Introduction

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Paul R. Barach, Jeffrey P. Jacobs, Peter C. Laussen, and Steven E. Lipshultz

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P.R. Barach, BSc, MD, MPH (✉)
Department of Health Management and Health Economics, University of Oslo, Oslo 1074, Norway
e-mail: pbarach@gmail.com

J.P. Jacobs, MD, FACS, FACC, FCCP
Division of Cardiac Surgery, Department of Surgery, Johns Hopkins All Children's Heart Institute, All Children's Hospital and Florida Hospital for Children, Johns Hopkins University, Saint Petersburg, Tampa and Orlando, FL, USA

Division of Cardiac Surgery, Department of Surgery, Johns Hopkins University, Baltimore, MD, USA
e-mail: jeffjacobs@msn.com; jeffjacobs@jhmi.edu

P.C. Laussen, MBBS, FCICM
Department of Critical Care Medicine, The Hospital for Sick Children, Toronto, ON, Canada

Department of Anaesthesia, University of Toronto, 555 University Avenue, Toronto, ON, Canada
e-mail: peter.laussen@sickkids.ca

S.E. Lipshultz, MD, FAAP, FAHA
Carman and Ann Adams Department of Pediatrics, Wayne State University School of Medicine, University Pediatricians, Children's Hospital of Michigan, Detroit Medical Center, Children's Research Center of Michigan, 3901 Beaubien Boulevard, 1K40, Detroit, MI 48201-2196, USA
e-mail: lipshultz@med.wayne.edu

This book, entitled "***Pediatric and Congenital Cardiac Care***: ***Outcomes Analysis***, ***Quality Improvement***, ***and Patient Safety***," is Volume 1 of one of a two volume textbook. The focus of Volume 1 is outcomes analysis. The focus of Volume 2 is quality improvement and patient safety. The first volume of this textbook concentrates on measurement and analysis of health outcomes. Leading work has been undertaken in pediatric cardiac care to understand and measure improved patient outcomes and how to establish collaborative definitions and tools of measurement. The book highlights best practices for measuring outcomes of pediatric cardiac care. Meaningful analyses of outcomes requires a database that can incorporates the following seven essential elements: (1) Use of a common language and nomenclature; (2) Use of a database with an established uniform core dataset for collection of information; (3) Developing a mechanism for evaluating case complexity; (4) Using a mechanism to assure and verify the completeness and accuracy of the data collected; (5) Collaboration between medical and surgical subspecialties with assistance by health service researchers; (6) Standardization of data collection protocols; and (7) Incorporation of strategies

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for quality assessment and quality improvement. Volume 1 of this textbook will focus on these seven essential areas while, volume 2 will cover both implementation science for continuous quality improvement, safety science and systems improvement.

The fields of pediatric cardiology and cardiac surgery have grown and developed faster than most other fields in medicine. The fundamental biological embryological causes contributing to congenital heart disease are far from understood. There are great variations in the complexity of congenital cardiac defects, but nevertheless there are well established treatment options for correction and palliation of most defects. It seems, however, that despite unprecedented levels of spending on pediatric cardiac care, preventable medical errors have not been reduced, uncoordinated care continues to frustrate patients, parents and providers, and healthcare costs continue to rise [1]. The US Institute of Medicine estimates that 100 patients die each day in the United States from iatrogenic causes. There are many possible factors related to this unexpected circumstance, including the introduction of new technology that alters rather than improves systems for care, the lack of engagement of front line staff in decision making the complexity of patient disease and the increasing toxicity of medical treatments.

Delivering safe pediatric cardiac care is complex and complicated. The way, we organize as teams, the systems of care we develop, and the means by which we collaborate and share information are crucial for delivering safe and cost effective care [2]. Indeed, the delivery of safe and reliable patient care is an international health system priority. In the early days of pediatric cardiac surgery, mortality rates were very high. During the past three decades, survival among children born with even the most complex cardiac defects has increased substantially so that from 2005 to 2009, the discharge mortality of index cardiac operations was 4.0 % (3,418/86,297) in the Congenital Heart Surgery Database of the Society of Thoracic Surgeons (85 centers from the United States and Canada) [3, 4]. Across the world, mortality figures have declined, suggesting that perhaps this outcome variable is perhaps no longer the best metric by which cardiac surgery programs can be evaluated. However, the mortality rates between institutions continues to vary up to sixfold, suggesting there is still many modifiable factors related to case volume, experience, and practice variability [5]. Morbidity and preventable adverse events are better metrics for the evaluation of performance and competence, but are difficult to measure, vary between and by systems of care, and are dependent on the socio-technical interactions of the care we provide and decisions we make [6]. Complications and adverse events result in higher morbidity, and the potential for longer-term disability and decreased quality of life. The quality of life achieved by our patients following the care we deliver is arguably the most important outcome metric for children with heart defects.

Rapid advancements that followed from improved diagnostic modalities (i.e., 2D echocardiography among others), improved technology in cardiopulmonary bypass, and new management paradigms and prostaglandin E1 infusions to maintain patency of the arterial duct, have all contributed to the remarkable successes in treating these children. Despite remarkable advances, there still remains a relatively high rate of early and late adverse events (mortality and morbidity), particularly in newborns and infants. The frequency of events and the focused patient population means that providers caring for children with congenital and pediatric cardiac disease are compelling model for investigating resilient systems, human errors, and their impact on patient safety [2].

This first of a kind cross-disciplinary collaboration by four lead clinician editors from disparate medical disciplines (i.e., cardiac surgery, cardiology, anesthesia, and critical care), has pulled together an international community of scholarship with articles by luminaries and cutting edge thinkers on the current and future status of pediatric and congenital cardiac care.

Intense scrutiny and measurement of clinical outcomes is increasing at a rapid rate, beyond institutions, regions, and borders. Simultaneously, the requirement and demand for more transpar-

ency and more public reporting, new regulations, and penalties when reported outcomes do not meet expectations is increasing. We believe the current multi-disciplinary approaches in pediatric cardiac care can provide a collaborative road map for other disciplines and fields in healthcare such as medicine, surgery and general practice. Proscriptive rules, guidelines, and checklists are helping to raise awareness and prevent harm. However, to provide an ultra-safe system for patients and their families, we need to engage users in more creative ways that rely on systems thinking, involved redesign of work practices [2].

Although the field of pediatric and congenital cardiac care has received worldwide recognition as a leader in outcomes analysis, quality improvement, and patient safety and has advocated for system-wide changes in organizational culture, opportunities remain to lower costs, reduce risks, and improve performance. The field has many complex procedures that depend on a sophisticated organizational structure, the coordinated efforts of a team of individuals, and high levels of cognitive and technical performance. In this regard, the field shares many properties with high-technology systems such as aviation and chemical manufacturing in which performance and outcomes depend on complex individual, technical, and organizational factors and the interactions among them [6].

Several factors have been linked to poor outcomes in pediatric cardiac care, including institutional and surgeon- or operator-specific volumes, case complexity, team coordination and collaboration, and systems failures [7]. Safety and resilience in these organizations are ultimately understood as a characteristic of the system—the sum of all its parts plus their interactions. Further, many regulatory and government agencies are examining more closely the utility, management of risk, relationships of programmatic volume, and outcomes in the field.

Interventions to improve quality and strategies to implement change should be directed to improve and reduce variations in outcomes. It is imperative that there be an appreciation of the impact of human factors in the field, including an understanding of the complexity of interactions between:

- The technical task,
- The stresses of the treatment settings,
- The consequences of rigid hierarchies within the staff,
- The equipment and physical architecture,
- The lack of time to brief and debrief, and
- Cultural norms that resist change.

Technical skills are fundamental to good outcomes, but non-technical skills—coordination, followership, cooperation, listening, negotiating, and so on—also can markedly influence the performance of individuals and teams and the outcomes of treatment [8].

Pediatric cardiac surgical care has been the subject of well publicized inquiries. A consistent theme from these inquiries is that many staff, patients, and managers had raised concerns about the standard of care provided to patients before the sentinel event. The events surrounding the Bristol Royal Infirmary [9], the Manitoba Healthcare [10], and the Mid Staffordshire [11] inquiries highlight the importance of engaged leaders and clinicians who appreciate the impact of human factors and systems improvement in improving outcomes in pediatric cardiac surgery.

The accidents and adverse events that still occur within systems that possess a wide variety of technical and procedural safeguards (such as operating rooms and intensive care units) have been termed organizational accidents [11, 12]. These are mishaps that arise not from single errors or isolated component breakdowns, but from the accumulation of delayed action failures lying mainly within system flaws that set up good people to fail [13]. People often find ways of getting around processes which seem to be unnecessary or which impede the workflow. This concept is known as normalization of deviance [14]. This accumulated and excepted acceptance of cutting corners or making work-arounds over time poses a great danger to healthcare systems. Similar findings have been described in other investigations into major episodes of clinical failure, and healthcare systems need to heed similar lessons from other industries [15, 16]. This concept is shown schematically in Fig. 1.1.

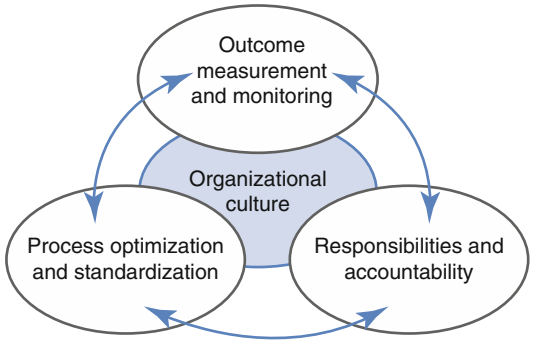

Fig. 1.1 High reliability organizations and their organizational culture (Reprinted from Berg et al. [30])

The study of human factors is fundamentally about appreciating the nature of socio-technical systems and optimizing the relationship between people, tasks, and dynamic environments [17]. Although a particular human action or omission may be the immediate or suspected cause of an incident, closer analysis in pediatric care usually reveals a preceding series of events and departures from safe practice, potentially influenced by the working environment and the wider organizational context [18]. An organizational accident model proposes that adverse incidents be examined both [19]:

- From an organizational perspective that incorporates the concept of active and latent conditions, and
- From an individual perspective that considers the cascading nature of human error.

To improve outcomes of children with heart defects, we need to create and support an organizational conditions, resources, and culture in which clinicians can produce safe outcomes. Leaders in our field must create the climate that allows people to acknowledge mistakes and encourages clinicians to innovate. There is tight coupling and complexity across pediatric cardiac care, and the ability of the team to recognize and respond quickly and appropriately to errors and threats is essential to minimize the consequences and ensure recovery [20, 21].

High reliability—or consistent performance at high levels of safety over prolonged periods—is a hallmark for non-health-related, high-risk industries, such as aviation and nuclear power generation [22]. High reliability is centered on supporting and building a culture of trust, transparency, and psychological safety [23]. In the face of health reform and increased competition in the market, moving to high reliability requires adopting and supporting a culture that appreciates the relationships among a variety of organizational risk factors and their effect on patient harm and procedural inefficiency. Improving safety and quality, and providing true value in pediatric cardiac care, will require clinicians to acknowledge their primary responsibility to the care of their patients and their families, as well as managing processes for optimization, standardization, and continuous measuring and monitoring of outcomes [24].

Finally, trust and collaboration within teams, between institutions, and across institutional and jurisdictional borders are essential elements in pediatric cardiac care to ensure clinicians feel safe and empowered to speak up and talk about processes and outcomes that could be improved [25–27].

This book came about from a long standing friendship and camaraderie of the editors who collectively believe that we should continuously strive to do much better for our patients, and their families, in delivering safer, higher value, and patient centered pediatric cardiac care. The book evolved from two successful special issues of Pediatric Cardiology [28, 29]. The editor's feel strongly that no one repository exists for the three inter-related domains of outcomes analysis, quality improvement, and patient safety.

We believe that innovation in patient care is best designed in concert with those on the front lines of healthcare delivery—patients and clinicians—and incorporating relevant knowledge from other scientific disciplines such as operations research, organizational behavior, industrial engineering, and human factors psychology. In order to best engage with medical staff, the focus of improvement efforts should be on bringing even more scientific discipline and measurement to the design of healthcare delivery. The need exists to develop innovative models of care that lower the complexity and cost of delivering health care, while simultaneously

improving clinical outcomes and the patient experience.

The editors are indebted to the wonderful contributions from leaders across the world from a wealth of disciplines with expertise in pediatric cardiac care. The authors are all "thought leaders," have lead important change, and are visionaries. We hope this book provides readers with a roadmap and a common reference source of current initiatives in outcomes analysis, quality improvement, and patient safety in our field of pediatric and congenital cardiac care. Moreover, we hope the content and the authors of this text will inspire readers, foster engagement, and change, and that through collaboration and sharing, pediatric cardiac care with be enriched and improved.

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