

March 2020

Barriers and Facilitators Influencing Compliance with Enhanced Recovery After Surgery Protocol: A Qualitative Study

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BARRIERS AND FACILITATORS INFLUENCING COMPLIANCE WITH ENHANCED RECOVERY AFTER SURGERY PROTOCOL: A QUALITATIVE STUDY

A Thesis

Submitted to the Graduate Faculty of the
Louisiana State University and
Agricultural and Mechanical College
in partial fulfillment of the
requirements for the degree of
Master of Science

in

The Department of Mechanical and Industrial Engineering

by

Paige Marie Boudreaux
B.S., Louisiana Tech University, 2017
May 2020

Acknowledgements

I would like to thank my major professor Dr. Craig Harvey for the opportunity to study and learn at this university and his continued assistance with this research. I would also like to thank Dr. Tonya Jagneaux for participating on my committee and providing the opportunity for me to better understand the innerworkings of healthcare. In addition, I would like to thank Dr Isabelina Nahmens for continued support and guidance throughout this research. I also want to express my appreciation for all of the staff at Our Lady of the Lake who have cooperated with this study and welcomed me into their organization.

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Abstract

Standardization in many industries has proven to lead to improved productivity and efficiency, however, standard practice in healthcare has proven difficult due to patient and physician variation. Evidence-based practices provide an opportunity to create more standardization. Enhanced Recovery After Surgery (ERAS) programs are attempting to standardize the surgical pathways of patients by implementing standard evidence-based steps, beginning in the surgeons office and continuing through a patients discharge (Ljungqvist, Scott, & Fearon, 2017). Implementing ERAS to standardize the surgical care of patients has shown to improve patient outcomes, reduce length of stay and reduce readmissions, however, there is a lack of studies detailing the implementation process to be successful.

A literature review by Stone et al. (2018) found only 53 papers on ERAS that discussed implementation. The review organized barriers and facilitators using the Consolidated Framework for Implementation Research (CFIR). The CFIR is a framework organized with five domains and constructs within each domain that could affect implementation (Damschroder et al., 2009). The purpose of this research is to detail implementation and identify barriers and facilitators that impact compliance with an ERAS protocol for colorectal surgery.

This research begins by detailing seven steps taken prior to implementing ERAS. Compliance with 19 of the ERAS components will be tracked to measure improvements over the implementation timeline. The first objective is to measure if compliance with the process measures increased from the pre-implementation to post-implementation. The second objective is to measure if implementation leads to a decrease in length of stay. The third objective is to identify barriers and facilitators with implementation by conducting semi structured focus groups with nursing, surgeons, anesthesia and leadership. The outcome of these findings will be an implementation framework.

The results of this study showed a significant increase in compliance with 10 of the process measures as well as a significant decrease in length of stay, as measured by a t-test. The semi-structured focus groups analyzed by the CFIR indicated that inner setting and implementation plan were the most discussed. Key facilitators to implementation were gaining leadership support and engagement, establishing a multidisciplinary team that meets regularly, and showing process measure and outcome data as feedback. These items are essential to implementation of an ERAS protocol.

1. Introduction

1.1. Motivation and Significance

Standard practice in many industries, such as manufacturing, has proven to be extremely effective in productivity, quality and efficiency of work, however, standardizing medical practices can be difficult. There has been a major push in the medical field to move towards evidence-based practice which requires a shift in current practices. Varkey and Antonio (2010) defined change management as a strategic intervention aimed at effectively transitioning a business process from current state to a desired future state. Technological and medical advancements as well as political, financial and social transformations are all influences on the rapid change in healthcare. Healthcare has difficulties in the change management process of transferring clinical evidence into practice. Balas and Boren (2000) found that it takes an average of 17 years for the dissemination of evidence into practice.

In relation to surgery, a major development of standardized evidence-based practice is implementing an Enhanced Recovery After Surgery (ERAS) program. This program focuses on all elements of the perioperative pathway, beginning with the surgeons office, day of surgery preoperative, through intra-operative and post-operative components (Ljungqvist, Scott, & Fearon, 2017). The goal is to utilize a multidisciplinary team of surgeons, anesthesiologist, nurses and hospital leadership members to create a standard pathway (e.g., procedural interventions) based on evidence. Later in the study, these components will be more defined. Previous literature dives into the benefits of implementing these ERAS protocols, such as improved patient outcomes and cost-effectiveness, but there is a need for more studies on the implementation process (Stone et al., 2018). The review found 536 articles that described evidence-based pathways (EBP), of these only 53 addressed implementation with original, empirical evidence. Many decisions in healthcare processes are based on physician preferences and it is very difficult to track whether a standard protocol is being followed. The change management culture of healthcare can make implementing a program like ERAS very difficult, therefore, there is a need to study the many barriers and facilitators that are encountered when implementing standard surgical practices such as ERAS.

2. Literature Review

2.1. Enhanced Recovery After Surgery

2.1.1. Definition and Significance

The Enhanced Recovery After Surgery (ERAS) protocol has been developed and implemented over many years. A group of academic surgeons in Europe began the original development of ERAS in 2001 by building upon studies of fast-track surgery (Ljungqvist et al., 2017). The term “fast-track” surgery dates back to a study by Engelman et al. (1994) where a protocol involving 8 elements for coronary bypass patients reduced length of stay from 8.3 to 6.8 days. Following the first “fast-track” study, other reports utilized a multimodal approach and also found a shortened length of stay (Bardram, Funch-Jensen, Jensen, Crawford, & Kehlet, 1995; Engelman et al., 1994). Studies began to focus on subsets of outcomes, such as pain management, mobility improvement, and improved metabolic preparation.

The initial European ERAS group meeting in 2001 sought to develop a multimodal protocol that would optimize the perioperative care pathway based on published evidence (Fearon et al., 2005). The result of this meeting was 17 components beginning in the preoperative phase through discharge. Over the years, ERAS has developed into 24 core elements that have supporting evidence. Figure 1 is a flow chart developed by Ljungqvist et al. (2017) that identifies the elements in each time period and the responsible profession or discipline for each element. This ERAS process can also be referred to as an Early Recovery Pathway (ERP) (Stone et al., 2018). The Improving Surgical Care and Recovery (ISCR) program initiated by the Agency for Healthcare Research and Quality (AHRQ) ultimately involves implementing an ERAS or ERP pathway ("AHRQ Safety Program for Improving Surgical Care and Recovery ", 2017).

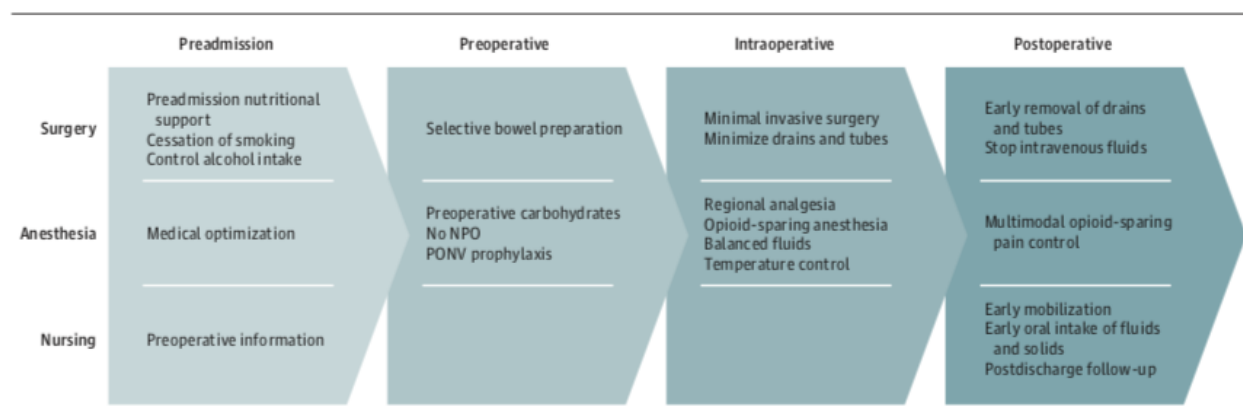


Figure 1. Enhanced Recovery After Surgery Flowchart by (Ljungqvist et al., 2017) (No NPO refers to fasting guidelines of intake of *clear* fluids and carbohydrate drinks up until 2 hours before surgery. PONV refers to postoperative nausea and vomiting)

Enhanced Recovery After Surgery protocol, also called “fast track surgery,” involves all phases of care beginning with optimally preparing patients preoperatively, reducing stress responses

typically associated with surgery perioperatively, and advancing postoperative recovery for faster return to normal activity (Rogers et al., 2018). The first published literature on ERAS guidelines was for colonic resections (Fearon et al., 2005), however, the literature continues to develop evidence based guidelines for more surgical disciplines (Ljungqvist et al., 2017).

Enhanced recovery after surgery (ERAS) pathways have become widely promoted primarily for its proven outcomes, and also because ERAS provides an innovative, standardized implementation to evidence-based care (Ban, Gibbons, Ko, & Wick, 2017). The benefits of an ERAS protocol are shown through improved patient outcomes such as reduction in length of stay and complications. Technical evidence reviews were performed on surgical and anesthesia components that are included in pathways provided by AHRQ during the ISCR program (Ban et al., 2017; Ban et al., 2018). The findings from those reviews are summarized in Table 1 by expected outcomes. The direct relationship between the ERAS elements and improved patient outcomes presents a need for adherence with all the components.

Table 1. Outcomes Related to ERAS Interventions

Outcome	Associated ERAS Elements	Phase of Care
Reduction in surgical site infections (SSIs)	Bowel Preparation (PO antibiotic and mechanical bowel prep)	Immediate preoperative
	Preoperative at-home bathing	Immediate preoperative
	Skin Preparation	Intraoperative
	Antibiotic prophylaxis	Intraoperative
	Normothermia	Intraoperative
	Glucose management	Postoperative
Reduction in length of stay (LOS)	Patient education	Preoperative
	Carbohydrate loading	Immediate preoperative
	Mu Opioid Antagonists	Immediate preoperative
	Laparoscopic surgical technique	Intraoperative
	Fluids/goal-directed fluid therapy	Intraoperative
	Early mobilization	Postoperative
	Early alimentation (diet)	Postoperative
	Early IV fluid discontinuation	Postoperative
Faster Return of bowel function	Carbohydrate loading	Immediate preoperative
	Mu Opioid antagonists	Immediate Preoperative
	Laparoscopic surgical technique	Intraoperative
	Early mobilization	Postoperative
Reduction in pain, opioid use and postoperative nausea and vomiting (PONV)	Multimodal pre-anesthesia medication	Immediate preoperative
	Standard intraoperative anesthesia pathway	Intraoperative
	Standard postoperative multimodal analgesic regimen	Postoperative
Venous Thromboembolism (VTE)	Preoperative VTE prophylaxis	Preoperative
	Postoperative VTE prophylaxis	Postoperative

The combination of all the elements into a multimodal bundle can ultimately lead to better results as evidenced by studies by Li, Jin, Min, Liu, and Liu (2017). Li et al. (2017) found

reductions in surgical site infections (SSIs) as compliance increased. Surgical site infection rate was 24.2% when compliance was less than 60% and reduced to 6.9% when compliance was greater than 80%. They also found a reduction in pulmonary infections, from 18.2% at less than 60% compliance and 6.9% with greater than 80% compliance. Length of hospital stay reduced from 12.5 days when there was less than 60% compliance to 8 when compliance was greater than 80% (Li et al., 2017). It has been difficult to link compliance with ERAS protocol to a reduction in readmissions (Li et al., 2017; Zhaohua, Kun, Haijiang, Xinzhong, & Jianxing, 2017). However, a study by (Gramlich et al., 2017) found a 7.9% reduction in readmissions. Ultimately, increasing compliance with all components has been found to eventually lead to improved patient outcomes.

2.1.2. Compliance

Compliance is defined as "the action or fact of complying with a wish or command" (Cochran, 2011). Compliance can be defined in various ways depending on the treatment component that is being analyzed. Many articles analyze compliance with ERAS components, but do not define what compliance means. A review by Ahmed, Khan, Lim, Chandrasekaran, and MacFie (2012) assessed 188 studies to find relevant information regarding compliance to ERAS protocols in routine practice of colorectal surgeries. Only 11 studies were found to meet their research criteria. Studying compliance to the ERAS components is an essential part of implementation to identify where there are gaps in the ERAS protocol and define which steps require further implementation efforts.

Compliance parameters can be analyzed in two ways: the percentage of elements performed per patient, and compliance broken down by element over time (Pędziwiatr et al., 2015). Studying elements over time can be done by breaking down the percentage of treated patients that received the ERAS component (Nygren et al., 2005). Following this method, a study by Didier Roulin et al. (2017) calculated compliance with each element by dividing the number of compliant patients by total number of patients for each ERAS component. Tracking compliance with many treatment components is done solely with a yes/no answer (Pędziwiatr et al., 2015).

Compliance with the protocol per patient can be calculated as the number of successfully applied elements divided by the total number of elements (Didier Roulin et al., 2017). Compliance may not reach 100% due to the nature of the patient and necessity to occasionally waiver from the strict protocol (Pędziwiatr et al., 2015). Although ERAS pathways aim for standardization, there is still room for physician discretion to deviate from the protocol to meet patients' needs, however, rational should be documented.

Studying compliance with each element is required to define elements that are leading to improved patient outcomes. A review by Day et al. (2015) found that few studies reported the compliance and failure rates for individual components. Even if studies report compliance with individual elements, comparison with other studies can be difficult due to the variation in the number of elements involved. Comparison of compliance between studies could be done by the

phase of care, for example, results are similar in showing lower compliance with post-operative phase (Didier Roulin et al., 2017).

Compliance barriers can be predicted during staff education as staff discusses concern for these new elements of care. During education on a specialty nursing unit, nurses expressed the most difficult elements would be early mobility, early drain removal and utilizing nonopioid medication to manage pain (Tezber et al., 2018). Reinforcing the elements with proof of improved outcomes can help staff to feel more confident with the nontraditional elements of care. Logistically challenging elements, such as distribution of nutritional drinks, was overcome by incorporating the distribution of the drinks into a routine process (Georgia et al., 2017). Lack of a routine process for this element could lead to other aspects of patient care taking priority.

The literature review by Ahmed et al. (2012) found trends of high compliance with the use of epidural analgesia, early diet and mobilization, avoidance of mechanical prep and nasogastric tubes. They found that most studies reported lower compliance during the postoperative phase of care, which could be contributed to the multidisciplinary alignment that must occur for successful implementation. This is supported in a later study by Didier Roulin et al. (2017) who found 63% compliance in post-operative measures, compared to 96% and 82% in preoperative and intraoperative measures respectively. Li et al. (2017) identified the items with lowest compliance were carbohydrate drinks, anesthesia protocols, perioperative fluid management, multimodal analgesic approaches, early oral intake, early mobilization, early removal of drainage tubes, and early removal of urinary catheter. Clinicians are less likely to comply with these practices that do not follow traditional surgical care, and patients may be resistant as well.

Nurses expressed concern that patient preferences may lead to low compliance if the patient does not accept the ERAS protocols (Pearsall et al., 2015). Didier Roulin et al. (2017) proved this barrier by finding nurses and patients to be mostly responsible for low compliance with early mobility. A contributing factor could be patient attitudes and resistance to mobilizing out of fear of injury or pain because traditionally patients are kept on bedrest. Patient characteristics can be a predictor of noncompliance. Male gender, age over 75 years and American Society of Anesthesiologists (ASA) score of 3 / 4 were found as independent predictors of noncompliance with post-operative elements (Feroci et al., 2013).

Deviation from the ERAS protocol, which results in noncompliance, can be due to a variety of reasons. Analyzing compliance further can be done by drilling into who is responsible for the decision to deviate from the protocol and whether the decision was medically justified (Didier Roulin et al., 2017). A study found that surgeons and anesthesiologist were mostly responsible for the decision and 78% of the cases had medical justification for deviation (Didier Roulin et al., 2017). Even though the ERAS protocol is a bundle of elements that prove to be beneficial in outcomes, flexibility should remain to adapt to patients' needs.

The phase of implementation also influences compliance. More analyses on compliance with each variable during the beginning stages of implementation will allow new adopters of ERAS to

understand which variables typically have implementation difficulties. Tracking compliance over the course of implementation provides a means to measure sustainability. Implementation of an ERAS protocol should be gradual and one study found that high compliance requires a minimum of 30 patients and 6 month time period (Pędziwiatr et al., 2015). A study by Gillissen et al. (2015) compared compliance during implementation and post implementation. Post-implementation showed a large drop in compliance with the post-operative elements. Similar to other studies, implementation of post-operative elements were found to be most difficult to adhere to, which could contribute to the lack of sustainability (Ahmed et al., 2012; Gillissen et al., 2015; Didier Roulin et al., 2017). Adherence difficulties could be due to the nature of these elements requiring involvement of multiple professionals and various factors such as patient characteristics, physicians, nurses and therapists (Gillissen et al., 2015).

2.1.3. Implementation Barriers and Facilitators

A systematic literature review utilized The Consolidated Framework for Implementation Research (CFIR) framework to classify major facilitators and barriers to implementation of enhanced recovery pathways (ERP) (Stone et al., 2018). For the purpose of the review, enhanced recovery pathway was defined as a bundle of multiple peri-operative interventions involving a multidisciplinary team, labeled differently than traditional care and had a formal way of measuring outcomes. Implementing ERAS requires the development of an enhanced recovery pathway; therefore, the identified barriers and facilitators are also referring to ERAS. If the definition was met, the article must specifically address ERP implementation barriers and facilitators. The initial search returned 536 articles that described an ERP, but only 53 included barriers and facilitators of implementation (Stone et al., 2018). This is an identified gap in the literature.

The Consolidated Framework for Implementation Research introduces 5 major domains: (1) intervention characteristics, (2) inner setting, (3) outer setting (factors outside of the

institution, (4) characteristics of the individuals involved in the implementation process and/or who use the intervention, and (5) process of implementation (Damschroder et al., 2009).

Figure 2 shows the domains and their individual constructs (Stone et al., 2018). Facilitators and barriers that were found in the literature were grouped into these domains and their corresponding constructs.

Table 2 shows summaries of the main conclusions for barriers and facilitators within each construct.

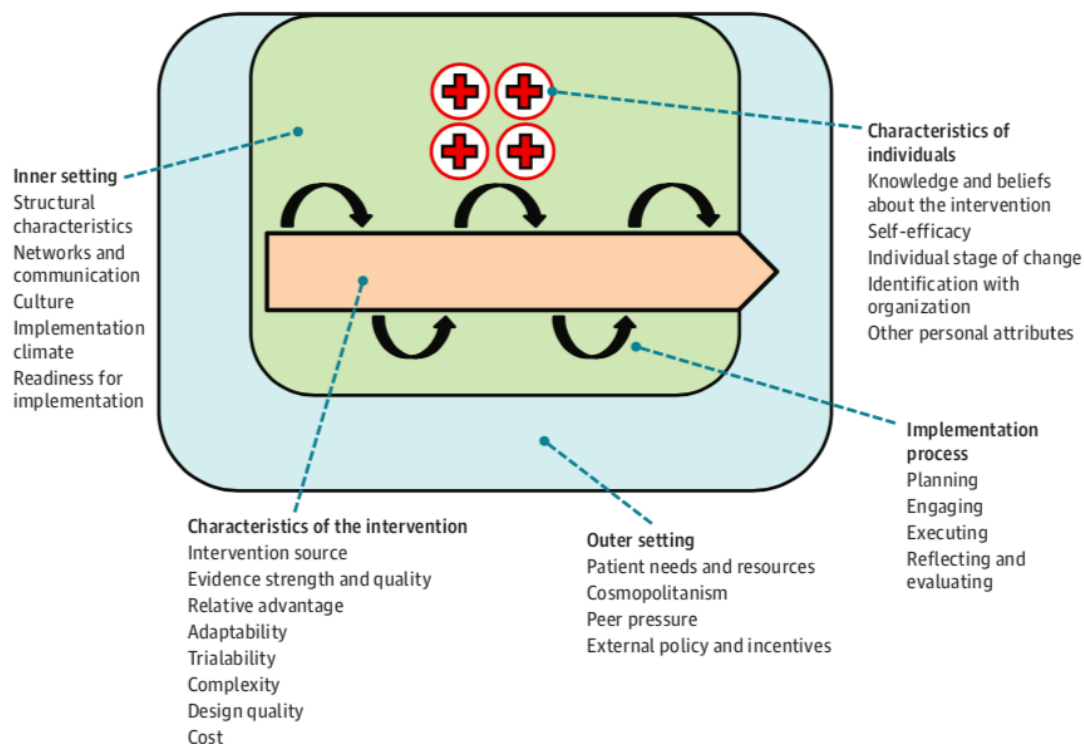


Figure 2. Schematic Diagram of Consolidated Framework for Implementation Research (Stone et al., 2018)

Table 2. Summary of Barriers and Facilitators using CFIR (Stone et al., 2018)

CFIR Domain	Facilitators of implementation	Barriers to implementation
Intervention Characteristics		
Adaptability	Flexibility during guideline development to adapt the ERP to local practice	Absence of clear guidance on when to deviate from the ERP in practice
Trialability	The “early wins” of successful pilot projects in catalyzing momentum for wider implementation	

(table cont’d)

CFIR Domain	Facilitators of implementation	Barriers to implementation
Complexity		Poor adherence to postoperative ERP elements
		Poor adherence to ERP elements perceived as disruptive to standard surgical practice
Design quality and packaging		Lack of proper messaging to staff about why it is important to implement an ERP
Inner Setting		
Networks and communication	Effective communication and collaboration among caregivers throughout the pathway	Poor communication, particularly across disciplines
	Creating a community of practice among surgery, anesthesia and nursing supporters	
	Modeling positive behaviors by senior medical staff	
Culture		Failure to create a fast-track culture
Tension for change	Frontline clinicians identified problems underscoring the need for ERP implementation	
Compatibility	Alignment between ERP principles and a departments existing quality improvement structure	Clinician resistance to significant practice changes, particularly those perceived to be potentially harmful to patients
Leadership engagement	Strong leadership support, particularly in terms of anesthesiology leadership	Lack of division head support
Available resources	Resources for structural changes	Time and personnel restrictions
	Work schedules that allowed a limited team of surgeons, anesthesiologists, and nurses to consistently staff ERP cases	Lack of protected time for supporters
		Limited hospital resources
Access to information and knowledge	Educational materials that were readily accessible to staff	Challenges with integrating the ERP into the electronic medical record system
Outer Setting		
Patient needs and resources		Patient factors (ex complex comorbidities) and expectations (ex preconceived ideas about the hospital experience)
		Lack of specialized care in rural communities to which patients were being discharged
Cosmopolitanism	Opportunities to network and share best practices across hospitals involved in multisite implementation efforts	

(table cont'd)

CFIR Domain	Facilitators of implementation	Barriers to implementation
Characteristics of Individuals		
Knowledge and beliefs about the intervention		Clinicians resistance to any change
		Clinicians negative views about ERPS that were perceived to be held by senior medical professionals in particular
		Surgeons' perceptions of a lack of support from other disciplines
Self-efficacy		Lack of self-efficacy to follow the ERP in times of uncertainty, felt most acutely by nurses and junior residents
Implementation Process		
Planning	Involving a multidisciplinary team in guideline development	
	Soliciting and incorporating feedback from staff during multiple stages of the design process	
Engaging	Leveraging supporters to raise awareness, deliver updates, and conduct face-to-face meetings to actively engage staff	Failing to appropriately engage and support supporters (ex. Assigning the supporter role vs asking; failing to provide protected time)
	Securing allocated funding for a full—time ERP coordinator	
	Engaging patients through preoperative and postoperative education	
Executing	Using formal quality improvement frameworks to guide implementation efforts	Difficulty in scaling ERPs from pilot programs to full-scale clinical operations
	Creating a timeline with specific and accountable actions	Fast pace of implementation process
	Changing the visibility of the ERP program from high to low visibility over time to promote normalization	Lack of consistency in staffing (particularly from anesthesia)
Reflecting and evaluating	Capability to provide up-to-date data about ERP outcomes	
	Data sharing across hospitals involved in multisite implementation efforts	
	Ongoing audit and feedback	

The inner setting and implementation process identified the most facilitators. The inner setting refers to structural and cultural characteristics, implementation readiness, and networks and communications of the organization (Damschroder et al., 2009). Stone et al. (2018) found multiple studies that stressed the importance of team communication between project leaders and frontline providers. Regularly scheduled meetings and transparency of results was found to

aid in communication barriers (McLeod et al., 2015; Smith et al., 2014). A close collaboration of the multidisciplinary team is necessary for a comprehensive perioperative pathway. Full implementation is unsustainable without cooperation from all team members, and evidence and guidelines alone will not lead to effective implementation (Pędziwiatr et al., 2015). Lack of proper leadership involvement on the team is a barrier to implementation. In healthcare professionals opinion, leadership at the surgeon, nursing and anesthesia level is required for initial enthusiasm and guidance, however, relying on one person permanently is a risk for sustainability (Georgia et al., 2017). Engagement from all relevant stakeholders is crucial to success and ERAS protocols should become embedded in normal processes.

The inner setting also includes culture, defined as the norms, values, and basic assumptions of an organization (Martin, 2002). An enabler for culture shift is tension for change, or the degree for which stakeholders perceive the current situation as intolerable (Damschroder et al., 2009). Providing stakeholders with focused gaps in current practice can aid in highlighting an opportunity for better patient outcomes and creating a tension for change (Stone et al., 2018). Designing ERPs in alignment with existing culture, engaging hospital leadership and providing adequate resources all aid in culture changes that will improve implementation and compliance. Resources play a primary role in enabling or hindering implementation. A lack of time and resource restrictions were among the most commonly referenced barriers (Pearsall et al., 2015). Surgeons were specifically concerned with a lack of nursing time because nurses are mainly responsible for executing the interventions.

A key component of the inner setting is continuous staff education. Education was discussed frequently as a facilitator if successful, and barrier if not effective. Successful implementation requires continuous education, cooperation and evaluation of results (Pędziwiatr et al., 2015). Education must include the benefits of the ERP, but also the documentation required and how the team will work together. Educational material providing clear guidelines with support from strong scientific evidence can aid in transforming traditional patterns (Pędziwiatr et al., 2015). Training staff prior to full implementation will enable anticipated difficulties to be addressed. Organizing staff education is seen as one of the most difficult elements due to inflexible schedules of healthcare professionals (Georgia et al., 2017). Lack of education results in noncompliance due to staff not being aware of the changes (Pearsall et al., 2015).

The literature review by Stone et al. (2018) discussed many facilitators identified within the implementation process made up of 4 major steps: planning, engaging, executing and evaluating. Many studies found development and engagement of a multidisciplinary team in the planning phase to be a key facilitator. Involving champions from departments of anesthesiology, nursing and surgery increased engagement and aids in spreading knowledge of successes in problem solving (Conn, M., Pearsall, & McLeod, 2015; McLeod et al., 2015). Facilitators of execution included using a formal quality improvement framework, advertising a formal start date and shifting visibility from high to low over time (Stone et al., 2018). A strong facilitator of evaluating is using the EHR to collect data and provide feedback to the team members on outcomes related to the protocol elements. Tracking adherence with variables is important for measuring compliance, however, healthcare professionals are concerned that

monitoring ERAS protocols can lead to implementation of mundane documentation that takes time away from focusing on the patient (Georgia et al., 2017).

The characteristics of individuals' domain refers to the people involved in the intervention such as patients and clinicians (Stone et al., 2018). The literature review found that characteristics of individuals provided only barriers to implementation. The main barrier with individuals is simply their resistance to change. Surgeons resistance to change was identified by nurses as a potential risk because nurses cannot perform the tasks without an order (Pearsall et al., 2015). Without an order, nurses lack self-efficacy when to deviate from the ERAS pathway. Personal preferences and resistance to change by surgeons and residents would be difficult based on solely not liking change and the belief that it would not make a difference in patient outcomes (Pearsall et al., 2015).

Senior medical professionals' negative views of certain elements within the ERP can especially lead to a lack of adherence. For example, a study exploring healthcare professionals views of the ERAS program, found a need to "break down entrenched surgical dogmas" when implementing standardized feeding practices especially within colorectal specialty (Georgia et al., 2017). In a survey by Nadler et al. (2014) younger physicians, such as residents, were found less likely to adhere to the postoperative elements. Resident's hesitance to advance patients post operatively could be due to a lack of education and experience. Residents use a more conservative approach before getting approval from senior level physicians.

Combining these two observations, one can conclude that characteristics of individuals is a barrier for both senior and entry level physicians. This could be overcome by more education of the benefits of ERAS to senior surgeons and enabling younger members to deviate from traditional elements of care (Stone et al., 2018). Team leads can use auditing and training to overcome difficulties related to traditional approach habits, lack of necessary skills and fear of new approaches (Pędziwiatr et al., 2015).

The CFIR groups characteristics of patients into outer setting. Within the construct of patient needs and resources, factors such as comorbidities, age and low socioeconomic status are barriers to ERP implementation. As discussed previously, Feroci et al. (2013) identified male gender, age over 75 years and American Society of Anesthesiologists (ASA) score of 3 / 4 were found as independent predictors of noncompliance with post-operative elements. Patients preconceived ideas of the hospital experience is a barrier, however, patient education is a key piece to the ERAS pathway that can aid in facilitating this issue. The outer setting can also be a key facilitator when organizations are networked with other external organization. Enrollment in the collaboration with AHRQ to Improve Surgical Care and Recovery (ISCR) is an example an opportunity to engage with other hospitals and learn from their experiences.

The review by Stone et al. (2018) summarizes some major considerations when implementing ERP and also calls for more studies on the implementation process. Organizations are encouraged to adapt these protocols to fit their specific needs. The multidisciplinary team should seek alignment and provide data-driven feedback and education to facilitate

engagement with frontline providers. All stakeholders, including senior executives, must be engaged for successful implementation. Lack of executive support can lead to insufficient resources and staffing to support the change. Even with executive support, engagement must flow through the entire hierarchy with the most commonly referenced barrier being resistance from frontline clinicians. To be successful, organizations should consider all previously identified barriers and adopt known facilitators when planning for implementation of an ERAS protocol.

2.2. Operationalizing Implementation

2.2.1. Implementation Approach

Steps in successful change management include assessing readiness for change, forming a steering team, developing an implementation plan, executing a pilot, disseminating change and securing sustainability of the change (Varkey & Antonio, 2010). A study on implementing ERAS across an entire health system to transform surgical care utilized the QUERI (Quality Enhancement Research Initiative) approach to detail implementation from start to finish (Gramlich et al., 2017). Change management adapted to healthcare is shown in the QUERI approach by the following steps: (1) identifying high-risk/high-volume problems (eg colorectal surgeries), (2) identify best practices, (3) define existing practice patterns and outcomes, (4) identify and implement interventions to promote best practices, (5) document that best practices improve outcomes, (6) document that outcomes are associated with improved health related quality of life (Stetler, McQueen, Demakis, & Mittman, 2008).

A previous study found success with implementation through the training program provided by the ERAS society (D. Roulin et al., 2013). A similar approach is the ISCR program by the AHRQ. Pearsall and McLeod (2018) identified key components of implementation frameworks as first assessing the current status, then forming quality initiatives based on evidence, developing strategies to support implementation, and measuring performance to provide feedback to team members.

A recent paper addresses steps to implementation of ERAS (Pearsall & McLeod, 2018). Taking steps involving key stakeholders before implementation will aid in success. Utilizing baseline data to identify a gap in care will help create a shared need among stakeholders. Pearsall and McLeod (2018) recommend that key stakeholders should be surveyed or interviewed prior to implementation to understand local barriers and develop strategies. Successful implementation of ERAS requires the use of local champions, collaborating with multidisciplinary teams, education, and reporting outcomes and feedback (Pearsall & McLeod, 2018). Systems and structures should also be in place to support implementation, such as standardized order sets, nursing flowsheets and patient education materials.

2.2.2. Qualitative Studies of Barriers and Facilitators

Qualitative studies have been chosen to analyze barriers and facilitators to implementation of elements in the ERAS protocol. In the review by Stone et al. (2018), of the 53 studies included, 18 were identified as qualitative.

Table 3 provides a summary of the qualitative approaches, sampling strategies, participants and data collection methods that were used in each study. Four studies were not included in the table due to lack of relevant information.

Table 3. Literature review for qualitative approach

Source	# of sites	Qualitative approach	Sampling Strategy	n	Roles of participants	Data collection methods	Nvivo?
(Alawadi et al., 2016)	1	Interview-based exploratory research design	Purposive	37	Patients, attending physicians, surgical residents, anesthesia staff, perioperative nursing staff, and operating room nurses	Semi-structured interviews	No
(Ament et al., 2014)	10	Case Study	Snowball	18	Surgeons, nurses unit coordinator, physician assistant	Semi-structured interviews	Yes
(Archer, Montague, & Bali, 2014)	1	IPA approach	NA	14	Patients	Semi-structured Interviews	
(Conn et al., 2015)	15	N/A	Purposive	58	surgeon, anesthesiologist, nurse champions and ERAS coordinators.	Semi-structured interviews	Yes
(Jeff & Taylor, 2014)	1	Grounded Theory	Purposive	8	Nurses	Semi-structured interviews	Yes
(Kahokehr, Robertson, Sammour, Soop, & Hill, 2011)	1	Cross-sectional survey study design	N/A	76	Colorectal surgeons	Survey	
(Knott et al., 2012)	32	Delphi Technique	N/a	86	Colorectal surgeons, anesthesiologists, musculoskeletal specialists, gynecologists and urologists, ERAS facilitators	Questionnaires	
(Lyon, Solomon, & Harrison, 2014)	1	Grounded Theory	N/a	18	Colorectal consultants, nursing managers, ERAS coordinator, and other various roles.	Semi-structured interviews	Yes
(McLeod et al., 2015)	8	Grounded Theory	Purposive	55	General surgeons, anesthesiologist, nurses	Semi-structured interviews	

(table cont'd)

Source	# of sites	Qualitative approach	Sampling Strategy	n	Roles of participants	Data collection methods	Nvivo?
(Nadler et al., 2014)	1	N/A		58	Residents	Questionnaire with 33 questions	
(Pearsall et al., 2015)	7	Grounded Theory	Purposive and snowball	55	Surgeon, anesthesiologist, nurse champions	Semi-structured interviews	
(Short et al., 2016)	1	N/A	Purposive	16	Patients	Semi-structured interviews	Yes
(Wykes, Taylor, & Wilkinson, 2013)	12	N/A	Purposive	10	Dietitians	Semi-structured interviews	
IPA - Interpretative phenomenological analysis							

As shown in

Table 3, most of the studies used a purposive sampling strategy to collect data by selecting participants who had the most experience with the ERAS protocol and were involved in the implementation process. Some of the roles of participants varied, however, majority included surgeons, nurses and anesthesiologist. The literature review revealed a large range of the number of interviews conducted. Most studies with many interviews included studies with multiple sites. The range of participants was from 8 to 76 participants for studies with only 1 site. Three sites had participant values between 10 and 20.

Most of the studies used semi-structured interviews to collect data. Interview questions were related to implementation barriers, facilitators, processes and experiences of ERAS protocol as a whole and individual elements (Conn et al., 2015; McLeod et al., 2015). Guiding theories can be used to develop interview questions to help with the initial coding process. As mentioned, Stone et al. (2018) used the Consolidated Framework for Implementation (CFIR) to group barriers and facilitators.

For data processing, five of the studies used Nvivo to aid in transcription, analysis and management of interview data. Previous studies chose a qualitative methodology using grounded theory because qualitative research can be helpful when there is limited previous research (Jeff & Taylor, 2014; Pearsall et al., 2015). As identified previously, there has been little research on a proven implementation framework for an ERAS protocol. Studies using a qualitative approach produce diverse and multi-faceted information, and using grounded theory allows for development of behavior patterns, themes and attitudes that can draw conclusions that explain the given intervention (Pearsall et al., 2015). Grounded theory methodology is used to develop theories from collecting and analyzing data in four stages: codes, concepts, categories and theory (Schroth, 2019). Rather than seeking verification of pre-identified hypotheses, grounded theory provides a method for formulating hypotheses based on conceptual ideas found in data. This methodology can be applied to form hypotheses on barriers and facilitators that are influencing compliance with variables in the ERAS protocol.

3. Project Overview and Problem Definition

3.1. Background and Environment Overview

This project is being carried out at Our Lady of the Lake (LOL) Regional Medical Center in Baton Rouge, LA. Our Lady of the Lake is an 800-bed hospital and the area's only Level II Trauma Center, serving 35,000 inpatients and 650,000 outpatients annually. Leadership decided to enroll as a cohort in a collaborative Improving Surgical Care and Recovery (ISCR) program with The Agency for Healthcare Research and Quality (AHRQ) that is very similar to Enhanced Recovery after Surgery (ERAS) program.

The program with AHRQ provides a framework for implementing pathways to ultimately Improve Surgical Care and Recovery (ISCR) for various surgical lines ("AHRQ Safety Program for Improving Surgical Care and Recovery ", 2017). The AHRQ, in collaboration with the American College of Surgeons and the Armstrong Institute for Patient Safety and Quality at Johns Hopkins University, have a combined vision to implement best practices for perioperative care in over 750 hospitals over various surgical lines during the next 5 years (Ban et al., 2017). Our Lady of the Lake chose to initially enroll only in the colorectal cohort. This narrows the scope of this project to 40 current procedural terminology (CPT) codes that are procedures including incision, resection, or anastomosis of the large intestine; includes large-to-small and small-to-large bowel anastomosis.

In fiscal year 2018, 418 surgeries were performed that met the CPT codes defined, averaging 35 surgeries a month. The primary surgeons who perform these procedures are divided into two surgical clinics. One clinic is colorectal focused and includes four (4) surgeons. In fiscal year 2018, this group performed 202 surgeries that met the criteria. The second clinic is a general surgeon's clinic; however, many general surgeons perform colorectal surgery and includes seven (7) surgeons. This group performed 127 surgeries that met criteria. These two groups perform about 80% of colorectal surgeries at LOL.

3.2. Implementation Approach

Our implementation approach emerged from four main sources:

1. Implementation phase line provided by AHRQ in Figure 3.
2. Literature on previous implementation approaches to ERAS as well as barriers and facilitators to implementation.
3. Overall start to finish framework from Quality Enhancement Research Initiative (QUERI) model.
4. Previous experiences from Lean Leads at LOL.

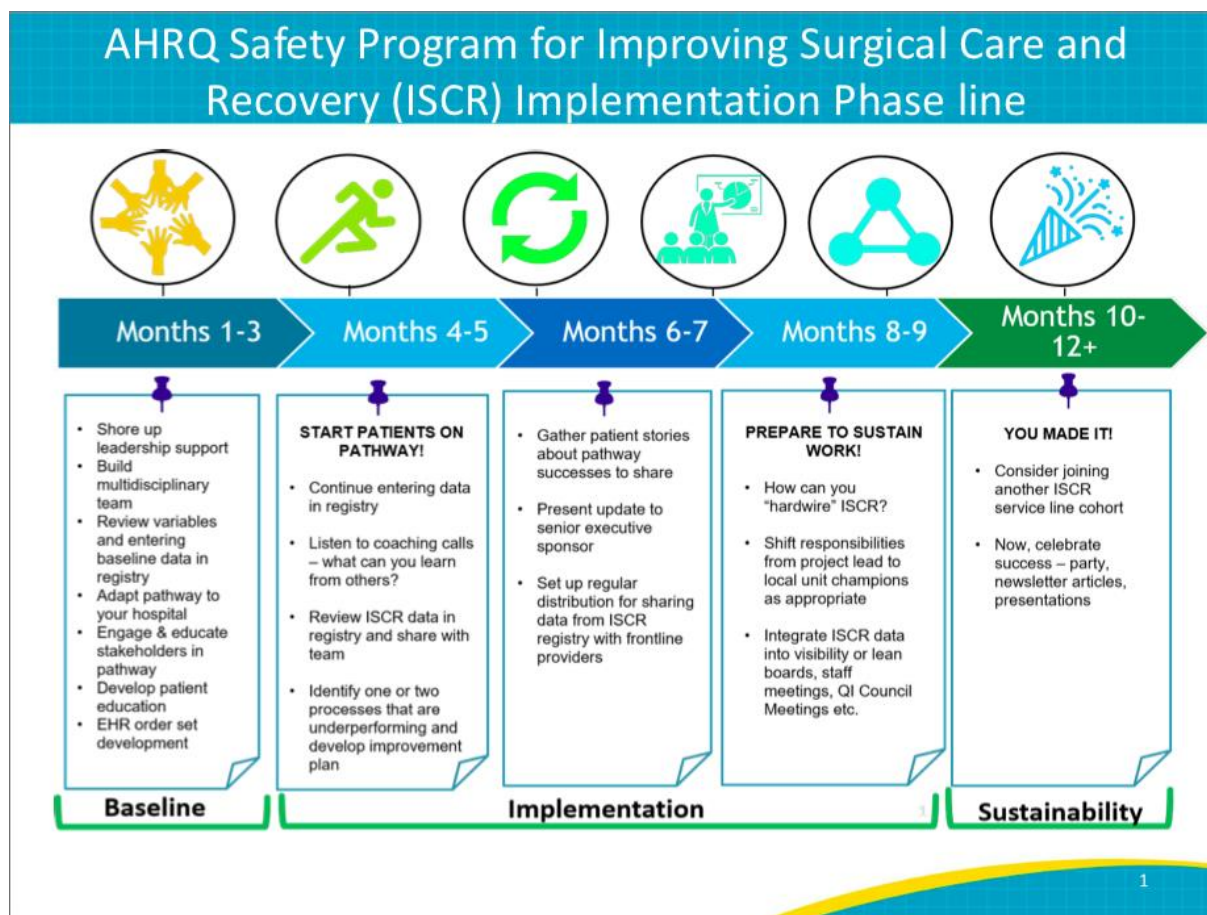


Figure 3. AHRQ implementation phase line

Table 4 shows how OLOL’s implementation action steps align with the QUERI model as well as the AHRQ implementation phase line. Our implementation approach (e.g., OLOL action steps in Table 4) closely aligns with the QUERI model previously discussed that first requires identifying high-risk or high-volume problems (Stetler et al., 2008). Leadership identified that patients undergoing colorectal surgery were at a higher risk for surgical site infections (SSIs), which led to the enrollment in the AHRQ Improving Surgical Care and Recovery (ISCR) program to help improve outcomes related to these surgeries. Detailed descriptions of the implementation steps are provided in this section.

Table 4. Implementation references and OLOL action steps

QUERI model Step	AHRQ Implementation step	OLOL Action step
	Shore up leadership support and develop multidisciplinary team	Development of multidisciplinary team
Identify best practices – find or develop practice guidelines	Adapt pathway to your hospital	Pathway development
Define variations from best practices and their determinants	Review variables and entering baseline data in registry	Tracking compliance and outcomes
Identify and implement interventions to promote best practices	EHR order set development	Modifying the electronic health record (EHR)
Identify and implement interventions to promote best practices	Engage and educate stakeholders	Staff education
		Identifying an ERAS navigator and process owner
Identify and implement interventions to promote best practices	Develop patient education	Operationalizing each of the 23 components

3.2.1. Multidisciplinary Implementation Team

The first step in the implementation process was the development of a multidisciplinary team. The importance of team development is stressed in many reviews (Georgia et al., 2017; Pędziwiatr et al., 2015; Varkey & Antonio, 2010). The review of facilitators and barriers by Stone et al. (2018) specifically lists involving a multidisciplinary team in the planning phase as a facilitator. The AHRQ program provided tools and recommendations to develop and report the members of our team.

The project lead, director of performance improvement and quality physicians at OLOL, made strategic decisions on who would fill the role of executive sponsor, surgeon champions, anesthesia champions, and local champions. Local champions include a nursing champion from each phase of care for effective collaboration. Leadership selected members based on qualities such as strong buy-in to the ERAS/ISCR principles, change agent within the organization, well-respected and trusted by others, and time available to commit to meetings. Surgeon, nursing, anesthesia champions and quality physicians make up the majority of clinical decision makers that will develop the pathway.

Lack of division head support was noted as a barrier to implementation; therefore, leadership strategically chose the Chief Operating Officer as our executive sponsor. Using formal quality improvement framework and aligning ERAS principles with existing quality improvement structure are facilitators; therefore, our organization chose a project lead from the lean team within the performance and quality improvement department. This department is made up of industrial engineers that have successfully facilitated projects at our organization using lean methodology. This person also served as the data abstractor by performing chart audits to analyze compliance.

Our main team has 16 team members as shown in

Table 5, however, multiple other members of leadership and clinicians were involved over the course of the project.

Table 5. Multidisciplinary Team

ERAS Team Members	
4	Surgeon Champions
3	Nursing Champions
1	Anesthesia Champion
1	Certified Registered Nurse Anesthetist (CRNA)
3	Quality physicians
1	Project Lean Lead
1	Executive Sponsor
1	Data Abstractor
1	Pharmacy
1	Director performance improvement
15 Total Team Members	

3.2.2. Pathway Development

The next step recommended by AHRQ was to utilize the multidisciplinary team to develop the pathway adapted for our hospital. As previously mentioned, a facilitator of implementation is to allow for flexibility during guideline development that adapts the ERAS pathways to local practice. Pathways provided by the AHRQ ISCR program were used as a starting point for development and modified the pathway to make it unique for the organization. The AHRQ ISCR program provided options within each component such as various medications. Making their pathway adapt to our organization included making decisions regarding medications and protocols for each component.

3.2.2.1. Weekly 30-minute meetings for clinical decisions

An initial meeting was held to introduce the ERAS program to all team members. Following this meeting, the original approach included weekly 30-minute weekly meetings to find agreement on each of the 23 elements. The meeting's goal was to establish agreement on the clinical components of each element while reducing the conversation about technical details of workflow implementation. Two (2) additional meetings followed this format and were only able to get agreement on five (5) out of 23 components due to discussions and disagreement on evidence support. The unpredictable schedule of surgeons also became a barrier to these meetings, so the quality improvement physician's feedback was sought out on an approach to best find agreement on each element.

3.2.2.2. Merged previously developed ERAS protocol with the pathway provided by AHRQ with the help of the quality physicians.

The colorectal surgeons group previously developed an ERAS protocol for their patients two years prior to this initiative. While they developed a protocol, their implementation was less robust as the proposed implementation plan. Likewise, and as Maessen et al. (2007) emphasizes - a protocol is not enough for success with ERAS. Many of the components were similar to the pathways proposed in the ISCR program by AHRQ. Team leads agreed to utilize their previously developed ERAS pathway as a basis for decision making.

The project lead and quality physicians worked together to develop an initial pathway by combining the colorectal ERAS protocol, the AHRQ recommended pathway, and literature review on evidence-based practice regarding each element. The final meeting for pathway development consisted of a yes/no decision for each component. The team was able to find agreement on 20 of 23 elements, showing more productivity than the original meetings that opened up more discussion. Agreement on evidence support was the main barrier to making decisions on the other three components.

The development of the pathway took a total of four 30-minute meetings over one month. Utilizing the quality physicians for evidence review and the ERAS pathways previously developed by the colorectal group aided in rapid decision making. A full copy of the final pathway can be found in upon request.

3.2.3. Tracking Compliance and Outcomes

In many of ERAS studies it is unclear how data is collected regarding compliance, and methods used find factual compliance with each variable is missing. This study will provide locations in the electronic health record (EHR) that determine compliance for each variable. This is a very important aspect of the study due to the many difficulties with documentation in the EHR. Compliance with 16 ERAS components will be accomplished.

In addition to compliance, this study will also track outcome measures including 30-day occurrence of SSIs, readmissions, and length of stay. It is expected that compliance with the ERAS protocol will improve outcomes over time, however, this study focuses on initial stages of implementation so improved outcomes may not be immediately visible in the data.

Data collection began 5 months prior to implementation to identify gaps in the current process and show improvement over time. The process began by running reports to identify patients with the appropriate CPT codes. The data abstractor investigated the electronic health record to develop an initial source of truth for each variable. A document identifying the source of truth for each variable within the EHR can be found in Table 6 and further explained in the Methods. For some components, the location may change with the implementation of new EHR components and this will be accounted for in a final source of truth document. Full description of the data collection process is in the methods section.

Resources provided by AHRQ included criteria that must be met to assign the appropriate response. Most variables are tracked using a Yes/No answer, while some variables require a date, such as first post-op mobilization, or intake of liquids/solids. Compliance with a variable requiring a date is first checked to see if there is documentation. If there is documentation, then the date of the occurrence will be subtracted from the date of operation to see what post-op day (POD) the element was executed. Noncompliance is determined by no documentation or noncompliance with the amount of time it should take for that variable to occur. For example, post-op mobilization would be noncompliant if there is no documentation or if the patient was not mobilized by POD 1.

Data regarding compliance with each component, as well as outcomes, will be tracked over the course of the project so that one can identify improvement over time and address variances in adhering to the protocol. Using this data has been found helpful in keeping all stakeholders engaged. As implementation progresses, data will be shared to all team members through a dashboard. This will be done on a monthly basis through monthly meetings to help identify areas for improvement and develop interventions to improve compliance. This cycle is commonly known as plan – do – study – act (PDSA). The project lead will reference the data to identify components that need further analysis using the PDSA cycle.

3.2.4. Electronic Health Record Development

Since integrating changes into the EHR has been found to be a barrier, the goal became to address these issues as best as possible before full implementation. The main result was identifying changes to the electronic health record (EHR) that will aid in documentation and surgeons order sets. The team also met with the quality physician that will serve as the liaison for changes needed in the EHR. This physician is on the steering committee and will assist in creating a standardized order set for surgeons as well as additional documentation for nursing.

It is important to standardize expectations regarding workflow in the EHR, since it is our main source for data collection. Modifying the EHR will create new tools to track compliance with multiple variables that previously did not have a reliable location. Table 6 provides locations in the EHR that are used to collect each variable. If the location changed, it is noted in this table. The team spent two months consulting with other organizations on using different tools to best standardize EHR components. The additions being made to the EHR include:

- Pre – op order set
- Post – op order set
- Pre – op questionnaire (nursing documentation in Figure 4)
- Anesthesia macro (standardizing anesthesia workflow)
- Post – op mobility flowsheet (nursing documentation in Figure 5)

The order sets will be used by the surgeons to order medications. The order sets were built with pre-selected medications to reduce variance by surgeon.

Pre-op

Events

Family Communication

Collect Specimens

ARRIVAL

Summary Report

BestPractice

Tasks

Travel/Exposure

Preop Call Info

Summary

Consents

Device Select

PreOp Nurse

Allergies

Home Medications

History

Care Everywhere

Spec. Collect

ASSESSMENT

Vitals

NPO Status

ERAS Checklist

Head to Toe

Skin Risk

Psychosocial

Fall Risk

LDAs

Checklist

Care Plan

TIMEOUT

Timeout

DISCHARGE PLAN

Education

Charge Capture

Outcome State...

Verify

ERAS Checklist - ERAS Checklist

Time taken: 1007

7/25/2019

Values By

Create Note

ERAS Pre-Operative Checklist

ERAS Patient	Yes	No
Pre-Operative Patient Education: Written or Digital Information Provided	Yes	No (comment)
Bowel Prep Completed?	Yes	No (comment)
Pre-Op Oral Antibiotics: Patient reports taking antibiotics as prescribed?	Yes	No (comment)
Pre-Op Bathing: Patient reports antiseptic shower completed?	Yes	No (comment)
Pre-Op Carb Loading: Patient consumed clear liquid carb drink morning of surgery?	Yes	No (comment)
Clear Liquids Counsel: Patient was advised he/she could consume clear liquids up to 3 hours before surgery?	Yes	No (comment)

Restore

Close

Cancel

Head to Toe

Figure 4. Pre-op Nursing questionnaire

Core Measures - Child... Core Measures - Stroke Core Measures - VTE Core Measures for Mom... Core Measures - Surgi... Core

Search

Hide All Show All

Mobility Scale ☒

Hester Davis ... ☒

Sedation Sca... ☒

Confusion As... ☒

Accordion Expanded View All

Admission (Discharged) from 7/16/2019 in OUR LADY OF THE LAKE REGIC

	7/16/19	7/17/19	7/18/19	
	1000	1500	0100	1000

Mobility Scale

Highest Level Mobility

Hester Davis Fall Risk Assessment

Last Known Fall	0	0	0	0
Mobility	0	0	1	1
Medications	1	1	1	1
Mental Status/LOC/Awareness	0	0	0	0
Toileting Needs	0	0	0	0

07/29/19 1500

Highest Level Mobility

Select Single Option: (F5)

- Lying in bed (1)
- Turn self in bed/Bed activity/Dependent transfer (2)
- Sit on edge of bed (3)
- Transfer to chair (4)
- Stand for 1 minute (5)
- Walk 10+ steps (6)
- Walk 25+ feet (7)
- Walk 250+ feet (8)

Figure 5. Post - op Nursing Flowsheets

3.2.5. Staff Education

Staff education was found to be a main facilitator and should be continuous to account for staff turnover. Engaging the frontline clinicians can help to identify barriers that may arise after implementation (Tezber et al., 2018). Once the appropriate structure is in place, further engagement of staff will occur for education on what to expect with implementation of ERAS and why ERAS is important. Education should be easily accessible for staff and organizing sessions to fit with the busy schedules of clinicians can be difficult. Team members will plan to attend weekly/monthly team meetings to educate frontline staff. This period is expected to take 1-2 months.

3.2.6. ERAS Process Owner

Other studies have assigned a nurse to be responsible for facilitation, data auditing and providing feedback (Ljungqvist et al., 2017). OLOL is working to identify the appropriate group for this person within the organization. This person will continue to collect data and collaborate with the multidisciplinary team to address any gaps in the process. There is a risk to sustainment without having a designated person to continue the ERAS work. The ideal process

owner would be one with a clinical background and has support from all hospital operational groups.

3.2.7. Developing patient education materials

A main component of ERAS is patient education. One of the surgeon groups already has an educational booklet developed, however, AHRQ provided additional resources for patient education. The project lead collaborated with marketing to merge the material provided by AHRQ and the current booklet. The education booklet allows the patient to better plan for their surgery and know their expectations for their stay. It also provides information for how to best recover once they return home. Once the materials are ready, it will be the expectation of the surgeons groups to hand out the education materials and discuss with their patients.

4. Research Aims and Objectives

As mentioned in the literature review by Stone et al. (2018), there is a gap in studying the implementation of an ERAS protocol and what factors influence successful implementation. This study aims to address the gap by focusing on the following objectives.

Research Objective 1: To identify if the implementation process improved compliance with the 16 process measures.

Research Objective 2: To identify if implementation of the ERAS protocol improved patient length of stay.

Research Objective 3: Understand barriers and facilitators to implementing an ERAS protocol through interviews and focus groups with the multidisciplinary team.

Based on the results of these objectives, the organization will be able to develop standardized processes that lead to better healthcare. As a result of this research, a major outcome objective will be accomplished as below.

Outcome Objective: An outcome of this research is to provide a guide to implementation based on experiences from the findings from this research. This would include integral steps to success and a framework to lead to successful implementation of an ERAS protocol.

5. Methods

This will be mixed methods study including focus groups, interviews and patient chart abstraction to assess implementation of the ERAS protocol at our organization. Figure 6 provides a timeline of how our qualitative approach overlays with the implementation steps. An IRB was submitted prior to conducting focus groups. A copy of the consent form can be found in the appendices.

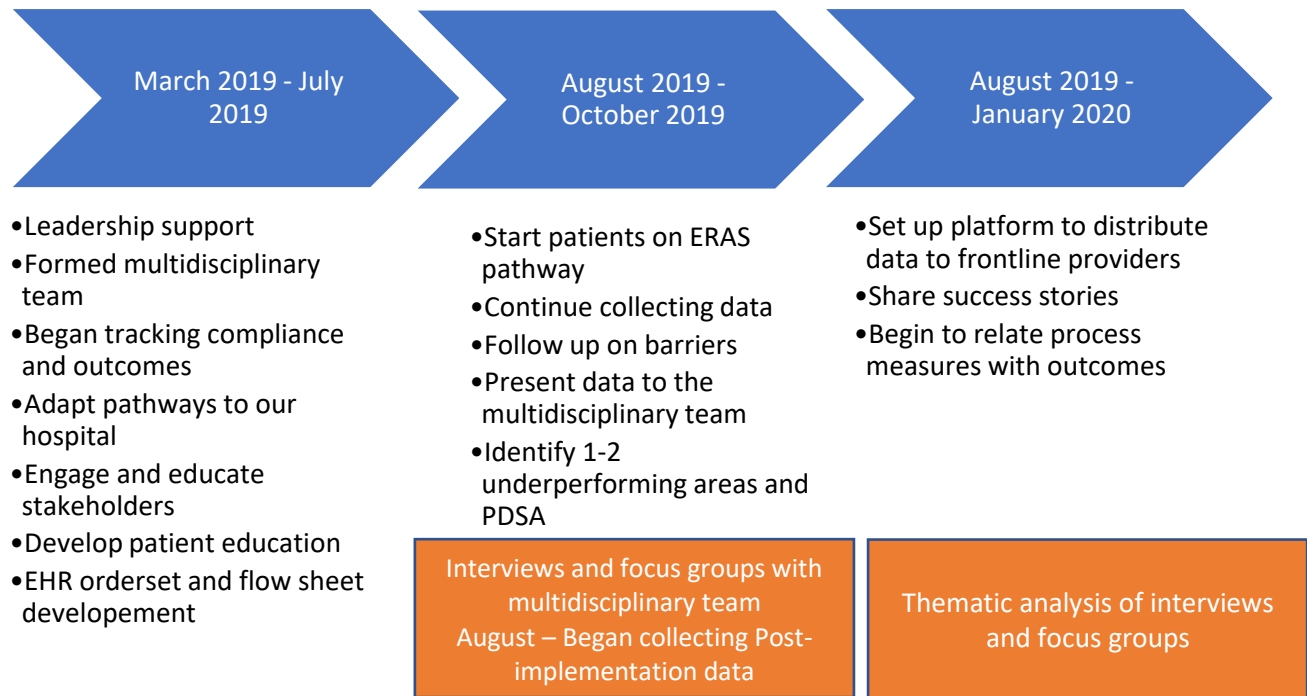


Figure 6. Implementation Timeline

5.1. Objective 1: Process Measure Analysis

A report was used to identify patients who had a planned colorectal surgery and needed to be reviewed for compliance with ERAS components. Compliance measures are tracked by a manual process of reviewing patient charts in the electronic health record (EHR). This process takes 30 minutes per patient on average.

Table 6 below shows how compliance was defined for each component and the location in the electronic health record (EHR). Excel, Tableau and Redcap were the main platforms for analyzing compliance by dividing number of “yes” responses over total number of patients. Patients with procedures in April – July will be categorized as pre-implementation and patients from August – December will be categorized as post-implementation. The implementation into the electronic health record serves as the main intervention between these two categories of patients.

Hypothesis: Compliance with each process measure will be significantly greater in post-implementation patients, as measured by a chi-square test.

Table 6. Compliance measures

Process Measure	Compliance Definition	EHR Location	Months collected
Patient Education	Yes – Patient reports receiving education materials (written or digital)	Office visit note	April – July
	No – patient does not report receiving education materials	Pre-op nursing questionnaire	August - December
Mechanical Bowel preparation	Yes – patient reports completing bowel prep as instructed	Office visit note	April - July
	No – patient did not perform bowel prep	Pre-op nursing questionnaire	August – December
Oral antibiotic bowel preparation	Yes – patient reports taking antibiotics as prescribed	Office visit note	April - July
	No – patient does not report taking antibiotics	Pre-op nursing questionnaire	August – December
NPO status up to 2 hrs before induction	Yes – patient reports being allowed to have clear liquids up to two hours before surgery	NPO status flow sheet	April – July
	No – patient was not instructed	Pre-op nursing questionnaire	August – December
Pre-op VTE Prophylaxis	Yes – VTE meds administered pre-op No – no VTE meds administered pre-op	MAR	April – December
Anti-emetic prophylaxis	Yes – documented administration of antiemetic intraoperatively No – No documentation of an anti-emetic	Anesthesia Record	April – December
Decadron (not given)	Yes – decadron not given No – decadron given	Anesthesia record	April – December
Regional Anesthesia	Yes – a TAP-block performed intraoperatively	Anesthesia Record	April – December

(table cont'd)

Process Measure	Compliance Definition	EHR Location	Months collected
Fluid administration goals	Yes – total intra op fluids below 500 ml/hr (closed procedure) or 800 ml/hr (open procedure) No – fluids per hr above guideline	Anesthesia Record	May – December
Tidal volumes < 8 ml	Yes – tidal volume remained in recommended range for pt height No – tidal volume went above recommendation	Anesthesia record	May – December
Appropriate intra-op abx given	Yes – abx were documented as given according to guidelines No – no abx documented or not appropriate	Anesthesia Record	April - December
VTE prophylaxis	Yes – VTE meds administered POD 0 No – VTE meds not administered POD 0	Medication Administration Record (MAR)	April – December
Multimodal Analgesia	Yes – Two oral pain meds administered simultaneously POD 0 No – guideline not followed	Medication Administration Record (MAR)	April – December
Post – op intake of liquids	Yes – patient consumes clear liquid diet POD 0 No – patient does not have liquids POD 0	Intake/output flowsheet (nursing documentation)	April – December
Post – op intake of solids	Yes – patient ordered solid foods by POD 1 No – patient not ordered solid food by POD 1	Surgeon’s orders	April – December
Post – op mobilization	Yes – documentation patient ambulated 10+ ft POD 0 No – no documentation or after POD 0	Daily cares flowsheet	April – July

(table cont’d)

Process Measure	Compliance Definition	EHR Location	Months collected
Post – op BID mobilization	Yes – documentation patient ambulated 10+ ft twice within 48 hrs	Daily cares flowsheet	April – July
	No – no documentation or after 48 hrs	Mobility flowsheet	August – December
Early catheter removal	Yes – catheter removed by POD 1	Intake/output flowsheet	April – December
	No – catheter removed after POD 1		
Minimize IV fluids	Yes – IV fluids discontinued POD 0 or not given	Medication administration record	April - December
	No – IV fluids discontinued after POD 0		
Note: POD 0 refers to the first 24 hrs following surgery. POD 1 is the first 48 hrs following surgery.			

5.2. Objective 2: Outcome Analysis

As evidenced in the literature review, implementation of an ERAS protocol is expected to impact patient outcomes. Length of stay was the main outcome measure in this study. A decrease in length of stay shows that patients are recovering faster and can also lead to a large financial benefit for the hospital and patient. This could also impact hospital reviews from patient experience. Data will be divided by pre and post implementation dates and compared for an impact on length of stay.

Hypothesis: Length of stay for patients after implementation will be significantly less than those prior to implementation, as measured by a t-test.

5.3. Objectives 3: Team Implementation Assessment

This research aims to understand barriers, facilitators and recommendations for implementation of an ERAS protocol through interviews and focus groups with the multidisciplinary team. Interview analysis will be coded and categorized according to the CFIR.

5.3.1. Interviews and focus groups

To align with previous studies, data collection will be done through semi-structured interviews and focus groups. The questions were developed using the CFIR interview tool. Questions were then refined through collaboration with an expert with previous interview experience in our setting. A sample of interview questions can be found in the appendices 0. Interview questions were built to align with organizational measurements. This strategy will allow for one to assess the feelings and views towards ERAS protocol experienced by the people involved in implementation. Previous studies conducted interviews after ERAS was implemented for an

extended period of time, however, interviews will be conducted in the third and fourth month of implementation. This will allow participants to reflect on the beginning stages of implementation, as well as the current state. Participants will be asked to describe barriers, facilitators and recommendations for implementation. Interviews will be conducted by a neutral party (research director at OLOL) and recorded using the NVivo software.

5.3.2. Sampling strategy

A purposive sampling strategy was the most common identified in the literature (Alawadi et al., 2016; Conn et al., 2015; Jeff & Taylor, 2014; McLeod et al., 2015). Our purposive sampling strategy included surgeons, anesthesiologists, nurses and leadership members involved in the planning implementation process by participating in our multidisciplinary team meetings as participants. Participants were separated by discipline to allow for team members to feel comfortable fully discussing implementation without influence. Focus groups and interviews will be conducted with the following team members:

- Focus group 1 – two surgeons from clinic 1
- Focus group 2 – two surgeons from clinic 2
- Focus group 3 – three nurse champions (pre-op and post-op nurses)
- Focus group 4 – two quality physicians (hospital leadership)
- Focus group 5 – two executive sponsors
- Focus group 6 – One anesthesiologist and one Certified Nurse Anesthetist (CRNA)

5.3.3. Qualitative Analysis

As identified in the literature review, grounded theory was the most used methodology for qualitative analysis (Jeff & Taylor, 2014; Lyon et al., 2014; McLeod et al., 2015; Pearsall et al., 2015). Rather than preidentified hypotheses, grounded theory results in hypotheses of theories related to an intervention. Thematic analysis is similar to grounded theory, but it does not attempt to generate a theory. Thematic analysis develops categories instead of themes and can be used for non-experts in qualitative analysis to generate patterns in data.

5.3.4. Data Processing

Data will be processed by more than one researcher and will begin with open coding to segment data into the domains and constructs identified defined by the CFIR. Researchers will utilize a code book from the CFIR Technical Assistance Website that defines inclusion and exclusion criteria for the CFIR construct and examples of barriers and facilitators that were identified in the literature review ("CFIR Technical Assistance Website," 2020). Initially the list will begin with all 39 constructs and original definitions and will be interpreted to fit the local context. Data segments will be defined as a paragraph discussing a single concept. After open coding, coders will identify subcategories of barriers and facilitators within each construct. These definitions will be based on local experiences of the team members with implementation at our organization.

The following steps will be used:

1. Decide which of the CFIR domains encompasses the data segment. (e.g., innovation characteristics)
2. Which CFIR code within the domain summarizes the data segment. (e.g., adaptability)
3. Whether the statement was a barrier or facilitator

5.3.4.1. Interrater Reliability and Validation

Interrater reliability will be accomplished by researchers coding a sample of interview transcripts, and then reviewing together to ensure they are using the same methods. Cohen's Kappa test will be performed and reported as to coder consistency in their methodology.

5.3.5. Data Analysis Outcomes

The CFIR will be used to organize trends in the data collected from the multidisciplinary team interviews. The outcome will be a list of identified barriers and facilitators to implementation of an ERAS protocol. This analysis will provide several factors and best practices for organizations to consider while developing an implementation strategy to begin, scale, and spread ERAS implementation.

5.4. Outcome Objective: Implementation Framework

The results identified in this study will be compiled into a recommended implementation framework. The steps to implementation previously identified will be further expanded on and evaluated using the feedback from the multidisciplinary team. The barriers and facilitators identified in the CFIR framework will be translated into recommendations for future implementation of an ERAS protocol.

6. Results

6.1. Objective 1: Process Measure Analysis

Process measures were collected prior to implementation of the ERAS protocol and after implementation. The pre-implementation group consisted of 76 patients from April – July 2019. The post implementation group consisted of 127 patients from August – December 2019. To compare compliance of the pre-implementation and post-implementation patient groups, a Chi-square test was completed for each of the 19 process measures. Table 7 shows the compliance with each process measure for the pre and post sample size, as well as the associated p-value. At an alpha of 0.05, we found a significant increase of compliance for 10 of the process measures. A significant decrease in compliance was found for appropriate intra-op antibiotics. This could be contributed to a change in the compliance definition to further align with evidence-based recommendations.

Table 7. Process Measure Analysis

Process Measure	Pre- implementation compliance (n=76)	Post- implementation compliance (n=127)	P-Value
Patient Education	31.58%	88.98%	< 0.0001*
Mechanical Bowel preparation	84.21%	88.98%	0.3254
Oral antibiotic bowel preparation	77.63%	81.10%	0.5511
NPO status up to 2 hrs before induction	47.37%	85.04%	< 0.0001*
Pre-op VTE Prophylaxis	42.11%	64.57%	0.0018*
Anti-emetic prophylaxis	89.47%	89.76%	0.9476
Decadron (not given)	31.58%	73.23%	<0.0001*
Regional Anesthesia	80.26%	92.13%	0.0128*
Appropriate intra-op abx given	97.37%	87.40%	0.0156*
Fluid administration goals	26.32%	58.84%	< 0.0001*
Tidal volumes < 8 ml	14.04%	39.37%	0.0006*
Post-op VTE prophylaxis	96.05%	93.70%	0.4738
Multimodal Analgesia	84.21%	89.76%	0.2439
Post – op intake of liquids	84.21%	90.55%	0.1757
Post – op intake of solids	56.58%	81.10%	0.0002*
First post – op mobilization	30.26%	66.14%	<0.0001*
First BID Mobilization	19.74%	44.88%	0.0003*
Early catheter removal	80.26%	81.10%	0.8832
Minimize IV fluids	48.68%	56.69%	0.2681
<i>*significant at alpha = 0.05</i>			

6.2. Objective 2: Outcomes Analysis

One of the main purposes of implementing an ERAS protocol is to impact patient outcomes. Patient length of stay (LOS) is the outcome used in this study. Data was grouped into pre and post implementation groups based on the “go-live” date in August. Table 8 shows the summary statistics for these two groupings, indicating a decrease in LOS by 0.77 days from pre-implementation and post implementation. Figure 7 shows the monthly length of stay from April – December.

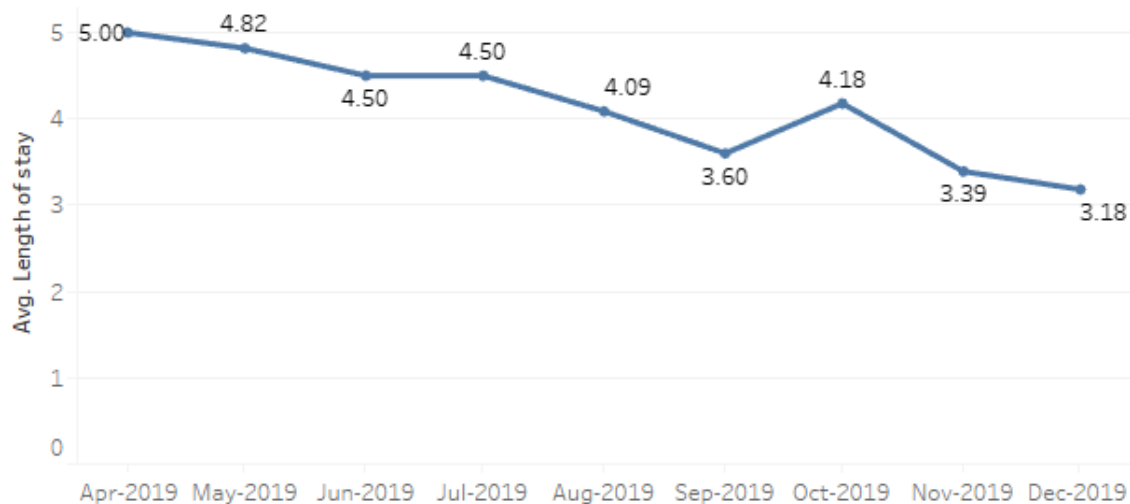


Figure 7. Length of stay by month

Table 8. Outcomes Summary Statistics

Group	n	Mean LOS	Std Dev
Pre (April – July)	76	4.68	3.27
Post (August – December)	127	3.91	2.68

The Anderson-darling test (p-value <0.0001) showed that the LOS data was not normally distributed. A Levene’s test was used to test the homogeneity of the two groups (p-value 0.1268) showing that the variances are equal. The LOS for the two groups were then analyzed using a t-test for equal variances (p-value <0.0349) concluding that the LOS for patients after the implementation of the ERAS protocol was significantly less than those prior to implementation.

6.3. Objective 3: Interview Analysis

Semi-structured focus groups were conducted with members from the multidisciplinary team. Focus groups were completed as planned and included members from anesthesia, quality physicians, surgeons, nursing and administrative leadership. Each focus group lasted between 15 – 30 minutes. The focus groups were transcribed using Otter.ai and then analyzed using the

NVivo 11 qualitative data analysis software. The transcriptions were coded using the CFIR framework as a guide. The CFIR outlines five domains that impact implementation: characteristics of individuals, implementation process, inner setting, intervention characteristics, and outer setting. Coding was done in three steps, first by CFIR domain, then the construct within that domain and then as a barrier or facilitator. A CFIR code book can be found on the CFIR Technical Assistance Website that defines inclusion and exclusion criteria for the CFIR ("CFIR Technical Assistance Website," 2020).

6.3.1. Interrater Reliability

An interrater reliability was done to assess validity of the CFIR constructs identified by the primary coder. A random sample of 10% of the data segments were re-coded by a secondary coder. The agreement between the two coders was a Cohen's Kappa value of 0.66 with a p-value of <0.0001. The agreement statistic of 0.66 is relatively appropriate considering the experience level of the coders. The third step in the coding process was to define each segment as a barrier or a facilitator. The interrater reliability was tested and the agreement between coders for assigning barrier or facilitator resulted in a Cohen's Kappa value of 0.87 with a p-value of <0.0001. Considering both agreement statistics being relatively close to 1, we can conclude that the coding methodology was adequate for the study (McHugh, 2012).

6.3.2. CFIR Analysis

Interviews were analyzed to identify which CFIR domains had the largest impact on implementation. In Figure 8, the size of the square represents the number of data segments within that domain or construct. This shows that the inner setting and implementation process seem to have the largest impact, specifically in the engaging portion of each. The adaptability of the intervention seemed to be the most important characteristic to the team. Characteristics of individuals were mentioned to be a barrier due resistance to change. The outer setting included patient characteristics which were not mentioned to impact much of implementation.

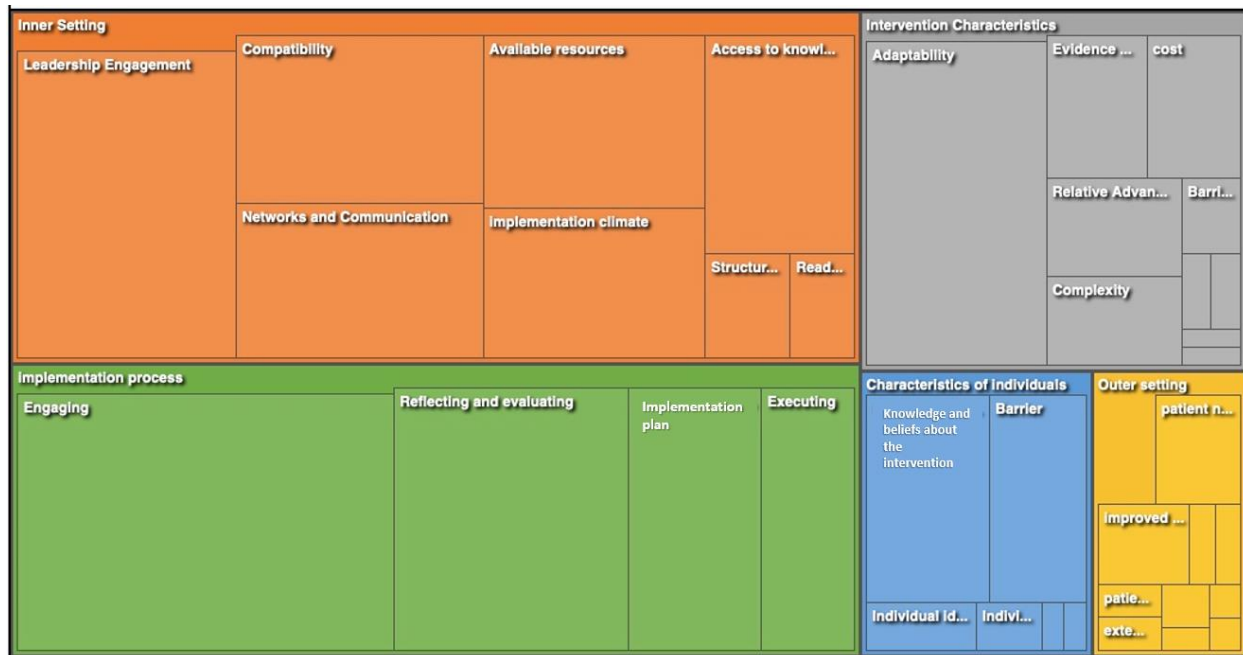


Figure 8. CFIR domain hierarchy

Each domain was further analyzed by focus group. Figure 9 shows charts for each domain and the percent of coverage from that domain identified in each focus group transcript. Figure 10 shows the same percent coverage in graphs by focus group. Nursing mentioned intervention characteristics more than any other group, likely due to nursing having the most process changes. Anesthesia is more involved with the surgeon than any other team member because they are present during surgery, and quality physicians assisted in mitigating personality barriers; therefore, it makes sense that these two groups discussed characteristics of individuals more than others.

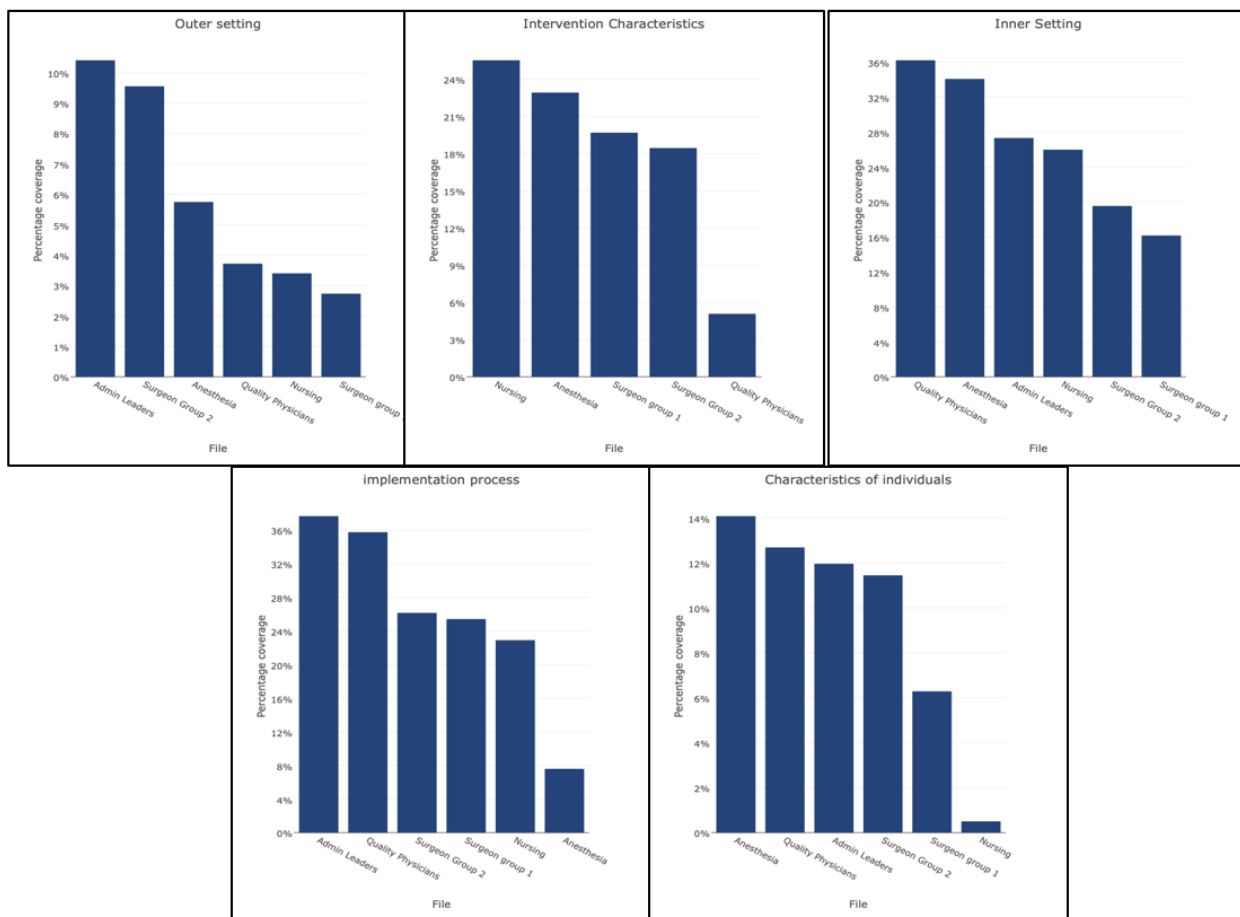


Figure 9. CFIR domain with percent coverage of focus group

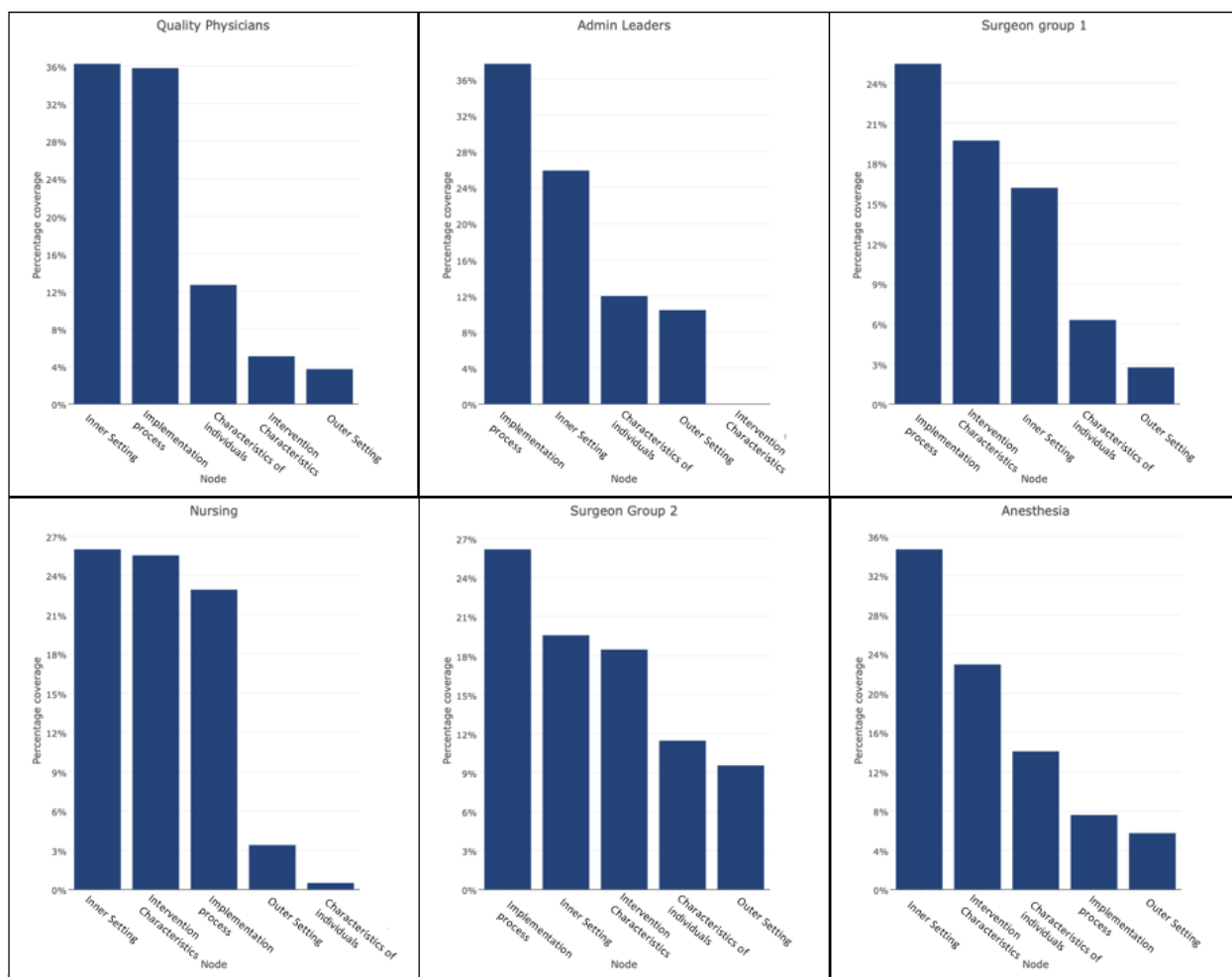


Figure 10. Focus groups with percent coverage by CFIR domain

Data was analyzed by CFIR domain and construct, then further identified as a barrier or facilitator. Barriers and facilitators that were identified multiple times are summarized here in the table below. Coders identified facilitators to be ideas that the team identified as helpful when implementing ERAS protocol or recommendations that would have made implementation easier. Barriers were things that hindered implementation. These summaries can serve a guide to organizations when considering implementation of an ERAS protocol.

CFIR Construct	Summaries	+ / -
Characteristics of Individuals		
Individual identification with organization	Surgeons from different clinics resistant to sharing with each other and commit to the greater goal of the organization	-
	Engaging surgeons who are not employed by the organization	-
Individual state of change	Difficulty for surgeons to give up control and fully comply with the pathway	-
	Individuals not knowing that there is a process change or individuals believing it is not necessary	-
Knowledge and beliefs about intervention	Individuals understanding that all components of the ERAS protocol need to be carried out to be successful	+
	Surgeon resistance to any change on how they should do things	-
	Changing anesthesia practices from their normal way of doing things	-
	Surgeons not following guidelines due to disagreement with evidence	-
	Merging implementation efforts with the belief that an ERAS protocol was already in place	-
Self-efficacy	Anesthesia staff uncomfortable with patients drinking a carb loading drink 3 hours prior to surgery	-
Implementation Process		
Engaging	Setting a clear vision and goal with buy in from major stakeholders with commitment to the process	+
	Creating a collaborative where nursing, surgeons and anesthesia can give their input on a regular basis and feel heard	+
	Post-op nursing expressed patients are engaged with education in the clinic so that they know post-op expectations	+
	Nursing engaged in tracking their post-op mobility through use of an interactive white board at the end of the hallway	+
	Getting buy in from multiple anesthesia providers who function as a private group	-
	Difficulty engaging all the players (e.g., nursing and anesthesia) due various shifts and large number of staff members	-
	Difficulties spreading to the broader surgical community and reaching surgeons who don't consistently operate at the organization	-
	Difficulties for surgeons to attend all meetings due to schedules	-
Formally appointed internal implementation leaders	Appointing a formal implementation leader from the lean team to take ownership and drive implementation progress	+
	Not having a formal clinical process owner	-
Opinion leaders	Physician leaders educating and sharing during staff meetings	+
	Involving too many opinions when building the protocol	-

(table cont'd)

CFIR Construct	Summaries	+ / -
Champions	Strong physician support from the beginning including surgeons and quality physician leadership	+
	Setting expectations from leadership and physician champions holding parties accountable to meet expectations through data	+
	Creating a multidisciplinary team of champions and allowing them to work with support from leadership	+
	Having an involved anesthesia representative	+
	Anesthesia expressed the need for champions to consistently supervise and bring people up to speed	-
	Risking burnout with the same champions driving implementation	-
Executing	Formalizing and standardizing across multiple groups rather than pockets of execution	+
	All disciplines executing their portion of the pathway	+
	Using data to show the difference in execution vs expectation	+
	Surgeons expressed seeing results with post-op nursing being motivated and cognizant about following the pathway	+
	Challenges informing weekend, night and PRN staff. Nursing recommended at least a month to introduce to all staff	-
	Relying on one person to execute a portion of the pathway and not running automatically	-
Implementation plan	Having all disciplines participate in guideline development including surgeons, anesthesiologists, CRNAs, Nurses and pharmacists	+
	Setting expectations to all follow the plan	+
	Intentionally selecting a group of surgeons that were engaged	+
	Setting up weekly 30-minute meetings to make initial decisions on the pathway components and continuing meetings bi-weekly for updates on progress and challenges	+
	Quick education through daily nursing huddles regarding mobility documentation led to a quick improvement in results	+
	Get a baseline of the current state	+
	Not enough time to plan and educate all staff members	-
	No formal “go live” date	-
	Not considering other organizational priorities when creating the implementation plan	-

(table cont'd)

CFIR Construct	Summaries	+ / -
Reflecting and evaluating	Being able to show progress in reducing clinical variation in a short period of time	+
	Using true information through data collection to guide implementation progress	+
	Sharing process and outcomes data with the multidisciplinary team to motivate progress	+
	Disciplines recognizing progress in areas other than their own (ie anesthesia recognizing progress made by nursing)	+
	Giving surgeons an opportunity to express individual patient concerns and providing feedback	+
	Use data as feedback to the staff on meeting goals	+
	Being able to show an improvement in patient outcomes (ie length of stay)	+
	Showing data by surgeon to entice competition and further show where there is room for improvement	+
Inner Setting		
Access to knowledge and information	Making education available in the anesthesia break room	+
	Creating fliers for easy access to education	+
	Having a surgeon lead seminar to educate nurses for continuing education credit	+
	Anesthesia and nursing expressed difficulties getting all staff members educated	-
	Some clinicians practicing in traditional ways due to not knowing the change	-
Available resources	Not having consistent anesthesia staffing for these cases	-
	Not having adequate equipment to monitor glucose	-
	Other hospitals being up to date on the use of TAP blocks with anesthesia	-
Compatibility	Applying the same approach as a blueprint to tackle other areas in reducing clinical variation and spreading to other facilities	+
	Using an evidence-based approach to get buy in from leadership	+
	Incorporating ERAS components in to pre-existing interdisciplinary huddles	+
	Incorporating electronic health record pieces into pre-existing workflows	+
	Aligning the approach with the performance improvement structure through the lean team	+
	Difficulties with providers that are already following a version of an ERAS protocol	-
Implementation climate	The institution is open and innovative	+
	Difficulties in making decisions regarding implementation	-
Feedback	Leadership at different levels in the organization acting on feedback from the frontline	+
Learning climate	Leadership promoting and helping staff bring ideas to fruition	+

(table cont'd)

CFIR Construct	Summaries	+ / -
Tension for change	Utilizing data to prioritize and strategize initiatives in terms of cost and impact on outcomes	+
	The organizations willingness to commit resources to implementation over time	+
	Quality physicians expressed a strong need for implementing interventions like an ERAS pathway	+
	Organization requires multiple leaders to drive change rather than a shared value statement	-
Leadership Engagement	Having support from the chief operating officer and VP of quality and patient safety with setting expectations and mitigating barriers	+
	Engaging physician leadership who were not surgeons to mitigate surgeon competition	+
	Mid-level manager involvement from nursing to ensure staff following the protocol	+
	Involving leaders from every discipline and major surgeon group	+
	Strong nursing leadership that supports new ideas and provides feedback	+
	Leadership involvement from the EHR team	+
	Weakness in enabling mid-level leaders to enforce change	-
	Leadership must drive majority of change rather than depending on a unified value statement	-
Networks and Communication	Seeing the impact of implementation across phases in the pathway	+
	Sharing and learning from challenges on other nursing units	+
	Utilizing multidisciplinary meetings to get everyone on the same page and setting up subgroup meetings with each discipline	+
	Nursing understands standard expectations from surgeons for all of these patients rather than individualized care	+
	Difficulties in communicating between disciplines that this is an ERAS patient	-
	Difficulty communicating with all surgeons at various clinics	-
Readiness for implementation	Implementing at the largest institution first	+
	Waiting to implement when the organization had bandwidth to get buy in from all parties	+
	Smaller hospitals may not be as accepting of change	-
Structural Characteristics	Difficulties implementing due to the size of the organization and health system	-

(table cont'd)

CFIR Construct	Summaries	+ / -
Intervention Characteristics		
Adaptability	Having an anesthesia team already accustomed to giving tap blocks	+
	Adapting existing practices into the protocol	+
	Creating patient education material based off of previous successful sources	+
	Trying the protocol for scheduled, elective surgeries first and then adapting the protocol for emergency surgery	+
	Surgeon clinics adapted quickly to educating patients on where to purchase the carbohydrate drinks	+
	Anesthesia expressed difficulty adapting the pathway to account for individual patient differences when necessary	-
	Nursing expressed difficulty using a paper process for flagging the patient and felt it should be more automated in the EHR	-
	Nursing expressed barriers with charting mobility consistently because the charting did not fall on their regular task list in the EHR	-
Complexity	Difficulty getting patients back on track if they do not follow the appropriate pre-operative steps	-
	Patients report nausea and cramping from pre-operative antibiotics	-
Cost	Pharmacy restricting access to IV Tylenol due to the cost	-
Design quality and packaging	Incorporating a standardized order set as a tool to complying with the pathway	+
Evidence Strength and quality	Using literature and evidence-based approach to get participants on board	+
	Lack of agreement on evidence strength for each component of the protocol	-
Relative Advantage	The pre-op medication regimen and tap blocks were successful in serving as an alternative to opioid use for pain management	+
	Nursing staff reported less workload because patients were recovering and becoming more independent quicker	+
Trialability	Making sure the protocol works at one hospital before spreading to the entire health system	+
	Trying out the protocol with a smaller subset of anesthesia staff	+
Outer Setting		
Cosmopolitanism	Using the AHRQ guidelines and recommendations as a template for implementation and learning from other large organizations	+
Patient Needs and resources	Quickly getting patients to their previous level of functionality with their pain under control	+
	Engaging patients in their recovery by using interactive mobility boards	+
	Educating patients in the surgeon clinic so that they know expectations for recovery	+
	Patients not following instructions regarding pre-operative components of the protocol	-

6.4. Outcome Objective: Proposed Implementation Guide

The results of this study can be used as a basis for future ERAS implementation. An administrative leader mentioned, “I think it can serve as a blueprint for some future improvement efforts, particularly where we engage an interdisciplinary group of our physicians, ancillary support and nursing.” An implementation guide was developed. This package is outlined in the presentation in appendix O. This presentation could be sent to other organizations in our health system who are interested in implementing ERAS. Other surgical service lines interested in an ERAS protocol can use this as a guide to implementation as well.

7. Discussion

The results of this study are two-fold, providing an analysis of clinical effectiveness and implementation recommendations of an ERAS protocol. The ERAS protocol requires standardization of many elements over the perioperative pathway for patients. This study tracked compliance with the protocol before and after implementation to show improvement. Length of stay was used as the primary outcome measure of the study.

Two pre-op, five anesthesia, and three post-op process measures showed a significant increase in compliance after implementation. Four of the process measures that did not show a significant increase were above 70% compliance in the pre-implementation phase, therefore, the processes did not have much room for improvement. IV fluid discontinuation within 24 hrs was the only variable that did not show a significant increase and was not above 70% compliant prior to implementation. In the final month of implementation, most of the variables were over the 70% compliance goal. The increase of compliance with the protocol led to a statistically and practical significant reduction in length of stay by 0.77 days, savings of over two hundred thousand dollars annually.

These findings are supportive of previous literature that identifies the clinical impacts of implementing an ERAS protocol, however, previous studies lack detail regarding the implementation approach and barriers and facilitators that the team experienced. The multidisciplinary team focus groups identified many practices to consider when implementing an ERAS protocol (Ban et al., 2017; Ban et al., 2018). Majority of factors fell within the inner setting and implementation process domain. This suggests that success depends strongly on organizational commitment and a structured intentional implementation approach. These findings are consistent with previous ERAS implementation literature, as well as traditional change management strategies (Varkey & Antonio, 2010).

The implementation process must begin with engagement from all levels of the organizational hierarchy. Members of executive leadership assisted with getting buy in from providers and setting expectations in the beginning stages of implementation. Successful implementation requires organizational priority and willingness to commit resources to the change. Executive leadership prioritized this implementation based off previous metrics and evidence-based recommendations.

The implementation plan followed closely with AHRQ's recommendations. All members identified the importance of having a multidisciplinary team of nursing, anesthesia, and surgeons involved throughout implementation. This is integral part of implementation is also mentioned in previous literature (Conn et al., 2015; McLeod et al., 2015). The team also recognized that having a project lead from the performance improvement team was essential. This person was responsible for planning and facilitating 30 minute bi-weekly meetings with the team. These meetings were one of the most cited facilitators. Team members liked the consistency of the meetings only being 30 minutes and getting to hear feedback from all

disciplines. This is similar to the finding by Stone et al. (2018) that using a formal quality improvement framework was a facilitator.

The initial stages of implementation required consensus on all protocol items. Merging protocol items with existing beliefs was a challenge. The non-surgeon physician champions assisted with mitigating these barriers with literature support. The team explored various options for incorporating these decisions into existing processes. The main process changes were utilization of standardized order sets, anesthesia using an ERAS specific EHR interface, creating a yellow sheet to identify patients on the pathway, using a pre-op flowsheet to track compliance with clinic components, and documenting mobility. The team aimed to incorporate all variables into existing workflows and then report compliance changes to provide show gaps and improvement.

Order set utilization by surgeon was presented to the team monthly and increased over the course of implementation, however, pre-op VTE chemoprophylaxis was the only process measure directly associated with the order set that showed a significant increase in compliance. This suggests that many of the surgeons were previously placing the appropriate orders, but nursing and anesthesia were not involved so they did not recognize and execute all components. Implementing only an order set will not lead to successful implementation. There must be education and engagement from nursing and anesthesia as well. This is in agreement with the study by Pędziwiatr et al. (2015) that mentions evidence and guidelines alone will not result in effective implementation.

In previous studies, post-operative measures were the most difficult to comply with (Didier Roulin et al., 2017). Pre-implementation data was consistent with these findings, showing that post-op elements needed improvement. Post-op nursing felt like mobility documentation was their biggest challenge. This was overcome through daily education in huddles and sending out an electronic education module. Nursing education happened very quickly and could have been done over a longer course of time. This is in agreement with previous studies that found successful implementation requires continuous education and training prior to full implementation (Pędziwiatr et al., 2015). Nursing also expressed that the process developed for identifying patients with a yellow sheet was too manual and should be more automated in the EHR. Even with these barriers, most post-op processes improved significantly. These results suggest that future implementation should include an automated way to identify patients and educate nurses earlier.

Anesthesia faced difficulties with informing and educating all providers. Similar to the findings of Stone et al. (2018), anesthesia expressed that it would have been easier to use a small subset of CRNAs and anesthesiologists to staff these cases. Anesthesia also felt difficulties adapting to a variety of surgeons and surgeon preferences. This was also mentioned by nursing in previous studies (Pearsall et al., 2015). Some anesthesia providers lacked self-efficacy to veer from the protocol when necessary for the patient. Although not mentioned in the focus group, a major implementation piece for anesthesia was incorporating reminders into their EHR workflow. Anesthesia performance improved significantly for tidal volume compliance, following fluid

administration goals, and reducing the use of Decadron. This indicates that even with some barriers, anesthesia showed reduction in clinical variance for these patients. Similar to findings by Li et al. (2017), even with significant improvement, the components with the lowest compliance are anesthesia protocols related to fluid administration goals and tidal volumes.

Data collection began at the very beginning of the project. This study and others identified that providing a baseline of all process measures to see an impact over time can aid in highlighting an opportunity for better patient outcomes and creating a tension for change (Stone et al., 2018). The project lead collected data through manual chart abstraction and presented it to the team monthly. The pre-implementation data created a shared need for improvement and highlighted the gaps in current performance. All team members cited availability of data as extremely helpful in motivating progress as they saw process measures and clinical outcomes improving. Data was also compared to the AHRQ national benchmark. The data review meetings also provided a forum for the team to discuss any barriers and get feedback.

Characteristics of individuals had minimal codes compared to the other domains, however, the team did express challenges with resistance to change. Surgeons were resistant to giving up control and fully complying with the protocol. Some resistance was due to differing opinions and agreement with evidence supporting each component. Many studies cite that surgeon resistance to change is a barrier, however, it is not clear on how to resolve this issue (Pearsall et al., 2015). In this study, having a non-surgeon, quality physician champion to address these inconsistencies aided in getting surgeon buy in and commitment to the change. Data was also displayed by individual surgeon to assist in identifying gaps and enticing competition. Other challenges were engaging surgeons that are not employed by the hospital, however, these surgeons account for a very small portion of the surgical volume.

Outer setting and intervention characteristics were also coded less frequently. Within patient needs and resources, all team members felt that the ERAS protocol proved to be effective for patient care. Patients were engaged through education in the surgeon's clinic which helped with setting expectations for their hospital stay and recovery. Nursing reported relative advantage of using the ERAS protocol over previous practices. The combined pathway made their job easier because patients were feeling better faster and did not need as much assistance. This is reflected in the reduction of length of stay.

This study offers a combination of clinical effectiveness and implementation recommendations for an ERAS protocol. As evidenced in the data, implementation was successful even though the team identified some barriers. The recommendations for implementation are mostly within the characteristics of the organization in inner setting and having a purposeful implementation process. The most essential pieces of the implementation process are engaging a multidisciplinary team and measuring success to motivate progress. These factors align with previous ERAS implementation studies and change management strategies.

8. Limitations

Several limitations to this study existed. Some limitations were related to data collection and analysis. The project lead measuring compliance through manual chart abstraction rather than visualizing execution was a limitation to the quantitative analysis. Some measures may be charted but not executed and vice versa. A limitation of the qualitative analysis was the experience level of the coders. The quantitative analysis did not include a control group to understand the impact on patients if we did not implement the protocol, so one could argue that there may have been various other influences that impacted the outcomes. Even with these limitations, the results were consistent with previous findings and supportive of compliance with the ERAS protocol leads to improved patient outcomes. Further research could be done using other implementation research frameworks.

Other limitations were related the experiences being unique to this organization and replicating this process at a different organization could be challenging. Time commitment limited the depth of feedback that participants could give. Researchers could not collect feedback at multiple stages in implementation to account for a change in opinions. The focus groups collected were only a reflection from the multidisciplinary team members and not frontline staff. The focus groups were also separated into individual disciplines, rather than the entire team together. Additional focus groups with the entire team could have been conducted to allow for collaboration and feedback. Future research could expand to include multiple stages of implementation, as well as feedback from the frontline staff. Patients could also be involved in future research to understand their impact and engagement with the protocol. Even though focus groups were facilitated by a neutral party, responses could have been influenced by the primary researcher also serving as the project lead. Further studies could expand on the recommendations from this research; however, these limitations must be understood.

9. Conclusion

Ultimately, this study provided support for the clinical effectiveness and implementation of an ERAS protocol. Healthcare professionals face many barriers when implementing standardized practices such as the ERAS protocol, however, barriers can be mitigated through organizational leadership commitment and a structured implementation process. The results of this study show that implementation led to an increase with compliance of following an ERAS protocol and a decrease in length of stay. The experiences from the multidisciplinary team could be used by other organizations as recommendations when considering implementation of an ERAS protocol. In addition, these findings could also support any initiative aimed at reducing clinical variation with a multidisciplinary team.

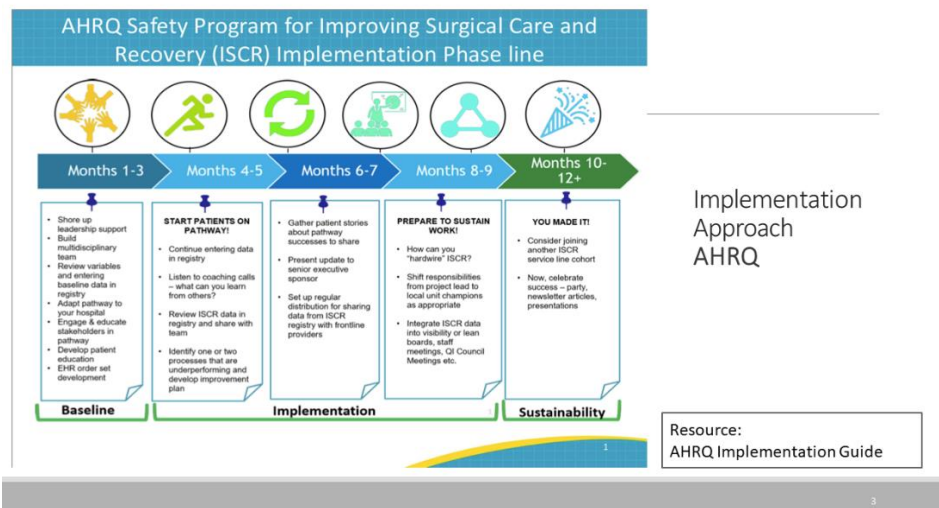
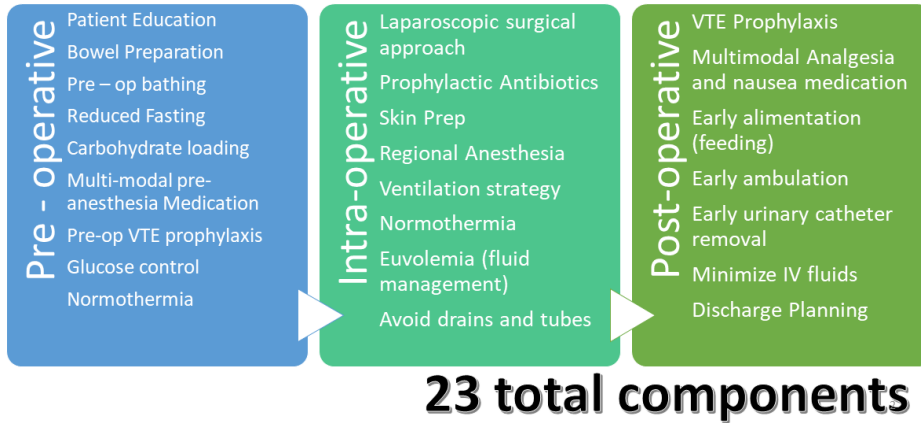
Appendix A. Focus group guide

1. How do you think the program is going?
 - a. Why do you say that?
2. Has there been or do you foresee any barriers to complying with the protocol? Why or why not?
3. What kind of supporting evidence or proof is needed about the effectiveness of ERAS to get staff on board?
4. What level of endorsement or support have you seen or heard from leaders?
 - a. Who are these leaders and how has this affected things so far? Going forward?
5. Who are the key influential individuals to get on board with this implementation and what are they saying about ERAS?
6. How well do you think ERAS will meet the needs of the individuals served by your organization?
 - a. Do you think they will face any barriers in participating?
7. To what extent are new ideas embraced and used to make improvements in your organization?
8. Is there a strong need for this intervention?
9. What have you done (or what do you plan to do) to get a plan in place to implement ERAS?
10. Has ERAS been implemented according to the implementation plan?
 - a. [If Yes] Can you describe this?
 - b. [If No] Why not?
11. Is there anything that could have been done in the planning process and implementation plan to help make ERAS more successful? What are some examples?
12. Has ERAS been effective in your setting?
 - a. Why or why not?

Appendix B. Outcome Objective: Implementation Framework

What is Colorectal Enhanced Recovery Pathway?

Agency for Healthcare Research and Quality (AHRQ) Improving Surgical Care and Recovery (ISCR) program for Colorectal Surgery



Begin tracking baseline compliance data

Months 1-3

- 1 Began with utilizing compliance definitions provided by AHRQ
- 2 Begin tracking data using RedCap survey and AHRQ platform. Data Tracked using Yes/No answers or date and time of occurrence.
- 3 Data will be shared to all team members on a monthly basis to share progress and identify areas for improvement.

Resources: Data Tools

- Colorectal ISCR Data Collection Process
- ISCR Colorectal Variables and Definitions 9.5.18
- LOL ISCR Pathway with compliance definitions

Leadership support and multidisciplinary team

Month 1-3

Position	Description
Surgeon Champion(s)	Assists with guiding pathway decisions based on best evidence
Nursing Champions	Nursing leaders from pre-op, PACU and each surgical floor that patients will land post-operatively to help facilitate any nursing changes.
Anesthesia Champion	Drives anesthesia change in practices
Certified Registered Nurse Anesthetist (CRNA)	Assists in change of anesthesia intra-operative practices
Quality Physician Champion	Helps to facilitate change and drive decision making.
Project Lean Lead / Data Abstractor	Plans and leads team meetings, assists all disciplines with getting on board, collects process and outcome measure data and presents to the team
Pharmacy	Aids in guiding decisions and implementing any medication related changes
Executive Sponsor	Demonstrates support and enthusiasm for the program, and is accessible to address local barriers.

Adapt pathway to your hospital

Months 1-3

Project lead sets up weekly 30 minute meetings to review and agree on clinical components of the pathway

TIPS:

- Send pathway components 1 week prior to the meeting asking for the team to review and come with decisions
- Guide meeting discussion to receive a Yes/No answer for each variable – if cannot reach agreement in 5 mins assign No answer and move forward. Attempt to get decisions for as many variables as possible.
- Work with your surgeon and/or physician champion to find best evidence regarding the variables that you could not get consensus (No variables) and share with the team.

Resources: Pathway Components

- ISCR Colorectal pathway (AHRQ)
- OLOL ISCR Pathway
- Anesthesia Technical Evidence review
- Surgical Technical Evidence Review

Patient and staff education

Months 1-3

Patient education bundle

- Created education booklet from AHRQ resources. Surgeons will distribute these at their clinic
- Ensure clear form for patient to purchase carb loading drink
- Chlorhexidine scrub tip sheet

Staff education

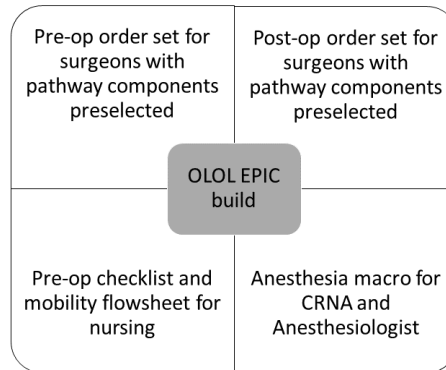
- Created nursing CBL in health stream ([2019 LAKE ERAS - Colon Rectal](#)) to assign to all surgical floor and float pool nurses
- Used fliers to educate on the Johns Hopkins Highest Level Mobility score
- Use of ERAS audit tool to identify patients and document process measures
- Created tip sheet to identify patients
- Hosting clinical education series led by surgeon

Resources: Patient and Staff Education

- Colorectal Surgery PT Ed Booklet
- OLOL Pre-surgery drink form
- Chlorhexidine shower instructions
- Nursing ERAS Education
- Defining ERAS patient
- ERAS Audit tool
- HLM Scoring

Electronic health record development

Months 1-3



- Resources: EPIC Build
- Order sets:
 - Post-op colon rectal surgery pathway
 - Pre-op colon rectal surgery pathway
 - ERAS checklist in pre-op navigator
 - Highest level mobility flowsheet

Other Small Group Meetings

During first 2 months of implementation

	Objectives	Resources
Nursing	<ul style="list-style-type: none"> Include pre-op, PACU and post-op nursing staff Review CBL education modify as needed Identify education resource to assign CBL Review process for identifying patients that are on the pathway – modify as needed Discuss implementing any visual management tools 	<ul style="list-style-type: none"> Patient identification process ERAS Yellow sheet Mobility dry erase boards at end of hall – patient checks off when they walk down the hall
Surgeon clinic staff	<ul style="list-style-type: none"> Review gaps for clinic components – pt education, Ensure clear carb drink, antibiotics, bowel prep, chlorhexidine scrub Work with surgeon and clinic staff to integrate these into process 	<ul style="list-style-type: none"> Colorectal Surgery PT Ed Booklet Pre surgery drink form Chlorhexidine shower instructions

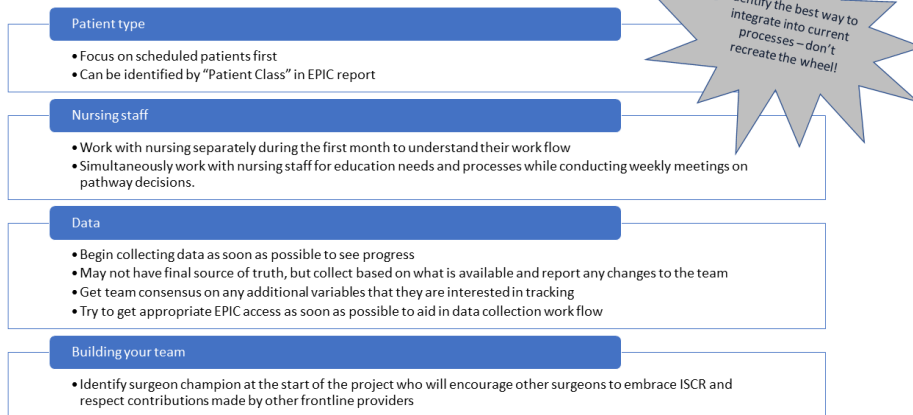
Steering Committee Meeting Review

	Objectives	Resources
Weekly	Meeting 1 <ul style="list-style-type: none"> Present the goal and purpose of this project High level overview of the pathway components Present overview of objectives for the next 3 months. Get consensus to hold weekly meetings for pathway review Send pathway components for review (pathway decision ppt) 	<ul style="list-style-type: none"> Meeting 1 agenda Meeting 1 ppt
	Meeting 2 – 4 (could be more or less) <ul style="list-style-type: none"> Consensus on all pre-operative, intra-operative and post-operative components using Yes/No approach Follow up with evidence support for “No” components 	<ul style="list-style-type: none"> Meeting 2 -4 agenda OLOL ISCR Pathway ppt
	Meeting 5 <ul style="list-style-type: none"> Review EPIC components – order set and nursing flowsheets Set “go live” date 	<ul style="list-style-type: none"> Order set screen shots Nursing flowsheet screen shots
Biweekly	Meeting 6 <ul style="list-style-type: none"> Review/discuss any implementation barriers and outstanding components Present baseline data Review monthly data report process 	<ul style="list-style-type: none"> Data management plan – in data report out template
	Meeting 7 <ul style="list-style-type: none"> Continue bi-weekly meetings to review data and address gaps 	<ul style="list-style-type: none"> Data Report out template Data Report Example

Patient identification process



Lessons Learned



Appendix C. Interview Consent form

ID#: _____

Page 1 of 1
FranU#: 2019-151
LSU IRB#: E11791
Consent date: 10/07/2019

Informed Consent form – Medical Staff Consent Form

- 1) **Study Title:** Barriers and Facilitators Influencing Compliance with Enhanced Recovery After Surgery Protocol: A Qualitative Study
- 2) **Purpose of Project:** The purpose of this project is to study implementation of an Enhanced Recovery After Surgery protocol for colorectal surgery. Barriers and facilitators to implementation will be assessed through semi structured interviews and a validated survey. The study will take place over a period of 6 months. The semi-structured interviews/focus groups will be conducted in month 1 and 6 and surveys will be administered monthly. Interviews will take between 30 -45 minutes and the survey should take approximately 10 minutes.
- 3) **Risks:** No risks greater than experienced in normal work activities. Every effort will be made to maintain the confidentiality of your study records. Files will be kept in secure cabinets to which only the investigator has access
- 4) **Benefits:** This project is designed to improve patient outcomes by implementing a standardized ERAS protocol. Studying implementation will help project leads to better understand the barriers and facilitators to carrying out ERAS components.
- 5) **Alternatives:**
 - a) The other choice you have (alternative) is not to be in the project.
 - b) Choosing not to participate will in no way affect your standing at Our Lady of the Lake Regional Medical Center
- 6) **Investigators:** the following investigators are available for question about this study, M-F, 8:00 Am – 4:30 pm, Paige Boudreaux, 337-256-6137; Dr Craig Harvey, PhD, P.E., 225-578-8761; Dr Dianna Hamer, PhD, 225-757-4092.
- 7) **Performance Sites:** Our Lady of the Lake Regional Medical Center
- 8) **Number of Subjects:** There will be 1-3 participants per interview/focus group and surveys will be administered to a maximum of 100 participants per month
- 9) **Subject Inclusion:** Individuals between the ages of 18 and 65 who do not report psychological or neurological conditions and are current employees of Our Lady of the Lake.
- 10) **Right to Refuse:** Subjects may choose not to participate or to withdraw from the study at any time without penalty or loss of any benefit to which they might otherwise be entitled. You may refuse to be in this project (participate) or stop being in the project (withdraw from the study) at any time without risking your position at Our Lady of the Lake.
- 11) **Privacy:** Results of the study may be published, but no names or identifying information will be included in the publication. There will be no identifying information collected in this study.
- 12) **Signatures:**

The study has been discussed with me and all my questions have been answered. I may direct additional questions regarding study specifics to the investigators. If I have questions about subject's rights or other concerns, I can contact Dennis Landin, Chairman, LSU Institutional Review Board, (225) 578-8692, irb@lsu.edu, or www.lsu.edu/research as well as Franciscan Missionaries of Our Lady University (FRAN U) IRB, Michael Dreznick at 225-214-6982, or IRB@fran.edu. I agree to participate in the study described above and acknowledge the researcher's obligation to provide me with a copy of this consent form if signed by me.

Subject Signature: _____ Date: _____

The study subject has indicated to me that he/she is unable to read. I certify that I have read this consent form to the subject and explained that by completing the signature line above, the subject has agreed to participate.

Signature of Reader: _____ Date: _____

Appendix D. IRB Approval



ACTION ON EXEMPTION APPROVAL REQUEST

To: Craig Harvey
Industrial Engineering

From: Dennis Landin
Chair, Institutional Review Board

Date: August 5, 2019

Re: IRB# E11791

Title: Barriers and Facilitators Influencing Compliance with Enhanced Recovery After Surgery Protocol: A Qualitative Study

Institutional Review Board
Dr. Dennis Landin, Chair
130 David Boyd Hall
Baton Rouge, LA 70803
P: 225.578.8692
F: 225.578.5983
irb@lsu.edu
lsu.edu/research

New Protocol/Modification/Continuation: New Protocol

Review Date: 8/5/2019

Approved X **Disapproved**

Approval Date: 8/5/2019 **Approval Expiration Date:** 8/4/2022

Exemption Category/Paragraph: 2b

Signed Consent Waived?: No

Re-review frequency: (three years unless otherwise stated)

LSU Proposal Number (if applicable):

By: Dennis Landin, Chairman 

**PRINCIPAL INVESTIGATOR: PLEASE READ THE FOLLOWING –
Continuing approval is CONDITIONAL on:**

1. Adherence to the approved protocol, familiarity with, and adherence to the ethical standards of the Belmont Report, and LSU's Assurance of Compliance with DHHS regulations for the protection of human subjects*
2. Prior approval of a change in protocol, including revision of the consent documents or an increase in the number of subjects over that approved.
3. Obtaining renewed approval (or submittal of a termination report), prior to the approval expiration date, upon request by the IRB office (irrespective of when the project actually begins); notification of project termination.
4. Retention of documentation of informed consent and study records for at least 3 years after the study ends.
5. Continuing attention to the physical and psychological well-being and informed consent of the individual participants, including notification of new information that might affect consent.
6. A prompt report to the IRB of any adverse event affecting a participant potentially arising from the study.
7. Notification of the IRB of a serious compliance failure.
8. **SPECIAL NOTE: When emailing more than one recipient, make sure you use bcc. Approvals will automatically be closed by the IRB on the expiration date unless the PI requests a continuation.**

* All investigators and support staff have access to copies of the Belmont Report, LSU's Assurance with DHHS, DHHS (45 CFR 46) and FDA regulations governing use of human subjects, and other relevant documents in print in this office or on our World Wide Web site at <http://www.lsu.edu/irb>

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[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(95\)90643-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(95)90643-6/fulltext)

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Vita

Paige Marie Boudreaux was born in New Iberia, LA in 1995. She received her bachelor's degree in Industrial Engineering at Louisiana Tech University in May 2017. After graduation she began working at Century Link in a leadership development program. She started her work towards the master's degree in Industrial Engineering in August 2018. She received the Donald W. Clayton Graduate Engineering Excellence Award and worked as a graduate assistant. In June 2019 she began working at Our Lady of the Lake hospital as a lean lead while finishing her master's degree and plans to receive her master's degree in May 2020.