Quality Improvement Methodologies Increase Autologous Blood Product Administration

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Abstract: Whole blood from the heart–lung (bypass) machine may be processed through a cell salvaging device (i.e., cell saver [CS]) and subsequently administered to the patient during cardiac surgery. It was determined at our institution that CS volume was being discarded. A multidisciplinary team consisting of anesthesiologists, perfusionists, intensive care physicians, quality improvement (QI) professionals, and bedside nurses met to determine the challenges surrounding autologous blood delivery in its entirety. A review of cardiac surgery patients’ charts (n = 21) was conducted for analysis of CS waste. After identification of practices that were leading to CS waste, interventions were designed and implemented. Fishbone diagram, key driver diagram, Plan–Do–Study–Act (PDSA) cycles, and data collection forms were used throughout this QI process to track and guide progress regarding CS waste. Of patients under 6 kg (n = 5), 80% had wasted CS blood before interventions, whereas those patients larger than 36 kg (n = 8) had 25% wasted CS before interventions. Seventy-five percent of patients under 6 kg who had wasted CS blood received packed red blood cell transfusions in the cardiothoracic intensive care unit within 24 hours of their operation. After data collection and didactic education sessions (PDSA Cycle I), CS blood volume waste was reduced to 5% in all patients. Identification and analysis of the root cause followed by implementation of education, training, and management of change (PDSA Cycle II) resulted in successful use of 100% of all CS blood volume. Keywords: autologous blood, cell saver, quality improvement, Plan–Do–Study–Act, fishbone, key driver diagram, multidisciplinary team, cardiopulmonary bypass, continuous quality improvement, cell saver waste, pediatric.

Healthcare systems are adopting quality improvement (QI) methodologies. In 2001, the Institute of Medicine (IOM) published an article highlighting shortcomings in the quality of health care (1). This article provoked improvement in health care, system processes, and patient outcomes; however, this improvement has been slow. The U.S. Agency for Healthcare Research and Quality defined “quality” as “doing the right thing at the right time, in the right way, for the right person—having the best possible results” (2). This interpretation of “quality” is applicable to all aspects of healthcare. Many QI tools have been successfully adapted from their use in the manufacturing industry to healthcare and management practices (3,4). This article seeks to describe some of those tools and describes an example of how they were used to impact this institution’s autologous blood administration practice.

Quality improvement is linked to safety and best outcomes in healthcare. In 1999, the IOM published a report stating that as many as 98,000 deaths occur each year as a result of medical errors. This report highlighted the need for quality improvement practices to reduce medical errors and improve patient outcomes.
result of medical errors (5). With the growing complexity of health care and the continuously changing practices, health care has room for improvement. In a report by the IOM in 2001, it was stated that the health care that we now have and what we could have “lies not just a gap, but a chasm” (6). As quality of care and systems improve in health care, hospitals are working toward creating safer environments for patients. Avedis Donabedian described quality design as a continuous relationship among structure, process, and outcomes (7). A structure needs to be in place to allow processes to develop and improve patient outcomes. With regard to a systems approach to quality and safety, our institution was the first pediatric healthcare institution to develop a preventable harm index (PHI) (8,9).

Within the healthcare literature, there is proof that each blood transfusion exposes the patient to certain risks; based on this evidence, we set out to monitor and improve our cell saver (CS) product administration with other added benefits of reducing blood transfusions in the cardiothoracic intensive care unit (CTICU) (10–12). The purpose of this article is to describe how QI tools were used to reduce the amount of autologous blood waste in all patients.

Background

Our hospital embraces safety and processes that reduce PHI in all departments. In an effort to embrace this culture of safety and QI, all departments must produce measurable QI initiatives to improve their specific clinical environment. A QI project should set forth with a specific aim statement, to guide the journey to improvement. To create an effective aim, the scope of the project needs to be realistic, measurable, and results focused. Four components of an aim statement are 1) what the project will increase or decrease; 2) group or population the project will affect; 3) baseline (from what) to desired result (to what); and 4) timeframe (by when and sustain for how long) (Figure 1).

Problem

Whole blood from the heart–lung (bypass) machine may be processed through a cell salvaging device (i.e., CS) and subsequently administered to the patient during cardiac surgery. It was determined at our institution that some of this CS volume was being discarded.

METHODS

A multidisciplinary team consisting of anesthesiologists, perfusionists, intensive care physicians, QI professionals, and bedside nurses met to determine the
challenges surrounding autologous blood delivery in its entirety. Three primary drivers were identified: intensive care unit (ICU) factors, blood conservation education, and anesthesia practices. A root cause analysis was conducted, with the multidisciplinary team, using a fishbone (Ishikawa) diagram (also called a cause-and-effect diagram) (Figure 2). The fishbone diagram seeks to help answer why a system or process is performing in a certain way. This tool begins with a specific outcome the team seeks to improve. The adverse outcome will remain at the “head” of the diagram. A useful exercise is asking the question “why is this occurring” and continue to ask “why” five more times (the five “whys” of a problem); this assists in finding the root cause of the problem (Figure 3). Each response should be used as a “tail” on the fishbone diagram. These responses are also separated into key categories, which typically include people, policies, procedures, or measurements. These categories typically become key drivers for process improvement. A potential next step is to create a key driver diagram (KDD). A KDD was developed to conceptualize potential interventions that could resolve system constraints that may contribute to CS blood waste (Figure 4). This allowed for the development of a pathway to achieve the desired outcome of reducing CS blood waste. A KDD can be considered a roadmap to focus the team’s efforts in communicating among team members, across the organization, and finally to track improvements. A KDD should evolve over the lifetime of a project, whereas the key function of a KDD remains connection of the project’s aim statement to the key drivers with the changes that need to occur (interventions). Key drivers are considered significant causes that influence the specific aim; they are the “what” that impacts the aim. Interventions are specific items of change; they describe “how” to impact the aim. A process map was also created to visualize steps needed to optimize CS administration. This helped identify redundancy, process gaps, delays, and practice variation (Figure 5).

The KDD and process map defined specific interventions that were to be implemented using a Plan–Do–Study–Act (PDSA) QI tool. A PDSA cycle model was used for improvement and testing of change. A PDSA cycle begins with a plan to test a small change or hypothesis (Plan); implementing the change (Do); observing, analyzing, and learning from the implementation (Study); and determining what additional modifications should be made (Act). The PDSA cycle is repeated as necessary with each iteration of the PDSA cycle being an expansion and/or enhancement of the previous cycle. PDSA cycles start in small areas and can grow to become unit or even hospital-wide with limitless potential to a national or global culmination (13) (Figure 6).

Interventions
The plan in Phase I of this PDSA was set and determined by the multidisciplinary team. This step involved planning education sessions for all clinicians in the operating room as well as in the CTICU. The “Do” portion involved data collection forms to analyze CS administration, to define the institutional use, and to assess if change was needed. It was determined that CS blood was being wasted and, thus, the improvement discussions were continued. The “Act” involved an educational session for ICU physicians, ICU nurses, perfusionists, and anesthesiologists. Additionally, a nurse rounding sheet was introduced during the CTICU morning rounds as part of nursing continuing education on CS product administration. Presentations were given at the CTICU QI meetings as well as the operating room QI meetings to update and inform clinicians on improvements.
that were occurring and how their input and assistance was vital. The “Act” portion of the Cycle I PDSA may then become the “Plan” of the PDSA Cycle II. After the education sessions and several PDSA cycles, a review of 62 patient charts was conducted to measure the change in CS administration (“Do,” Phase II). “Study,” Phase II was then conducted to analyze the data collection forms. The last phase of “Act” was to sustain the improvements in CS product administration and continue improvements over time. PDSA cycles provide opportunities for two-way exchanges between clinicians and QI professionals attempting to make improvements while promoting the desire to demonstrate evidence-based practice (EBP) (14). They also typically include data collection in small samples with adaptations to implement improvement in health care (2). A run chart and a control chart (Shewhart) were created to show change over time based on the collected data regarding CS product administration. Run charts track change over time and can assist with determining if change is occurring. Control charts show the mean of the data set (as a solid center line) with upper and lower control limits. The control limits represent three standard deviations from the mean.

Descriptive statistics were computed to summarize all variables of interest. For continuous variables, mean and standard deviation were provided for normally distributed data. Count with frequency and percentage were estimated for categorical variables. A two-sample t test or Wilcoxon rank-sum test, where appropriate, was used to evaluate effect differences between preintervention and postintervention groups. Type I error will be strongly controlled at $\alpha = .05$ for a single comparison. The data were analyzed using the statistical software SAS Version 9.2 (SAS Institute, Cary, NC).

**RESULTS**

A review of pediatric cardiac surgery patients’ charts (n = 21) was conducted for analysis of CS waste. Of patients under 6 kg, 80% had wasted CS blood; 25% of the patients larger than 36 kg had wasted CS blood volume, preintervention. Of those patients under 6 kg who had wasted CS blood, 60% received packed red blood cell transfusions in the CTICU within 24 hours postoperatively. The total CS waste volume preintervention (35%, n = 21) versus postintervention (5%, n = 116) was statistically significant ($p < .05$), illustrating the impact of the PDSA cycles for improvement. Comparing the total volume of CS product produced, by weight group, preintervention compared with postintervention was not significant, indicating the volumes pre- and postintervention were similar ($p = .46$). The average discard volume preintervention (39 ± 68) versus postintervention (11 ± 34) demonstrated a significant improvement ($p < .05$). Comparing the total volume of CS that was discarded preintervention (11 ± 6 mL) to postintervention (7 ± 6 mL), by weight group, only the >36 kg group reached statistical significance ($p < .05$). Heparin dose–response compared with CTICU transfusion rate was not significant, overall or when compared with preintervention and postintervention.

Tracking if the autologous blood was being given in the operating room by anesthesia or given in the CTICU helped narrow the areas of focus for further interventions.

![Figure 4. Key driver diagram (KDD) illustrating factors contributing to use and decreased waste of cell saver in the pediatric cardiothoracic intensive care unit. This image has evolved with the project, interventions that were implemented during this study were previously not initiated or established and are now established, supported, and effective.](image-url)
such as seeing if information sessions and training made an impact. The amount of CS product administered by anesthesia preintervention (39 ± .7%) versus postintervention (82 ± .9%) was statistically significant ($p < .05$). The amount of volume given by the CTICU was not significantly different preintervention versus postintervention.

Rate of CS administration preintervention averaged 66% and postintervention averaged 94% (Figure 7). Immediately after the CTICU education session, implementation of the nursing rounding sheet, and the QI meeting presentation, a marked increase in compliance was observed. The control chart illustrates the same improvement postinterventions (Figure 8). A shift in the baseline was justified after seven consecutive data points below the median.

**DISCUSSION**

The use of multidisciplinary teams, for QI, dated back to the 1930s and was embraced in the 1960s with the work of industrial quality experts such as Joseph Juran (13,15). One limitation to this study was the relatively small preintervention sample size compared with larger cohort studies. However, this is not uncommon in nonrandomized longitudinal studies of this type. Using a PDSA QI tool requires multiple and repeated tests of change, which inherently leads to small sample sizes to track early and small tests of change. Using control charts provides an assessment of whether the improvement was significant enough to change the system and if the improvement was sustained. The KDD and fishbone diagram provided a visual representation of context to the multidisciplinary team. This enriched discussions and educational sessions by helping the multidisciplinary team to see factors contributed to the problem. Increasing the amount of CS product administered by anesthesia, in the operating room, decreased the amount of CS waste because CS blood was given sooner and less likely to expire before it could be returned to the patient. An additional intervention that was considered was
the use of a thermo-regulated storage device for the CS product to allow for a longer expiration time (16,17). However, this was untenable as a result of regulation from the American Association of Blood Banks with regard to tracking and management of the temperature while the CS product was being stored. This would have also required the purchase of a refrigerator and increased workload to track the temperatures. There was also a safety risk that was greater than the possible benefits of prolonging the CS expiration time. Storage of multiple patients’ CS blood in a refrigerator presents a unique challenge to manage and ensure each patient receives the correct product. Thoughtful considerations of these factors lead the team to seek out alternative interventions to increase CS administration.

CONCLUSIONS

Quality improvement will involve change, but measuring if that change is indeed an improvement is vital to the success of any project (17,18). Our continued efforts will be to access further clinical effects of reducing CS blood waste and blood transfusion rates. The results show administration of CS significantly impacts postoperative hematocrits ($p < .05$) and may lead to fewer blood product transfusions. This multidisciplinary team will continue to collect data on CS administration for 6 months to ensure the improvement is sustained. The team will also begin to work on a new KDD to assess and improve transfusion rates at our institution.

Transparency and team involvement assisted with change management and collaboration with each member of the system. Allowing individuals to give feedback and input to the success of the QI initiative was beneficial and assisted with the success of this initiative. It has been our experience that when a multidisciplinary team has success in improving care, it provides momentum...
for future successes. The benefit realized from collaboration across cardiothoracic surgery specialties will be a foundation on which we will build future success and improvements.

REFERENCES


**Figure 8.** Annotated monthly control chart (p chart) illustrating a shift of baseline after Plan–Do–Study–Act (PDSA) Cycle I. An additional shift of baseline (significant improvement) occurred after PDSA Cycle II as a result of improvement postintervention.
