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Quality Improvement Basics: A Crash Course for Pediatric Cardiac Care

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Abstract

Background: Lack of knowledge of quality improvement (QI) methodology and change management principles can explain many of the difficulties encountered when trying to develop effective QI initiatives in health care. **Methods:** An interactive QI workshop at the 14th Annual Meeting of the Pediatric Cardiac Intensive Care Society provided an overview of the role of QI in health care, basic QI frameworks and tools, and leadership and organizational culture pitfalls. The top five QI projects submitted to the meeting were later presented to an expert QI panel in a separate session to illustrate examples of QI principles. **Results:** Workshop presenters introduced two major QI methodologies used to design QI projects. Important first steps include identifying a problem, forming a multidisciplinary team, and developing an aim statement. Key driver diagrams were highlighted as an important tool to develop a project's framework. Several diagnostic tools used to understand the problem were discussed, including the "5 Why's," cause-and-effect charts, and process flowcharts. The importance of outcome, process, and balancing measures was emphasized. Identification of interventions, the value of plan-do-study-act cycles to fuel continuous QI, and use of statistical process control, including run charts or control charts, were reviewed. The importance of stakeholder engagement, transparency, and sustainability was discussed. Later, the top five QI projects presented highlighted multiple "QI done well" practices discussed during the preconference QI workshop. **Conclusions:** Understanding QI methodology and appropriately applying basic QI tools are pivotal steps to realizing meaningful and sustained improvement.

Keywords

congenital heart disease (CHD), intensive care, patient safety, quality improvement

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Abbreviations and Acronyms

CAUTI	catheter associated urinary tract infections
CICU	cardiac intensive care unit
DMAIC	define-measure-analyse-improve-control
PDSA	plan-do-study-act
QI	quality improvement

Introduction

In the nearly two decades since the Institute of Medicine released its groundbreaking reports, *To Err is Human*[1] and *Crossing the Quality Chasm,*[2] a multitude of health-care resources have been dedicated to improving safety and quality in health care. Although there have been some victories (eg, the World Health Organization surgical checklist, Solutions for Patient Safety), overall this commitment has not yielded proportionate progress toward a goal of eliminating preventable harm[3,4] and maximizing health-care value. Even if improvement is accomplished, it frequently is not sustained.[5,6] While many barriers to implementing quality improvement (QI) have been cataloged in the literature,[7,8] one significant and persistent barrier for many health-care providers is a lack of knowledge of basic QI methodology, tenets of safety science, and change management. Clinical staff value their autonomy and may chafe at projects they view as neither relevant nor practical, making identifying appropriate problems for QI interventions a critical first step. In addition, well-intentioned individuals or teams will implement QI initiatives without doing the required, but essential, background work and use incomplete, flawed, or indiscernible methods.

In response to these real-world struggles, an interactive workshop (*QI Crash Course*) and a moderated panel discussion (*QI Shark Tank*) were developed in connection with the 14th Annual Meeting of the Pediatric Cardiac Intensive Care Society. The goals of the workshop were three-fold: (1) describe the role of QI in health care, (2) explore basic QI frameworks and tools, and (3) define leadership and organizational pitfalls in real-world QI. The goal of the moderated panel discussion was to illustrate principles of QI using exemplary projects.

Methods

The *QI Crash Course* workshop was organized by three members of the team (K.E.B., J.C., and M-A.M.). Known QI leaders representing different congenital heart centers and varied professional roles, including a physician, nurse leader, and quality leadership (including N.K.C., M.C.M., and A.M.) were invited to discuss different aspects of QI within the context of their respective single-center experience. Each presenter summarized key learning points from their presentation and the summaries were organized and condensed by two authors (K.E.B. and M.A.M.) and reviewed by all authors. The *QI Shark Tank* session included presentations of the top six successful QI projects selected by meeting organizers and a QI expert panel discussion. Each presentation was summarized here to demonstrate real-world examples of "QI done well."

Results

Quality Improvement Methodologies:

The two major QI methodologies used in health-care settings are the Model for Improvement[9] and Lean/Six Sigma's define-measure-analyse-improve-control (DMAIC). These methodologies have many similarities and the choice of which to follow is influenced by the improvement goal, expertise within the team, and institutional preference. When utilizing the Model for Improvement, the team answers three fundamental questions to guide their process:

1. What are we trying to accomplish?
2. How will we know that a change is an improvement?
3. What change can we make that will result in an improvement?

While these questions are presented in a specific order, teams typically move fluidly between the questions and revisit individual aspects as more is learned about the problem. For example, a team that develops ideas for specific measures prior to identifying the first intervention may choose to add a measure of compliance with the intervention to their list of measures. In contrast, the DMAIC model uses a more linear, structured approach, and is particularly well-suited for examining processes and workflows to discover and minimize defects.[10]

Although these overarching methodologies have slightly different approaches to understanding the problem, both rely heavily on a simple method based on small tests of change. The most common cycle used within health care is the plan-do-study-act (PDSA) cycle in which the team develops a plan (plan), carries out the test (do), observes the consequences (study), and then determines modifications to the test as a next step (act).[10] Through rapid cycle testing of small changes, this method forms the backbone of the iterative nature of QI and feeds directly into a continuous QI process.

Quality Improvement: A Brief "How to" Guide

For ease of use, the remainder of this article is structured using the Model for Improvement's three questions as a framework. Answering these questions in a written team charter can be an effective way to build shared understanding and engagement around the QI problem at hand.[9]

1. What are we trying to accomplish?

Regardless of the improvement framework chosen, it is critically important to spend a significant amount of time and energy understanding the problem and its scope.

Getting Started

Identifying a Problem. Deciding to work on a specific challenge is a complex process that may be influenced by a variety of factors. Some QI projects are necessary responses to external requirements, institutional goals, or local adverse events. Other QI projects may be identified by review of local performance or registry data (eg, Society for Thoracic Surgeons, Pediatric Cardiac Critical Care Consortium[11]). Although all registries have limitations, benefits include the ability to benchmark with other centers, thus putting an individual center's performance in context and minimizing additional resource needs for data collection. Some projects may arise based on participation in collaborative learning efforts such as the Pediatric Acute Care Cardiology Collaborative,[12] which is a structured method of multicenter learning previously described by multiple authors.[13–15] Regardless of the source, assessing and measuring the impact of a potential QI project allows the quality team to focus on high-yield projects and avoid exhausting limited resources.

Building a QI Team. After identifying the problem, the next step is to assemble a multidisciplinary improvement team with relevant subject matter experts. Changes being made to work flows and policies must involve those who carry them out on a daily basis, thus these groups must be represented via appropriate frontline membership on the team. For example, a team working to prevent unplanned extubations in the cardiac intensive care unit (CICU) should at minimum include a physician, bedside nurse, and respiratory therapist (if applicable). Depending on the local CICU culture, it may be appropriate to include a QI expert, trainee physicians, physician and nursing leadership, pharmacists, techs, and ideally, a patient or family member.

Defining the Goal-Aim Statements. The next step is to create an aim statement, which answers the question "What are we trying to accomplish?" Although the aim statement is specific, it should be broad enough to encompass the entire QI project goal. The "SMART Goals" (specific, measurable, achievable, realistic, and timely) framework[9] is useful since strong aim statements indicate the setting and/or population as well as specific numeric and temporal goals for the outcome. Of note, the aim statement should not identify a specific intervention before the investigative work has been completed. A concise problem statement forms the basis for every successful project. Examples of strong and weak aim statements are listed below.

Strong: By December 31, 2019, we will increase the rate of Foley catheter removal on postoperative day 1 from 30% to 75%.

Weak: We will decrease catheter-associated urinary tract infections.

Building a Key Driver Diagram. A key driver diagram (Figure 1) is a concise, ordered roadmap to communicate the structure, plan, and results of the improvement effort and should be used and updated throughout the project to reflect the team's learning.[16] Key driver diagrams include primary drivers which communicate the high-level elements that must change to impact the outcome of interest. Secondary drivers in the diagram are specific components that affect primary drivers; secondary drivers may be specific to one primary driver or may be relevant to multiple primary drivers. Change strategies outline the specific interventions that are theorized to impact key drivers. Typically, these change strategies demonstrate the actions that will be tested to assess impact on the primary outcome.[16]

Diagnosing the Problem: Tools to Consider

To inform the key driver diagram components, the QI team may utilize one or more diagnostic tools to further explore the identified problem. In this section, we summarize tools that are frequently used in health-care QI. Additional diagnostic tools may be helpful depending on the problem and can be found at https://asq.org/quality-resources/quality-tools. Asking focused questions and being aware of preconceived biases about the underlying causes of a problem are critical to the initial steps of any QI project. If a team starts a project assuming they know what the major contributing factors are and exactly which interventions will succeed, they will undoubtedly miss key issues that impact the problem.

A cause-and-effect diagram, also called an Ishikawa or fishbone diagram (Figure 2), is a visual tool to help teams understand the many facets contributing to the identified problem and the relationship these elements have to each other.[6] The most common categories used in a cause-and-effect diagram include equipment, process, people, materials, environment, and management; however, teams do not need to restrict their analysis to these categories. Figure 2 shows an example from a project to improve nursing handoffs between shifts utilizing a standardized handoff tool.[17]

The "Five Whys" tool (Figure 3) enables a QI team to do a simple root cause analysis by asking "Why?" as many as five times to get past a symptom to the cause of a problem. This tool can be helpful to determine core issues and create measurable and targeted problem statements.[18]

A Pareto chart (Figure 4) is used to identify the most significant factors contributing to the stated problem. This chart is rooted in the concept that 80% of an effect may come from only 20% of the causes. Once the "vital few" causes are identified, the team can focus on addressing them to achieve maximum effect.

Another diagnostic aid is a process flowchart or process map (Figure 5) which visually represents steps and decision-making points within a process. A process flowchart is particularly helpful in communicating the complexity of a seemingly "simple" process, identifying points of failure or variation, and delineating interconnected systems and processes.[19] Process flowcharts can also be used to represent a desired future state.

2. How will we know that change is an improvement?

Identifying a Family of Measures. Effective measurement and data analysis is essential to effective QI. Quality improvement projects typically use a "family of measures" consisting of

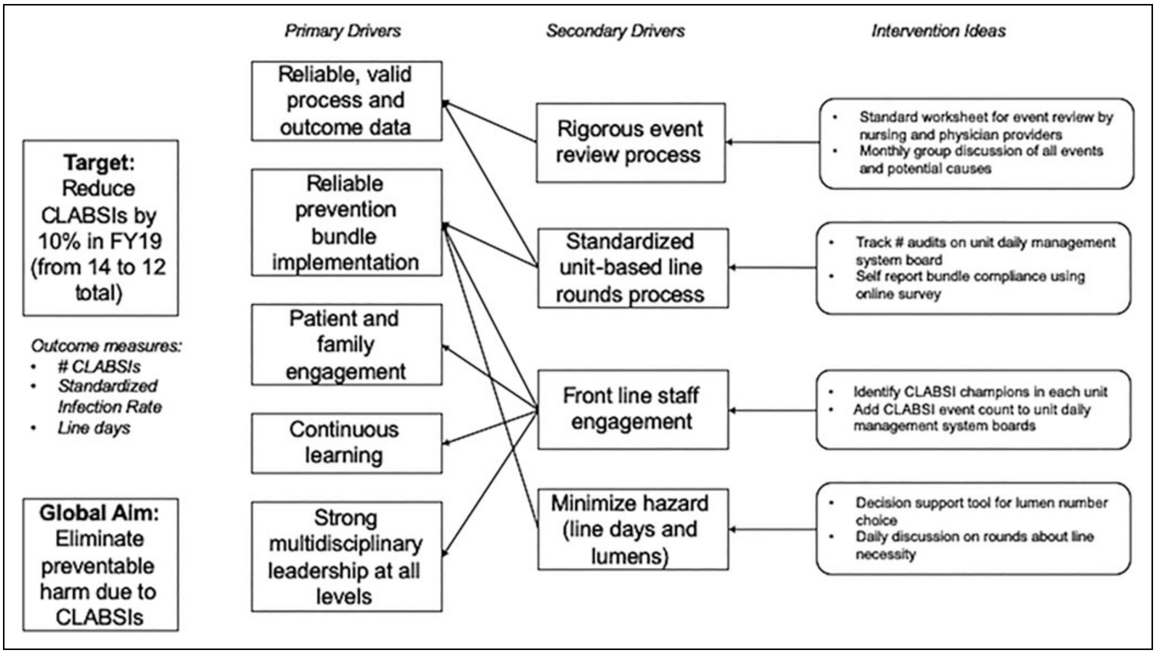

Figure 1. Key driver diagram: Reducing CLABSIs. CLABSI indicates central line–associated blood stream infection; fy19, fiscal year 2019.

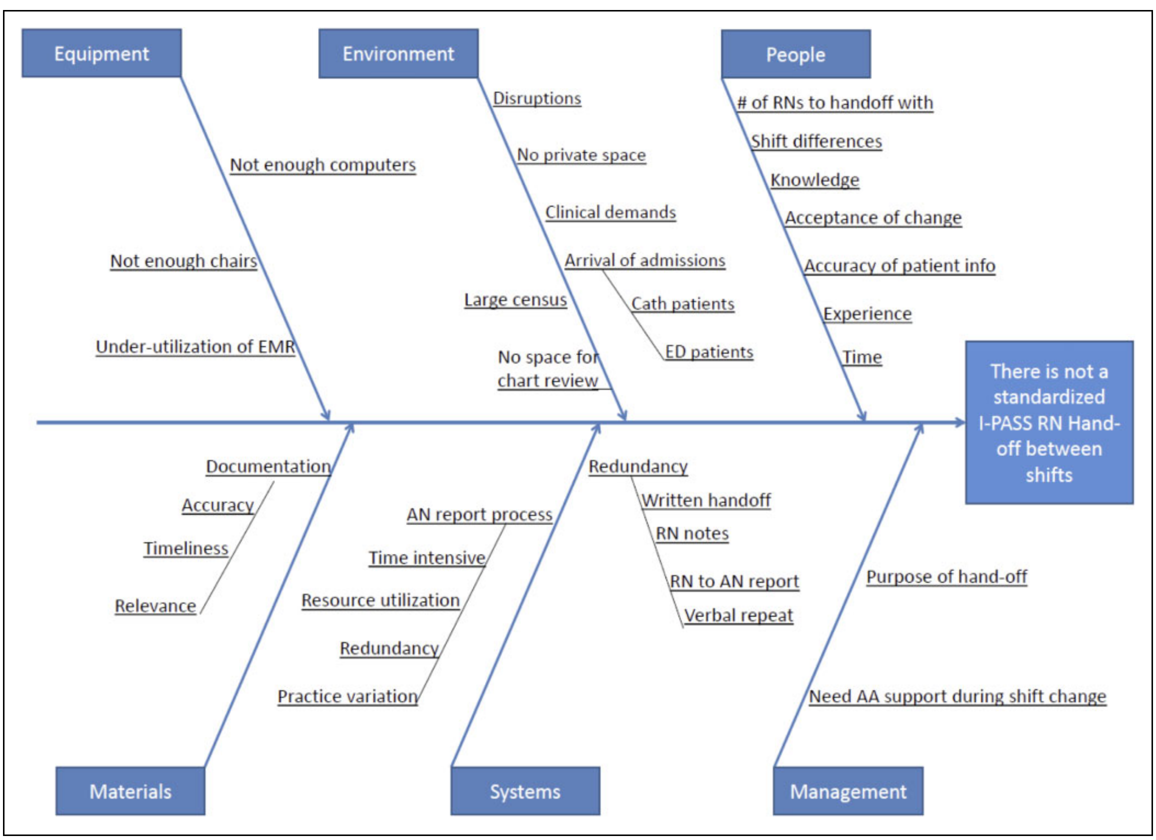

Figure 2. Fishbone diagram: Reasons for lack of standardized nursing handoff between shifts. AN indicates administrative, that is charge, nurse; ED, emergency department; I-PASS, mnemonic for handoff; RN, registered nurse.

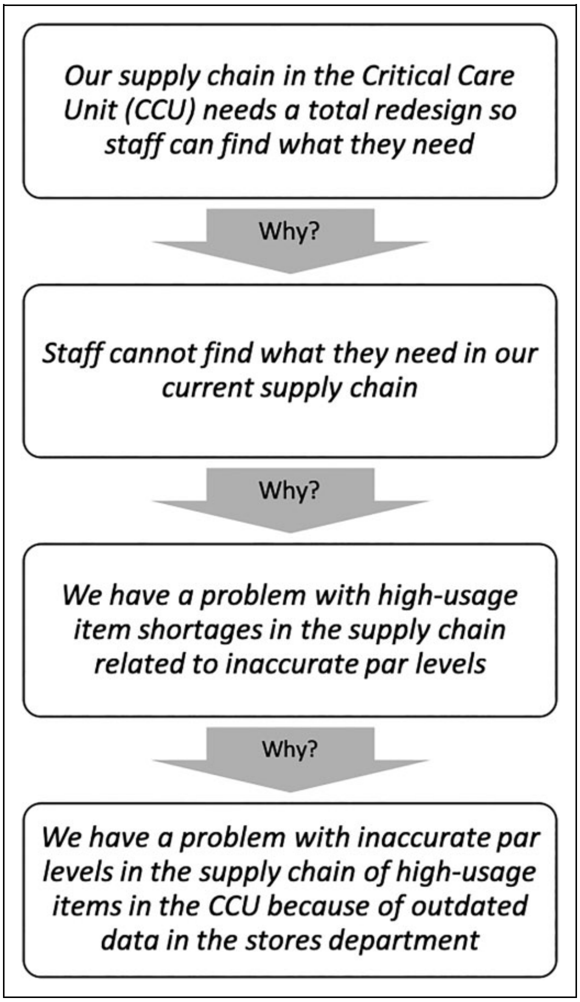

Figure 3. Five Whys tool: ICU supply delivery. ICU indicates intensive care unit.

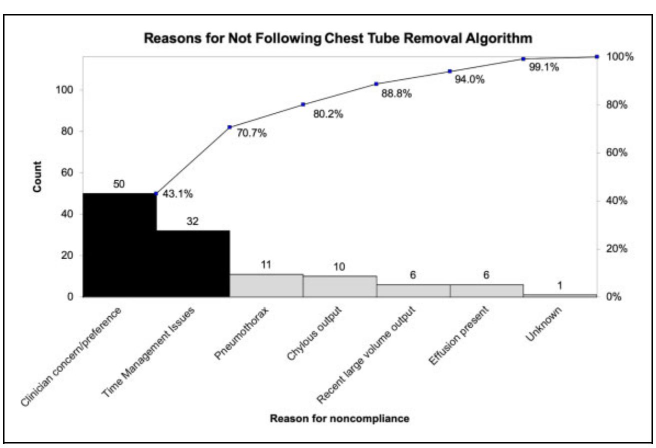

Figure 4. Pareto chart: Noncompliance with chest tube removal algorithm.

outcome, process, and balancing measures. While it is very important to measure and achieve the outcome target, it is equally important to follow process and balancing measures as part of a comprehensive QI plan.[9] Table 1 provides an example of a family of measures for a project focused on improving rates of early extubation after cardiac surgery. The outcome measure should be clearly stated in the aim statement. When possible, it is helpful to use outcome measures that are directly linked to patient outcomes to motivate clinicians. Process measures evaluate compliance with interventions that the team has chosen and are vital to determining whether an intervention has changed practice. For example, a project to reduce surgical site infections might track appropriate administration of perioperative antibiotic prophylaxis as a process measure. Balancing measures monitor unintended effects from the intervention: for example, a project to reduce readmissions to the CICU might include a CICU length of stay as a balancing measure. A team that does not take into consideration potential balancing measures may design interventions that have unintended consequences and as a result, poor uptake and sustainability.[9]

The number and types of measures depend on the size and scope of your project (5-7 is usually appropriate). Each measure requires a clear operational definition and a plan for collecting and analyzing the data. For example, a team might choose to record the incidence of grade 3 to 4 pressure injuries per 1,000 patient days based on information obtained during weekly surveillance rounds as an outcome measure.

Analyzing Measures Over Time. It is important to recognize that limiting analysis to classic research methodology and statistics (eg, pre–post study design) will fail to reveal important dynamic processes within QI, hindering assessment and development of appropriate interventions. In addition to collecting data prior to implementing a QI project, teams should collect data during and following each PDSA cycle and upon completion of the QI project. Run charts and control charts are powerful tools to track performance over time and define if performance changes in a significant way.

In a run chart (Figure 6), performance is plotted over time with at least ten data points required to assess the effectiveness of an intervention. Run charts may allow QI teams to determine performance of a process, whether a process has truly changed versus exhibited natural variation, and may provide information about the value of each change.[20]

Shewhart control charts (Figure 6), also called run control charts or statistical process control charts, are similar to run charts but use statistical process control to determine whether a system is stable and whether a change in performance falls within the current variability of the system (common cause variation) or qualifies as special cause variation. There are a variety of ways to meet criteria for special cause variation including single data points beyond control limits and several consecutive increasing or decreasing data points. An in-depth discussion of statistical process control is beyond the scope of this report; however, there are multiple practical guides available.[11,12]

3. What changes can we make that would result in an improvement?

After working through the first two questions of the Model for Improvement, teams often have many ideas for interventions.

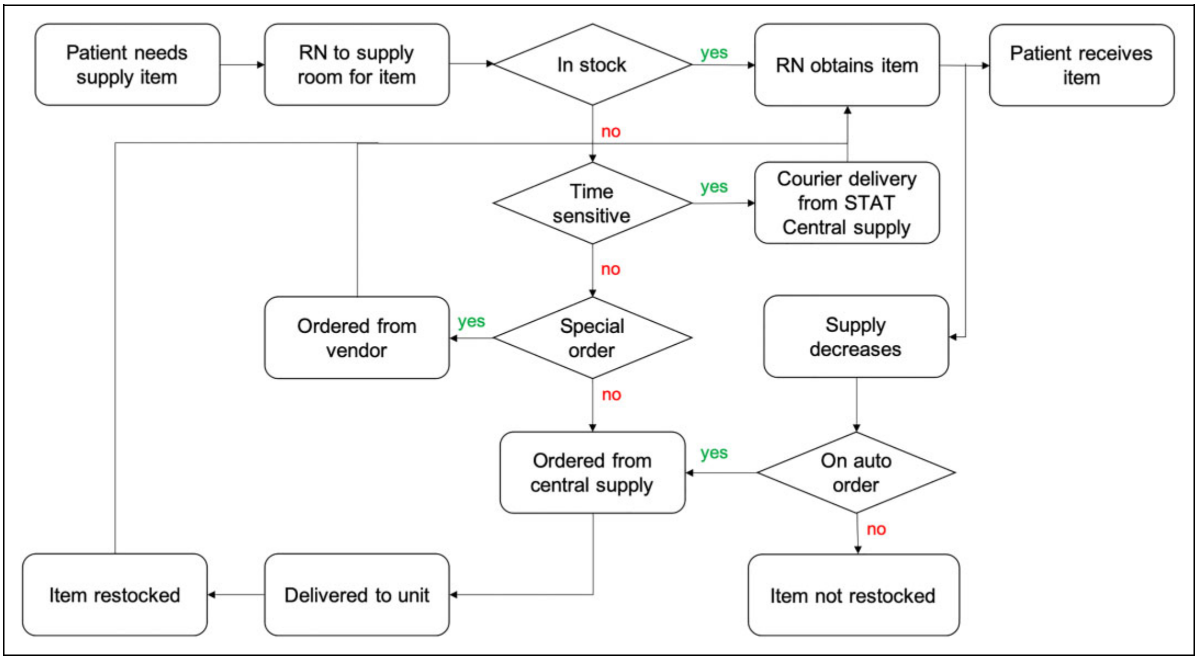

Figure 5. Process flowchart: ICU supply delivery. ICU indicates intensive care unit; RN, registered nurse.

Table 1. Example of QI Family of Measures: Early Extubation After Cardiac Surgery.

Measure Type	Example
Outcome	1. Percentage of children extubated within six hours of postoperative CICU admission
	2. Postoperative CICU length of stay
Process	3. Percentage of children whose anesthesia plans followed early extubation algorithm
	4. Percentage of children where plan to extubate early was communicated to CICU team
Balancing	5. Percentage of children who required reintubation within 48 hours of early extubation

Abbreviation: CICU, cardiac intensive care unit.

Selecting which interventions should be tested first should be guided by baseline data, the aim statement, and diagnostic work done early in the project planning. Teams should be cognizant of the hierarchy of interventions from a human factors engineering perspective. Interventions that focus on education and training, or rules and policies, are often the least effective in changing outcomes but certainly are not without merit. Teams should emphasize solutions that include automation, forcing functions, and simplification as they can be the most likely to produce sustainable results.[13] It is important that the right thing to do is designed as the easy, or only, thing to do wherever possible. Once the first intervention has been selected, the team should begin planning PDSA cycles to test its effects on the problem at hand.[21]

Sustainability. Creating sustainability is often the most difficult aspect of any QI initiative, even with the best methodology and intent. It is important to understand what barriers will exist during and after implementation and to plan for them at the beginning of the initiative wherever possible. Continually tracking process, outcome, and balancing measures postimplementation is critical to continued uptake. The best success will come when metrics are shared among the team regularly and transparently in accordance to high-reliability principles. A well-designed, high-order intervention that enhances work flow and decreases defects will often not need to be revisited time and time again.[22]

Practical Principles. Stakeholder engagement is pivotal to success with QI initiatives; however, engagement done quickly or haphazardly will negatively affect uptake and results. Through consensus building, practical obstacles and individual biases can be identified and addressed early in the process to avoid potential disruptions during the early implementation phase. By identifying key stakeholders, often those with experience and influence, a clear process can be developed. Critically, there must be buy-in and support from all necessary levels of work (a top-down meets bottom-up approach) in the improvement effort. Senior leaders should help align a given project with larger institutional goals and help surmount barriers the improvement team will inevitably face while frontline staff provide invaluable insight into "work as done" as opposed to "work as imagined." Importantly, during the final phase of implementation, this group of invested stakeholders will become the strongest advocates for any new processes. Engaged and informed participants are more likely to embrace the change proposed.

Transparency also plays a critical role in successful QI work: Sharing the QI team's progress promotes a community of change outside of the QI team itself. Communication

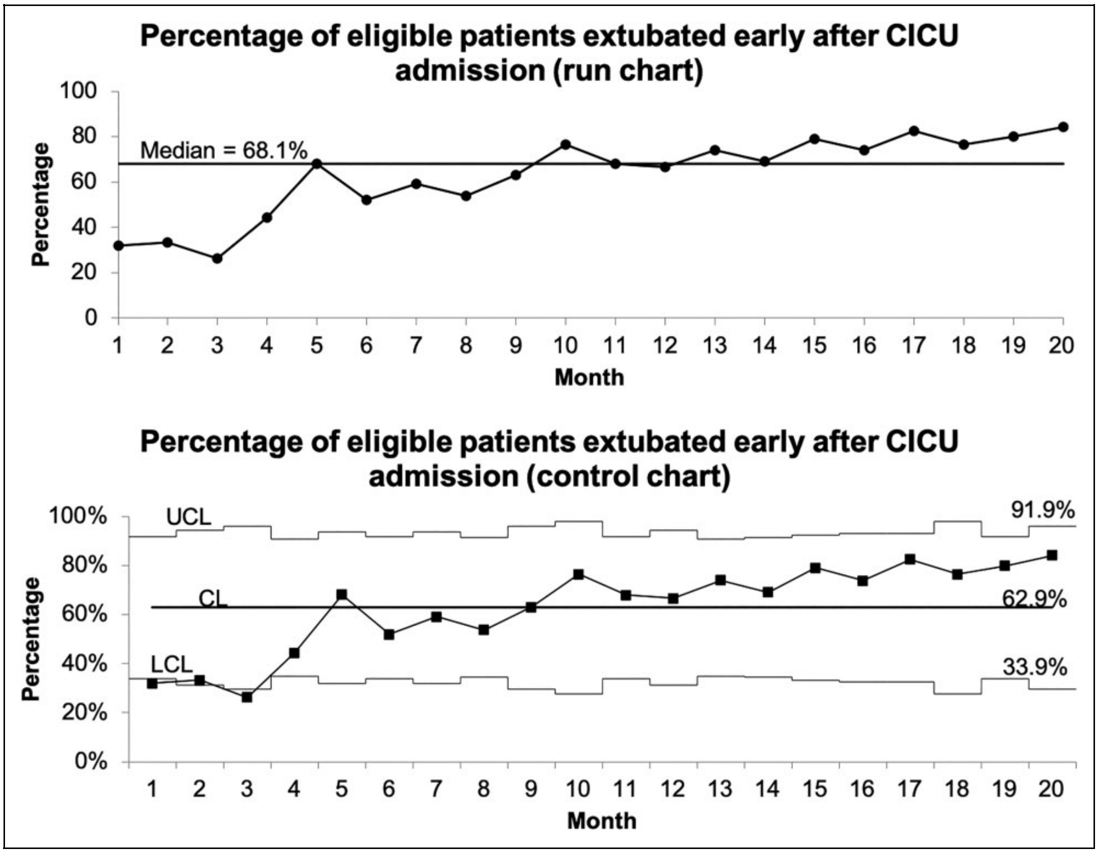

Figure 6. Run chart and control charts: Early extubation after admission to the CICU. CL indicates center line or mean; LCL, lower control limit; UCL, upper control limit.

through shared platforms allows an early identification of successes and failures during testing and implementation. It's also important to note when designing a QI initiative that scope and regulation should be considered. Projects involving changes in care or policy that might affect patient outcomes should be submitted through the appropriate channels (eg, QI department of Research Ethics Board) for approval. This is critical when considering projects that can affect patient privacy, include personal health information, or require consent for participation.

Real-World Examples of Effective Pediatric Cardiac Critical Care QI

Following the *QI Crash Course*, a series of preselected QI projects was presented for feedback to a panel of experts in the *QI Shark Tank*. Here, we summarize the projects presented and utilize them as case studies to demonstrate the use of core QI principles discussed in the preconference *Crash Course*.

- Spillover of Early Extubation Practices From the Collaborative Learning Study (Witte et al)

Summary: An early extubation clinical practice guideline was created and implemented at four study sites in the Pediatric Heart Network Collaborative Learning Study. This study found decreased time to extubation in infants not included in the study protocol, indicating a spillover effect for lower complexity surgery, particularly ventricular septal defect closure.

Quality improvement principles applied well: (1) Collaborative learning: Standardization of care was optimized using collaborative learning to write a clinical practice guideline (including clearly defined patient inclusion and exclusion criteria, intraoperative anesthesia management, and postoperative sedation/analgesia management) that could be adapted and implemented at multiple institutions. (2) Balancing measures: Reintubation rate was tracked to ensure that a focus on early time to extubation did not increase this adverse event.

- Dashboarding Sedation Medications Allows for Targeted Improvement Strategies (Watrin et al)

Summary: Nursing leadership guided improvement work to decrease sedation medication administration using a dashboard that enabled an individual provider to visualize performance on the number of times an as-needed sedation medication was prescribed >1 standard deviation above the average. Overall use of as-needed narcotics and benzodiazepines decreased significantly.

Quality improvement principles applied well: (1) Use of outcome measure: Robust data visualization transparently provides the opportunity for actionable insight at both an individual and unit level. (2) Balancing measures: This study also tracked unintended extubations to ensure that lower administration rates of as-needed sedation medication did not increase these events.

- Chest Tube Removal Algorithm Decreases Chest Tube Duration in Pediatric Cardiac Surgical Patients (Bertrandt et al)

Summary: An algorithm standardizing the criteria and timing of assessment for chest tube removal was implemented with the aim of decreasing chest tube duration and potentially CICU length of stay. Chest tube duration decreased but ICU length of stay did not change significantly.

Quality improvement principles applied well: (1) SMART goals: This initiative was designed around clearly stated goals that were measurable and achievable, using institutional historical data as a baseline. Process, outcomes, and balancing measures were included and clearly defined. (2) Use of control charts: Process and outcomes measures were clearly depicted with control charts accounting for both baseline data and each phase of the implementation process.

- Surgical Site Infections (Myres et al)

Summary: An algorithm standardizing the use of decolonization in preoperative patients prior to cardiac surgery was implemented to decrease the incidence of surgical site infections. Rates of surgical site infections decreased by 43% in delayed sternal closure cases and 30% for all other cases.

Quality improvement principles applied well: (1) Engagement of multidisciplinary key stakeholders: This algorithm was created with the input of numerous stakeholders involved along the entire spectrum of patient care from outpatient preoperative clinic to the ward. (2) Use of run charts: The surgical site rate per 100 procedures was documented monthly to understand variation and the impact of the algorithm. (3) Plan-do-study-act cycles: Throughout implementation, all surgical site infection cases were reviewed to identify barriers to algorithm utilization and to inform future reiterations of the algorithm.

- Multidisciplinary Code Review (Florez et al)

Summary: A dedicated code review team was created with a global aim to improve the efficiency and effectiveness of resuscitation practices in the CICU. The team successfully increased the number of formal resuscitation reviews from 0% to 100% over eight months. A standardized debriefing tool was utilized in all resuscitation reviews.

Quality improvement principles applied well: (1) Key driver diagram: A key driver diagram clearly outlined the global aim, specific SMART aims, key drivers, and specific interventions. (2) Transparency: Learning points from resuscitation reviews were disseminated to all care providers in a transparent yet nonpunitive manner so that everyone could be aware of potential systems issues and to create a safe platform for shared solutions to common problems.

- Catheter-Associated Urinary Tract Infections (Bigelow et al)

Summary: Through several well-defined cycles of change, Bigelow et al decreased the rate of catheter-associated urinary tract infections (CAUTI) in the CICU from 8.21 per 1,000 Foley days in 2011 to 0 in 2018.

Quality improvement principles applied well: (1) Plan-do-study-act cycles: The group used six specific PDSA cycles ranging from the creation of indications for inserting and/or maintaining bladder catheterization to reviewing all cases of Foley catheter use >three days. (2) Use of run charts: Days since last CAUTI and average days between events were clearly visualized within the context of each of the PDSA cycle implementation dates.

Comment

Recognition and appreciation of the power of data-driven, continuous QI to impact performance, patient outcomes, and resource utilization are key to implementing and sustaining meaningful QI initiatives. In this report, we summarize lessons learned from an academic meeting of pediatric cardiovascular clinicians including an interactive QI workshop designed to address inadequate training and understanding of QI science. Fundamentally, QI methodology and tools provide mechanisms to harness, align, and direct individual clinical providers' motivation to deliver high-quality care. Living by the old adage, "You have to go slow, to go fast" when implementing QI will ensure ongoing success, sanity, and results.

Authors' Note

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