
Improving Pediatric Cardiac Care with Continuous Quality Improvement Methods and Tools

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Abstract

The healthcare delivery system is overly complex, impersonal and inefficient. Stakeholders are searching for effective remedies to ensure and enable that high quality care is readily available to all no matter their socio-economic standing and their location. High-performing healthcare organizations differentiate themselves by focusing relentlessly and continuously on process-improvement initiatives to advance patient care. Continuous quality improvement offers a powerful way of thinking about how to transform clinical operations and healthcare teams to this end. Quality improvement methods are ideally suited for applications in complex cardiac care. In particular, we find five quality improvement tools—checklists, process maps, Ishikawa diagrams, run charts, and control charts—most relevant to improving the process and outcomes of pediatric cardiac care. The tools help visualize, analyze, and track process and outcome data for both individual and groups of patients. These tools should be taught to healthcare providers and managers and should routinely be deployed by clinicians and healthcare systems to evaluate and improve care.

Keywords

Continuous quality improvement • Patient safety • Pediatric cardiac surgery • Process mapping • Control chart • Check list • Run charts • Fishbone diagrams

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A History of Quality Improvement

Continuous quality improvement (CQI) is both a management philosophy and a management method. It offers an approach, a set of tools, and a way of thinking about how to more effectively assess and study clinical flow and operations to achieve better results for patients, providers and healthcare delivery systems [1].

The evolution of CQI in health care may be traced to the pioneering work of Florence Nightingale in 1850s. Nightingale used empiric observations and robust statistical methods to link unsanitary conditions with the high number of preventable deaths during the Crimean War [2].

In the 1960s, an approach known as *Kaizen* (literally “change good” or “improvement”) was introduced in Japan [3]. Grounded in Japanese local village knowledge and practices, the key features of *Kaizen* include:

- The ideas come from the workers themselves; thus they are less likely to be radically different and, therefore, easier to implement and less prone to induce resistance
- Small improvements are less likely to require major capital investment than major process changes
- Employees will continually seek ways to improve themselves by improving their own performance while encouraging workers to take ownership for their work, thereby improving worker motivation and engagement.
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From *Kaizen* came “quality function deployment,” which combined quality assurance and quality control with function deployment in value engineering [4]. Quality function deployment helped to focus improvement efforts on the customer’s needs by attending to and respecting the voice of the customer (VOC) above all. Translating these needs into design and engineering characteristics could help dramatically improve a product or service [5]. The same concepts and activities are now often referred to as “quality improvement” or “quality management” or even sometimes simply as “improvement” [6]. These concepts have now spread throughout the world and across multiple economic sectors, including healthcare. What was originally called *total quality management* (TQM) in the manufacturing industry evolved into *continuous quality improvement* (CQI) as it was applied to healthcare administrative and clinical processes.

Cross-disciplinary learnings and influence between manufacturing and healthcare were spurred during the 1990s by the increasing

awareness that healthcare was lagging behind other industries in providing poor and uneven value. This highlighted the need to focus on reducing waste, inefficiencies, and harms. This awareness of the limitations of traditional methods to improve patient outcomes and contain costs forced healthcare to look to other domains for solutions [7]. However, from the perspective of healthcare providers, the industrial perspective of quality is limited in that it (1) ignores the complexities and dynamic nature and nuances of the patient–practitioner relationship; (2) downplays the knowledge, skills, and intrinsic motivation, as well as the ethical obligations of practitioners; and (3) provides less emphasis on influencing professional performance through “education, retraining, supervision, encouragement, and censure” [1].

Donabedian suggested that much can be learned from industrial quality and the industrial model of quality that calls attention to several important considerations [7]:

1. The need for even greater attention to consumer requirements, values, and expectations
2. The need for greater attention to the design of systems and processes as a means of quality assurance
3. The need to extend the self-monitoring, self-governing tradition of physicians to others in the organization
4. The need for a greater role by management in assuring the quality of clinical care
5. The need to develop appropriate applications of statistical control methods to healthcare monitoring
6. The need for greater education and training in quality monitoring and assurance for all concerned.

CQI is distinguished in healthcare by the recognition that service excellence and high-value outcomes are predicated on meeting the patients’ needs. Meeting these needs is the key to sustaining quality. However, these needs may change over time with changes in expectations associated with education, economics, technology, and culture. Such changes, in turn, require continuous improvements in the administrative and clinical methods vision and leadership that affect the quality of patient care.

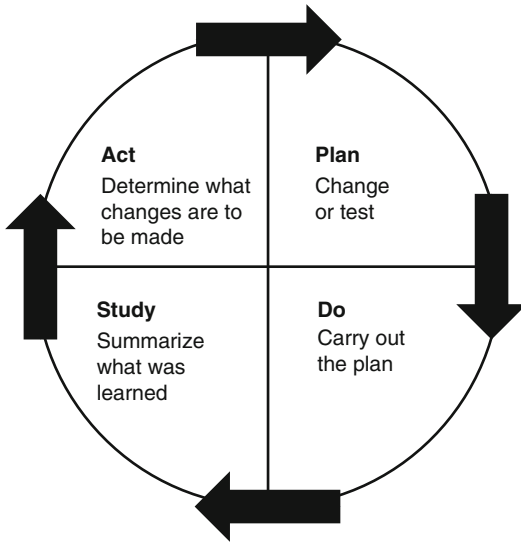


Fig. 3.1 The plan-do-study-act cycle (Adapted from Langley et al. [6])

Approaches to Quality Improvement

Several successful, multi-level, broad-based approaches have evolved across a range of health-care disciplines, including pediatric cardiology and cardiac surgery. These approaches can be thought of as an umbrella that encompasses specific change methods. The most notable of these approaches are the plan-do-study-act (PDSA) cycle, the Model for Improvement, quality improvement collaboratives, lean manufacturing, and Six Sigma—each will be described below.

Walter Shewhart, at Bell Laboratories, introduced the iterative approach called **Plan-Do-Study-Act** (PDSA; Fig. 3.1) [8]. (Although the PDSA cycle is often attributed to Deming, he called it the Shewhart cycle.) [9] The **Model for Improvement** (Fig. 3.2), which was introduced in 1992, integrates the PDSA cycle as its core method [6]. Central to its application are three key and recurring questions:

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?

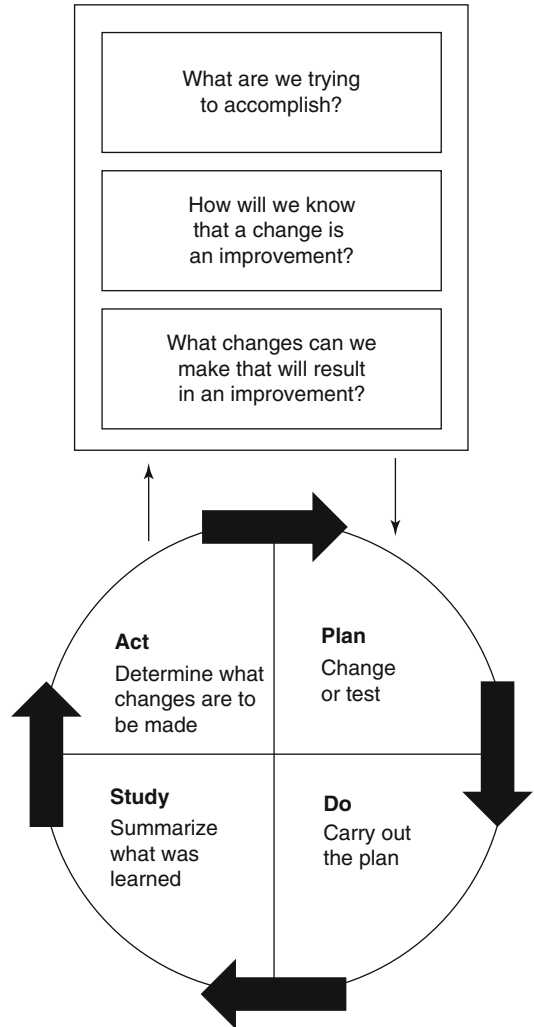


Fig. 3.2 The Model for Improvement, which incorporates the plan-do-study-act cycle (Adapted from Langley et al. [6])

The wide use of the PDSA cycle and the Model for Improvement in healthcare is the direct result of their elegance and simplicity, as well as to the transferability and application of these approaches across multiple care and non health settings.

Improvement collaboratives are another approach to quality improvement. A **quality improvement collaborative** consists of “multidisciplinary teams from various healthcare departments or organizations that join forces for several months to work in a structured way to improve their provision of care” [10].

One of the first uses of collaboratives was the Northern New England Cardiovascular Disease

Study Group in 1986 [11]. Their continuing and effective use in cardiovascular care is described in a systematic review of the management of heart failure, published in 2006, 20 years after this management process was begun. This review concluded that collaboratives “[have] significant potential to improve the outcomes of patients, particularly those with [heart failure] and chronic cardiovascular disease. The success and widespread adoption of collaboratives are directly related to the growing trust, respect, and data sharing among like-minded clinicians. This trust leads to meaningful exchanges and insights among experts and peers who then apply best practices to improve their care. Learning collaboratives can also use the PDSA approach [11] and are arguably the most effective way for systems to rapidly learn from each other about improving their process and patient outcomes.

Improvement collaboratives are successful and popular ways of improving health service delivery in disciplines ranging from cystic fibrosis, to heart failure, to trauma care [12, 13]. However, collaboratives are expensive and their results are difficult to measure with traditional epidemiological methods [14].

In the 1980s the Motorola Corporation developed the **Six Sigma Methodology** [15]. Six Sigma starts with a process mapping activity that involves elements of defining what a business does, assigning responsibilities, identifying performance standards, and deciding how success will be determined (see below). After these critical elements have been defined, Six Sigma analyzes each through the DMAIC methodology (Define, Measure, Analyze, Improve, and Control) [16].

“**Lean**,” also known as “lean manufacturing,” “lean enterprise,” or “lean production,” is a CQI approach that considers as wasteful any resources that are allocated to any goal other than creating value for the customer and that are thus targets for elimination [17]. Value is defined from the customer’s perspective and includes any action or process for which a customer would be willing to pay.

For many, Lean is an approach to improvement that helps to identify and steadily eliminate waste in processes (or *muda*, in Japanese). As waste is eliminated, quality improves and

production time and costs are reduced. Essentially, lean is centered on *preserving value with less work*. Lean optimizes the trade-off between productivity and quality and highlights the axiom that improved quality translates to improved profitability, or good quality is good business.

Quality Improvement Tools

Several CQI tools can help improve pediatric cardiac care and surgery [18]. The most relevant tools for pediatric cardiac surgery are listed in detail below and include checklists, process maps, Ishikawa diagrams, run charts, and control charts.

Checklists

The checklist has received the most attention (and press) for improving patient safety. Evidence supports greater adoption of checklists in surgery [19] and in other medical specialties [20–22]. In June 2008, the Safe Surgery Saves Lives Initiative of the World Health Organization (WHO) released the WHO Surgical Safety Checklist. In a little more than 2 years, more than 3,900 hospitals in more than 122 countries were registered in the Initiative. Of these 3,900 hospitals, more than 1,800 have reported using a checklist in at least one operating room [23].

The Dutch SURPASS study, conducted from October 2007 to March 2009, found that hospitals using checklists had surgical complication rates that were more than one-third lower, and death rates that were almost one-half lower (from 1.5 to 0.8 %), than they were in hospitals not using checklists [24].

Researchers at Stanford found that the observed-to-expected mortality ratio declined from 0.88 in quarter one, to 0.80 in quarter two, with the use of a modified version of the WHO Surgical Safety Checklist [25]. The use of checklists also improved communication among the surgical team, and thus the quality of care. Quality was measured by the frequency with which staff reported “Patient Safety Never Events” (i.e., the kind of events that should “never happen”). The number of Patient Safety

Never Events related to errors or complications decreased from 35.2 to 24.3 %.

The website Safesurg.org provides resources for implementing the WHO checklist or for modifying an existing checklist. Modified checklists created by other institutions can also be downloaded (<http://www.who.int/patientsafety/safesurgery/checklist/en/>). [26] Modifying checklists to fit local practices and needs is encouraged to enhance acceptance.

Although checklists have been widely adopted, their effectiveness has been highly variable if they are casually applied only as tick-box forms and in a top down approach [27]. Ineffective top-down engagement and inauthentic partnering with clinicians inhibits positive behavior change and encourages normalized deviance [28]. Introducing a checklist in an environment characterized by a lack of trust causes clinicians to feel jeopardized professionally and personally, encourages gaming and lead to marginal to no improvement of care or outcomes [29]. Effective adoption requires local championship, sustained clinician engagement, and a commitment to interprofessional teamwork [30, 31].

Process Maps

A process map or flowchart is a visual representation of the care process that is created with information provided by team members. The process mapping exercise can help clinicians clarify through visualization the complex and many step process of their environment and determine what they want to do to improve it. The exercise helps clinicians make assumptions and expectations explicit and can provide insight into how to improve the process of care or to overcome barriers to its improvement [32].

A high degree of process awareness often drives the design changes needed to sustain improvement. Process mapping describes precisely what an individual provider is required to do and when, in terms of cognitive processes, actions, or both, to achieve the system's goal. Data are collected from observations or interviews that carefully break down complex clinical processes into discrete, measurable, and clear tasks [32]. Team members can gain insights into

how they and their colleagues perceive the same tasks and hopefully come to a shared understanding of the process.

Ultimately, improving patient outcomes requires appreciating the inherent links between structure, process and outcomes [33]. Process maps help focus improvement efforts, not solely for the individual provider, but for the entire clinical microsystem. Visualizing the process can also help identify inefficiencies (e.g., parallel or redundant processes that have emerged for whatever reason), clarify roles, and reduce ambiguity among team members, all of which can help coordinate patient care. This process is particularly useful in improving transitions of care and avoiding readmissions and patient bounce back to intensive care and high-dependency units [34, 35].

Process maps can be created at different levels of detail to illustrate the major phases or detailed activities in that process. It is important to map the current process, not the *desired process*, to identify opportunities for improvement. We have used process mapping in pediatric cardiac surgery to better understand the current process of care (Fig. 3.3) and to summarize the data on near misses and adverse events (Fig. 3.4) [32, 36].

Ishikawa Diagrams

Ishikawa diagrams, also known as “cause-and-effect diagrams,” “fishbone diagrams,” and “root-cause analyses,” are visual representations of the sources of variation in a process [37]. The diagram is often created by brainstorming with key stakeholders to identify the causes and their effects on a process. The causes are generally allocated to five general categories: place (environment), equipment, procedures (processes), people (patients and providers), and policies (Fig. 3.5). Routine root cause analysis with Ishikawa diagrams can be very powerful in analyzing surgical adverse events. A detailed analysis in one major hospital over 4 years (Table 3.1) established the fact that excellent surgical outcomes depend on appreciating and integrating individual, team, technical, and organizational factors [38].

Reviewing the root cause categories helps the team estimate the resources needed to address the

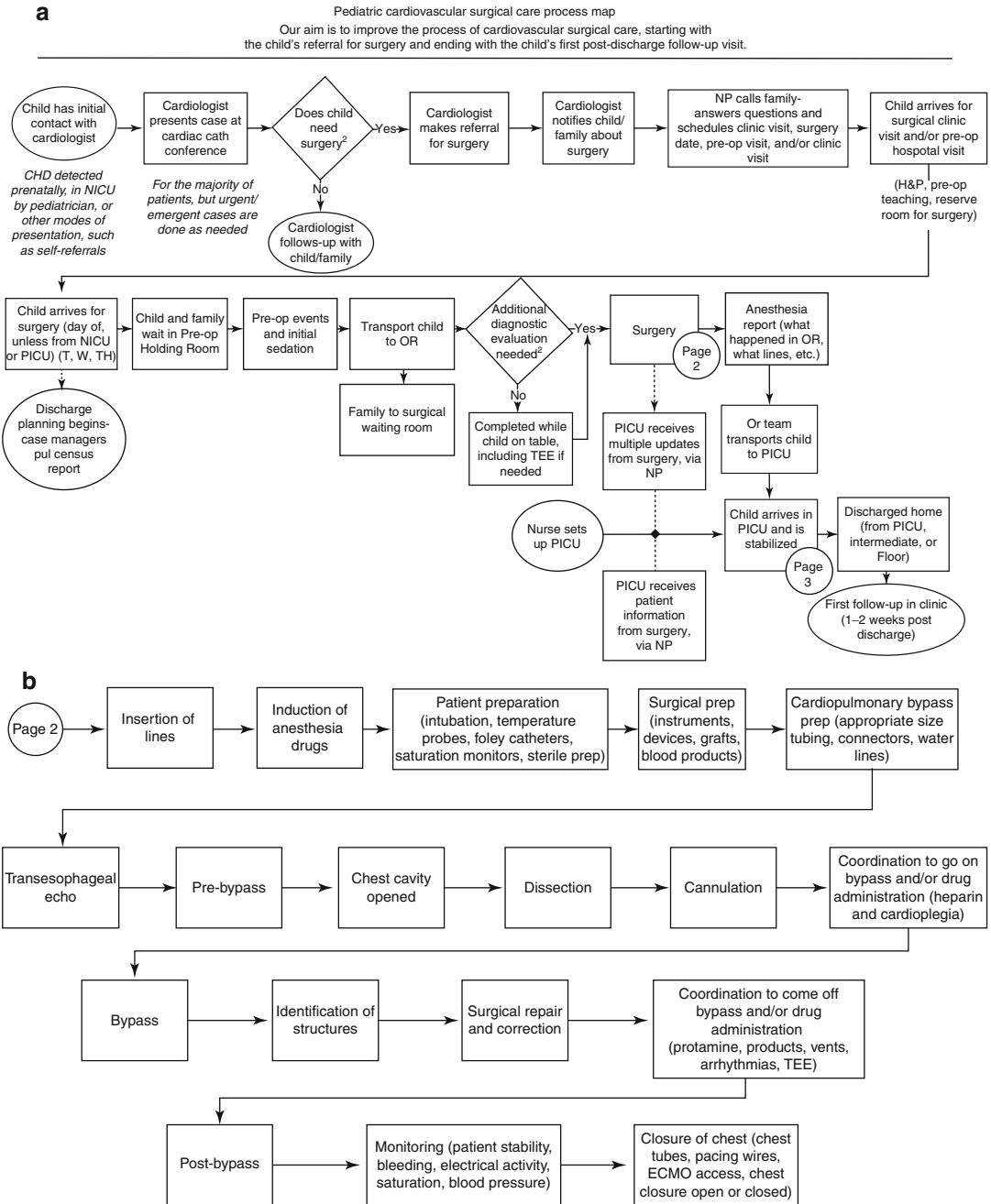


Fig. 3.3 A process map of pediatric cardiac and cardiac surgical care. (a) Preoperative processes. (b) Operative processes. (c) Postoperative processes (Source: Barach and Johnson [32]6, page 113. Used with permission)

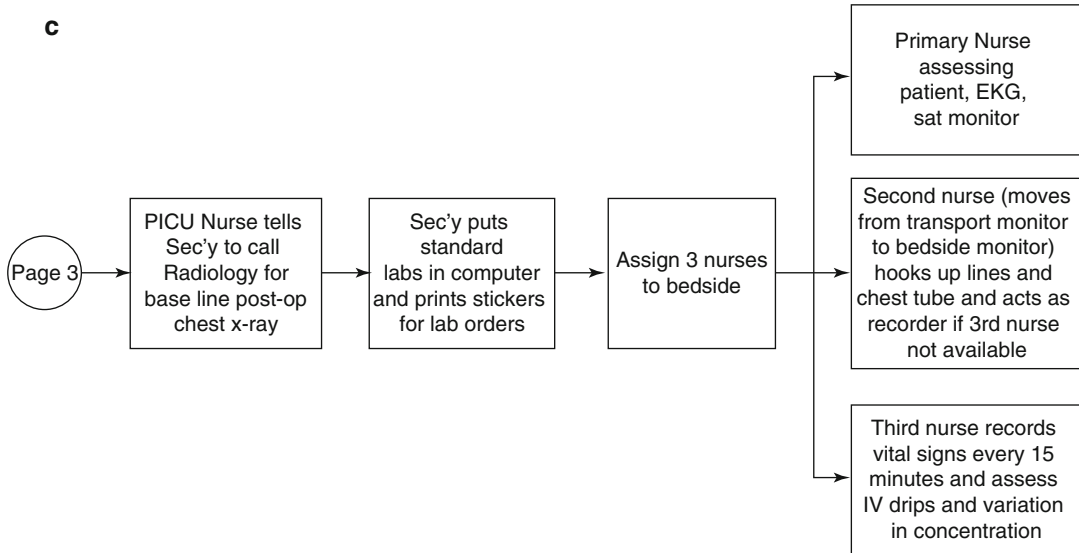


Fig. 3.3 (continued)

causes of process variation. These diagrams help identify potential improvements and which improvements might be transferable to another setting.

Run Charts and Control Charts

Two of the most powerful CQI tools are run charts and control charts [8, 39]. These tools are valuable for analyzing variability in clinical processes [40], in part because the data usually does not go beyond what is generally collected to meet reporting requirements. The run chart is a simple plot of a measurement over time with a line drawn at the median value. The data can be related to patients, organizations, or clinical units. Run charts are particularly useful because they can reveal subtle changes over time that would otherwise go unnoticed.

Important uses of the run chart for clinical improvement are to:

- Display data to make process performance visible
- Determine whether tested changes improve the process or endpoints
- Determine whether the changes are lasting

- Allow for a temporal view of data versus a static view [41].

For example, a team wanting to improve patient outcomes on mechanical ventilation might measure time-to-extubation for patients undergoing closure of atrial septal defect or ventricle septal defect. Team members start by plotting the data over time in a run chart for 30 consecutive patients (Fig. 3.6), where the time to extubation ranged from 2 to 48 h after the procedure, with a median of 14 h. As the team changes the process, they can continue plotting data to determine whether the changes decreased time-to-extubation and thus improved overall care or made no different on outcomes.

The control chart was developed by Shewhart in the 1920s to improve industrial manufacturing [8]. Like run charts, control charts display data over time, but control charts provide upper and lower control limits of variation that help determine whether a process is stable or unstable (Fig. 3.7). Control limits are calculated using median values and the moving ranges of the data. The factors leading to instability must be addressed before the process can be improved.

Shewhart and Deming define two types of variation in a process. Briefly, “common cause variation”

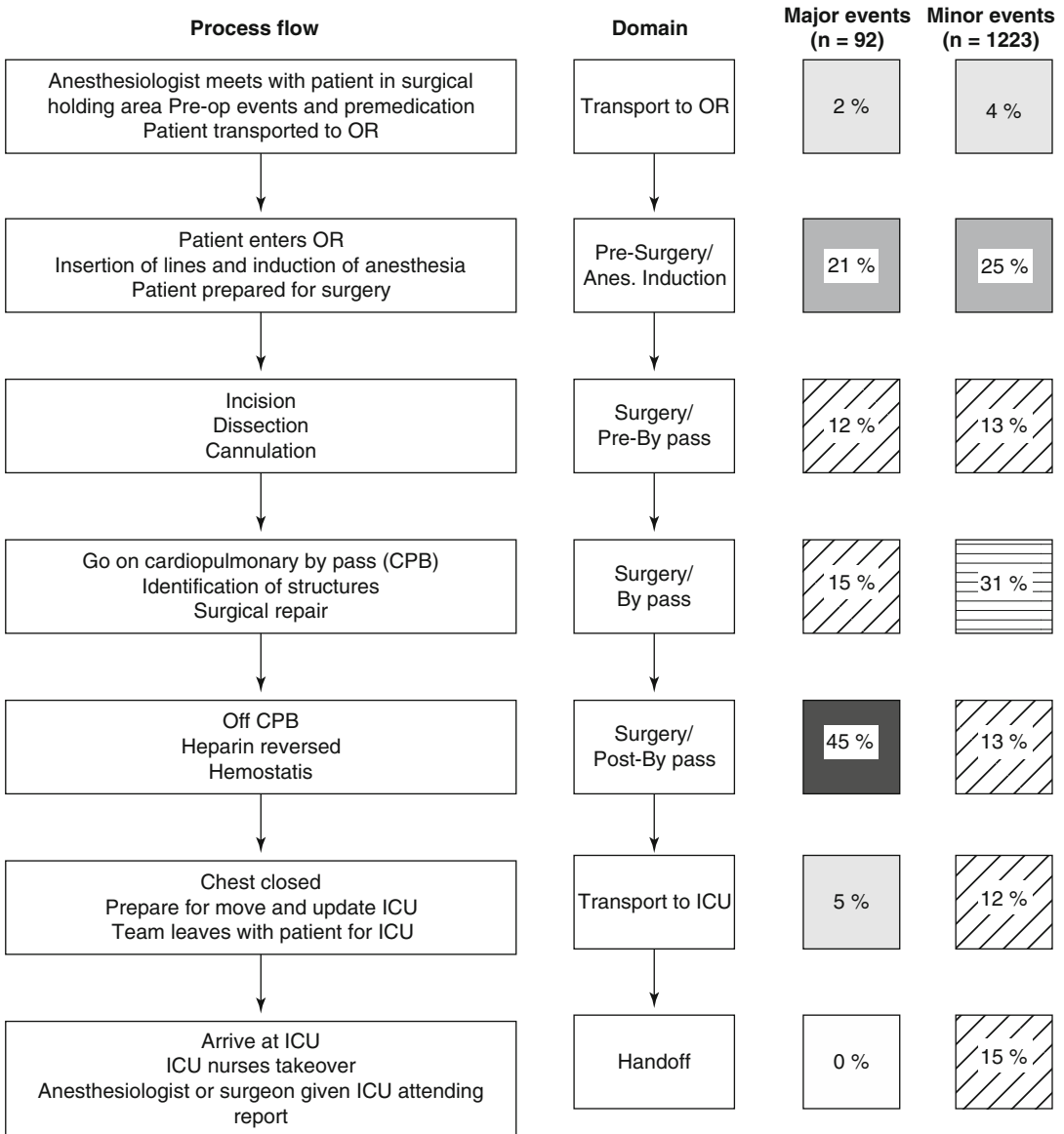


Fig. 3.4 A process map showing minor and major adverse event data in pediatric cardiac surgery (Source: Barach et al. [36]. Used with permission)

is the usual, historical, quantifiable variation in a system, whereas “special cause variation” is unusual, not previously observed, non-quantifiable variation [42]. In surgical procedures, common cause variation might include fluctuations in the severity of a patient’s risk factors, the skills of operating team members, or changes in equipment settings [43]. Common cause variation suggests that improving outcomes will require

changing the processes that produced the results. Special cause variation is the result of factors extraneous to the process; for example, variation introduced by a new manager, drive for more productivity or by equipment breaking during a procedure. It is not possible to predict (or control) variation caused by special causes.

If the control chart indicates that the process is currently under control (i.e., it is stable, with

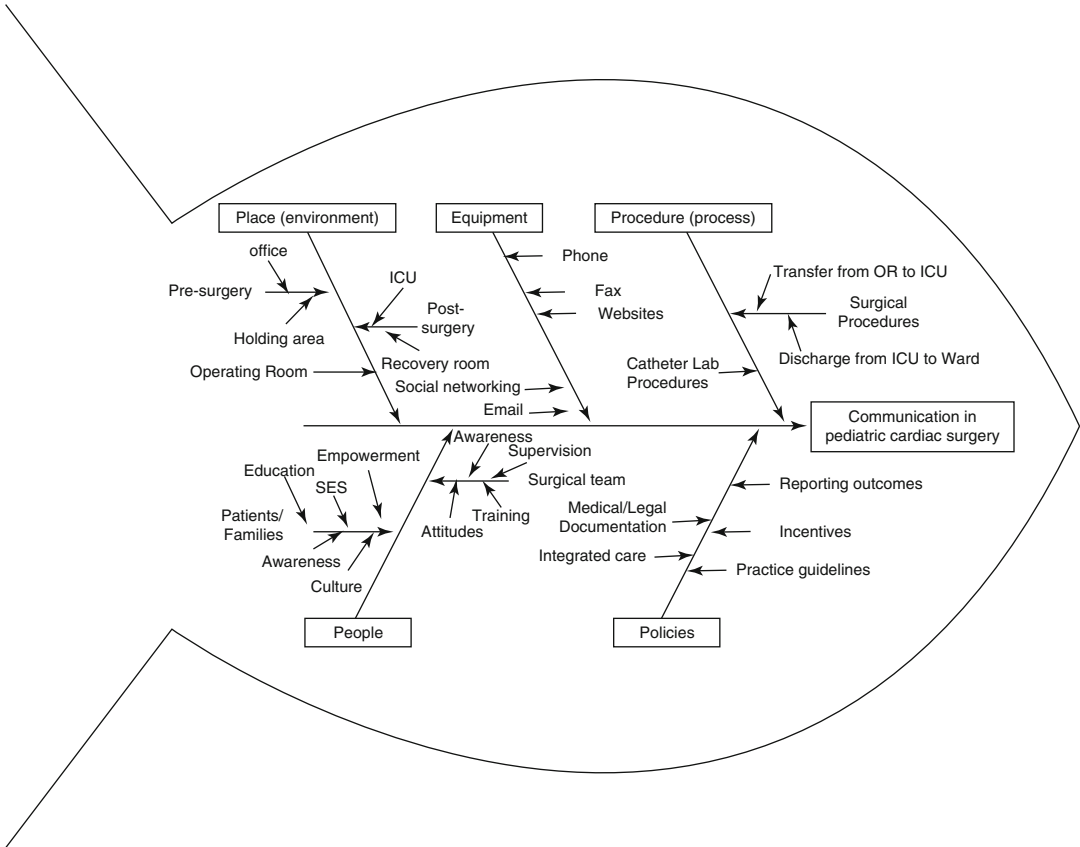


Fig. 3.5 An Ishikawa diagram for pediatric cardiac surgery

Table 3.1 Results of a root cause analysis of process variation of cardiac surgery

Theme	Issues identified
Failure to recognize or respond appropriately to the deteriorating patient within the required timeframe	Post CABG complications Postoperative sepsis Postoperative hyponatremia
Workforce availability and skills	Orientation, training, and supervising new or junior members of the surgical team, especially outside normal working hours
Transfer of patients for surgery	Difficulty in organizing an OR for surgery Failure to handover information about patient acuity
Trauma management	Coordination and response of trauma teams Clinical decision making process for trauma patients Coordination of care between multiple clinicians
Access to emergency operating room	Antepartum hemorrhage and emergency cesarean Urgent orthopedic procedure Urological complications requiring urgent OR
Missed diagnosis	Thoraco-lumbar fracture in a trauma patient Brain abscess mistaken for cerebral metastasis Sub arachnoid hemorrhage thought to be drug overdose
Unexpected procedural complications	Airway obstruction after thyroidectomy Failed intubation
Sentinel events	Wrong site procedure—spinal fusion at wrong level Retained surgical products requiring surgical removal

Adapted from Cassin and Barach [38]

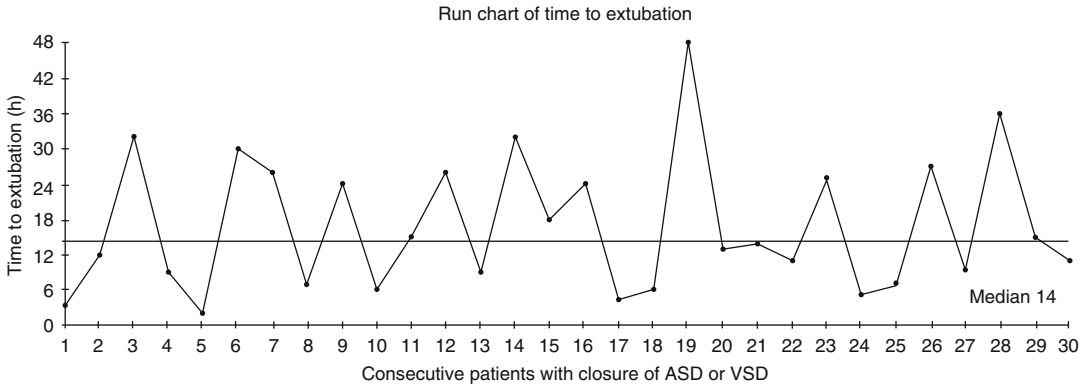


Fig. 3.6 A run chart of time to extubation for patients undergoing closure of atrial septal defect and ventricle septal defect in the intensive care unit (ICU)

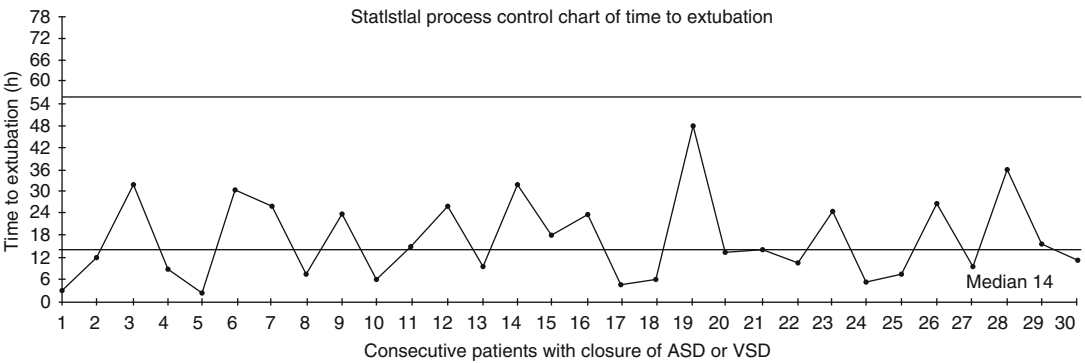


Fig. 3.7 A control chart of time to extubation for patients undergoing closure of atrial septal defect and ventricle septal defect in the ICU. The chart shows that the variation is the result of common cause variation and not

special cause variation. That is, *without any changes* to the process, the time to extubation will continue to fall within a range that will not exceed the upper control limit of 55 h

variation only coming from sources common to the process), then data from the process can be used to predict the future performance of the process. If the chart indicates that the process is not under control, the chart can help determine the sources of variation, which can then be eliminated to bring the process back under control (Fig. 3.7). These data can inform the team about when to act, but also, especially in healthcare systems that are constantly tweaking their systems, when to hold and not to act, depending on the cause of the variation.

The control chart illustrates the variation that is due to a common cause and not to a special cause variation. The implications in our example about when to extubate the patient is that *without any changes* to the process it will be difficult to predict the time to extubation.

Control charts are appropriate for analyzing data from procedures that are performed frequently, consistently, and with relatively standard methods [43]. In addition, patients should be separable into more homogeneous subsets for analysis, for example, by stratifying them by procedure, and the procedures should have a

documented range of favorable and unfavorable outcomes.

Conclusions

This chapter described several CQI tools that should be part of improving the processes and outcomes of pediatric cardiac care. Detailed descriptions of how to apply the tools are beyond the scope of this chapter. Improving teamwork is an important factor in improving patient outcomes. In fact, it is a requirement for using these CQI tools effectively. Indeed, ongoing quality improvement efforts are not about which tools are used but about how these tools can produce insight, provide feedback, engage the team members and track progress. Their purpose is to help people function as a team, as well as to improve patient outcomes.

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