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RESEARCH

Implementation of an Enhanced Recovery After Surgery (ERAS) Clinical Pathway Using Lean Six Sigma Principles: A Framework for Ongoing Quality Improvement

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ABSTRACT:
Enhanced Recovery after Surgery (ERAS) clinical pathways are quality improvement initiatives that employ evidence-based recommendations to standardize perioperative care and improve patient outcomes. ERAS clinical pathways have been shown to decrease hospital length of stay in a variety of surgical patient populations including major abdominal surgery.

ERAS clinical pathways encompass multiple patient care areas and multiple disciplines, which can make design and implementation challenging. Lean Six Sigma (LSS) methodology provides a framework for design and implementation of quality improvement processes such as ERAS clinical pathways. LSS principles focus on patient-centered, multidisciplinary approaches to improve patient care. Additionally, LSS principles emphasize continuous quality improvement and sustainability. LSS was therefore the vehicle for successful design and implementation of an ERAS clinical pathway for pancreatic surgery at our institution.

KEY WORDS: Quality Improvement, Quality Culture, Anaesthesia, Surgery, Hospital Care, Cancer, Care Pathways/Disease Management, Teamwork.

INTRODUCTION

Enhanced Recovery After Surgery (ERAS) clinical pathways for perioperative quality improvement have been shown to reduce hospital length of stay(1-5) and decrease hospital expenses(4, 6). ERAS clinical pathways are complex, as they cross multiple disciplines and span multiple patient care areas. Successful implementation involves creation of a multidisciplinary team of physicians and nurses, ongoing assessment and improvement of the perioperative process, and creation of sustainable measures to ensure long-lasting results(7).

Given the complexities of implementing a large perioperative quality improvement pathway such as ERAS, our team chose to employ the Lean Six Sigma (LSS) method. The LSS method provided a framework for success, as it included a multidisciplinary team approach to implementation and processes to ensure continuous improvement and sustainability.

Lean Six Sigma Principles: Background and Introduction to Core Concepts

Lean Six Sigma was originally a business philosophy for quality improvement that focused on eliminating waste (or non-value added activities) while maximizing value from the customer's perspective. Automobile companies, namely the Ford Motor Company and Toyota Production System, were two of the first organizations to adopt lean principles to eliminate wasteful steps and improve production efficiency.

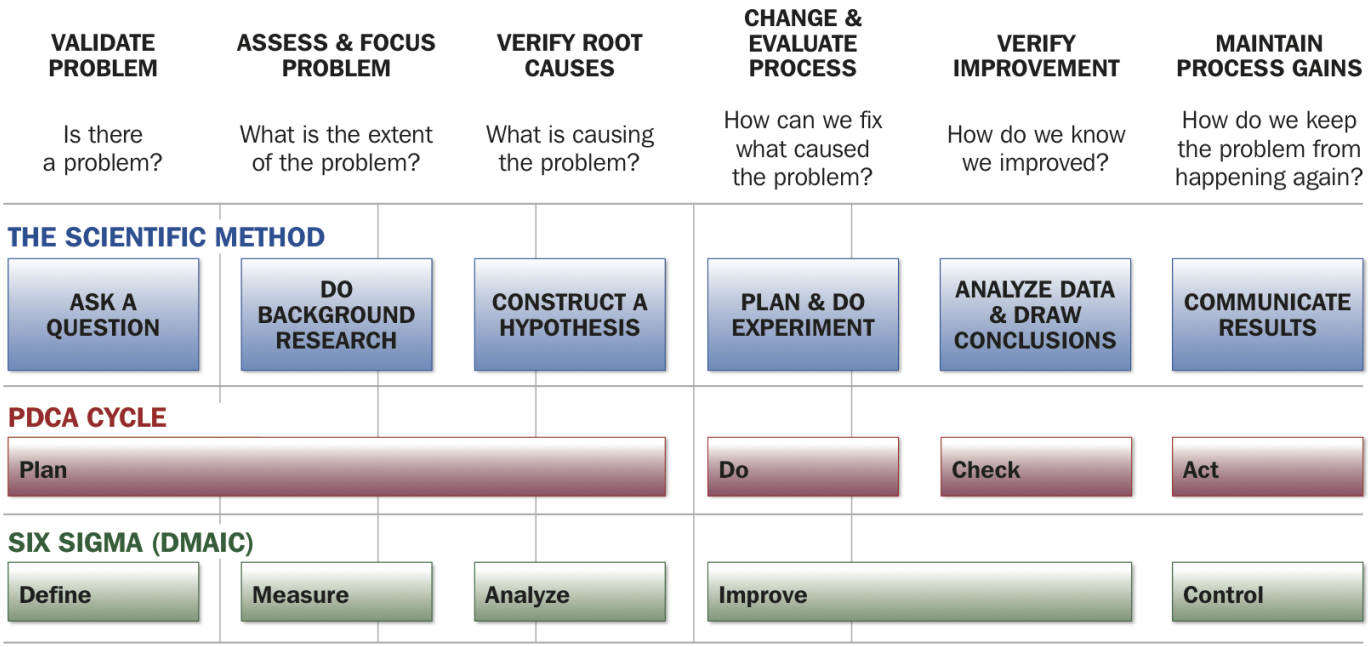
Many other organizations have followed suit, including hospital systems. Application of lean philosophy and principles in health care aims to improve the quality of care for the patient by 4 eliminating waste. Members of the healthcare team work together to develop quality improvement measures to make their daily work easier by eliminating waste and inefficiencies, and the patient becomes the beneficiary. (8)

Two oPage | 18f the pioneers in applying lean principles to the healthcare industry are Virginia Mason Medical Center in Seattle, Washington and ThedaCare Appleton Medical Center in Appleton, Wisconsin. Both of these healthcare organizations began their "lean transformations" in the early 2000's and have ultimately become examples of how to transform

the culture of a large healthcare organization.(9, 10) For example, ThedaCare identified cardiac surgical care as an area for significant quality improvement. Over a period from 2002 through 2009 and after several lean-structured quality improvement projects in the Department of Cardiovascular Surgery, the mortality rate for coronary bypass surgery was reduced from 4% (12 deaths per year) to less than 1%. Simultaneously, the hospital costs for coronary artery bypass surgery declined by 22% and the average length of hospital stay decreased from 6.3 days to 4.9 days. Since introduction of lean principles throughout their healthcare system, ThedaCare has saved more than 27 million dollars.(9)

The lean frameworks or processes for quality improvement are rooted in the scientific method, a process familiar to most clinicians (Figure 1).

Figure 1: Lean Six Sigma Processes for Quality Improvement:



One such lean framework for quality improvement is called a "DMAIC", or "Define, Measure, Analyze, Improve, and Control" improvement cycle. First, a key problem is identified, including identification of confounding issues. Next, baseline data is obtained by measuring the current
5 state or impact of problem. After obtaining baseline data, a detailed analysis of the data is performed to identify root causes of the problem. When the root causes are identified, processes are put into place to address and eliminate the each particular problem. Lastly, the newly defined processes must be continually monitored with ongoing data analysis to ensure sustainability.

In addition to a framework for quality improvement, lean also provides a set of team building tools that help members of an organization eliminate roadblocks and inter-department "silos". The individual "silos" of practice for nurses and physicians across multiple disciplines and patient care areas are broken down in an effort to combine the expertise of these clinicians. The collaboration of a multidisciplinary team is a powerful tool for quality improvement. Lean principles include a focus on communication, transparency of the process, and ongoing feedback and analysis. This serves to keep all "stakeholders" or team members (e.g., nurses, physicians, hospital leadership) actively involved in the quality improvement process.

Define, Measure, Analyze, Improve, and Control (DMAIC):The LSS tool for design and implementation of an ERAS clinical pathway

The problem that was defined at our institution was wide variability in the preoperative, intraoperative, and postoperative management of patients having major pancreatic surgery, specifically distal pancreatectomy and pancreaticoduodenectomy (Whipple) procedures. We sought to implement an Enhanced Recovery After Surgery (ERAS) pathway to decrease this variability and ultimately improve patient outcomes. Published literature supporting

ERAS pathways for pancreatic surgery has shown to decrease length of hospital stay and improve patient outcomes(2, 11, 12)

During the design and implementation phases of the ERAS pathway, we employed the LSS tool "DMAIC" to guide our process (figure 2) (13). After defining the problem (variability in perioperative care) in pancreatic surgical patients, we measured the variability by conducting a thorough historical review of the perioperative medical records from this patient population. From our analysis, we found that there existed a wide variability in hospital length of stay, rate of ICU admissions, intraoperative fluid administration, and postoperative pain scores. We therefore felt confident our pancreatic surgical patient population would greatly benefit from an ERAS clinical pathway. An ERAS pathway for pancreatic surgery at our institution would serve to standardize clinical practice and reduce this variability. As we will describe in the next section, control was achieved and maintained as a result of the sustainability efforts that were put in place from the outset of our ERAS pathway implementation.

Figure2:"Define,Measure,Analyze, Improve, Control" (DMAIC) for Design and Implementation of an ERAS Clinical Pathway for Pancreatic Surgery at our Institution:

Define	The defined problem was wide variability in length of stay for pancreatic surgical patients.
Measure	The mean length of stay for patients undergoing distal pancreatectomy was 9.1 days (Standard deviation 4.41 days) and the mean length of stay for patients undergoing pancreaticoduodenectomy (Whipple procedure) was 11 days (Standard deviation 4.78 days).
Analyze	The entire perioperative process for was evaluated for standardized work flow and clinical practice. There was lack of standardization in the preoperative, intraoperative, and postoperative management of patients undergoing pancreatic surgery.
Improve	The ERAS pathway for pancreatic surgical patients was implemented. Plan-Do-Check-Act (PDCA) cycles were performed to confirm sustainability of the process.
Control	Continue to work with the stakeholders across the perioperative experience to ensure pathway compliance and sustainability.

The Implementation Process: Collaboration and Education

Since ERAS pathways encompass the entirety of the perioperative patient experience,the implementation process can be complex as the team composition extends well beyond the operating room (e.g. clinics, PACU, nursing units) (Figure 3). We recognized the importance of establishing working relationships between the surgical and preoperative anesthesia clinics, operating room, recovery room, and nursing units. As a result, a research coordinator was hired to bridge these gaps and eliminate the practice silos surrounding the care of patients in the ERAS pathway. This person served as the day-to-day contact person for care providers to consult when issues arose or variance from the pathway was encountered.

Team education and timely communication repeatedly surfaced as vital issues throughout the implementation process. The core members of the ERAS team (surgeon, anesthesiologists, research coordinator, hospital leadership) all participated in LSS team building and training at our institution through the Department of Operational Efficiency. ERAS leaders or "champions" were identified at each level of the project: surgical clinic, preoperative anesthesia clinic, preoperative

holding area, intraoperative area, PACU, and nursing floor. These champions served as liaisons for communicating important updates to the core team members, as well as education of the staff and patients in these areas.

Patient education was also a key part of the implementation process. Written patient educational material on components the ERAS clinical pathway was created. This educational material included instructions on when to consume a carbohydrate drink on the day of surgery, explanation of the role of thoracic epidural analgesia in the perioperative period, and a description of the patient's active role in recovery (early ambulation).

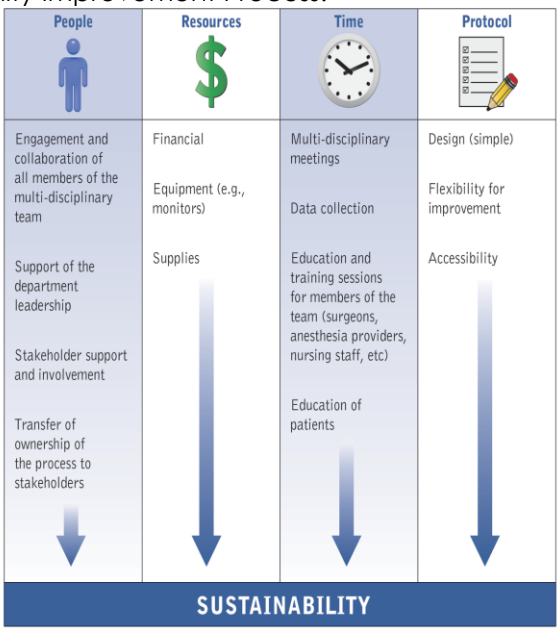
Opposition from some care providers (e.g. experienced anesthesiologists and nurses) to changing clinical practice was identified as a key potential barrier to implementation of our ERAS protocol(14). We therefore chose to identify a core group of intraoperative anesthesia providers (anesthesiologists, CRNAs, and residents) for the implementation process, who were thoroughly educated on aspects of ERAS intraoperative management including goal-directed fluid therapy, thoracic epidural analgesia management, and ventilator management. This core group of anesthesia team members served as intraoperative "champions" after the implementation process to teach other anesthesia care providers about the ERAS clinical pathway.

Figure 3: Multidisciplinary Components of the ERAS Clinical Pathway:

Sustainability: Ensuring Long Term Compliance and Continuous Improvemen

Sustainability is described as the "continuation of the programs and practices that were implemented within organizations, systems, or communities after initial implementation efforts or funding ended".(15) As simple as that may seem on the surface, sustainability is influenced by a wide variety of factors that contribute to a project's ability to continue successfully past the initial implementation phase (Figure 4). Such factors include an institution's "culture", endorsement of departmental leadership, funding sources,equipment and resources, stakeholder support and involvement, training and education of the effect staff, collaboration and partnership,and continuous evaluation.(15) These factors are quite broad and dynamic,which can make planning for a sustainable project a significant challenge. Failure to recognize the crucial importance of sustainability during the design phase of a quality improvement project, such as ERAS pathways, could explain why initially successful quality improvement projects at many institutions fail within a year of implementation. Hence, our ERAS quality improvement pathway was developed with a focus on sustainability from the outset.

Figure 4: Factors that Influence Sustainability of a Quality Improvement Process:

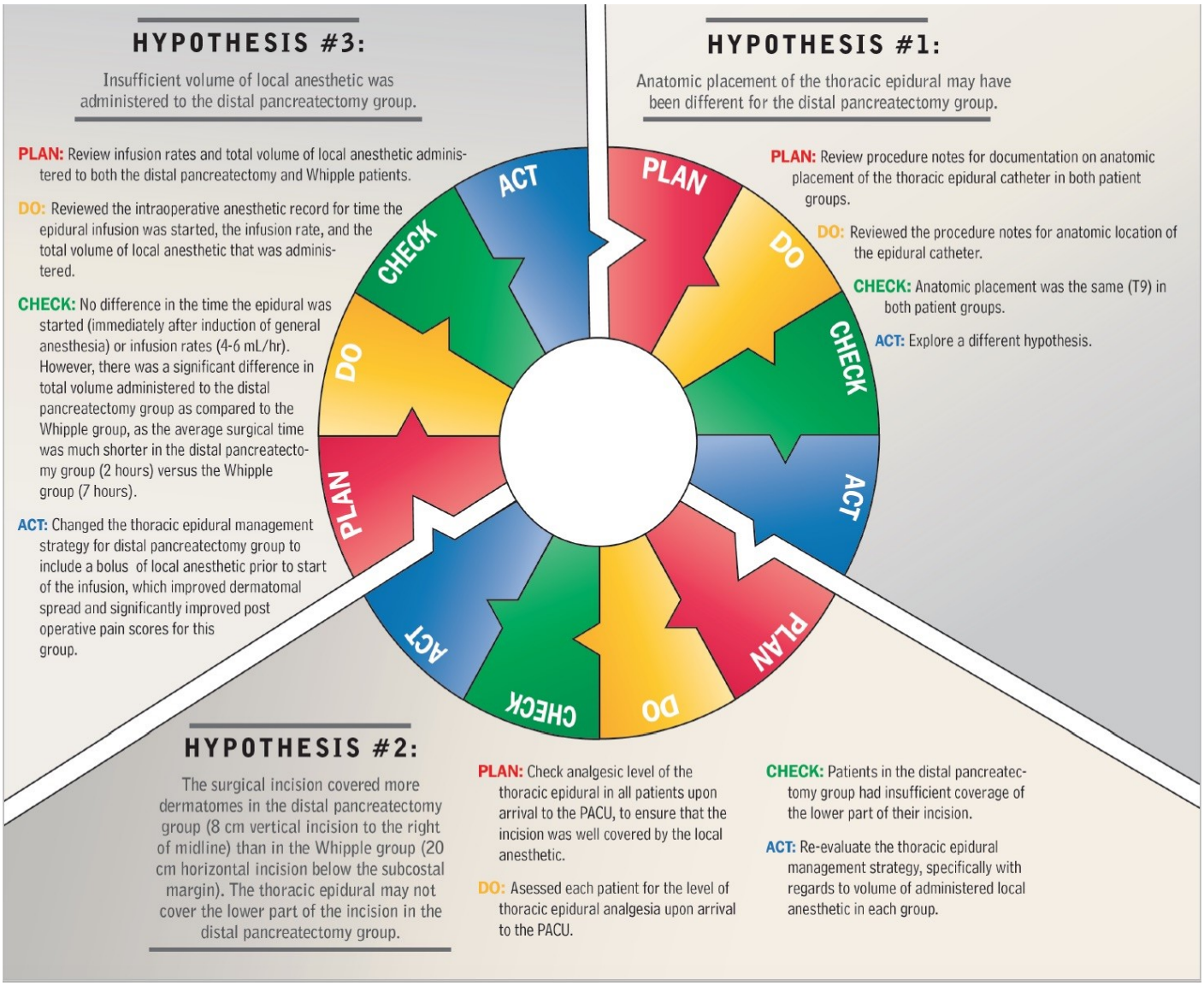


The first sustainable measure employed by our program was the formation of multidisciplinary collaborative relationships with a surgeon committed to continuous quality improvement, a core group of anesthesiologists and nurse anesthetists, nursing administrative leaders from the preoperative, intraoperative and postoperative patient care areas, and with the operating room staff dedicated to surgical oncology patients. These multidisciplinary collaborative relationships are possibly the most valuable resource in the creation, implementation, and sustainability of an

ERAS pathway. The relationships promote and sustain organizational culture change through 9 "unity of purpose", which is one of the key principles for any lean six sigma project.(9) Although there are many people in several different departments on the ERAS team, we created a cohesive unit by using a variety of methods such as quarterly face-to-face meetings across nursing units to solicit feedback, monthly email newsletters to communicate pathway success and alteration, and daily appreciation to all of the members for their continued contributions.

The second sustainable measure that was implemented during inception of our ERAS pathway was the creative use of resources and equipment already available at our institution for intraoperative goal directed fluid therapy. Many previously published ERAS protocols employed a variety of expensive and technically challenging monitoring devices for intraoperative goal directed fluid therapy.(1) However, there is no absolute consensus on which monitoring device (e.g. esophageal doppler, non-invasive cardiac output monitor) or which hemodynamic variable (e.g. stroke volume variability, pulse pressure variability) leads to the best patient outcomes.(16-19) Given our limited financial resources and lack of hard evidence to support purchase of an expensive monitoring device, we developed our intraoperative goal directed fluid therapy protocol using pulse pressure variation (PPV) monitoring, which (i) already existed in our current hospital-wide monitoring systems and (ii) was very familiar to most of our clinicians.

Figure 5: "Plan-Do-Check-Act" (PDCA) Cycle for Ongoing Improvement: An Approach to Addressing Increased Postoperative Pain Scores in the ERAS Clinical Pathway:



The third sustainable measure put into place was the effort to provide accessibility of the pathway documents and related pathway information. The ERAS clinical pathway was made
easily accessible through both electronic resources (e.g., published on a secure internal department website) and hard copy resource (e.g., laminated copy placed in the drawer of the 10anesthesia machine). A second example was the use of the electronic medical record for rapid access of patient information related to the ERAS clinical pathway.An ERAS preoperative template was created to auto-populate important information from the preoperative evaluation (e.g. baseline blood pressure measurements, ideal body weight) and the intraoperative management goals (eg. blood pressure parameters).

After the design and the initial rollout of the entire ERAS pathway, our team evaluated each individual component of the project for its ability to provide ongoing quality improvement. We employed the LSS method of "Plan-Do-Check-Act", or PDCA, to assess all of the components.(20) The "Plan-Do-Check-Act" method is a series of "experiments" used to confirm or reject a hypothesis within a particular quality improvement project. As an example, we found that patients in the ERAS pathway who had a distal pancreatectomy experienced higher PACU pain scores than ERAS pathway patients who had a Whipple procedure. Initially, both groups of patients had the same intraoperative thoracic epidural management strategy. Figure 5 shows how we employed the PDCA method to evaluate and correct this discrepancy in pain scores.

CONCLUSION

When applied to perioperative quality improvement initiatives such as ERAS, Lean Six Sigma principles provide a framework for ongoing quality improvement. We have used these principles to design and implement a highly successful and sustainable ERAS quality improvement pathway for major pancreatic surgery. Our ERAS quality improvement project has now become the model for multi-disciplinary quality improvement at our institution for perioperative patient care. Lean Six Sigma is a vehicle for anesthesiologists to create cultural change within their institution and become leaders perioperative care.

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