

Paul R. Barach
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Steven E. Lipshultz
Peter C. Laussen *Editors*

Pediatric and Congenital Cardiac Care

Volume 1:
Outcomes Analysis

 Springer

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Paul R. Barach • Jeffery P. Jacobs
Steven E. Lipshultz • Peter C. Laussen
Editors

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Volume 1: Outcomes Analysis

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ISBN 978-1-4471-6586-6 ISBN 978-1-4471-6587-3 (eBook)
DOI 10.1007/978-1-4471-6587-3
Springer London Heidelberg New York Dordrecht

Library of Congress Control Number: 2014956025

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Printed on acid-free paper

Springer is part of Springer Science+Business Media (www.springer.com)

We would like to dedicate this book to all patients receiving pediatric and congenital cardiac care and their families. Each of the Editors would like to make the following additional dedications:

To Elijah, to Tore, to Harrison, and to the love of my life, Julie, who makes it all possible.

Paul R. Barach

To my parents David and Marilyn Jacobs for giving me the opportunity, to my wife Stacy for supporting and loving me, to my children Jessica and Joshua for making me proud and motivated, and to my patients, who represent the rationale for this initiative.

Jeffery P. Jacobs

To my wife Tracie and our children Hannah, Zach, Emma, and Sarah, who have always inspired me to do everything possible to improve the health of children. Their motivation has guided me, in the words of others, to “treat every child and family I have the privilege to care for as if they were my first and every day that I am entrusted with their care as if it was my last.” These volumes are part of the covenant I have made with many patients and their families to do our very best for them and those who follow. This has been made possible by the wisdom and collaboration of my cherished colleagues and mentors.

Steven E. Lipshultz

To Julia and Joan for their wisdom, guidance, and love. To my children and precious Emery, an inspiration for the future. To the patients I care for and who teach me every day.

Peter C. Laussen

Foreword

A parent taking a child into hospital for diagnosis and treatment hopes for a cure and the restoration of a normal quality of life in the future. They fear many things, ranging from the worst—the death of the child—through their pain and suffering to uncertainty about how to manage the complexity of their own lives, which have so suddenly been disturbed. What they have a right to expect is that the people treating their child know what they are doing, are well trained, and particularly will put the needs of their child at the center of their decision making.

They are handing over their precious bundle of joy to strangers to care for, aware that that very care might actually threaten the life of that child as well as offer treatment. They are *loaning* their child to these professionals. It demands an enormous amount of trust to do that. As professionals, we need to be able to recognise that level of trust and repay it. Trust is a two-way thing.

The remarkable fall in the mortality for repair of congenital heart defects over the last 60 years could lead to complacency. But we must not forget that mortality is only one outcome measure and cannot reflect all the issues which concern parents. Medicine is dangerous. Many readers will have seen the famous diagram which charts the relative risk of accidents affecting users of organisations, which shows that there are high-reliability organisations like European railroads, western airlines and the nuclear industry but that medicine is about as safe as bungee jumping. This is due to errors that we make, problems we fail to address, complications we fail to tackle. There is no room for complacency if we want to deserve the trust of the parents who have loaned us their child.

If it were my child being treated, this is what I expect:

- I *expect* that my child will be cared for safely in a modern hospital.
- I *expect* my child to be looked after by a well-functioning multi-disciplinary team.
- I *expect* the staff will know the results of the treatment they propose not just in the literature but in their own hands.
- I *expect* the staff to know the complication rates in their hospital and put in place ways to reduce them.
- I *expect* that they will be collecting complete and validated data on all they do and that they will share those data openly with other professionals and the public.

- I *expect* the staff will do all they can to mitigate the certain human error that will occur, by putting in place systems which limit both risk and harm.
- I *expect* that the staff will be honest, open and transparent in all their dealings with me and that if they don't know something, they will say so and let me get a second opinion.
- I *expect* to be involved in decisions about the care of my child and to have my views respected.
- I *expect* that any harmful incident will be fully, openly and honestly investigated as quickly as possible and that learning from the incident will spread widely so that no one else can suffer.
- I *expect* that the team will be interested in the long-term outcome of treatment, not just in hospital, and that they will have mechanisms in place to gather the relevant information.
- I *expect* the truth and to be treated as if I were a friend, with warmth and empathy.

The Editors of this timely book have gathered an array of experts to give guidance as to how these expectations should be met. They give valuable insight into methods and use their own experience to highlight what we can do to be better. Being better, continuous improvement is what it is all about. Our speciality has done well with a relentless pursuit of excellence and is further advanced than many in being open about its results. Yet, it has much to learn from other disciplines, particularly oncology, about the benefits of collaboration over competition. Our discipline was built on the drive and energy of highly competitive alpha males and the disruptive technology of cardiopulmonary bypass. A second wave of disruption has followed the introduction of trans-catheter interventions. But this too has resulted in the same kind of rush to glory that we saw in the 1970s with surgical heart valve implementation and design. We need good studies, strong data and multi-center collaboration if we want to give the best care as quickly as possible.

This book exemplifies the move to collaboration and the drive towards openness and transparency. All our patients and their families are now 'digital natives'. They access the collective memory of Google just as we do. They expect to see our results and can quickly find their way around PubMed. We have a duty to give them insight into the facts they can read. The information provided in this text will help units realise both the importance of good data but also the methods by which it can be used, evaluated, interpreted and reported.

Don't forget, your duty is to keep the child safe and make it as well as you can. This book will help.

London, UK

Martin Elliott, MD, FRCS

Preface

The idea that clinical data could be analyzed by multiple congenital heart centers was shared by many enlightened individuals who foresaw the utility of such an organizational structure in the early 1980s. Discussions led to ideas that resulted in primitive data collection systems that catalogued diagnoses, procedures, complications, and survival statistics. The difficulty with these systems was that the nomenclature was not uniform and the challenge of comparing diagnoses and procedures prevented accurate analysis. In short, nomenclature categories were diverse owing to substantial and justified differences of opinion by many leading anatomists. Parallel publications by surgeons and cardiologists resulted in more uniform parochial nomenclature systems, but still there were significant differences between the two that challenged future collaborative efforts. The call to arms was answered by concerned clinicians and anatomists and resulted in a computer mapping strategy that was successful in categorizing diagnoses and procedures by what is actually described and performed and not by what it is called. As a result, the types of ventricular septal defects, atrial septal defects, truncus arteriosus, and the like now had a computer number and not a name. It was revolutionary in concept and comprehensive in scope. It was as if the world had one language even if the cultures varied. Before long, North and South America, Europe, Asia, and Africa were using the standard nomenclature.

This was just the beginning. Data were collected, analyzed, and interpreted to reveal or contradict theretofore clinical assumptions, biases, and largely undocumented hearsay conclusions. Data verification strategies by professional volunteers were planned, and audit visits were instituted. Concurrently, participating center data were to be assessed and compared with the combined experience of the participating centers. This allowed the possibility of program assessment and quality improvement. Complexity scores were developed based on Delphian principles until the time that enough data were collected to allow data-driven risk stratification.

The subsequent analysis of the databases and the developed nomenclature became exponential. Government agencies accepted the documents and instituted registries based on the developed principles. Long-term outcome analyses became a reality with database linking to both the Department of Health and Human Services Centers for Medicare and Medicaid Services Database and the Social Security Death Master File. Ethical issues were being discussed and used to clarify rules and regulations. In addition to these innovations, database documentation of complications has been used to guide

the clinician to perform more extensive data-driven informed consent. In an interesting twist of phrases, the database was used to inform the informed consent process.

The benefits of the database systems and the supporting nomenclature were simply too much to document in an expanded treatise. It could only have been accomplished by a book, the like of which is offered in this informative and excellent text. The reader will enjoy this book not only for the rich references that accompany the prose but also for the enjoyable historical account of what some people refer to as simply unbelievable.

Orlando, FL, USA

Constantine Mavroudis, MD

Acknowledgments

The Editors of *Pediatric and Congenital Cardiac Care: Volume 1 – Outcomes Analysis and Volume 2 – Quality Improvement and Patient Safety*, Paul R. Barach, Jeffrey P. Jacobs, Peter C. Laussen, and Steven E. Lipshultz, would like to thank all the authors of chapters in this two-volume set of textbooks, the families of these authors, our administrative staff, and our Editorial and Publishing team.

- Our authors represent an international community of scholarship, with chapters written by luminaries and cutting-edge thinkers.
- All the family members of these authors are indeed owed a debt of gratitude because writing chapters markedly decreases the time available with them.
- Finally, this set of textbooks is possible only because of the tremendous efforts of our administrative staff and the Editorial and Publishing team, and we especially acknowledge the coordination throughout this project by Mitzi Wilkinson and the hundreds of hours devoted to this project by Flora Kim and Grant Weston.

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Part I

Introduction

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Keywords

Patient safety • Systems improvement risk management • Patient outcomes • Culture of care

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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 incorporate 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

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, suggest-

ing 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.

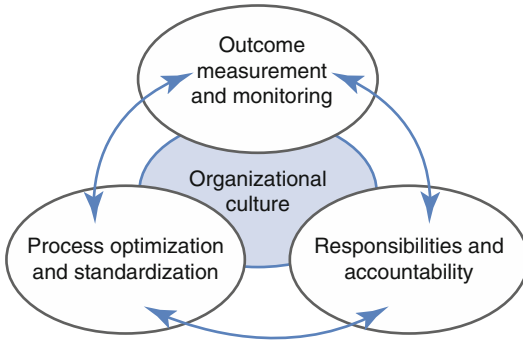


Fig. 1.1 High reliability organizations and their organizational culture (Reprinted from Berg et al. [30])

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 will be enriched and improved.

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