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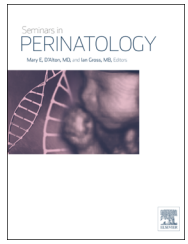

Tools and methods for quality improvement and patient safety in perinatal care

Amy T. Nathan, MD[a,*], *and Heather C. Kaplan, MD, MSCE*[a,b]

[a]*Department of Pediatrics, Perinatal Institute, Cincinnati Children's Hospital Medical Center, 3333 Burnet Ave, MLC 7009, Cincinnati, OH 45229*

[b]*Department of Pediatrics, James M. Anderson Center for Health Systems Excellence, Cincinnati Children's Hospital Medical Center, Cincinnati, OH*

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ABSTRACT

The quality of health care is now recognized to vary widely in all medical specialties, including perinatal medicine. A national focus on quality improvement (QI) and patient safety is prompting providers to change and improve the care given to patients. All QI and safety efforts require the use of an improvement model to manage the complex process of improving care. This article reviews the most common frameworks in use today, including the Model for Improvement, Six Sigma, and Lean. Specific tools such as affinity, key driver and fishbone diagrams, process maps and statistical process control, as well as checklists are reviewed, with examples from the perinatal literature to illustrate their use in perinatal QI efforts.

Introduction

The Institute of Medicine (IOM) describes quality as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[1] In the relative past, there was a tacit assumption that the quality of care provided by physicians and hospitals was not to be questioned and that medical mistakes were rare and unfortunate events. Several studies have since illustrated vast variability in outcomes, and issues of safety and quality now solidly have the attention of the health care community and the public—we are in the midst of a "quality revolution."[2,3]

Quality improvement (QI) is an applied field tethered to strong, formal science; data and testing are at the heart of these methods.[4] The foundation for modern QI began in the 1920s with the work of Walter Shewhart, W.E. Deming, and Joseph Juran. As part of efforts to increase efficiency in a range of industries, these innovators developed scientifically based tools and methods to streamline production processes, minimize opportunity for human error, use data and understanding of variation to drive decision-making, and build a culture of improvement whereby frontline workers and management are committed to improving work practices. These core concepts and tools that were initially successfully applied in business and industry are now the cornerstones of the health care "quality revolution."[5] There are many examples of the success and impact of a comprehensive QI or patient safety program in the perinatal literature.[6–9] The key strategy in applying these QI tools and methods in health care is to understand their strengths and weaknesses and to understand which tool is appropriate for a particular problem at hand. The objective of this article is to review several common methods and tools used in health care quality improvement and patient safety, and to illustrate their use specifically in the field of perinatal medicine.

*Corresponding author.
E-mail address: Amy.Nathan@cchmc.org (A.T. Nathan).

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General improvement approaches

All QI and safety efforts require the use of an improvement model to manage the complex process of improving care. There are a number of models that can be used to manage change.

Model for Improvement

The Model for Improvement was developed by Associates for Process Improvement and is heavily used by the Institute for Healthcare Improvement. The Model for Improvement is based on the following three questions: (1) What are we trying to accomplish? (2) How will we know that a change represents an improvement? (3) What changes can be made that will result in improvement? This model is a fairly universal platform which starts with a concise expression of goals in terms that are measurable and time-specific as applied to a population that is clearly defined. A basic tenet of QI is that improvement always requires change, but this change does not always imply improvement, therefore relevant metrics need to be measured and monitored to track performance (e.g., How will we know if a change represents an improvement?). Measurement also informs decision-making as to which areas deserve initial focus for improvement. The three following types of measures are commonly used in QI projects: (1) outcome, (2) process, and (3) balancing. The outcome measure is the true assurance that improvement is happening, but process measures are vitally important to guide the specific improvement strategies being used. Balancing measures ensure that improvement in one area does not lead to a detrimental effect in another part of the system.

Once measures are identified, the critical next step in this model is selecting changes to test, and this relies on team members with insight into the relevant system complexities and operational realities.[10] First-order change (often called "tinkering") involves individuals "trying harder" or "being more careful." This type of change rarely brings about true or lasting improvement. Instead, second-order (or system-level) change refers to a redesign of the system to reliably produce the desired outcome. Testing of changes is accomplished in an iterative fashion through Plan-Do-Study-Act (PDSA) cycles. PDSA cycles are designed as an iterative, rapid-cycle, action-oriented learning approach. The scale of these PDSA cycles is very small initially, and the results of each test are analyzed. This informs the next cycle of testing, and the decision whether to adopt (and expand) the change, adapt or modify the change, or abandon the change. Failed PDSA cycles are just as important as successful ones, as failures may reveal incorrect assumptions or highlight variables that have not been previously considered by improvement teams.

The Model for Improvement can support improvement efforts from the very informal to the most complex and it is widely used in perinatal QI efforts. For example, the Ohio Perinatal Quality Collaborative (OPQC) used the Model for Improvement as the key improvement framework in their statewide QI collaborative to reduce late-onset sepsis in preterm infants in Ohio. OPQC used the Model for Improvement to: (1) guide aim setting, with their aim being to reduce the incidence of late-onset bloodstream and CSF infections in infants born at 22–29 weeks' gestation by 50% in Ohio NICUs in 1 year, (2) select appropriate process (compliance with catheter care bundles) and outcome (proportion of infants discharged with at least one nosocomial infection) measures, and (3) assist teams in using PDSA cycles to test changes required to implement evidence-based catheter care bundles. Furthermore, to understand whether the changes made resulted in improvement, aggregate and site-specific data were tracked over time and feedback was provided to QI teams.[11] Another example of PDSA cycles is outlined by a group from Children's Mercy as part of a QI project to standardize the use of nasal cannula oxygen in their unit. A structured QI method was used to implement and test changes, and the authors credit this iterative process with the achievement of buy-in and enthusiasm for their new standardized order forms.[12]

Six Sigma and Lean

Six Sigma and Lean are improvement frameworks that focus heavily on supporting improvement of the reliability and efficiency of processes.[13] DMAIC is the core tool used to guide Six Sigma QI projects. The DMAIC acronym stands for the 5 steps in the Six Sigma improvement approach: Define, measure, analyze, improve, and control. In order to *define* the problem, teams may create a charter, as well as a high-level overview of the process in question. *Measurement* is central to Six Sigma, just as in the Model for Improvement. *Analysis* of data is used to establish a baseline of current performance, and to look for clues to the main drivers or causes of a problem. In the *improve*ment phase, potential solutions or ideas are implemented and then verified. The final step of *control* speaks to the importance of hard-wiring a change so that the demonstrated improvement is sustained.

Lean is another approach to system improvement that was originally applied to production lines (most notably the Toyota Production System), but is now widely used in service industries as well. The focus of this method is the efficiency of processes by the elimination of waste (which can include energy, time, or materials). A process is predicted to be more reliable if the goal can be attained with fewer steps (without a decline in performance), as removing unnecessary steps reduces chances for error in the system. This also makes it easier to interpret failures, as there are fewer variables to analyze. In addition, reduction of waste provides value as it tips the cost-benefit ratio in a positive direction. There are following 5 key principles to Lean methodology: (1) identify what is valuable from the customer's perspective (not from the company's perspective), (2) map the steps necessary to bring the product to production in order to identify areas of waste, (3) prioritize the steps that are necessary for imparting value and make these happen without delays or sidetracks, (4) let the customer's needs dictate what is produced, and (5) consistently improve the system by removing waste as it is discovered. The distinction between Lean and Six Sigma is somewhat artificial and a combination of the two methods is most helpful with a central focus on process innovation. Lean and Six Sigma have strengths that are complementary and an