondson L, Berry WR, Gaweande AA. Effective surgical safety checklist implementation. J Am Coll Surg. 2011;212(5):873–8.

9. Fourcade A, Blache JL, Grenier C, Bourgain JL, Minvielle E. Barriers to staff adoption of a surgical safety checklist. BMJ Qual Saf. 2011;21:191–7.
10. Regenbogen SE, Greenberg CC, Studdert DM, Lipsitz SR, Zinner MJ, Gawande AA. Patterns of technical error among surgical malpractice claims: an analysis of strategies to prevent injuries to surgical patients. Ann Surg. 2007;246(5):705–11.

Epilogue: Future Directions Towards a Global Culture of Patient Safety

More than 200 million surgeries are performed worldwide each year. Any patient admitted to a hospital to undergo a surgical procedure should rightfully expect to be better off after the intervention than before. However, recent reports reveal that adverse event rates for surgical conditions remain unacceptably high, despite multiple nationwide and global patient safety initiatives over the past decade. These include the '100,000 Lives Campaign' (2005/2006) and subsequent '5 Million Lives Campaign' (2007/2008) by the Institute for Healthcare Improvement (IHI), the 'Surgical Care Improvement Project' (2006) and 'Universal Protocol' (2009) by the Joint Commission, and the WHO 'Safe Surgery Saves Lives' campaign accompanied by the global implementation of the WHO surgical safety checklist (2009).

The new textbook *Patient Safety in Surgery* is designed to outline current patient safety protocols and to highlight shortcomings and 'hidden threats' that continue to endanger our mission of providing high quality, safe care to our patients. Many of the current limitations to the creation of a globally recognized and consistently practiced '*culture of patient safety*' stem from the lack of surgeon-driven leadership. Transparent leadership and credible role modelling are the prerequisites to ensure unwavering 'buy-in' by all members of the health care team for adoption of safety practices in daily routine, including strict adherence to patient safety checklists and safety core measures. We are furthermore lacking a uniform system for reporting and analysis of surgical complications, which could be modelled on the *Problem Reporting and Corrective Action* (PRACA) quality assurance database by the National Aeronautics and Space Administration (NASA). Errors in the surgical care of our patients frequently lead to unintentional harm on first occurrence in absence of a 'fail-safe' backup option. We should learn from other high-risk domains, including nuclear technology, professional aviation, naval submarine technology, and aerospace engineering that have historically embraced a culture of safety as a basic tenet for the success in their respective missions. In engineering, 'redundancy' implies the 'fail-safe' duplicate or triplicate availability of critical components or system functions. For example, NASA endorses the fundamental principle of being 'double-fail-safe' in all aspects of their enterprise.

Patient safety in surgery should model on the five core principles from NASA's proven safety culture paradigm:

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7, © Springer-Verlag London 2014

1. *Reporting culture*—Reporting concerns without fear of reprisal.
2. *Learning culture*—Learning from successes and failures.
3. *Flexible culture*—Changing and adapting to meet new demands.
4. *Engaged culture*—Everyone is doing their part.
5. *Just culture*—Treating each other fairly.

The extrapolation of these proven safety pillars from aerospace engineering to patient safety in surgery is challenged by multiple barriers imposed by our current health care system. Based on the premise that "*Good judgment comes from experience which comes from poor judgment*," NASA's safety culture originated from lessons learned through system failure analysis after dramatic fatal accidents, including the Apollo 1 cabin fire in 1967, and the space shuttle disasters in 1986 and 2003. In surgery, we are still falling short of implementing a formal '*culture of reporting and learning*.'

In the absence of the long overdue legislative tort reform needed to avoid penalties for publicly reporting medical errors, surgeons remain understandably reluctant to disclose surgical complications in an open and transparent forum. The deterrent of potential punitive measures could be mitigated by adopting a model from professional aviation safety, such as the amnesty program used by the *U.S. Federal Aviation Administration* (FAA). The FAA program is designed to incentivize pilots and air traffic controllers to report poor personal conduct, including sleeping on duty or falsifying records. The FAA claims that since the implementation of the amnesty program "*No other safety program has identified and fixed more local and systemic problems in any other high-risk domain*."

In medicine, the absence of formal amnesty programs combined with the daunting threat of legal repercussions for admitting and reporting errors and complications, appears to breed a converse '*culture of silence and intolerance*.' The current pressure of the medicolegal industry furthermore promotes a '*culture of defensive medicine*' by setting a standard expectation for diagnostic precision that borders on fantasy. The unintentional fallout from practicing defensive medicine is a drastic exacerbation of health care costs, with little or no benefit to the patient, in conjunction with an increased risk for 'collateral damage' by the overuse of diagnostic testing. For example, the exponentially increased use of medical imaging by computed tomography scans in recent years has been associated with an incremental long-term risk of radiation-induced cancer. Further unresolved problems include the wide variation of surgical indications worldwide, the inequity of access to surgery for disparities, and a questionable long-term sustainability of surgical quality at the current rate of progress associated with increasing costs for modern and innovative procedures.

An additional serious challenge to patient safety in surgery consists of the questionable quality of training for the next generation of surgeons. The desperate need for more primary care doctors in the coming years and decades prompted selected medical schools in the United States to shorten their teaching curriculum to just 3 years by shaving off one full year of training. This 'fast-track MD' program is certainly appealing by saving tuition costs and addressing the predicted shortage of

primary care physicians. However, cutting the training curriculum of new physicians appears rather counter-intuitive from a patient safety and quality perspective. Additionally, the surgical experience of residents in training has been drastically impaired by the implementation of resident work hour restrictions. Ironically, work hour restrictions were implemented as a patient safety measure to mitigate the risk of surgical complications originating from overworked and fatigued residents. Contrary to the original intent, a decade of international experience with resident work hour restrictions revealed that patients are not safer, but rather more susceptible to harm originating from handovers of care, equivocal physician accountability, and breakdowns in communication within the team. In addition, multiple studies on millions of hospital admissions in different countries reported a lack of an effect of resident work hour restrictions on patient morbidity and mortality, bringing into question the primary intent of the program in the first place.

Surgeons are under an increasing amount of pressure and expectation to perform at the highest level. They must deliver absolute diagnostic accuracy and infallible surgical quality under the conflicting paradigm of patient safety and maximal cost efficiency. In addition, surgeons are expected to have the highest standards of ethical values and professionalism, to act as respected role models, dedicated teachers, academic researchers, successful administrators and entrepreneurs. While no medical student would ever learn about managing a business during medical school, surgeons are increasingly requested to provide cost-efficient care under an increasingly competitive 'health care market.' These expectations come close to the task of squaring the circle even for experienced surgeons, but are virtually unattainable for physicians in training who are denied adequate access to surgical 'hands-on' training in the current age of work hour restrictions and 'fast-track' teaching curricula. We are worried that the next generation of surgeons may not have an adequate opportunity of learning 'how to cut' and may have to postpone the 'learning curve' from training to an unsupervised surgical practice in later years. This is certainly not in the patients' best interest.

An intuitive solution, in light of the demonstrated absence of a positive effect of resident work hour restrictions on patient safety and outcomes, is for accreditation councils of residency programs to reconsider the value and far-reaching consequences of work hour restrictions, and to potentially drop this ineffective program. In addition, it is our obligation as senior surgeons to act as role models to our trainees with regard to professionalism and individual physician accountability, and to prove these values in daily interactions with our team. As we observed the historic paradigm shift from a '*culture of blame and shame*' to a '*culture of systems safety*,' we have now reached a tipping point in which the expectation of systems are exhausted, and a physician-driven approach is needed to build and sustain a '*culture of individual accountability*.' A classic example is hand hygiene as a simple core measure with immense impact on patient safety with regard to decreasing the incidence of hospital-acquired infections. International estimates show that overall compliance with hand hygiene among health care personnel is as low as 5–30 %. A 'perfect' system can provide staff training programs and logistic support, including door signs, checklists, and hand sanitizer dispensers in- and outside of patient

rooms. However, in absence of individual accountability and physician-driven leadership, the expected goal of 100 % hand hygiene compliance remains utopic. How is it possible that low-wage workers in the meat packing industry are able to sustain 100 % compliance with hand hygiene protocols, but physicians can't? Intriguing insights from our own institution reveal that hand hygiene compliance rates drop from more than 90 % when officially observed and monitored, to less than 40 % when we feel unobserved. This phenomenon likely relates to the 'Hawthorne effect' by which a subject's behavior changes as a result of being observed, and reflects poorly on the physicians' accountability for '*doing the right thing*' for our patients at all times.

On a positive side, the historic dogma that physicians are infallible has worn off and has been replaced by a modern concept of patient-centered care, with patient safety as its core tenet. The concept of involving patients and families in a 'shared decision-making' approach for surgical care has globally evolved in recent years as a cornerstone of patient-centered care ("*Nothing about me without me!*"). Despite all limitations and barriers outlined in this textbook which continue to impede the implementation of a sustainable and global '*culture of patient safety*,' we are extremely positive that the future for our patients is bright! We see the bright future every day in the eyes of our trainees, medical students and residents, in their unlimited enthusiasm and proactive engagement in all aspects related to patient safety, quality assurance and quality improvement. The only benchmark for our success as mentors is to produce trainees who will be better surgeons and stronger patient safety advocates than we could have ever been in our own life time.

The legendary Flight Director of the lunar Apollo missions, Gene Kranz, stated in the wake of the Apollo 1 disaster in 1967:

> *From this day forward, Flight Control will be known by two words: 'Tough and competent.' Tough means that we are forever accountable for what we do or what we fail to do. We will never again compromise our responsibilities. Competent means we will never take anything for granted. We shall never be found short in our knowledge and in our skills.*

It is time for surgeons to become 'tough and competent' in patient safety!

Philip F. Stahel, MD, FACS
Cyril Mauffrey, MD, FACS, FRCS

Appendix 1. Definitions

Safety	The condition of being protected from (or at diminished risk of) danger and harm.
Complication	Any occurrence that deviates from an anticipated uneventful recovery from illness or surgery, independent of patient harm.
Adverse event	Any occurrence that leads to escalation of care, prolonged hospital stay, or an unplanned return to the operating room, independent of patient harm. Underlying root causes include human (provider) issues, system (process) issues, and technical (equipment) issues.
'Near miss' event	Any unanticipated occurrence with the potential of resulting in patient harm that was recognized and aborted in time before reaching the patient.
'No harm' event	Any unanticipated occurrence that was not recognized or aborted in time, reached the patient, but did not induce harm.
'Never event'	'Never events' are severe adverse events which derive their designation from the philosophical notion that they should 'never' happen. There is a common confusion between two distinct entities defined as 'never events' by the National Quality Forum (NQF) and the Centers for Medicare and Medicaid Services (CMS) **NQF**: "Serious reportable events in health care" (e.g. wrong-site surgery, wrong-patient surgery, unintentionally retained foreign object after surgery, etc.) **CMS**: "Non-reimbursable serious hospital-acquired conditions" (e.g. surgical site infections, thromboembolic complications, etc.)
Preventable adverse event	Any adverse event with an identified underlying root cause and an opportunity to improve care. The adverse event would have likely been prevented or substantially ameliorated by taking appropriate preventive steps.

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7, © Springer-Verlag London 2014

Non-preventable adverse event	Any adverse event that lacks an identified underlying root cause and for which reasonable and appropriate preventive steps have been taken.
Error of omission	Any error resulting from a required action that was not performed.
Error of commission	Any error resulting from an action that should not have been performed, or should have been performed differently.
Unplanned readmission	Any unplanned re-hospitalization within 30 days after hospital discharge, as a surrogate indicator for quality of care provided during the preceding hospitalization.
Unplanned return to the operating room	Any unplanned revision surgery which was not anticipated as part of the post-operative care plan after the preceding index procedure.
Quality of care	The degree to which health services to individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional medical knowledge.
Quality assurance (QA)	A standardized concept of ensuring quality from the level of the producer, supplier, to the ultimate consumer of the provided product or service.
Quality control (QC)	A standardized concept focused on recognizing and eliminating problems within the scope of the QA process.
Quality management	All functions involved in the determination and achievement of quality (=QA+QC).

Quality of care framework

- **Structure**: The attributes of settings where health care is delivered.
- **Process**: The attributes of good medical practices.
- **Outcome**: The combined effect of structure and process, reflecting the impact of care provided on the consumer's health status.

Quality improvement (QI) — A continuous process that employs rapid cycles of improvement, focused on the following parameters:

- **Safety**: Avoiding unintentional harm to patients related to the health care provided.
- **Effectiveness**: Providing integrated care and preventive services to address the most pertinent and prevalent conditions in vulnerable patient populations, while refraining from providing services that are not likely to benefit.

- **Patient-centered**: To ensure that patient values, preferences, and needs guide all clinical decisions in their care.
- **Timeliness**: To reduce wait times and potentially harmful delays in access.
- **Efficiency and sustainability**: To rationalize treatment, monitor costs, share costs, and avoid 'waste'.
- **Equity**: To provide health care to the underserved population, without variation in quality due to personal characteristics, including gender, ethnicity, and socio-economic status.

Shared decision-making	A patient-centered approach, where surgeons communicate with patients and patient families using the best available evidence to discuss all options, risks and benefits in the decision-making process for a surgical procedure. Patients and patient families are supported to deliberate and question the recommended course of action and inquire about alternative treatment options, including the request for a formal second opinion. The shared decision-making strategy represents a 'team approach' founded on respect for patient autonomy. The philosophical aspect of this modern concept is best reflected by the anecdotal notion, "Nothing about me, without me!"

Appendix 2. Denver Health Weekly Orthopedic M & M Case Review Form

Name: **Admitted:**
Ortho M&M: **Ortho Team:** /
MRN: **FIN:** **Trauma#:**
Reported Event:

I. Status
- ☐ A. Complication
- ☐ B. "Near miss" event
- ☐ C. "No harm" event
- ☐ D. Death
- ☐ E. Not a complication
- ☐ F. Not an Ortho complication

II. Specific Complication
- ☐ A. Postoperative infection
- ☐ B. Failure of reduction/fixation
- ☐ C. Misplaced implant
- ☐ D. Fracture-Nonunion
- ☐ E. Wound healing issue
- ☐ F. Failure of flap or replantation
- ☐ G. Postop bleeding/hematoma
- ☐ H. Vascular injury
- ☐ I. Neurologic injury
- ☐ J. Medical complication
- ☐ K. DVT/PE
- ☐ L. Death
- ☐ M. Other: _____
- ☐ N. Missed Injury

III. Patient Harm

1. DHMCQSS
- ☐ QSS 1: "'No harm" to patient
- ☐ QSS 2: "No harm", but increased risk of harm
- ☐ QSS 3: Harm requiring escalation of care
- ☐ QSS 4: Harm resulting in prolonged disability
- ☐ QSS 5: Life threatening or resulting in death

2. Revision Surgery
- ☐ None
- ☐ Yes- Planned Return to OR
- ☐ Yes- Unplanned return to OR

IV. Contributing Root Cause
- ☐ A. Communication
- ☐ B. Supervision
- ☐ C. Indication
- ☐ D. Technique
- ☐ E. Treatment concept
- ☐ F. Judgment error
- ☐ G. Aftercare
- ☐ H. System issue

Preventable VI.-1

- ☐ I. Patient compliance
- ☐ J. Patient selection
- ☐ K. Co-morbidities
- ☐ L. Injury severity

Non-Preventable VI. - 3

- ☐ M. No root cause evident — Equivocal VI. - 4
- ☐ N. Other:_____

V. Corrective Action
- ☐ A. Education at QA Conference
- ☐ B. Guideline/protocol
- ☐ C. To PI Committee/Peer Review

VI. Preventability
- ☐ 1. Preventable
- ☐ 2. Potentially Preventable
- ☐ 3. Non-Preventable
- ☐ 4. Equivocal
- ☐

- ☐ A. Disease Related
- ☐ B. Provider-Related
- ☐ C. System-Related

VII. Disclosure
- ☐ A. Occurred
- ☐ B. Did not occur - Reason: _____

Procedure Start: **Heparin Start:**
Procedure End:
Antibiotics Start: **Last Heparin:**
Total Tourniquet Time:

Loop Closure Comments:
No deviation from standard of care
See separate dictation
Deferred loop closure to PI Committee

Definitions:

Complication: Any event that deviates from an anticipated uneventful recovery from illness or surgery

"Near Miss" Event: An unplanned event with the potential of resulting in a preventable injury, which was recognized and aborted in time before inducing patient harm.

"No Harm " Event: An unplanned event which was not recognized or aborted in time, but did not result in patient harm, and did not meet the criteria for the definition of a "true" complication

Unplanned Return to OR: Any return to the OR for an unanticipated event or complication

Preventable: Expected or unexpected sequela of procedure, disease or injury that is likely to have been prevented or substantially ameliorated by taking appropriate steps.

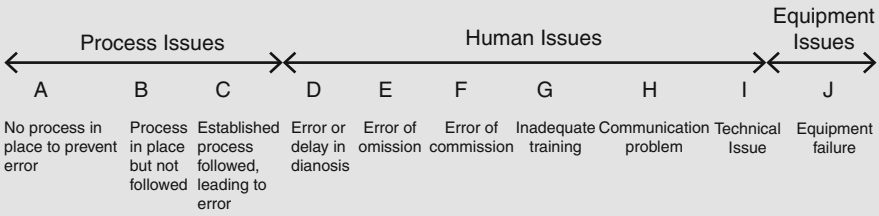
Non-Preventable: Expected or unexpected sequela for which reasonable and appropriate preventive steps had been taken

Potentially Preventable: Expected or unexpected sequela which had the potential to be prevented or substantially ameliorated.

Confidential Privileged Quality Management Documenper C.R.S. § 25-3-109

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7, © Springer-Verlag London 2014

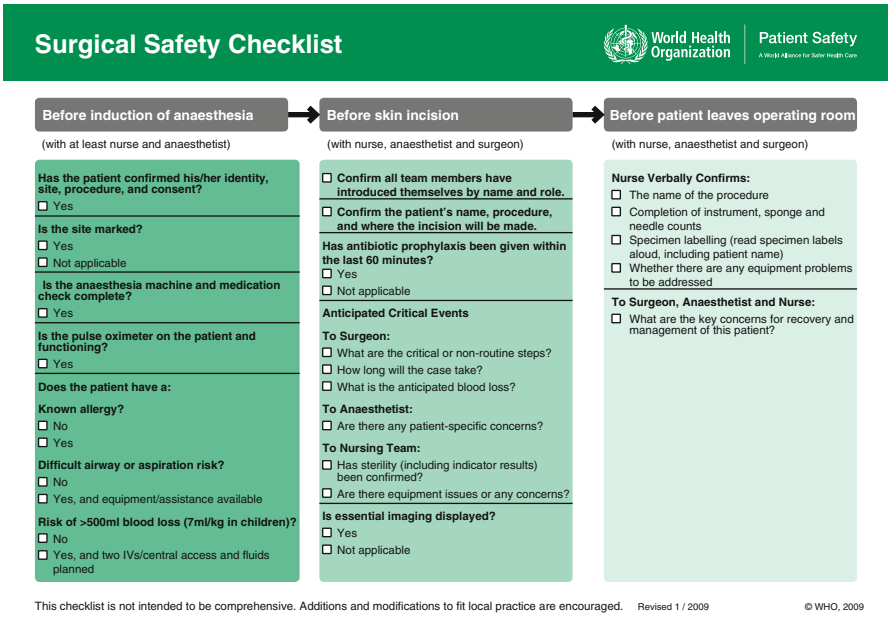
Appendix 3. Denver Health Safety Concern Score



Score Value	Outcome
1	No harm to patient
2	No harm but increased risk of harm
3	Harm requiring escalation of care
4	Harm resulting in prolonged disability
5	Life-threatening harm or death

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7, © Springer-Verlag London 2014

Appendix 4. WHO Surgical Safety Checklist



Surgical Safety Checklist

World Health Organization | Patient Safety
A World Alliance for Safer Health Care

Before induction of anaesthesia
(with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?
- ☐ Yes

Is the site marked?
- ☐ Yes
- ☐ Not applicable

Is the anaesthesia machine and medication check complete?
- ☐ Yes

Is the pulse oximeter on the patient and functioning?
- ☐ Yes

Does the patient have a:

Known allergy?
- ☐ No
- ☐ Yes

Difficult airway or aspiration risk?
- ☐ No
- ☐ Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?
- ☐ No
- ☐ Yes, and two IVs/central access and fluids planned

Before skin incision
(with nurse, anaesthetist and surgeon)

- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**

Has antibiotic prophylaxis been given within the last 60 minutes?
- ☐ Yes
- ☐ Not applicable

Anticipated Critical Events

To Surgeon:
- ☐ What are the critical or non-routine steps?
- ☐ How long will the case take?
- ☐ What is the anticipated blood loss?

To Anaesthetist:
- ☐ Are there any patient-specific concerns?

To Nursing Team:
- ☐ Has sterility (including indicator results) been confirmed?
- ☐ Are there equipment issues or any concerns?

Is essential imaging displayed?
- ☐ Yes
- ☐ Not applicable

Before patient leaves operating room
(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:
- ☐ The name of the procedure
- ☐ Completion of instrument, sponge and needle counts
- ☐ Specimen labelling (read specimen labels aloud, including patient name)
- ☐ Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:
- ☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged. Revised 1 / 2009

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7, © Springer-Verlag London 2014

Appendix 5. Further Resources

Editor's Selection: Patient Advocacy Groups, Patient Safety Organizations, Resources for '2nd Opinions', and Recommended Readings

- **Citizens for Patient Safety**
  http://www.citizensforpatientsafety.org
- **Patient Advocate Foundation**
  http://www.patientadvocate.org
- **Center for Advancing Health**
  http://www.cfah.org
- **Center for Disease Control and Prevention (CDC) – "Ten Things You Can Do to Be a Safe Patient."**
  http://www.cdc.gov/Features/PatientSafety/
- **U.S. Food and Drug Administration (FDA) – MedWatch Program**
  http://www.fda.gov/Safety/MedWatch/
- **Institute for Safe Medication Practices (ISMP)**
  http://www.ismp.org/
- **MediGuide America**
  http://www.mediguide.com/
- **The Joint Commission**
  www.jointcommission.org/topics/patient_safety.aspx
- **National Patient Safety Goals**
  www.jointcommission.org/assets/1/6/HAP_NPSG_Chapter_2014.pdf
- **National Patient Safety Foundation**
  www.npsf.org
- **Agency for Healthcare Research and Quality (AHRQ)**
  www.pso.ahrq.gov
- **The Leapfrog Group**
  www.leapfroggroup.org/patients
- **Qangl Health – Take control of your healthcare choices**
  www.qangl.com
- **Patient Empowerment**
  http://patients.about.com

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7, © Springer-Verlag London 2014

- **The Empowered Patient**
  www.theempoweredpatient.com
- **The Empowered Patient Coalition**
  http://empoweredpatientcoalition.org/publications
- **Empowered Patient – Free iTunes App**
  https://itunes.apple.com/us/app/empowered-patient/id674642098?mt=8
- **Patient Safety in Surgery – Free PDF articles**
  www.pssjournal.com
- **The Faces of Medical Error – From Tears to Transparency**: **The Story of Michael Skolnik (DVD Learning Program).**
  Transparent Learning Inc, Chicago, IL
  http://transparentlearning.mybigcommerce.com/
- **The Faces of Medical Error – From Tears to Transparency**: **The Story of Lewis Blackman (DVD Learning Program).**
  Transparent Learning Inc, Chicago, IL
  http://transparentlearning.mybigcommerce.com/
- **Crew Resource Management: From Patient Safety to High Reliability (2009).**
  David Marshall (ISBN 978-0-9843851-2-6)
  http://transparentlearning.mybigcommerce.com/
- **When Doctors Don't Listen – How to Avoid Misdiagnoses and Unnecessary Tests (2013).**
  Leana Wen & Joshua Kosowsky, St. Martin's Press, New York, NY (ISBN 978-0-312-59491-6)
- **Unaccountable – What Hospitals Won't Tell You and How Transparency Can Revolutionize Health Care (2012).**
  Marty Makary, Bloomsbury Press, New York, NY (ISBN 978-1-60819-836-8)
- **Complications – A Surgeon's Notes on an Imperfect Science (2002).**
  Atul Gawande, Picador, New York, NY (ISBN 978-0-312-42170-0)
- **Better – A Surgeon's Notes on Performance (2007).**
  Atul Gawande, Picador, New York, NY (ISBN 978-0-312-42765-8)
- **The Checklist Manifesto – How To Get Things Right (2009).**
  Atul Gawande, Metropolitan Books, New York, NY (ISBN 978-0-8050-9174-8)
- **The Not So Patient Advocate – How to Get the Health Care You Need Without Fear or Frustration (2009).**
  Ellen Menard, Bardolf & Co, Sarasota, FL (ISBN 978-0-9778199-6-6)
- **How We Do Harm: A Doctor Breaks Ranks About Being Sick in America (2012).**
  Otis Webb Brawley, St. Martin's Press, New York, NY (ISBN 978-0-312-67297-3)
- **The Take-Charge Patient: How You Can Get the Best Medical Care (2012).**
  Martine Ehrenclou, Lemon Grove Press, Santa Monica, CA (ISBN 978-0-9815240-3-0)

- **Design to Survive – 9 Ways an IKEA Approach Can Fix Health Care and Save Lives (2013).**
  Pat Mastors, Morgan James Publishing, New York, NY (ISBN 978-1-614484332)
- **How Doctors Think (2007).**
  Jerome Groopman, Houghton Mifflin Hartcourt, Boston, MA (ISBN 978-0-54705364-6)
- **The Art of Thinking Clearly (2013).**
  Rolf Dobelli, HarperCollins, New York (ISBN 978-0-06-221968-8)

Index

P.F. Stahel, C. Mauffrey (eds.), *Patient Safety in Surgery*,
DOI 10.1007/978-1-4471-4369-7, © Springer-Verlag London 2014