Developing and Executing Quality Improvement Projects (concept, methods, and evaluation)

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Abstract: Continuous quality improvement, quality assurance, cycles of change—these words of often used to express the process of using data to inform and improve clinical care. Although many of us have been exposed to theories and practice of experimental work (e.g., randomized trial), few of us have been similarly exposed to the science underlying quality improvement. Through the lens of a single-center quality improvement study, this article exposes the reader to methodology for conducting such studies. The reader will gain an understanding of these methods required to embark on such a study. Keywords: quality improvement, study design, methodology.

The foundation of science is reproducibility. Many of us recall being taught the fundamentals of research: the scientific method. Our teachers engrained in us that research requires us to 1) state a testable hypothesis; 2) design and explicitly describe our methodology so that others could reproduce our results; 3) describe the results of our experiment; and 4) state the conclusions of our experiment. If followed, this recipe would allow us to use objective criteria for assessing the entire experiment as well as archive our work in such a way that others might verify or refute our findings.

Although experimental methods are part of traditional academic curricula, few of us have been exposed to the science underlying quality improvement (1). Although the science underlying this field is certainly evolving, it requires an equivalent amount of conviction and precision (2). Unfortunately, such methods are often not taught in medical school or equivalent postgraduate education, and few journals explicitly seek out articles focused on the topic of quality improvement (3). As a consequence, we miss important opportunities to learn from each other regarding how best to transform health care or more explicitly cardiovascular perfusion.

This article will inform the reader about how to execute quality improvement studies, including their design, execution, and evaluation. Prior publications in this journal have focused on the topics of developing research questions, synthesizing the literature, and using databases to address particular clinical questions (4–6). It is the hope that investigators interested in conducting quality improvement studies will use this article as a guide.

DESCRIPTION

Although many of us use terms such as research, quality assurance, and quality improvement, some may have little notion of what these terms really mean (Table 1). Although seemingly mundane, such definitions are important as we discuss how to embark on developing and executing quality improvement studies. Many of us have participated in research projects. Many of these might have been in vitro experiments (those conducted in test tubes or involving “wet laboratories”), whereas others have been in vivo experiments (those conducted on humans). For the latter, we recognize the importance of communicating with our Institutional Review Board (IRB, “ethics board”), which has the jurisdiction to determine whether proposed studies involving human subjects should be conducted.
Quality improvement may be defined as a systematic approach for reducing waste or improving efficiency, reliability, and performance of a service or product. Quality assurance may be defined as the systematic study or evaluation of a service or product to ensure its performance meets predefined standards for quality. Quality improvement may be defined as a systematic approach for reducing waste or improving efficiency, reliability, and performance of a service or product.

Table 1. Definition of key terms.

| Research may be defined as generalizable knowledge or knowledge that may be germane or applied outside the population under investigation. |
| Quality assurance may be defined as the systematic study or evaluation of a service or product to ensure its performance meets predefined standards for quality. |
| Quality improvement may be defined as a systematic approach for reducing waste or improving efficiency, reliability, and performance of a service or product. |

We strive everyday in the operating room to provide the best cardiac surgical care for our patients. However, what defines quality from a perfusion standpoint? As a starting point, we might define quality based on our performance in a given clinical case: the percentage of measured activated clotting time values that are within a center’s targeted range. As another example, we might use a measure that reflects the care we provide over a series of patients such as the percentage of cases in which a patient is transfused with red blood cells. We use such information to assess our own performance with the goal in this example of having fewer patients being unnecessarily transfused.

Although we have certainly witnessed a greater level of scrutiny of perfusion practice over the last several decades, real, substantial, and long-lasting improvements in care require us to develop expertise in how to transform health care (7). It is no longer sufficient for us to simply perform perfusion as part of our job; instead, we must also lead efforts in transforming the way care is provided. Unfortunately, few of us have had real or tangible experience leading quality improvement projects. In the absence of this knowledge or experience, we are unable to tackle this new challenge.

As a starting point, perfusionists should become adept at understanding how to develop a concrete study question based on a clinical concern, examining the medical literature concerning the evidence base, designing a test of change, collecting and feeding data back to team members, and reporting their results. To serve as a useful guide for those wishing to embark on these studies, the reader will be introduced to a single-center quality improvement study focused on rationalizing the treatment of anemia in the setting of cardiac surgery.

Concept

As a faculty member previously at Dartmouth Medical School, I participated in a number of studies related to red blood cell (RBC) transfusions, especially as a member of the Northern New England Cardiovascular Disease Study Group (8). We noted morbidity associated with RBC transfusions with patients exposed to 1–2 units of RBCs having significantly higher odds of short- and long-term morbidity and mortality (9). At Dartmouth-Hitchcock Medical Center (DHMC), we wished to rationalize RBC transfusion practice so that RBC practices were standardized across our cardiac surgical program. To this end, we embarked on an 18-month study to reduce the variability in RBC transfusion practice at our institution (10).

Study Goal

We sought to reduce the number of perioperative transfusions associated with cardiac surgery.

Where Did We Start?

A grant proposal was funded by DHMC’s Quality Research Group Program. The project was divided into three phases: 1) documenting the status quo (understanding which patients receive blood, indications for transfusions, how decisions are made, who makes the decisions, etc.); 2) educating staff members regarding the risks and benefits of transfusions, developing new protocols to guide transfusion practice, and assessing the impact of transfusions. During this phase, team members received monthly reports reflecting transfusion practices. Data were plotted over time using process control charts; and 3) assessing whether the intervention resulted in lasting reductions in transfusion practices (that is, were early results just the “Hawthorne effect?”).

Methods

With the study’s goal and approach identified, we embarked on developing the requisite tools for each phase of the study. First, and before any data collection, we submitted an Institutional Review Board (IRB) review to govern the data collection and analysis for this quality improvement study. [Important: Make sure you start the IRB process earlier rather than later, because it may otherwise delay the initiation of the study.] We initiated this process at the same time that we submitted our intramural grant. We recognized that our study would require patient-identifying information, although it would have minimal risk to patients. [Note that IRB personnel can help you determine the appropriate type of submission for your study. Some types of studies may require less paperwork and overall review than others. It often is not as onerous as you might imagine.]

We developed a multidisciplinary team composed of a perfusionist, intensive care unit nurse, pathologist, surgeon, anesthesiologist, and quality improvement experts. Importantly, each team member contributed their expertise, experience, and context knowledge. The development of multidisciplinary teams is vitally important, especially as one seeks to strategically redesign clinical care without inadvertently disenfranchising one’s colleagues by not engaging them in the design and execution of the intervention. The team met on a routine basis to ensure that the study progressed. [Important: Make sure you develop, support, and meet with this team on a frequent basis!] We
recognized that we needed to first map the current process (Figure 1) for how transfusion decisions were made both in the operating room and in the postoperative setting. Interestingly, each team member provided a different perspective. We leveraged existing data sources to assess patient demographics, blood product delivery, and resource utilization; there was no need to duplicate existing data collection. However, we needed to develop a data form to assess the indications for each unit of transfusion, to document how decisions were made, and by whom.

Once we had IRB approval, we next piloted our data form with our staff. [Important: These tools will change in their structure and content over time.] We were particularly interested in determining some of the following:

1) feasibility of our data collection process: were the fields on our form actually available through the medical record? 2) How onerous was the data collection process? 3) Could we validate that we received all of the requisite data collection forms? Of note, the published version of our paper shows version 11.4 of our data form (Figure 2).

At the same time we were developing our form, we developed mock figures that we ultimately would share with our multidisciplinary team, including the rate of transfusions per month. We strove to embed data collection as part of the daily work activities of our clinical team, although this goal was not always possible (11).

**HOGBEN**

**PERIOPERATIVE TRANSFUSION DATA FORM**

**TYPE OF SURGERY**

Discharge Status (0=alive, 1=dead)

Priming Volume (mL)

BSA ___ (m²)

Admission to CTICU: Date (mm/dd/yyyy) ___/___/___

Time (hh) ___

Surgeon conducting index operation(\(\checkmark\)): (LD) ___ (WN) ___ (AD) ___ JS ___ Anesthesia ___ (initials)

Patient transfused intra- or postoperatively ___ (\(\checkmark\))

If yes, Surgeon making transfusion decision(\(\checkmark\)): (LD) ___ (WN) ___ (AD) ___ JS ___

Unit/location of transfusion order (OR, CTICU, ICU, Other: please specify):

**SECTION A: INDICATIONS FOR TRANFUSION. CHECK ALL THAT APPLY.**

Preoperative Prediction for Low Hct. ___ (\(\checkmark\))

Low hemoglobin ___ (gm/dl)

Low hematocrit ___ (%)

Low oxygenation state ___

Pulse oximetry ___

ABG ___

Confusion ___

Other (specify) ___

Slowly falling hematocrit with symptoms ___

Failed diuresis [Hct after diuresis ___ (%)]

Patient hemodynamically unstable ___

Incr./Excessive blood loss from chest ___

Wound/Thoracic tubes ___

Incr./Excessive blood loss from leg wound ___

Suspected blood loss into abdomen ___

Other (please specify): ___

Unknown ___

**SECTION B: IMPACT AND LOCATION OF TRANSFUSION**

Number of units of PRBCs given: ___

First Hematocrit on bypass (\(\checkmark\)):

Most recent Hct: (1) Prior to transf (\(\checkmark\)):

For blood prime-1st PRBC Hct (2) after transf (\(\checkmark\)):

For blood prime-1st Hct on CPB POD 3 Hct (%):

Cardiac Index (for blood primes and CPB transf, record pump index): Before transf: ___

After transf: ___

Unit/location of transfusion order (OR, CTICU, ICU, Other: please specify):

(Unit 1) Date (mm/dd/yyyy) ___/___/___

Time Begun Transf (hh) ___

Exp date (mm/dd/yyyy) ___/___/___

(Unit 2) Date (mm/dd/yyyy) ___/___/___

Time Begun Transf (hh) ___

Exp date (mm/dd/yyyy) ___/___/___

(Unit 3) Date (mm/dd/yyyy) ___/___/___

Time Begun Transf (hh) ___

Exp date (mm/dd/yyyy) ___/___/___

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**HOGBEN** code = first 3 letters of last name, first letter of first name and the six digit birthdate.

For example, John Smith 6/20/45 = SMJ062045

ADD ADDITIONAL DATA FORMS AS NEEDED FOR EACH UNIT TRANSFUSED. IF MULTIPLE UNITS ARE TRANSFUSED PER ORDER, (1) PLEASE ONLY INCLUDE ONE DATA FORM AND SPECIFY NUMBER OF UNITS DELIVERED, (2) PLEASE SPECIFY EXPIRATION DATE FOR EACH UNIT, AND (3) LAST HEMATOCRIT ASSOCIATED WITH THE END OF THESE MULTIPLE UNITS ORDER TRANSFUSIONS.

Please Forward Completed Data Form to William Schults (5-8388), CT Surgery

The second phase of our study was focused around developing and executing our multifaceted intervention. We started with inviting an outside speaker to present at multidisciplinary grand rounds to discuss the evidence base supporting blood transfusions. We shared medical literature with our intra- and postoperative team members. After this talk, we developed a consensus (Figure 3) among our cardiac surgical team regarding our threshold for transfusing patients during the intra- and postoperative period. This consensus was informed by our prior work and the evidence base within the medical literature, although it did not result in a formal institutional protocol. We subsequently began feeding data back to the team on a monthly basis concerning the percentage of patients who were transfused according to our consensus.

The third phase of our study was focused on documenting the effectiveness of our interventions in terms of reducing RBC transfusion practices. [Important: quality improvement studies are subject to many of the same methodological issues as more traditional approaches.] In nonrandomized trials, there is often concern that clinicians modify their behavior because they are being studied. As such, any measure of effectiveness is thereby contaminated in some regard. To address this concern, we studied the effectiveness of our intervention through our ongoing clinical registry data. During this phase, we no longer collected and shared data stemming from our data collection tool and stopped meeting as a multidisciplinary group. Instead, we relied on existing clinical registry data using the Northern New England Cardiovascular Disease Study Group forms (http://nnecdsorg/data_forms_2.htm).

**Evaluation**

Quality improvement studies are iterative in nature. By iterative, I mean that they inevitably involve conducting and evaluating the effectiveness of small tests of change. Based on data feedback coupled with generalizable and context knowledge, teams might initiate changes in care and subsequently determine whether the changes resulted in measurable improvement (Note that not all changes will result in measurable improvement.). Such studies require careful stewardship, including appropriate documentation of multidisciplinary meetings, documenting how changes in the process of clinical care affect the local care team, estimating resources necessary for supporting local practice changes, and synthesizing the findings of your tests of change and overall project learning. Such detailed information is in part what distinguishes these studies from traditional research projects.

In our own work, we found that 59% of intraoperative and 43% of postoperative transfusions were for low hematocrit, whereas 16% of postoperative transfusions were the result of failure of a patient to adequately diurese. Our efforts were associated with a significant decrease in the rate of both intra- and postoperative transfusions (Figure 4A–B) not only in Phase 2, but also Phase 3, suggesting that these results were not attributed to a Hawthorne effect. Specifically, intraoperative transfusions reduced from 33% in Phase 1 to 26% in Phase 2, and 23% in Phase 3 ($p < .001$). Postoperative transfusions reduced from 18% in Phase 1 to 12% across Phases 2 and 3 ($p < .001$).

**DISCUSSION**

The key opportunity for moving healthcare delivery science forward is to embark on conducting quality improvement studies in a standardized manner. If conducted well and reported through a peer-reviewed journal, such studies will be reproducible and offer insight into how others might
make similar changes in their own practice. Over time, our patients and wider healthcare system will benefit through concerted approaches aimed at increasing efficiency, reducing unnecessary morbidity and resource use, and improving professional satisfaction.

Perfusionists are well situated to contribute to the science underlying the reflection and redesign of clinical care. Our profession has intimate knowledge of the patient’s intraoperative care, the setting and context in which decisions are made, and insight into how these treatment decisions might be modified to improve the patient’s clinical course. Unfortunately, the science underlying how to conduct quality improvement studies is not traditionally taught within perfusion schools. The intent of this article was to provide some insight into how to conduct these studies with the intended goal to help foster the initiative, conduct, evaluation, and reporting of future quality improvement studies. A short list of references is attached as an Appendix as a guide for those wishing to pursue this field in further detail.

REFERENCES


Appendix. General information concerning quality improvement


How to Write a Quality Improvement Study

Relatively recently, Frank Davidoff and Paul Batalden developed a set of guidelines for documenting the conduct and analysis of quality improvement studies. The stated aim of this project is to “help authors write excellent, usable articles about quality improvement in healthcare so that findings may be easily discovered and widely disseminated.” These guidelines certainly promote the science underlying quality improvement and serve as a useful resource for those that wish to implement the findings from these studies into their own practice.


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