Progress in Pediatric Cardiology 54 (2019) 101139

Contents lists available at ScienceDirect

Progress in Pediatric Cardiology

journal homepage: www.elsevier.com/locate/ppedcard

Editorial

Evidence-based, safety management policies for pediatric cardiac care in New York State

ARTICLE INFO

Keywords:
Congenital heart surgery
Quality
Safety
Outcomes
New York State Department of Health

"*They took something they can't give back.*"
Rosana Escamilla, whose daughter Alexcia was paralyzed after a surgical heart procedure was done in 2016 [1].

Pediatric cardiac care is among the most complex, demanding, and consequential interventions in all of medicine. As healthcare delivery moves away from a volume-based reimbursement model to an efficiency-and-quality-oriented model, providing high-quality, evidence-based, and value-based care has challenged policy makers, surgeons, and healthcare systems. Why has it taken so long to improve pediatric cardiac care? [2].

Congenital heart lesions occur in about 17 per 1000 live births [3]. These lesions are the most common cause of admission to the pediatric intensive care unit and the most common non-infectious cause of death in infants [4,5]. Medical and surgical advances in the past three decades have increased the survival rate of children born with complex cardiac defects [6]. Despite these advances, however, these defects still cause permanent disability or death in hundreds of children in the US each year. Although the overall mortality in pediatric cardiac surgery is below 4%, at least 20% of these deaths are believed to result from preventable adverse events [7]. For neonates, the margin of error is particularly low and is accompanied by a limited ability to recover from these errors and to prevent poor outcomes. About 10% of neonates undergoing complex cardiac surgery die within 30 days of surgery, and survivors may experience major long-term or even life-long consequences, such as impaired brain development and reduced psychomotor abilities [8]. The resultant burden of these consequences on children, their families, and their community is profound.

The opportunity to provide cardiac care is a privilege. Many patients and families regard this care as a true "miracle" when it improves quality of life or longevity. At the same time, concern about errors in delivering this care is drawing considerable and intense public scrutiny [9]. The backlash against the limitations of managed care and the proliferation of public information purporting to judge the performance of health plans, hospitals, and doctors, have all contributed to a vigorous discussion about the nature of quality care, the problems in achieving it, and how these problems can be resolved [10].

In pediatric cardiac surgery, harm can manifest as suffering and morbidity, the need for additional care, longer-term disability, and death. If complications or unexpected outcomes lead to major life-altering or life-ending results, patients, families, and the community are usually unforgiving. This high-risk and high-reward specialty demands a culture of systems reliability that supports unusually high standards of quality and safety, and in this respect, it is similar to other high-risk activities, such as air travel [11].

All members of the health system, including policy makers, administrators, cardiac surgeons, and other healthcare providers are responsible for creating sustainable and high-quality models of care for children with heart defects. Three major public policy reports published in the past year have suggested that, despite major funding and much research and a growing awareness of safety issues, healthcare delivery continues to vary widely among centers and can cause lasting but preventable harm to children and adults [12–14].

New York State holds a special place in the world for furthering the evolution of reliable and safe care. The seminal 1989 Harvard Medical Practice Study, funded by the New York State Health Commissioner, Dr. David Axelrod, remains the standard for guiding evidence-based public policies for population health and patient safety [15]. Furthermore, in 1988, when confronted with data showing large and long-standing variations in short-term mortality and complications among hospitals providing cardiac surgery, the state developed the first clinical registries for cardiac surgery in 1989 and for percutaneous coronary interventions in 1992 [16]. In 1990, the New York State Department of Health, for the first time anywhere in the world, released risk-adjusted cardiac surgery mortality rates for individual hospitals. Shortly thereafter, it released similar data on hospitals and physicians for percutaneous coronary interventions, cardiac valve surgery, and pediatric cardiac surgery (only hospital data) [17]. Publication of these data continues and remains a best-practice that has been emulated by other states and countries.

The New York state policy to publish risk-adjusted mortality data for cardiac surgery in adults, prompted comprehensive efforts by hospitals to improve their cardiac surgery programs and made publically available, meaningful validated feedback to healthcare units as indicators of the overall system performance[18]. In the intervening

https://doi.org/10.1016/j.ppedcard.2019.101139

Available online 08 August 2019

28 years, the New York "experiment" of releasing provider data to the public has been well accepted and proven to be effective in improving care. The experiment has been a model for similar statewide efforts (e.g. Pennsylvania, Massachusetts, New Jersey, and Michigan) [19], and current initiatives by federal agencies and professional associations. These initiatives preceded the Bristol Royal Infirmary's cardiac surgery inquiry that shaped planning and governance of pediatric cardiac services in the United Kingdom [20].

The recent alleged high-profile breakdowns in pediatric cardiac care at the University of North Carolina [21], Johns Hopkins [22], St. Mary's Children's Hospital in West Palm Beach [23], and the University of Nebraska [24] have increased public scrutiny and the increased awareness of the risks, complexity, and need for reforms in pediatric cardiac care. These breakdowns also increased public scrutiny of healthcare executives and increased their personal vulnerability and job security as they shift their institutions away from reacting to adverse events to taking a frank and deep interest in preventing these events and in improving the performance of pediatric cardiac care systems. However, many of these executives still underestimate the serious challenges that lie ahead for them, given the disruptive and rapidly accelerating pressures to improve system performance [25].

All of this local exposure is occurring against the backdrop of an increasing international awareness of the value of regionalized pediatric cardiac care; an awareness stimulated by major investigations of pediatric cardiac surgery care in Bristol, United Kingdom; Nijmegen, Netherlands; Manitoba, Canada; and Sydney, Australia [26]. For example, Norway centralized 4 pediatric cardiac surgery centers into 1; the UK, from 21 to 13 (with a recommendation to centralize further to 9); and the Netherlands, from 8 to 4 [27]. Nevertheless, the results of centralization and the success of the accompanying reorganizations based on integrated care pathways remain hotly contested.

A systems' approach, because it involves evaluating and changing the wider organization and its management, communications, and culture, is the best way to prevent individual or component failures in the healthcare system [28]. That is, safety in the operating theater, catheterization laboratory, and at hospital discharge is sometimes greatly affected by seemingly remote influences, such as inter-departmental relationships, attitudinal differences, and organizational cultures that tolerate unnecessary risks [29,30].

Upstate New York recently implemented several well-documented best practices in pediatric cardiac surgery reducing peri-operative mortality and improving longer-term outcomes, as described by Swartz et al. [31]. The authors attributed their success to consolidating three surgical centers—at Buffalo, Rochester, and Syracuse—into two, in which the same cardiology service provided care in a networked arrangement at all three clinical centers. Thus, the systems model of "one network, two surgery sites, three hospitals" is attractive. The seamless integration of care, irrespective of the presenting site, might be the biggest and yet unmeasured reason that overall surgical outcomes have improved [32].

Managing these centralized surgical networks effectively requires maintaining a pervasive culture of collegiality, trust, truth telling and a and collective purpose. To date, however, research has tended to focus on single clinical environments or organizational settings; that is, on component failures in primary or secondary care, operating theaters, or the emergency department. Missing is a foundational safety management learning system [33] that focuses on system-wide improvements and operational management approaches. A high degree of professional and personal trust (psychological safety), the transparent sharing of clinical protocols and outcome data across sites, and a no-blame culture (e.g., fixing the problem, not the blame) support effective system improvements and can produce exceptional outcomes [34,35]. This success naturally leads to a discussion of how this regional model of surgical practice addresses or influences the usual local characteristics of high-performing microsystems providing care at all levels of complexity [36].

The systems approach specifically considers the complex barriers and drivers of patient safety as a product of a constellation of factors operating within and between care processes. These factors include regulatory pressures, organizational boundaries, perverse financial incentives, shifting professional responsibilities, and poor organizational alignments. The socio-technical, systems approach to improving pediatric cardiac care suggests that adverse incidents should be examined from the perspective of a high-reliability organization, which considers both unstated, underlying conditions and the chain reactions of human error that begin with upper-management decisions and end in undesirable patient or provider outcomes [37]. Care teams in a high-reliability organization are better equipped to learn to prevent and recover from errors before patients are harmed, whereas care teams in a lower-reliability organization that lacks a strong culture of trust, self-assessment, and learning, continue to repeat the same errors and patient harm [38].

Changes in specialized health services in New York State are currently being proposed on the reasonable assumption that regionalization will produce better outcomes. Evidence-based approaches are needed to centralize pediatric cardiac care in New York State, to inform policy, and to understand how decisions can improve healthcare as these health systems are restructured [39]. The desired effects include transforming poorly performing healthcare systems while at the same time engaging providers in a more respectful manner. The potential benefits and mechanisms of more specialized care also pose great challenges to the patient hand-off processes between centers and among professionals who are geographically separated and who are required to provide care in different regions [40].

Several factors have been linked to poor outcomes in pediatric cardiac care, including institutional and surgeon-specific volumes, burnout among surgeons, poor team performance, case complexity, and microsystem failures [41]. Current mortality and morbidity rates among pediatric cardiac care centers are high and vary by as much as a factor of 4, indicating a compelling need to better understand how some teams are better at managing error, better at sharing lessons, and better at applying new learning methods [42,43].

Another aspect and potential benefit of regionalization relates to surgical burnout, defined as "a syndrome of emotional exhaustion and depersonalization that leads to decreased effectiveness at work" [44]. This syndrome has been recognized for well over a decade. Several studies have drawn attention to its rising incidence, with surgeons in some specialties reporting burnout rates higher than 50% [45] and 30% screening positive for depression [46]. Aside from the obvious negative impact on outcomes, on individual surgeons, and on their family, physician burnout also impairs patient care. Surgeon burnout (in particular emotional exhaustion and depersonalization) is directly associated with an increased likelihood of committing a major medical error, being rude to patients, lower career satisfaction, and an earlier retirement age [47,48].

1. New York State public policy recommendations

The future of pediatric cardiac care in New York State requires adopting a bold agenda that allows new hypotheses to be tested and to involve researchers working closely with clinical teams supporting short- and long-term quality improvement efforts and research [49]. Regionalization of pediatric cardiac services in New York State will inevitably involve far-reaching changes in the local delivery of care by transforming care processes, pathways, and teams; by reconfiguring organizational and interorganizational care systems, and by rethinking

the wider regulation, financing, and organization of regional care services.

Regulation is a major way in which governments influence the market economy, including quality of care. However, the recent international deliberations around the Boeing 737 MAX jet crashes have raised serious questions about regulatory capture in aviation and invite a similar look into the independence and impact of healthcare regulation [50]. Do regulatory agencies responsible for healthcare safety and quality have enough qualified people and the independence to understand and regulate the governance and quality of complex pediatric cardiac care? [51]. How can regulators, with only limited data supporting accreditation as a quality indicator [52], be more responsive to the marketplace, support internal quality-improvement efforts, and remain nimble, despite the influence of special-interest money and politics? Finally, how can we improve the quality of regulations and regulating in the real world?

Regionalization also has substantial implications for patients and caregivers, who needs must also be considered when designing the interventions needed to enhance the integration, effectiveness, safety, and focus on patient- and family-directed care of centralized specialized services [53]. These interventions need to be identified, evaluated, and revised to ensure that the safety and needs of the patients are always at the center of the changing network of healthcare organizations [54].

We believe the following recommendations may improve the safety and quality of care in pediatric cardiac surgery in New York State:

1. Create a New York State Safety Management Care Model based on the principles of “Resilience and Safety 3.0” that require better understanding of the needs of the workplace (“work as is” versus the “work as imagined”), particularly as they relate to the surgical workforce; team training and performance improvement; financial and practical sustainability; and the generalizability of such arrangements to other settings [55].
2. Partner (co-produce) with patients and their families in developing newer models of care that better support families in achieving reliable and safe outcomes [56]. Related to these models is the need to identify the critical moments of contact with patients and families; that is, we need to determine when the patient and family decide to trust care providers, and we need to understand the mindset behind patients' actions, expectations, and loyalties to make their expectations more realistic and their experience more productive. Finally, we need to identify the measurable quality requirements that parents care most about (e.g. timeliness, consistency, compassion, etc.) and can indicate whether our clinical policies are meeting the expectations of the children and their parents [57].
3. Develop a patient outcomes and performance improvement service at the New York State Department of Health that tracks pediatric cardiac outcomes using pre-operative clinical data from state-based registries. The service should also maintain a database of advanced diagnostic services, genetic testing, and psychological support. Such data could help determine and inform proposed legislation about when family care is not required and what impact the absence of local surgical care has on short and long-term outcomes in pediatric cardiac care and population health [58].
4. Establish a New York state task force to determine how to improve the effectiveness of training cardiac care teams for patient safety by applying current evidence-based practices [59]. Such training must be supported and reinforced by the organization in which it occurs. In particular, several factors need to be addressed [60] including:
   Organizational climate: Does the organizational culture support/incentivise striving for patient safety? Does it allow for non-punitive reporting of problems and near-misses? [61].
   Organizational support: Do trainees receive dedicated training time during which they are temporarily excused from their regular duties? Is training viewed as more than just a bureaucratic exercise? Is teamwork training widespread across the organization?
   Extent of training: Does the organization only train isolated teams? Does the training of perioperative teams incorporate the “wider” perioperative team (e.g., including specialists and upstream and downstream care providers)?
5. Examine the performance of non-surgical pediatric cardiology services, as well as the protocols by which children are referred to surgical sites when required. Such referrals raise thorny and unresolved questions around assessing the risk of transport, appropriate and defensible communication protocols, coordination, and hand-offs of care between organizations [62].
6. Establish a New York State Pediatric Cardiac Care Learning Collaborative modeled after the Northern New England Cardiovascular Disease Study Group [63], The Michigan Society of Thoracic and Cardiovascular Surgeons [64], and the National Pediatric Cardiology Quality Improvement Collaborative [65] registry. These models require all centers doing pediatric cardiac care to develop trust in each other's data while agreeing to learn from each other in an open and transparent manner on how to achieve the quadruple aims of gratifying providers, improving population health, reducing care costs, and satisfying patients [66].
7. Trust is so fundamental to peer-to-peer relationships and to organizations that employ providers that it is assumed to exist without question. Given changes in health care and society at large, trust is increasingly understood to be at risk and in need of attention [67]. Learning collaboratives can help implement peer-to-peer learning, in improving child growth milestones and mortality, in highlighting and demonstrating the value of working with parents, and in tapping the power of site visits and group deliberations [68]. The collaborative can provide implementation toolkits, pathways, protocols, and templates that have been used successfully by other centers in New York State and can provide access to dedicated staff to assist their institution in creating achievable stretch goals and coaching to achieve these goals. Importantly, this collaborative should examine the key barriers and organizational challenges for implementing best practices in pediatric cardiac care, and how to measure these barriers across surgery types and settings.

In sum, pediatric cardiac care is an example of the benefits of regionalization in New York state, and one that can be generalized to other high-risk interventions in the state, such as for organ or bone marrow transplantation, trauma and spinal care, neurosurgical tumor resection, and even chronic diseases, such as chronic obstructive pulmonary disease and cardiovascular diseases. If the lessons learned in improving safety in pediatric cardiac surgery can be applied to these other interventions, the savings in time, cost, and suffering should be substantial.

Declaration of competing interest

Authors have no conflicts of interest to declare.

References

[1] McGrory K, Bedi N. All Children's says 13 heart surgery patients were hurt by care Accessed July 29, 2019 from Tampa Bay Timeshttps://www.tampabay.com/investigations/2019/02/09/all-childrens-says-13-heart-surgery-patients-were-hurt-

by-care/; 2019, February 9.
[2] Phelps G, Barach P. Why the safety and quality movement has been slow to improve care? Int J Clin Pract 2014;68:932–5.
[3] Pasquali SK, Jacobs ML, O'Brien SM, et al. Impact of patient characteristics on hospital-level outcomes assessment in congenital heart surgery. Ann Thorac Surg 2015;100:1071–7.
[4] The Society of Thoracic Surgeons. STS National Database Accessed July 28, 2019 from http://www.sts.org/registries-research-center/sts-national-database.
[5] Jacobs JP. The Society of Thoracic Surgeons Congenital Heart Surgery Database public reporting initiative. Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu 2017;20:43–8.
[6] Jacobs JP, Mayer Jr. JE, Pasquali SK, et al. The Society of Thoracic Surgeons Congenital Heart Surgery Database: 2019 update on outcomes and quality. Ann Thorac Surg 2019;107:691–704.
[7] Martin GR, Anderson JB, Vincent RN. IMPACT Registry and National Pediatric Cardiology Quality Improvement Collaborative: contributions to quality in congenital heart disease. World J Pediatr Congenit Heart Surg 2019;10:72–80.
[8] Wernovsky G, Licht DJ. Neurodevelopmental outcomes in children with congenital heart disease-what can we impact? Pediatr Crit Care Med 2016;17(8 Suppl 1):S232–42.
[9] St. Louis JD. The search for data, the only true justice. World J Pediatr and Congenit Heart Surg 2019;10:276–7.
[10] Barach P, Lipshultz S. The benefits and hazards of publicly reported quality outcomes. Prog Pediatr Cardiol 2016;42:45–9.
[11] Amalberti R, Auroy Y, Berwick DM, Barach P. Five system barriers to achieving ultra-safe health care. Ann Intern Med 2005;142:756–64.
[12] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Care Services; Board on Global Health; Committee on Improving the Quality of Health Care Globallyeditor. Crossing the global quality chasm: improving health care worldwide. Washington (DC): National Academies Press (US); 2018 Aug. The National Academies Collection: Reports funded by National Institutes of Health.
[13] Kruk ME, Pate M, Mullan Z. Introducing the Lancet global health commission on high-quality health systems in the SDG era. Lancet Glob Health 2017;5:e480–1.
[14] World Health Organization, Organisation for Economic Co-operation and Development, The World Bank. Delivering quality health services: a global imperative for universal health coverage. Geneva: WHO, OECD and The World Bank; 2018.
[15] Hiatt HH, Barnes BA, Brennan TA, et al. A study of medical injury and medical malpractice. N Engl J Med 1989;321:480–4.
[16] Hannan EL, Sarrazin MS, Doran DR, Rosenthal GE. Provider profiling and quality improvement efforts in coronary artery bypass graft surgery: the effect on short-term mortality among Medicare beneficiaries. Med Care 2003;41:1164–72.
[17] Chassin MR, Hannan EL, DeBuono BA. Benefits and hazards of reporting medical outcomes publicly. N Engl J Med 1996;334:394–8.
[18] Hannan EL, Racz M, Kavey RE, Quaegebeur JM, Williams R. Pediatric cardiac surgery: the effect of hospital and surgeon volume on in-hospital mortality. Pediatrics. 1998;101:963–9.
[19] Hannan EL, Cozzens K, King SB, Walford G, Shah NR. The New York state cardiac registries: history, contributions, limitations, and lessons for future efforts to assess and publicly report healthcare outcomes. J Am Coll Cardiol 2012;59:2309–16.
[20] Baker E. Learning from the Bristol inquiry. Cardiol Young 2001;11:585–7.
[21] Gabler E. UNC Children's Hospital suspends most complex heart surgeries Accessed July 29, 2019 from The New York Timeshttps://www.nytimes.com/2019/06/17/us/heart-surgery-children-unc.html; 2019, June 17.
[22] McGrory K, Bedi N. New federal report details widespread problems at All Children's Accessed August 2, 2019 from Tampa Bay Timeshttps://www.tampabay.com/investigations/2019/02/22/federal-investigators-found-systemic-failures-at-all-childrens/; 2019, February 22.
[23] Shammas B. St. Mary's Medical Center ends pediatric heart surgery program, cites 'inaccurate' media findings Accessed August 2, 2019 from South Florida Sun Sentinelhttps://www.sun-sentinel.com/local/palm-beach/fl-st-marys-heart-program-20150817-story.html; 2015, August 17.
[24] Sievers K. Children's hospital lawsuit highlights 'own and control' issue Accessed August 2, 2019 from Norfolk Daily Newshttp://norfolkdailynews.com/news/children-s-hospital-lawsuit-highlights-own-and-control-issue/article_8eae4e72-180e-11e9-8a15-cfc306063d3d.html; 2019, January 14.
[25] Snyder S, Loiacano M, Carey S. Health care executives may be more vulnerable to disruption than they think Accessed August 2, 2019 from American Hospital Associationhttps://www.aha.org/news/insights-and-analysis/2018-07-11-health-care-executives-may-be-more-vulnerable-disruption-they; 2018, July 11.
[26] Marchese D. Health minister will have 'blood on his hands' if cardiac services aren't restored, doctor warns Accessed August 2, 2019 from https://www.abc.net.au/news/2019-05-30/doctor-warns-children-will-die-amid-sydney-hospital-dispute/11165208?pfmredir=sm; 2019, May 30.
[27] Wijnen MH. Centralization of pediatric surgery in The Netherlands. Eur J Pediatr Surg 2017;27:407–9.
[28] Dixon-Woods M, Baker R, Charles K, et al. Culture and behavior in the English National Health Service: overview of lessons from a large multimethod study. BMJ Qual Saf 2014;23:106–15.
[29] Bognar A, Barach P, Johnson J, et al. Errors and the burden of errors: attitudes, perceptions and the culture of safety in pediatric cardiac surgical teams. Ann Thorac Surg 2008;85:1374–81.
[30] Wahr JA, Prager RL, Abernathy 3rd JH, et al. Patient safety in the cardiac operating room: human factors and teamwork: a scientific statement from the American Heart Association. Circulation 2013;128:1139–69.
[31] Swartz MF, Orie JM, Egan M, et al. Five year outcomes after regionalizing pediatric cardiac surgery centers. Prog Pediatr Cardiol 2018;50:4–11.
[32] Winlaw D, Sholler G, Barach P. Regional consolidation of pediatric cardiac surgery in New York State – are we there yet? A destination reached or a step in the right direction? Prog Pediatr Cardiol 2018;50:1–3.
[33] Kleinman L, Barach P. Towards a learning system for pediatric cardiomyopathy: harvesting meaning from evidence. Prog Pediatr Cardiol 2018;49:20–6.
[34] Nahum LH. To tell the truth. Conn Med 1963;27:443–5.
[35] Rosenbaum L. Cursed by knowledge — building a culture of psychological safety. N Engl J Med 2019;380:786–90.
[36] Mohr J, Batalden P, Barach P. Integrating patient safety into the clinical microsystem. Qual Saf Health Care 2004;13:34–8.
[37] Sanchez J, Barach P. High reliability organizations and surgical microsystems: re-engineering surgical care. Surg Clin North Am 2012;92:1–14.
[38] Cassin B, Barach P. Making sense of root cause analysis investigations of surgery-related adverse events. Surg Clin North Am 2012;92:101–15.
[39] Dixon Woods M, Bosk CL, Aveling EL, Goeschel CA, Pronovost PJ. Explaining Michigan: developing an ex post theory of a quality improvement program. Milbank Q 2011;89:167–205.
[40] Barach P, Lipshultz S. Readmitting children with heart failure: the importance of communication, coordination, and continuity of care. J Pediatr 2016;177:13–6.
[41] Baker DP, Salas E, Battles JB, et al. The relation between teamwork and patient safety. In: Carayon P, editor. Handbook of human factors and ergonomics in health care and patient safety. 2nd ed.Boca Raton: CRC Press; 2011. p. 185–98.
[42] Kalfa D, Gottlieb D, Chen JM, Bacha E. Surgical volume and outcome relationship in pediatric cardiac surgery. In: Barach P, Jacobs J, Lipshultz S, Laussen P, editors. Pediatric and congenital cardiac care. London: Springer; 2015. p. 123–33.
[43] Jacobs JP, He X, Mayer Jr. JE, et al. Mortality trends in pediatric and congenital heart surgery: an analysis of the society of thoracic surgeons congenital heart surgery database. Ann Thorac Surg 2016;102:1345–52.
[44] Maslach C, Leiter MP. Understanding the burnout experience: recent research and its implications for psychiatry. World Psychiatry 2016;15:103–11.
[45] Shanafelt TD, Boone S, Tan L, et al. Burnout and satisfaction with work-life balance among US physicians relative to the general US population. Arch Intern Med 2012;172:1377–85.
[46] Shanafelt TD, Hasan O, Dyrbye LN, et al. Changes in burnout and satisfaction with work-life balance in physicians and the general US working population between 2011 and 2014. Mayo Clin Proc 2015;90:1600–13.
[47] Epstein RM, Krasner MS. Physician resilience: what it means, why it matters, and how to promote it. Acad Med 2013;88:301–3.
[48] Winlaw DS, Large MM, Jacobs JP, Barach P. Leadership, surgeon well-being and non-technical competencies of pediatric cardiac surgery. Prog Pediatr Cardiol 2011;32:129–33.
[49] Johnson J, Barach P. Quality improvement methods to study and improve the process and outcomes of pediatric cardiac surgery. Prog Pediatr Cardiol 2011;32:147–53.
[50] Dean J. Boeing and Airbus under the spotlight: safety 'doesn't come first' in the cosy world of aircraft regulation Accessed July 30, 2019 from The Timeshttps://www.thetimes.co.uk/article/boeing-and-airbus-under-the-spotlight-safety-doesn-t-come-first-in-the-cosy-world-of-aircraft-regulation-thxzvnqv2; 2019, July 29.
[51] Dekker SW, Leveson NG. The systems approach to medicine: controversy and misconceptions. BMJ Qual Saf 2015;24:7–9.
[52] Brubakk K, Vist GE, Bukholm G, Barach P, Tjomsland O. A systematic review of hospital accreditation: the challenges of measuring complex intervention effects. BMC Health Serv Res 2015;15:280.
[53] Sakai-Bizmark R, Mena LA, Kumamaru H, et al. Impact of pediatric cardiac surgery regionalization on health care utilization and mortality. Health Serv Res 2019;54(4):890–901.
[54] Lopez C, Hanson C, Yorke D, et al. Improving communication with families of patients undergoing pediatric cardiac surgery. Prog Pediatr Cardiol 2017;45:83–90.
[55] Ramaswamy R, Barach P. Towards a learning system for Enhanced Recovery After Surgery (ERAS): embedding implementation and learning evaluation. In: Ljungqvist O, Urman R, Francis N, editors. Enhanced recovery after surgery - a complete guide to optimizing outcomes. Basel: Springer; 2019. [in print].
[56] Batalden M, Batalden P, Margolis P, et al. Coproduction of healthcare service. BMJ Qual Saf 2016;25:509–17.
[57] Arya B, Glickstein JS, Levasseur SM, Williams IA. Parents of children with congenital heart disease prefer more information than cardiologists provide. Congenit Heart Dis 2013;8:78–85.
[58] Ochoa J. Bill would create more oversight at children's heart surgery centers Accessed August 2, 2019 from WUSF Newshttps://wusfnews.wusf.usf.edu/post/bill-would-create-more-oversight-children-s-heart-surgery-centers; 2019, February 21.
[59] Shouhed D, Gewertz B, Wiegmann D, Catchpole K. Integrating Human Factors Research and Surgery: A Review. Arch Surg. 2012;147(12):1141–6. https://doi.org/10.1001/jamasurg.2013.596.
[60] Entin E, Lai F, Barach P. Training teams for the perioperative environment: a research agenda. Surg Innov 2006;3:3–13.
[61] Barach P, Small DS. How the National Health Service can improve safety and learning by learning free lessons from near misses. Editorial. Br Med J

2000;320:1683–4.
[62] Hesselink G, Schoonhoven L, Barach P, Spijker A, Gademan P, Kalkman C, et al. Improving patient handovers from hospital to primary care. A systematic review. Ann Intern Med 2012;157:417–28.
[63] Likosky DS, Goldberg JB, DiScipio AW, et al. Variability in surgeons' perioperative practices may influence the incidence of low-output failure after coronary artery bypass grafting surgery. Circ Cardiovasc Qual Outcomes 2012;5:638–44.
[64] Prager RL, Armenti FR, Bassett JS, et al. Surgeons and the quality movement: the Michigan experience. Semin Thorac Cardiovasc Surg 2009;21:20–7.
[65] Bates KE, Yu S, Mangeot C, Shea JA, Brown DW, Uzark K. Identifying best practices in interstage care: using a positive deviance approach within the national pediatric cardiology quality improvement collaborative. Cardiol Young 2019;29:398–407.
[66] Anderson JB, Brown DW, Lihn S, et al. Power of a learning network in congenital heart disease. World J Pediatr Congenit Heart Surg 2019 Jan;10:66–71.
[67] Blendon RJ, Benson JM, Hero JO. Public trust in physicians. N Engl J Med 2014;371:1570–2.
[68] Cosman P, Pramudith S, Barach P. Building surgical expertise through the science of continuous learning and training. In: Sanchez J, Barach P, Johnson H, Jacobs J, editors. Perioperative patient safety and quality: principles and practice. Springer978-3-319-44010-1; 2017.

Paul Barach[a], Gul H. Dadlani[b], Steven E. Lipshultz[c,d,e,*]
[a] *Department of Pediatrics, Wayne State University School of Medicine, Detroit, MI, United States of America*
[b] *Pediatric Cardiology, Nemours Cardiac Center, Orlando, FL, United States of America*
[c] *Department of Pediatrics, University at Buffalo Jacobs School of Medicine and Biomedical Sciences, Buffalo, NY, United States of America*
[d] *Oishei Children's Hospital, Buffalo, NY, United States of America*
[e] *Roswell Park Comprehensive Cancer Center, Buffalo, NY, United States of America*
E-mail address: slipshultz@upa.chob.edu (S.E. Lipshultz).

* Corresponding author at: Department of Pediatrics, University at Buffalo Jacobs School of Medicine and Biomedical Sciences, Oishei Children's Hospital, 1001 Main Street, Buffalo, NY 14203, United States of America.