Frameworks for quality improvement in pediatric intensive care: A concise review

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ABSTRACT
Quality improvement programs focused on improving care in intensive care units have become standard at pediatric hospitals around the world over the past several decades. However, the methodology or framework by which these programs assess quality is not standard. This review describes the varying quality improvement frameworks that have been promoted by prominent pediatric and critical care societies and the strengths and limitations of these frameworks, as well as several notable international collaboratives in this domain.

The Donabedian three-part framework of quality assessment

Most experts in the field trace the origins of the modern quality improvement movement to Avedis Donabedian, MD, MPH. His 1966 paper, entitled “Evaluating the quality of medical care,” introduced the now classic three-part framework of “structure, process, and outcomes,” as the three domains by which to evaluate the quality of health care. Structure, by the Donabedian framework, refers to assessing the attributes of the setting in which care occurs. This includes such elements as material resources (facilities and equipment), human resources (the number and qualifications of the personnel on duty), and organization structures (such as how the medical staff is overseen, what structures are in place to perform peer review, etc). Process denotes every aspect of how care is actually provided and outcome denotes the metrics that define the health status of patients who received care in...
that environment, broadly defined to include not simply physical changes in their condition, but satisfaction with care and improvement in the patient’s knowledge as well.

Still later in 1988, in an update on this work, Donabedian wrote, “This three-part approach to quality assessment is possible only because good structure increases the likelihood of good process, and good process increases the likelihood of good outcome.” By stressing the linkage between the three parts, the Donabedian model emphasizes that health care outcomes cannot be understood in isolation, but only by first examining the effectiveness of the structure and the processes of care that produce those outcomes. The Donabedian three-part framework thus provides the overarching conceptual framework for quality assessment in health care. What the Donabedian model does not provide is a more detailed analytic tool to examine the effectiveness of each domain and their relationship to each other. The more detailed evaluative approaches are somewhat different in their methods, but variously referred to as PDSA, Lean, FMEA, and Six Sigma, and are further examined here.

Quality improvement methodologic frameworks

First, however, it is important to note that the science of quality improvement is necessarily different from the science of clinical or translational investigation. The former seeks to examine the organization of care as it is actually provided, in its dynamic environment with no attempt to limit or control the conditions under study. In quality improvement, an intervention or several interventions are deployed, data are measured over time and analyzed, the intervention is then further refined and redeployed, and the cycle continues. Thus, quality improvement methodologic frameworks ideally assess the effectiveness of interventions over time in an iterative manner, in effect small scale experiments to rapidly test new ideas. The science of clinical investigation, on the other hand, seeks to control the conditions under which a treatment is provided. Like a well-controlled experiment, a clinical trial is a time-limited study that assigns patients to treatment and control groups to minimize bias and promote comparability and where the outcome is binary, the treatment is either deemed more or less effective than the standard (or control).

A second notable difference between quality improvement methodology and clinical investigation is with the investigators. By examining the system of care, nearly all quality improvement assessments and interventions necessarily rely on multiple “investigators” or clinicians representing the multiple disciplines that comprise the program but not necessarily with formal education in the methodology deployed. Clinical investigation, on the other hand, is more typically led by one or a few principal investigators with formal training and expertise in clinical trial design and biostatistics, who define the hypothesis to be tested and the conditions under which the trial is conducted, as well as the statistical measures utilized to analyze the data.

Plan-Do-Study-Act (PDSA)

Among the quality assessment methodologies most easy to understand and adopt is the Plan-Do-Study-Act “PDSA” framework, first introduced in 1931 by Walter Shewhart, a pioneer in industrial quality control as “plan-do-check-act” cycles to systematically evaluate new ideas. This approach was later adopted into health care quality improvement by W. Edwards Deming, a pioneer of quality improvement in health care in the United States. The first step of the cycle is to develop a plan to test the change (Plan). Subsequently, investigators carry out the plan to test the change (Do). Both the Study and Act components of the cycle ultimately allow the investigators to evaluate the impact of the change and determine whether it is an effective change with positive outcomes. Today, the PDSA forms an essential part of the Institute for Healthcare Improvement’s “rapid cycle improvement” concept.

| TABLE 1 PICU International Collaborative quality metric sharing |
|---------------------------------------------------------------|
| Quality metric                                              | Definition: Numerator/Denominator                                      |
| Catheter-associated blood stream infection (CABSI) rate       | (# CABSI /1000 Line Days)                                             |
| Catheter-associated urinary tract infection (CAUTI) rate      | (# CAUTI events / total number of urinary catheter days)              |
| Unplanned re-admission rate                                  | # of unplanned re-admissions < 24 hours / (# of discharges - deaths). An unplanned re-admission is defined as any patient who is discharged or transferred from the ICU, who returns to the ICU within 24 hours of that discharge/transfer |
| Unplanned extubation/decannulation rate                       | (# of unplanned extubations/ decannulations/ [# of ventilator days] per 100 days) Unplanned extubations/decannulations are defined as the number of events when a patient’s endotracheal tube/tracheostomy tube became unintentionally dislodged. Ventilator Days are defined as the total # days patients with an endotracheal tube/tracheostomy tube receiving mechanical ventilation in the ICU |
| Standardized mortality ratio (SMR)                           | (# of observed deaths / # of expected deaths) × 100                   |

PICU, pediatric intensive care unit.
through their course entitled “Methods and Tools for Breakthrough Improvement.”

**Lean methodology**

The Lean methodology originated in the Toyota Production System and was designed to identify and mitigate the eight areas of waste that occur in every industry. As adopted into health care, Lean thinking seeks to minimize waste in every process, procedure, and task through an ongoing system of improvement. Under this approach, Lean thinking is deeply embedded into the culture of the health care organization, and clinicians as well as administrators continually focus on identifying waste and eliminating anything that does not add value to the care of the patient. Utilizing Lean methodology in the health care setting thus translates to a goal to eliminate the “eight wastes”:

1. Reduce waiting times for patients and idle times for employees.
2. Identify excessive inventory and find novel ways to decrease it.
3. Eradicate unsafe practices, system failures, and improve quality at every step.
4. Ensure that patient, caregiver, equipment, and supply movement is efficient.
5. Reduce caregiver motion to prevent injuries and save time.
6. Maximize resources by minimizing health care overproduction.
7. Eliminate repetitive, redundant, or less valuable processes that do not promote efficient and patient-focused care.
8. Reducing unnecessary caregiver tasks will lead to improved patient care and employee morale.

Hospitals that have adopted the Lean methodology claim that the key to its’ success is understanding that team members who do the work know what the problems are and have the best solutions. While Lean theory emphasizes a holistic view, most cases report narrower technical applications with limited organizational reach. Furthermore, without the active involvement of senior management, the ability to effect change across institutional divides with this process will be compromised.

**Failure mode and effects analysis (FMEA)**

The Institute for Healthcare Improvement defines Failure Mode and Effects Analysis (FMEA) as “a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change. FMEA includes review of the following:

1. Steps in the process
2. Failure modes (What could go wrong?)
3. Failure causes (Why would the failure happen?)
4. Failure effects (What would be the consequences of each failure?)

FMEA originated in industrial design where it has been an important tool for many decades, but it is only recently being used by health care organizations. FMEA is particularly useful in evaluating a new process prior to implementation and in assessing the impact of a proposed change to an existing process, but compared with PDSA or even the Lean methodology approach, it is relatively time consuming.

**Six Sigma: DMAIC**

The Lean and Six Sigma quality improvement frameworks are often referred together as “Lean-Six Sigma,” in health care quality literature, but they utilize very different methodologies. While Lean seeks to eliminate waste across the system, Six Sigma seeks to reduce variation in the quality of care by reducing defects in the process of care by utilizing advanced statistical methods. First introduced in 1987 as a quality improvement tool at the Motorola Corporation, Six Sigma was further developed by General Electric in the late 1990s and has since been incorporated at many health care organizations. Six Sigma deploys five phases: define, measure, analyze, improve, and control (DMAIC) that are utilized whenever there is a problem or breakdown in care. In the define phase, a charter is drafted that includes a cost-benefit analysis. If the cost-benefit analysis meets the company-established thresholds, the charter will be accepted, and the project will continue through the DMAIC process (i.e., the project becomes scheduled for solution and assigned to a team headed by a project manager with formal training in Six Sigma termed a Green Belt or Black Belt reporting to the project leader or Champion). In the subsequent measure phase, baseline data are assembled, and the diagnosis is started in earnest. The problem is translated into quantifiable terms using critical-to-quality (CTQ) characteristics. The analysis phase continues the diagnosis and involves an identification of possible causal relationships between inputs and the CTQs. After the diagnosis is completed, the team proceeds to the improve phase and suggests a solution to the problem. Finally, in the control phase, control systems are developed to ensure that improvements are maintained and the new improved process can be handed over to the day-to-day operations staff.

**What is the literature on the effectiveness of these frameworks?**

The true impact of these approaches is difficult to judge, given that there are no rigorous studies in the literature comparing the various quality frameworks examined.
here to suggest that one framework is superior to another in generating significant and sustained improvements in health care. While there is some evidence to suggest that Lean and Six Sigma are better adapted to settings where processes involve a linear sequence of events, most events leading to a lapse in the quality of care are not linear but instead involve a complex constellation of failures in structure, processes, and individual decision-making. For example, recent studies have revealed that there are many causes or contributing factors that explain failure to deliver quality care, and the constellation of causes in one hospital might not translate to the constellation of deficiencies at another hospital—or even at the same hospital with lapses in care leading to a poor outcome from a similar event. Thus, further research is needed to improve the evidence base for understanding more about QI approaches and how to achieve sustainable improvement. It may be the case that “one size does not fit all,” and that no single framework will be necessarily effective at every pediatric hospital seeking to improve the quality of health care in the intensive care unit.

**Where does pediatric quality improvement go from here?**

In the past decade, multiple pediatric hospitals across the world have formed networks to harness common frameworks to address quality of care concerns more effectively. Prominent among these is the Children’s Hospitals’ Solutions for Patient Safety (SPS) National Children’s Network, which represents more than 125 children’s hospitals across North America focused on high priority interventions to reduce and then eliminate serious harm for the children being cared for at these hospitals. SPS is focused on reducing harm by preventing readmissions, serious safety events, and 12 specific hospital acquired conditions, including:

1. Adverse drug events (ADE)
2. Catheter-associated urinary tract infections (CAUTI)
3. Central line-associated blood stream infections (CLABSI)
4. Falls with injury
5. Pressure injuries
6. Surgical site infections
7. Ventilator-associated events (VAE)
8. Venous thromboembolism
9. Peripheral intravenous infiltration and extravasations (PIVIEs)
10. Unplanned extubations
11. *C. Difficile* and antimicrobial stewardship
12. Nephrotoxic acute kidney injury

Other collaboratives worldwide are also focused on a similar mission: The Paediatric International Patient Safety and Quality Community (PIPSQC) is an informal, international collaborative of professionals who share a passion for patient safety and quality in pediatrics, and who interact together across organizational and geographic boundaries, to advance learning and improvements in these areas. More recently, the Making it Safer Together (MiST) Paediatric Patient Safety Collaborative is a new alliance of hospitals in the UK that is based on the SPS model. These organizations share the common goal of achieving harm-free pediatric health care through a process of a sustained, year-on-year, reduction in adverse events.

Since 2012, the pediatric intensive care unit (PICU) International Collaborative, now totaling 15 hospitals around the world over five continents, has been a network of the pediatric intensive care units at some of the largest hospitals in the world sharing quality outcome metrics in order to benchmark performance. Unique to this collaboration is that PICUs in the collaborative share best practices—in the form of clinical practice guidelines and polices—amongst each other. In this way, the collaborative is more than comparative benchmarking against one’s peers, but importantly allows for the sharing of best practices as well. The variables (and definitions) shared within the collaborative can be found in Table 1.

The PICU International Collaborative shares these data utilizing Control charts. The charts plot historical data and include a central line for the average of the data, an upper line for the upper control limit, and a lower line for the lower control limit. There are several guidelines that indicate when a signal of special cause variation has occurred on a control chart—when the data point appears outside the control limits. Since the control limits are set at three standard deviations from the mean, where a process which is producing normally distributed data means that the probability of a point appearing outside the precisely determined phase II control limits (upper or lower limit) is about 1 in 370. Thus, insights from the control charts can help the team make a critical differentiation; is the problem related to specific patients (special cause—the data points lie beyond the preferred control limit or even as random points within the control limit) or is the problem related to the need for more fundamental changes to the care pathway (common causes—random data points that are within the control limit)? Hospital quality improvement programs can thus use control charts to improve the precision by which important patient care outcomes are monitored, and understand the efficacy of initiatives to improve and sustain them over time.

**Conclusions**

Over the past several decades across the globe, pediatric hospital quality improvement programs, especially as they relate to pediatric intensive care medicine, have become increasingly more essential and effective at measuring, reporting, and benchmarking on key health care quality metrics for infants, children, and adolescents. While a number of frameworks exist for hospitals to assess and improve the quality of care they provide, whether it is...
PDSA, Lean, FMEA, or Six Sigma, no rigorous studies in the literature demonstrate that one is demonstrably more effective than another in leading to a significant and sustained improvement in patient care outcomes. The classic Donabedian three-part framework of “structure, process, and outcomes” remains the conceptual foundation of any quality improvement program, followed by the PDSA framework as the most intuitive and efficient tool for designing, implementing, and assessing quality improvement efforts in pediatric intensive care.

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CONFLICT OF INTEREST

The authors report no conflict of interests related to the material presented in this article.

REFERENCES

1. Donabedian A. Evaluating the quality of medical care. Milbank Q. 1966;44:166-206.
2. Donabedian A. The quality of care. How can it be assessed? JAMA. 1988;260:1743-1748.
3. Plan-Do-Study-Act (PDSA) Worksheet, 2019. http://www.ihi.org/resources/Pages/Tools/PlanDoStudyActWorksheet.aspx. Accessed May 21, 2019.
4. Glasgow JM, Scott-Caziewell JR, Kaboli PJ. Guiding inpatient quality improvement: a systematic review of Lean and Six Sigma. Jt Comm J Qual Patient Saf. 2010;36:533-540.
5. Blackmore CC, Williams BL, Ching JM, Chafetz LA, Kaplan GS. Using lean to advance quality improvement research. J Healthc Qual. 2016;38:275-282.
6. Mazzocato P, Savage C, Brommels M, Aronsson H, Thor J. Lean thinking in healthcare: a realist review of the literature. Qual Saf Health Care. 2010;19:376-382.
7. Failure Modes and Effects Analysis (FMEA) Tool. 2019. http://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx. Accessed May 21, 2019.
8. Dean Franklin B, Shehl NA, Barber N. Failure mode and effects analysis: too little for too much? BMJ Qual Saf. 2012;21:607-611.
9. de Koning H, Verver JP, van den Heuvel J, Bisgaard S, Does RJ. Lean six sigma in healthcare. J Healthc Qual. 2006;28:4-11.
10. Deblais S, Lepanto L. Lean and Six Sigma in acute care: a systematic review of reviews. Int J Health Care Qual Assur. 2016;29:192-208.
11. Children’s Hospitals’ Solutions for Patient Safety. https://www.solutionsforpatientsafety.org/. Accessed May 21, 2019.
12. WELCOME TO PIPSQC. 2019. https://www.pipsqc.org/. Accessed May 21, 2019.
13. Home. 2019. http://www.mist-collaborative.net/. Accessed May 21, 2019.
14. Boston Children’s Hospital. PICU collaborative mission. 2019, May. Personal communication with Dr. Nilesh Mehta.
15. Mohammed MA, Worthington P, Woodall WH. Plotting basic control charts: tutorial notes for healthcare practitioners. Qual Saf Health Care. 2008;17:137-145.

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