Strategies for Patient Safety

15

Case Study

The labor and delivery unit was unusually busy, and the resident was especially concerned about two of the patients he was watching closely. Patient A with a vertex/vertex twin pregnancy at 37 weeks of gestation had been in labor for 26 h. Patient B was full term with a Category 2 fetal heart tracing and intermittent decelerations. The resident consulted his attending physician about Patient B's fetal heart tracing, and it was decided that Patient B could be allowed to continue to labor with very close surveillance.

It was clear to the resident and attending physician that both of these patients might require a cesarean section (C-section). The decision was made to transfer Patient B to a specific labor room that can be quickly transformed into a second operating room for the unit. This transfer was standard procedure in the unit and in accordance with hospital policies. In addition, it is required that the anesthesia care team be informed that the patient may require an emergency C-section so they can set up their anesthesia equipment in that room in advance. The anesthesia care team would then remain in standby. For unknown reasons, this call was never made.

In the meantime, the resident and attending physician reevaluate Patient A with the twin gestation. Despite regular adequate uterine contractions and the patient's pushing efforts, the presenting twin has not descended further into the birth canal. The patient now has a prolonged second stage of labor. Although the fetal heart tracing remains a reassuring Category 2 with average variability and no decelerations, given the patient's state of exhaustion they agree that she cannot push effectively any longer. The station of the presenting twin is too high for a safe operative vaginal delivery. The patient is relieved and gives her informed consent for the C-section. The resident informs the anesthesia care team and the scrub nurses and asks them to come to the operating room for an "urgent" but not "emergent" C-section on Patient A.

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Preparations for Patient A's twin delivery by C-section are suddenly interrupted by the charge nurse informing the obstetricians that Patient B's fetal heart tracing is showing a severe bradycardia at 80 bpm. The midwives are not able to resolve the fetal bradycardia despite oxygen administered to the patient, fluid bolus, and changes of position. The attending physician calls for an emergency C-section for Patient B in her convertible labor room. Preparations for Patient A's C-section are put on hold and she is informed of this by the resident.

Chaos can be heard in the labor room as the midwives and other staff try to help set up Patient B's labor room for the C-section. Instrument kits are being opened and set up. The fetal heart rate is still in the 80s. In an effort to improve the fetal bradycardia by decreasing the frequent uterine contractions, one of the midwives starts a subcutaneous infusion of a tocolytic β2-agonist. The patient is being positioned in her bed as a midwife preps the abdomen and inserts a Foley catheter. The resident orders the charge nurse to inform the anesthesiologist about the change in plans and that urgency has increased to "emergency C-section" as he begins to scrub. When the anesthesia and surgical team finally do arrive, it becomes obvious that they had not been notified about the change of rooms and instead had been waiting in the regular operating room for the patient to arrive.

The resident feels badly that he was not clear about Patient B possibly needing a C-section to be done in this room in the first place and can't think how that important piece of information was missed. The anesthesia care team had no opportunity to set up their equipment, and they are working at maximum speed to get everything done safely under significant time pressure. The attending obstetrician is very concerned about the fetal bradycardia and is calling loudly for staff from the neonatal intensive care unit to be paged stat. The resident is thinking that he should have suggested bringing Patient B into the operating room once he found out that nothing was set up in this room, but he's afraid to speak up with everyone so upset and now the patient is already prepped and draped.

After completion of all preparations, anesthesia induction and intubation are done without difficulty. A few minutes after incision, a term male infant is delivered and handed over to the neonatology team. Everyone is relieved when after less than a minute of positive pressure ventilation, the infant begins to cry.

During the course of surgery, uterine atony is noted by the obstetrical team and requires significant uterotonics: oxytocin infusion and uterine massage, followed by methergine and then prostaglandin F2α. The patient has more bleeding than usual and the anesthesiologist decides to start a second i.v. line. It is only then that he notices the infusion pump with the tocolytic β2-agonist was never turned off. After disconnecting the tocolytic, uterine tone recovers and bleeding is minimal. The remainder of the surgery is uneventful.

Following the emergency C-section in the labor room, both teams proceed directly to the operating room to perform the C-section on Patient A under spinal anesthesia. Delivery of vigorous twin girls takes place without complications.

In a debriefing conducted shortly after the event, there is emphasis on the positive outcome. It turns out that neither the obstetric physicians nor the midwives had been aware of the existence of an interdisciplinary agreement, which regulates the commissioning of anesthetic equipment in the case of a possible cesarean section. Ignorance of existing standards, inadequate surgical preparation of the patient without the anesthesia team having time to set up their equipment and go through their checklist, and the lack of situational awareness due to the need to focus on tasks, stress, communication, and teamwork errors, including failure to speak up and failure to inform the anesthesia team of all medications administered, were discussed. The good outcome was not confused with good team performance. Transparent discussion of the teamwork and communication failures helps the team realize that it was the clinical experience of all involved in the case and perhaps a bit of luck that may have saved Patient B from a more serious adverse event.

15.1 The Organization's Mission: Patient Safety

For organizations, the temptation may be great to assess the safety of their patient care only by the outcome: As long as patients aren't harmed, there is no cause for concern. It is easily overlooked that in the unfolding of an incident such as the described emergency C-section, individual factors can add up in unpredictable ways (e.g., oblivion, stress, lack of communication), especially at the interfaces of professions and disciplines. Acute care medical organizations cannot rely on circumstances leading to a beneficial patient outcome. For safe patient treatment, hospitals need a functioning safety culture. However, this does not evolve by itself: Safety must be an ongoing and cross-functional management and leadership task for hospitals. Facing this task under the current conditions is a major challenge for hospitals. If a hospital is capable at any time of supporting patient-safe work conditions at any workplace, then we can call the hospital a reliable organization.

15.1.1 Working Safely: Reduce, Cope with, or Manage Complexity?

In order to increase patient safety, healthcare organizations are basically faced with two possibilities: For one, they can try to minimize the variability of processes and thus the complexity of tasks (Fig. 15.1.). That would mean reducing or avoiding uncertainty that leads to errors. Reduction of complexity can be achieved when dealing with routine processes, where activities will take place in a stable environment (Grote 2015). This applies, for example, to many aspects of patient care in

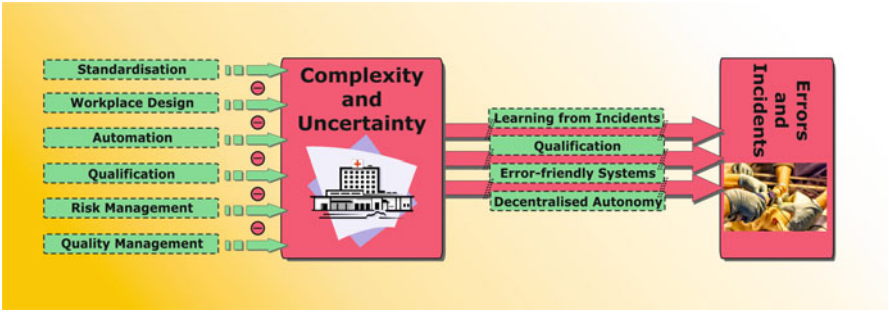

Fig. 15.1 Strategies for safety: reduction of complexity as well as the ability to cope with complexity and uncertainty are part of making an organization resilient and enhancing patient safety

general wards where elements of care, long-term medication, ordering and evaluation of diagnostic tests, and perioperative treatment pathways for elective patients can be designed as routine processes. Ways to achieve this mainly are:

- Standardization
- Workplace design and automation
- Staffing patterns and distribution of expertise
- Qualification of employees
- Quality management and risk management

In many areas of acute care, however, stable and routine conditions are not necessarily present. Lack of transparency, uncertainty, complexity, and dynamic change limit the possibility of planning and standardization. In these areas, an organization can enhance safety only by strengthening the ability to deal with complexity and uncertainty. This is the second path to patient safety: The focus changes from "preventing and managing errors" to "preventing and managing complexity."

In recent years, more and more healthcare organizations have developed into high-reliability organizations (AHRQ 2008; Bagnara et al. 2010; Resar 2006). Reliable organizations of course try to avoid errors as much as possible. Because they are aware of the inevitability of human errors, they do not expect flawlessness. Instead, they try to make the system more robust ("resilient") against the effects of errors: Mistakes shouldn't lead to patient harm.

This is done by:

- Employees' qualification
- Learning from incidents and errors
- Error-resistant system design
- Decentralized autonomy, as in high-reliability organizations (HROs)
- Mindfulness of processes among all workers

In theories of high reliability, accepting the fact that complexity will always be a central characteristic of the work environment is part of the strategy used to reduce complexity (Grote 2015). The idea of a central control of systems is abandoned and replaced by local control at the sharp end. By giving operational control to the employees, the entire system should become safer. Since these ideas are still fairly new to healthcare, it remains to be seen just how well the concept of local control will work in the actual implementation.

This chapter deals first with risk management and quality management. Then we will discuss standardization as a means to reduce complexity and avoid errors. Contrasting this approach, organizational development, knowledge management, and human factors-oriented system designs are discussed as approaches that accept complexity. Learning in organizations is discussed in Chap. 16, with a focus on education and training as well as learning from mistakes, incidents, and accidents.

15.1.2 Clinical Risk Management and Quality Management

In recent decades, efforts to improve processes in healthcare have led to quality management systems. Since the turn of the millennium, clinical risk management increasingly supplements this. It can be debated whether quality or safety is the higher-level concept and to which one "patient safety" belongs. The answer probably depends on one's professional background and current concerns. In the context of patient safety in acute medicine, it is important to know that all these efforts share the common goal of working as safely and effectively as possible. Whether "safe" is a part of "good" or "good" a part of "safe" will therefore not be discussed here.

15.1.2.1 Clinical Risk Management

Until recently, risk management in healthcare was only known as an economic function. Only in recent years has the concept of "clinical risk management" emerged. The economic point of view has the following definition: Clinical risk management is a prevention system that will reduce the risks of patient care and pursues the goal of continuous improvement of the quality of care and patient safety and serves as the defense against unjustified patient claims against the hospital. This practice follows the same cycle as business risk management: identify risks – evaluate risks – control/manage risks – monitor risks (e.g., Vincent 1996; ASHRM and Carroll 2010).

Clinical risk management seeks to identify hazards for patients before they happen. Risks are analyzed and evaluated: Which risks can be avoided? Which risks are unavoidable in medicine? Which risks can be tolerated? Many surgical procedures, drug therapies, and diagnostic procedures carry an inherent risk and thus patients are always at some degree of risk. So, it seems intolerable to increase their risk by unsafe working systems and faulty processes. The reality of healthcare, however, looks at the problem differently: Money and human resources are limited, and the

allocation of scarce resources is all about priorities and therefore the distribution of risks. Therefore, clinical risk management techniques accept some risk within its approach.

Risk management asks, "What is the worst-case scenario in our patient care?" A powerful tool to anticipate incidents and avoid errors is readily available: The imaginative creation of "worst-case scenarios" in which healthcare professionals, their team, or the entire organization rehearses their readiness to cope with a situation. This approach, also known as the "scenario-based risk identification" principle from risk management, is especially helpful with unusual problems and events. Similar to planning (Chap. 7), the scenario analysis of a hypothetical situation can help people think through the implications and consequences of their potential actions. Real events often serve as a basis for such scenario planning. For example, the communication failure described in the case study can be analyzed for specific risks that might arise in the context of interdisciplinary emergency care of cesarean section patients. Since the exact same case won't occur in the same constellation again, it is important to apply imagination and ask: How could a similar trajectory of the event (Reason 1990; Chap. 3) pass through all safety barriers? What else could have happened? How can the occurrence of similar constellation and series of events be prevented? These questions can be asked independently of formalized risk management, so every person's imagination is an important safety resource.

It is also part of clinical risk management to implement preventive measures and raise employee awareness for the risks to encourage learning from mistakes (Chap. 16). Risk-minimizing measures may then manifest vis-a-vis the creation of standards, education and training, the design of workplaces and equipment, or personnel management. In this way, risk management seamlessly merges with overall safety management.

15.1.2.2 Quality Management

"Quality management" means to design all processes in an organization in such a way that the results or products are all of good quality. In acute care, quality means first and foremost the quality of the treatment, but also the safety of the treatment. Quality also includes well-being, sustainable use of resources, cost-effectiveness, compliance with laws and standards, etc. To manage quality implies knowing how the processes should be, which in turn means that there are criteria for good quality within the organization.

The term *quality management*, like the term *risk management*, was initially introduced by business and industry. Quality management is defined as concerted activities to direct and control an organization aimed at improving the quality of products produced or services offered. The four main components include quality planning, quality assurance, quality control, and quality improvement. Quality management is focused not only on product and service quality but also on the means to achieve it.

In the medical context, the "product" and "service quality" are the patient's health and the quality of medical care. It should be noted that this is not about the optimum, i.e., best possible quality, but a predefined level of quality. Effort and

results have to be balanced, just as in risk management. Therefore, quality in the medical field is also defined as "sufficient and appropriate medical care," which means it meets demands, is oriented to the quality of life, professionally qualified, but also is economic, with the aim to raise the likelihood of desired health outcomes in individuals and in the population.

The focus of quality assurance is on the structure (e.g., resources, personnel, facilities, equipment) and the processes involved (e.g., the actual activities of patient care, information management, teamwork, and leadership) as well as on the resulting outcome (e.g., wellness, length of stay, morbidity, mortality; see Eichhorn 1995).

Continuous quality improvement (CQI), a related but somewhat different term, activities aim at delivery of the highest-quality care. By focusing on latent errors and poor system design, CQI tries to eliminate preventable morbidity and mortality as far as possible. The main instruments for CQI are regular clinical audits and the establishment of quality circles.

15.1.2.3 Methods for Risk and Quality Management

Clinical quality management (QM) and risk management (RM) make use of many different methods. We introduce two methods that can be implemented in everyday care in hospitals beyond the formal QM and RM audits and quality circles.

A clinical audit is a systematic and objective evaluation of an organization (e.g., department, hospital, relief organization) that aims to improve patient care. Aspects of patient care – including structure, processes, and outcomes – are selected and evaluated against explicit criteria and, where necessary, changes are implemented at an individual, team, or service level. Audit procedures include collecting, analyzing, interpreting, and documenting information. Auditors are either external auditors (independent staff assigned by an auditing firm) or internal auditors (healthcare providers from within the organization hired to assess and evaluate its system). Clinical audits are initiated and supported by the Board of Directors or top management.

Clinical audits in a medical high-stakes environment should focus on the structures and processes that are most likely influenced by latent errors: medical equipment (including maintenance), the preparation of planned procedures, patient positioning, drug administration, and the application of protocols and standard operating procedures (SOPs; Eichhorn 1995; O'Connor et al. 2002).

A *quality circle* (QC) is a small volunteer group of healthcare professionals who meet at regular intervals to identify, analyze, and resolve workplace and patient care-related issues (e.g., Robson 1989). QCs are usually led by a supervisor or a senior healthcare professional who acts as a moderator. The QCs neither decide on changes nor put improvements into practice, but they present ideas and suggestions to the management on how to improve the quality of healthcare processes and patient safety. QCs are driven by two principles: that employees can often make better suggestions for improving work processes than management and that employees are motivated by their participation to make improvements. Employee acceptance of the QC process is highly dependent on the extent to which management acts favorably on suggestions from the QC.

15.2 Complexity Reduction, Error Avoidance: Standardization

A view still widespread in the healthcare system is that safe patient care is the responsibility of the individual. However, this view ignores the fact that healthcare takes place in a particular organizational context with specific processes that need to be taken into account. An important approach to reduce the variety of possible system configurations and treatment alternatives is standardization. Standardization in medicine encompasses medical devices and IT systems as well as diagnostic and therapeutic processes and communication. On the other hand, outcome standardization – a common thing in industry – is not always possible when dealing with the anatomy and physiology of humans.

Medical devices and *IT systems* are standardized by legal and professional frameworks and manufacturer initiatives. The aims are:

- To increase user and patient safety
- To increase the simplicity and compatibility of system components
- To achieve technical and organizational interoperability of medical devices and IT systems through data and transmission standards

The standardization of *processes* can take place within an organization (e.g., nursing and therapy standards in intensive care units, clinical treatment paths within a hospital) or outside the organization by national societies (e.g., in the form of guidelines) or by international initiatives (e.g., WHO "High 5 s Project"; Leotsakos et al. 2014). Standardization of processes aims at:

- The reduction of process variability, so that the quality of care, safety, and resource consumption are independent of healthcare personnel, time, and place
- Ensuring that treatment follows the best method known at the time and minimizes care that is idiosyncratic to the practitioner (*equivalent actor* vs. *craftsman attitude*; Amalberti et al. 2005; Chap. 14)
- Supporting the training of new employees, who all get acquainted with the same procedures from the beginning
- Strengthening teamwork through shared mental models for processes

15.2.1 Standard Operating Procedures

A standard operating procedure, commonly abbreviated as SOP, is a detailed, written instruction aimed at achieving uniformity of the performance of a specific function. Standard operating procedures exist for routine operations as well as for emergency situations. The SOPs for emergency situations should enable a structured approach to a critical situation and be flexible enough to meet situational demands. They emphasize the medical and technical steps and are complemented by general steps of organized action (Cooper et al. 1993). The advantage is that SOPs describe successful guidelines for coping with an emergency situation. As a

result, the individual has less to figure out, which puts less stress on memory and, when designed well, provides especially welcome guidance in time-critical situations. Standardization is not only for specific medical management of certain diagnoses but should also be for daily procedures and information transmission (e.g., patient hand-off between the OR and recovery area, shift change in the ICU) and at the interface of interdisciplinary work. In the domain of intensive care medicine, evidence is mounting that standardization has an enormous potential to improve patient care and outcome and to reduce ICU and hospital length of stay as well as healthcare expenditures (Hasibeder 2010).

A lasting effect may be more likely if standardization is part of a larger scheme of efforts aimed at improving the safety culture of an organization (see below).

15.2.2 Standardization of Communication

Experience from other high-stakes environments (foremost civil and military aviation) has provided ample evidence that a standardization of communication techniques can help to reduce misunderstandings in noisy and stressful situations (Conell 1996). Standard terminology (comparable to that of civil aviation) and the resulting avoidance of misunderstanding can help to reduce errors. Standards for communication processes ensure that messages are clearly "received" and understood. These standards are termed *callouts*, *readbacks*, and *hearbacks*. A callout is a concise statement in a defined terminology. Readback and hearback are a redundant procedure aimed at verifying that both sender and receiver understand what the communication partner has said (Chap. 12).

Standard phraseology is not yet widespread in medicine. Announcements such as "Please step back, I will defibrillate!" most closely match a callout, but the phraseology doesn't have any cross-organizational reliability. The wording used in the case study, *urgent cesarean section*, is another example: Everyone in the participating teams may know that a cesarean section must be performed within 30 min. Communication conventions have emerged organically and locally in medical organizations but not necessarily consistent. Moreover, there is no industry-wide "seal of approval" as in aviation. Healthcare professionals, generally unfamiliar with the technique used in civil aviation, tend to dismiss communication standards as unnecessary. Nevertheless, if healthcare professionals in a high-stakes medical environment want to reduce misunderstanding, the establishment of communication standards would be a promising way to go. These standards would have to become a habit in daily practice; only then would healthcare professionals be able to use them effectively in critical situations.

15.2.3 Standardization of Patient Handover

The handover that includes relevant information and transfer of responsibility of a patient from one unit to another or from one caregiver to another in the same unit is

a significant and error-prone process. Patient handovers take place between emergency services and emergency department, between emergency room and normal wards, between ICU and operating room, but also at every change of shift of nursing staff and physicians. Despite the importance of this process, there are few studies that examined inhibiting and promoting factors for the process of patient handover. Recent studies suggest that a structured handover (e.g., checklists, iSBAR) can help to reduce information loss (Dawson et al. 2013; Segall et al. 2012; Riesenberg et al. 2009). Checklists give handover of patients a structure, but they typically do not convey all important aspects of patient care. Therefore, they shouldn't be the sole basis for the communication of information. Limitations of checklists will be discussed below.

15.3 Tool with Untapped Potential: Checklists

Until recently, healthcare has relied heavily on clinicians' ability to recall critical information during a medical emergency. During stressful situations, however, levels of cognitive function are compromised, resulting in a variety of planning and execution failures (Sect. 3.2), decreased compliance with standard operating procedures, and decreased proficiency.

Many inherently risky industries, such as aviation, aeronautics, and nuclear power have tried to overcome this limitation by mandating the use of and adherence to cognitive aids such as checklists and protocols. Typically, a checklist is a list of action items or criteria arranged in a systematic manner, allowing the user to record the presence/absence of the individual items listed to ensure that all are considered or completed (Hales and Pronovost 2006). Main objectives of a checklist are memory recall, standardization and regulation of processes, and its use as a diagnostic tool. Well-designed checklists standardize what, how, and by whom interventions are done. Under circumstances where the use of checklists is highly regulated and considered mandatory for practice, a checklist becomes a protocol and its completion from memory considered a violation (e.g., in civil aviation; Helmreich 2000).

15.3.1 Functions and Forms of Checklists

Checklists can support individuals and teams during:

- Preparation and execution of routine tasks
- Structuring of teamwork
- Problem solving

Working with checklists requires at least a partial standardization of processes. The great advantages of appropriately used checklists are that they give certainty of action, direct the attention to the task at hand, and help the team to build shared mental models and support each other (Fig. 15.2).

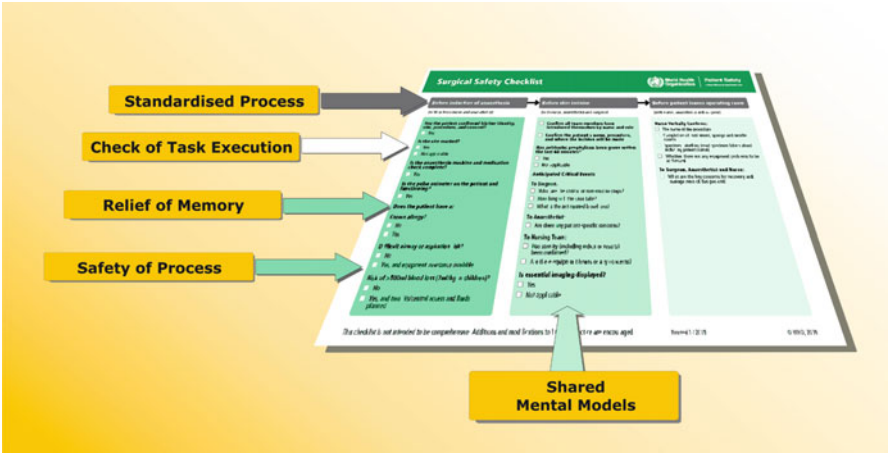

Fig. 15.2 Functions of a checklist that support the individual and the team

Checklists for *routine tasks* in complex systems contribute to a correct and complete execution of safety-relevant tasks. All steps involved are explicitly listed and have to be checked off in given order. Typical routine tasks that can be supported by checklists are machine checks and job preparation tasks. The obstetric department of the case study has a checklist for changing a labor room into an operating room. Also the WHO "Surgical Safety Checklist" (Haynes et al. 2009) is a routine tool. Evidence from many studies suggests that the implementation of that checklist in a locally adapted form improves the perceived quality of teamwork and helps reduce errors in teams (Lyons and Popejov 2014). But there have been other studies that do not find a reduction in morbidity or mortality after introducing the checklist (Urbach et al. 2014). It is likely that using the checklist establishes an opportunity for communication within the team where relevant information is transferred. In addition, safety awareness and safety culture can be improved. But when checklists are used incorrectly or when the team rejects them, the positive impact is lost and there can even be negative effects on teamwork (Russ et al. 2013).

Checklists for unexpected problems can support a structured approach to diagnose a problem or find the cause of an event.

Different from routine tasks or simple problems, in emergencies, a checklist cannot guide every step of action. For that reason, the term cognitive aid may be preferred. One aim of an emergency cognitive aid is to make sure that relevant information is available independently from memory (e.g., dosage, rarely used drugs, telephone numbers) and that critical steps in treatment are guided by best practices (Goldhaber-Fiebert and Howard 2013). Another function is to direct the problem solver's attention to those phases of problem solving that could get lost in action (e.g., setting priorities, risk identification, or control of action). And finally, cognitive aids help formation and functioning of teams in medical emergencies (Marshall 2015).

Table 15.1 Forms of checklists

Form of checklist	How it works	Example
Static parallel checklists	One person completes the checklist by checking a series of read and do items	Pre-use checkout of medical equipment, the anesthesia machine checklist
Static sequential checklists with verification	One person (or a computer) reads a series of items ("challenge"), and the other person verifies completion of the task or that items are within parameters ("response")	Catheter insertion checklist (Pronovost et al. 2006) Preparations for cesarean section (Hart and Owen 2005)
Static sequential checklists with verification and confirmation	Used most often in a team-based setting where team members are challenged by the person reading the checklist and respond according to their specific task	WHO checklist "Safer Surgery Safes Lives" (Haynes et al. 2009; Weiser et al. 2010) Checklist for the treatment of malignant hyperthermia (Harrison et al. 2006)
Dynamic checklists	Guide complex decision-making in emergencies using the format of a flowchart, and act as verification after execution of a task without necessarily leading users to a specific conclusion	Algorithms for BLS and ACLS Algorithms for the management of crisis under anesthesia (Runciman and Merry 2005) Algorithms for the management of the difficult airway

There are several forms of checklists. Some forms require a strict sequence of action; others just remind the user of relevant items. Some are made for individual physicians or nurses; others require teamwork. In some checklists, the control of every step is required. Table 15.1 shows the most common forms of checklists (Table 15.1, following Winters et al. 2009).

15.3.2 Barriers Against Checklists or Cognitive Aids

Whereas healthcare organizations have begun to follow aviation by promoting teamwork and implementing theories of crew resource management into the fabric of healthcare, they have been slow in adopting the policies of employing cognitive aids and checklists in both routine and emergency circumstances (Hayashi et al. 2007; Klopfenstein et al. 1998; Laboutique and Benhamou 1997; Langford et al. 2007; March and Crowley 1991). Thus, the reinforced standardization of processes by introducing mandatory checklist completion seems to be a more difficult task in medicine than in aviation. This is despite growing evidence from medicine that using checklists appropriately improves patient safety. Operational difficulties as well as cultural barriers may contribute to this difficulty. Below are some examples of thinking that are barriers to the use of checklists:

- *Humans can't be standardized by checklists*: Human physiology is far more varied and underspecified than structures and processes in the industrial setting. The resulting variations in the patient population make standardization of processes,

which constitutes the basis in designing and implementing a standardized checklist, difficult.

- *Emergencies can't be standardized by checklists*: Medical emergencies often follow an unpredictable and disorganized pattern, which makes it difficult for a checklist to cover all directions/ramifications in which a critical situation may evolve. For this reason, it is more appropriate to speak of cognitive aids.
- *Only what you know by heart is yours*: For many healthcare professionals, reliance on cognitive aids is considered second best choice as compared to reliance on one's own memory. Worse, some physicians feel that checklists insult their intelligence and consider the use of checklists an admission of weakness and convey a lack of skill and knowledge.
- *Checklists limit decision-making*: Healthcare professionals place high value on their professional autonomy. Attempts to standardize routine and emergency tasks are often viewed as limiting professional judgment and as threat to autonomous decision-making.
- *Once I realize I need a checklist, it's too late*: Sometimes it is difficult to know when to start using a checklist in the course of action. Also, in a team, the responsibility for starting or reading the checklist may not be clear.
- *Checklists are unwieldy*: Often, hospitals or departments lack effective technical strategies to make checklists readily available to everyone. Alternatives to unhandy paper-based checklists or handbooks could be software-based tools for cell phones and devices as well as electronic checklist systems implemented into the electronic monitoring or documentation system (Sawa and Ohno–Machado 2001).

15.3.3 Limitations of Checklists

15.3.3.1 Example: Patient Handover

Checklists can give structure to patient handover; however, as the sole basis for the communication of information, they entail the risk that important aspects of the complexity and mystery of patient care may not be communicated (Cohen et al. 2012). This is because people describe the situation depending on the circumstances, either on the basis of universal, context-independent principles ("paradigmatic") or through a story in which something special is expressed ("narrative"). Checklists as a paradigmatic representation are therefore suitable for simple or very complicated processes, but not for the description of complex facts that need to be told as a story (Hilligoss and Moffatt-Bruce 2014): *Simple* procedures (such as cooking a meal or starting a patient monitor) require little expertise and can be standardized and formulaic. *Complicated* processes (such as the preparation and implementation of an organ transplant or the entire treatment path of a patient from his hospital admission to discharge (DeVries et al. 2010)) consist of many individual sequences, but all can be structured by using checklists. *Complex* processes (such as the treatment of a hemodynamically unstable child with a congenital heart defect) are characterized by the interaction of many system components. Only a holistic

perception, as given in a narrative account, enables an adequate description of the situation.

15.3.3.2 Example: Safety Initiatives and Culture

Based on the stunning decline of catheter-related infections after the introduction of a checklist in 103 intensive care units (Michigan Keystone ICU Project, Pronovost et al. 2006) and the dramatic reduction of perioperative morbidity and mortality that could be observed after the introduction of the "Surgical Safety Checklist" in participating hospitals (Haynes et al. 2009), the press and parts of the healthcare sector were excited about the "small and simple checklists" that appeared to be the long-sought solution for the problem of patient safety risk. However, those who were responsible for this achievement contradicted this point of view (e.g.Bosk et al. 2009). Checklists were only one component of a broader program with the goal to change the culture of an intensive care unit, emergency room, or operating room. A much greater challenge than the definition of the necessary content of the checklist was to understand the social, political, organizational, psychological, and emotional barriers that needed to be overcome before scientific evidence could be applied in the form of a checklist. The real challenge for the introduction of a checklist is not simply in its creation but to overcome all the barriers to employing the checklist. The fallacy behind the concept of a "simple, small checklist" thus lies in the assumption that a *technical tool* (checklist) can solve a *sociocultural problem*.

15.3.4 Developing and Implementing Checklists

One of the great dangers of checklists is that they can easily be compiled and readily be applied to virtually every aspect of patient care. Under the well-intentioned assumption that checklists can prevent errors, mitigate harm, and reduce the costs associated with errors, an excessive mandated use might make the system overly complex and burdensome and impede the quality and speed of care delivery. In addition, it may generate an insidious clinical condition in the user: "checklist-fatigue syndrome."

Other risks seem to be associated with the introduction of checklists as well: Every time a system is changed to improve safety, we may defend against some known risks but unwittingly introduce new ones. An additional problem with checklists is that it may not be evident which checklist is the appropriate one to use. For instance, when an airplane's landing gear won't deploy, pilots know to go to that checklist in the manual. In clinical care, when a patient's blood pressure drops and the heart rate increases, it is not entirely clear which checklist should be employed. If checklists are not revised and updated on a regular basis, new scientific evidence will not be incorporated, hindering patients from getting state-of-the-art care. If clinicians adhere too strictly to checklists and become dependent upon these tools for their judgment, they may apply them even to clinical situations with incomplete evidence where the exercise of critical thinking would be more appropriate.

Because little is known about which specific checklists are truly linked to safety levels, how many checklists are too many, and when we have overburdened the checklist users, a systematic approach seems warranted before introducing a new checklist. The recommended steps to develop checklists include the following (Winters et al. 2009; Marshall 2013):

- Review existing literature.
- Understand the needs and workplace of the user.
- Include a multidisciplinary group in the design.
- Perform pilot testing in a simulated environment before full-scale implementation.
- Use an iterative approach for rigorous validation of the impact on service delivery: Benefits should be demonstrated rather than assumed.
- Reevaluate and update checklists periodically based on new scientific data and on feedback from caregivers.

In addition to following the recommended steps, it is sensible to apply principles from human factors engineering (Degani and Wiener 1993).

- List the most critical items at the beginning of the checklist whenever possible.
- Avoid long checklists when possible. Subdivide long checklists into small meaningful sections.
- Pay close attention to usability, including the time it takes to complete the checklist, and potentially negative effects of changes in practice.

15.4 Management of Complexity: Acute Medical Care of the Future

15.4.1 Promote Change

If acute medical organizations want to make patient safety an integral part of their corporate culture, they need to promote change in their processes, their self-concept, and the interactions of their members. Change always happens, and organizations continuously adapt to new circumstances. But if change is to be deliberate and systematic, it needs a framework and a roadmap. Such a framework is offered by concepts of *organizational development* that have been tried and tested in other industries (Senge 1990; Argyris and Schön 1995; Nonaka and Takeuchi 1995). Organizational development means to strategically plan and systematically change an organization with the goal of increasing effectiveness in problem solving. Organizational development must be planned long term and involve the employees. Starting points for programs of organizational development are new demands of the organization. Since organizations are not developed from the outside, but move toward their own targets, change can only come from inside. Core issues of the development of organizations are knowledge, learning, quality, leadership, and

flexibility. For acute medical care, important goals are patient safety and patient satisfaction, a transparent treatment chain, employee participation, and dedication to quality. Organizational change aims at those processes by which the "core service," patient care, is provided. The most important resources in successful development processes are always the employees, specifically their knowledge, skill, and motivation (see Chap. 16).

15.4.2 Knowledge Management

In the process of changing into a "learning organization," healthcare organizations will have to face the challenge of facilitating knowledge sharing and learning among the organization's members. Industry has addressed these issues by drawing heavily on theories of process and knowledge management. There is no generally agreed-upon definition of *knowledge management* (KM). Most often, the term refers to a range of systematic practices that support and achieve "the creation, sharing, retention, refinement, and use of knowledge; generally in an organizational context" (Edwards et al. 2005). One of the unifying elements across most KM theories is a shared understanding of knowledge as *the* intellectual capital and as a central factor in achieving improved performance and competitive advantage (Bali and Dwivedi 2006). Knowledge in this context includes both the experience and understanding of the people within the organization and its information artifacts, such as documents, guidelines, protocols, and reports, available within the organization (Stefanelli 2004).

Modern information technologies (IT) have provided organizations with the necessary tools to create and distribute knowledge within their sphere of influence, thus promoting the learning process of their members. These IT solutions include expert systems, e-learning, knowledge bases, corporate intranets and extranets, and other health IT infrastructures (e.g., computerized physician order entry, decision support systems; Handler et al. 2004); however, it is not enough to simply collect data. Only after information has been selected and processed to meet defined criteria is it usable knowledge in terms of KM. From this perspective, KM can be regarded as the art and science of transforming data into useful knowledge.

In view of this, which knowledge exactly is of interest for KM systems? Despite the diversity of their theoretical frameworks, most KM practitioners share the distinction between tacit and explicit knowledge (Nonaka and Takeuchi 1995):

- *Tacit knowledge* is subconscious and internalized knowledge and involves physical as well as perceptual skills (e.g., complex surgical interventions, situation assessment, diagnosing an X-ray). It is "know-how" knowledge held only in minds of organizational members. When tacit knowledge is employed, individuals are unaware of what they know and how they obtain particular results.
- *Explicit knowledge*, in contrast, is conscious and can be codified: A person is fully aware of what he or she knows and is able to communicate this information to others (e.g., calculating the IV dose of a drug, generating differential diagnoses). An example of external explicit knowledge is best practice recommendations.

The task of KM is, on the one hand, to convert internalized tacit knowledge into explicit codified knowledge in order to share it with other members of an organization. In a second step, the knowledge offered by a KM system has to be retrieved, understood, and internalized by individuals. This way, explicit knowledge is absorbed and results in new personal tacit knowledge. On the other hand, KM theories try to solve the problem of how an organization needs to be designed to facilitate knowledge processes. In other words, how the "right" information can be brought to the "right" people at the "right" time to enable the "right" actions.

In this context, acute medical organizations have to ask themselves:

- What cultural and structural barriers stand in the way of systematic knowledge management?
- How can knowledge be generated from the vast amount of medical information (e.g., publications)?
- How can knowledge be distributed and shared? Which method is best suited for which kind of knowledge?
- How can information technology be profitably and effectively used in this process?

An essential feature of acute medicine is that people from different departments or specialty units within the larger organization interact (e.g., emergency services and emergency room up to the intensive care unit) and continuously generate new information. As important pieces of information may be lost at the various interfaces, structured knowledge management can help to improve the interaction and cooperation. A systemic approach in which acute care medicine is thought of as a process with many participating organizations will help clinicians to incorporate the knowledge and to correctly channel the information required by the treatment chain (Edwards et al. 2005).

Safety-oriented knowledge management thus contributes to an informed and reliable corporate and healthcare culture. This brings us full circle to the topics discussed in Chap. 14.

15.4.3 System Design: Human Factors and Patient Safety

If future organizations of acute medicine want to treat patients safely, they have to keep in mind the principles of human factors in the design of processes and technological systems. This abstract-sounding statement means that the work system and all its components must be designed in a way to make safe work possible at *any workplace* at *any time*. In addition to safety, it is necessary for the health and well-being of employees to be taken into account.

Human factors-oriented system design includes considering human qualities and abilities as it organizes their interactions with technology, materials, jobs, and facilities. The following propositions are intended to illustrate what it would mean to translate these guiding principles for hospitals and healthcare facilities.

15.4.3.1 Management for Safety: Human Factors Knowledge and the Integration of Expertise

Decisions regarding the working conditions under which patients are treated are taken at the management level. Thus, patient safety is also a key responsibility of leaders. To set a framework that is safe for both patients and staff, management needs medical-technical knowledge and an understanding of human factors. Currently, it is rare to see new hospital or healthcare equipment or technologies being systematically chosen with human factors as an essential consideration. To do so will require an integration of management, employee participation, learning, and training (Carayon et al. 2012).

Knowledge of human factors is now mainly used to explain accidents and incidents (Chap. 16). For improving patient safety, it should come into play much earlier: Significant and expensive decisions can hardly be reversed if one learns *after* an accident that they weren't adapted to human characteristics and abilities. Structural parameters (e.g., location and arrangement of the trauma room) or large equipment purchases are examples for this. If human factors knowledge in hospitals is to be truly useful, human factors expertise must be involved from an early stage in the acquisition process as well as continuously in the processes of planning, design, training, and clinical use.

15.4.3.2 Human Factors for Patient Safety in Purchasing

The relevance of the design of medical devices for patient safety has been shown in many studies, especially concerning infusion pumps (reviewed in Vincent et al. 2014). For user-centered design of equipment, there is ample knowledge from decades of ergonomic research. The design of devices and operating concepts is, of course, beyond the direct reach of hospitals. But through purchasing policy and by contact with equipment manufacturers, some influence can be exercised. The uniformity of operating concepts in a hospital can be controlled within the organization (probably with short-term financial disadvantages) so that confusion by the variability of devices can be eliminated. But for that, buyers need to know about the potential sources of error and the role of system design for patient safety.

15.4.3.3 Human Factors Aspects of Workplace Design

It's not only about medical devices! The whole working environment should be designed in a way that is useful for workflows that allow for safe working conditions. A relevant example for workplace design in hospitals from a human factors point of view is the placement of hand sanitizer dispensers. Birnbach et al. (2010) pointed out that the compliance of physicians significantly increased when the dispensers were placed in their sight field. Such human factors interventions are powerful because they are effective, independent of individuals, their motivation, or their knowledge (of course, factors such leaders as role models continue to be important). Workplace design is also often less expensive than training to change behaviors. It needs to be implemented once, while behavioral changes must be practiced again and again due to staff turnover and to reinforce best practice.

15.4.3.4 Human Factors Aspects of Hospital Work Processes

Equipment and workplaces are the "hardware" of work. In the case study, the syringe pump is mounted below eye level – an arrangement that invites it to be overlooked under stress. However, on the "software" side, human factors interventions are also necessary and useful for patients and staff. This means designing work processes so that they correspond to human capabilities. An example of this is the avoidance of interruptions. To be interrupted while working on a task by another task can cause a person to forget operations or objectives of the first (interrupted) task (prospective memory failure Sect. 4.5). Human factors considerations can form work processes in a way to make interruptions rare. The reorganization of such processes requires knowledge of attention and memory processes. Even if interruptions are not completely preventable, it is still possible to lessen their effects. One method is to pause a few seconds before continuing the interrupted task because it helps to fully refocus on it (Brumby et al. 2013).

Obviously not all processes can be optimized in a human factors way in a hospital, especially in acute medicine. In the case study, a cesarean section had to be performed in a labor room without the resources of a real OR. Even in optimally designed hospitals, surgeries will have to be performed at night, although the error rate is known to increase significantly at night, especially from 2 to 5 o'clock. Such situations should be limited to emergencies. The current tendency to shift elective surgery to the late night hours may be economically feasible, but for patient safety and the health of employees, it is not. Whenever work must take place under unfavorable conditions, special attention should be paid to strengthen as many barrier layers as possible (Chap. 3). For example, good teamwork and good workplace design can help so that the increased probability of error does not lead to accidents.

15.4.3.5 Whole System Standards

Designing processes implies standardization. As shown in the example of introducing checklists, new processes cannot simply be thrown into a system. To make them work, the entire system must be considered. In the case of the checklist, that concerns issues such as communication, handovers, the effects of status and hierarchy, workload and disruptions, costs, problems in media changes from paper to computer, and others. To think through all of these aspects takes time and resources – but without that, standards will not be effectively and usefully implemented.

Standard processes need to be practiced which means that training is a critical component of systems change and improvement (Russ et al. 2013). Of special importance are processes that were altered or that must be mentally available in case of an emergency (handovers, resuscitation). These processes have to be learned, simulated, and practiced in everyday life. And yet, training and human factors aspects are a rather weak intervention (see Chap. 16 for more details) compared to truly ergonomic work conditions and processes.

15.4.4 Resilience in Acute Medicine

Since the beginning of the millennium, the concept of *resilience*, often in connection with the ideal of a high-reliability organization, has been much discussed in safety research (e.g., Hollnagel et al. 2006). The term, which means elasticity, adaptability, or flexibility, has its roots both in materials science and in engineering as well as in psychology. Originally, it described the ability of a material to be deformed and afterward to bend back to the original shape. In psychology, resilience is understood as the qualities or skills that enable a person to adapt to adverse conditions and to recover from trauma or bad events (e.g., Werner 1989). People who are resilient are not immune to bad events, but they are not broken by them. The study of resilient people shows that in addition to external support and emotional ties, some characteristics of the individuals themselves are crucial. These characteristics can also be useful for dealing with accidents and incidents. Resilient people accept the crisis or trauma. They do not assume the role of a victim, but take responsibility for themselves. They think in a solution-oriented and more optimistic way and are oriented to the future. They have networks on which they can rely and from which they get help. In medicine, resilience is mainly understood in that sense – as an attribute of an individual. Research about "resilience in the hospital" or "resilience in medicine" has focused primarily on mental health of employees, stress management, and courses for serenity.

The idea that organizations can be resilient is a very young one within safety research (e.g. Sutcliffe and Vogus 2003). That organizations deal with bad events and might even be strengthened by those is a fascinating concept, but hardly implemented in practice. Resilience in organizations could be understood as a further development of existing safety management systems and cultures. Resilience would then encompass the acceptance that accidents or crises occur but that it is possible to overcome the effects of them. This includes quickly returning to normal. We prefer the image of a tree that is buffeted and bent by a gust of wind, but straightens again. In order to do so, it must be flexible; at the same time, it needs strong roots, so that the wind does not knock it down. Roots of organizational resilience are, for example, risk management and error prevention in everyday work, a willingness to learn that is deeply rooted in the organizational culture (Chap. 16), and the willingness to make prompt decisions in a critical situation and to relinquish control to the local actors (Fig. 15.3).

To be able to return to normal after accidents or crises, organizations need characteristics (Sutcliffe and Vogus 2003) that would also be important for hospitals and other acute care facilities:

- Flexibility and the ability to improvise
- Ability to rapidly respond to an event and decide quickly
- Ability to mobilize reserves and to activate resources within the network

To respond to events or crises in such a way, organizations must be willing to adapt to change and to learn (Chap. 16), and they must know their weaknesses and

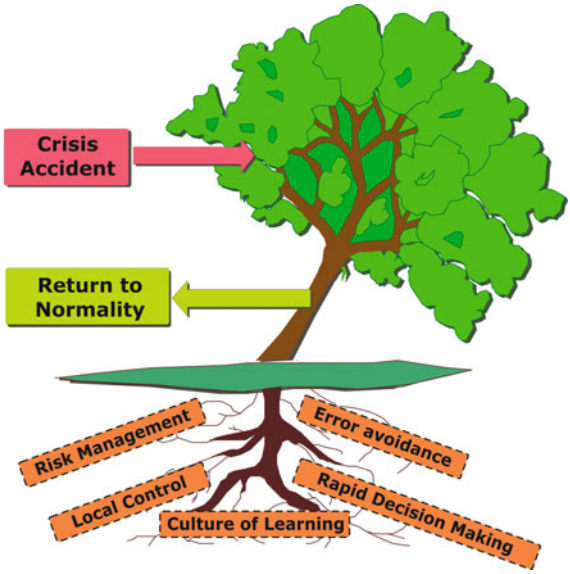

Fig. 15.3 Organizational resilience can be described with the metaphor of a tree buffeted and bent by the wind yet rising again – if it is flexible enough and the roots are strong enough to keep it from breaking

deal with them. That is where the concept of resilience meets with the notion of a high-reliability organization. Teams in an organization have a special role because they are the ones who, because of their adaptability, serve as the most likely entity to interrupt a chain of events from causing an error. This makes good team training all the more important (Chaps. 11 and 16).

In the context of patient safety, the adaptation of the concept of *resilience* is still nascent. What does it mean to be a resilient organization when a complication occurs? What does it mean when a patient has already been harmed? Currently "organizational resilience" does not seem ready for direct, operational implementation. However, the concept offers ideas and suggestions about how to effectively manage incidents and accidents – especially with flexibility, decision-making abilities, and resources based on a profound knowledge of the organization's weaknesses and strengths.

15.5 Reliable Acute Care Medicine in a Nutshell

- To increase patient safety, healthcare organizations are basically faced with two possibilities. They can try to reduce the variability of processes and the resulting complexity of the work environment, or they can strengthen their ability to cope with complexity and uncertainty. Of course it is possible to combine the two approaches.
- Clinical risk management is a prevention system intended to reduce risks in patient care and pursue the goal of continuous improvement of the quality of care and patient safety. The term is also used in a different sense, i.e., to describe a defense to counter unjust patient claims against the hospital institution.

- Quality assurance and continuous quality improvement efforts focus on the structure, process, and outcome of patient care.
- Quality management entails forming all processes in an organization in a way that the results or products have the desired quality. By quality we mean how good and also how safe the treatment is.
- Examples of methods for risk and quality management are clinical safety audits and quality circles.
- Because patients are always cared for in an organization-specific context, the system design and the design of treatment processes have to be taken into consideration when addressing patient safety.
- If acute care organizations of the future want to treat patients safely, they must follow the principles of human factors in the design of processes and technological systems. The work systems and components must be designed in a way to make safe work possible at any workplace and at any time.
- Organizational development means to strategically plan and systematically change an organization with the goal of increasing effectiveness in organizational problem solving. Since organizations are not developed from the outside, but move toward their own targets, change can only come from within hospitals themselves.
- Standardization, the deliberate strategy to maintain a high similarity in task performance, is aimed at guaranteeing the highest possible quality patient care in routine tasks.
- Standards support work and ensure quality, but they can also be seen as restricting the freedom and professionalism of caring and well-trained providers and the over-formalization of work.
- A checklist is a list of action items or criteria arranged in a systematic manner, allowing the user to record the presence or absence of the individual items listed, thereby ensuring that all have been considered or completed.
- The real challenge in introducing a checklist lies not in its creation, but in overcoming a number of sociobehavioral and technical barriers to the procedure described in the checklist.
- Patient handover at the different units is a significant and error-prone process in the context of patient care because both relevant information and responsibilities are transferred.
- Information does not equal knowledge. Only if information related to some goal is selected, sorted, processed, and finally used is it knowledge in the sense of knowledge management.
- Knowledge management refers to a range of systematic practices that capture and disseminate organizational knowledge to enhance organizational performance.
- Knowledge management faces two major challenges: First, implicit knowledge must be converted into explicit knowledge, since only explicit knowledge will be available for organizations. At the same time, processes must be designed in a way that makes explicit knowledge available when and where it is needed.
- Resilience means to accept that accidents or crises occur and to cope with them. For that, organizations need flexibility, decision-making skills, resources, and a willingness to learn.

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