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# Final Scholarly Project: Enhanced Recovery After Surgery (ERAS) Guidelines for Pancreaticoduodenectomies

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## **Final Scholarly Project: Enhanced Recovery After Surgery (ERAS) Guidelines for Pancreaticoduodenectomies**

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**Final Scholarly Project: Enhanced Recovery After Surgery (ERAS) Guidelines for  
Pancreaticoduodenectomies**

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Department of Nursing, Otterbein University

In Partial Fulfillment of the Requirements for the Degree Doctor of Nursing Practice

2024

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We have no conflicts of interest to disclose.

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### **Abstract**

A pancreaticoduodenectomy, or Whipple procedure, is the only curative option for pancreatic cancer. For those eligible for tumor resection, the Whipple procedure is a difficult surgery for both the patient and provider. Complications following pancreaticoduodenectomy are numerous and include infection, delayed gastric emptying, high hospital costs, and pancreatic fistulas. Enhanced Recovery After Surgery (ERAS) protocols exist to provide evidence supporting standardization of practices that lead to the improvement of these patient outcomes. An ERAS protocol for the pancreaticoduodenectomy, first established in 2012, is inconsistently implemented in healthcare facilities. Researchers collected data involving the use of the Whipple procedure ERAS guidelines in improving the following three outcomes: length of stay, incidence of incisional infection, and rates of delayed gastric emptying. After receiving approval from hospital administration, the project team will gather data from previous patients and educate staff members regarding the upcoming clinical practice change. A trial implementation period will last one year, or until 50 patients are enrolled. Following proper ERAS execution, investigators will again collect data and compare results in the three chosen outcomes. The project team expects that implementation will demonstrate an improved incidence rate of infection, delayed gastric emptying, and shorter length of stay following the pancreaticoduodenectomy. If the desired results are not realized, additional research will be necessary to investigate causative factors and ways to improve current practice.

*Keywords:* pancreaticoduodenectomy, Whipple, Enhanced Recovery After Surgery, ERAS, length of stay, delayed gastric emptying, infection

## **Final Scholarly Project: Enhanced Recovery After Surgery (ERAS) Guidelines for Pancreaticoduodenectomies**

### **Introduction**

Cancer affects millions of people across the world. According to McGuigan et al. (2018), pancreatic cancer is one of the most lethal forms of cancer, accounting for an estimated 432,242 deaths annually across the globe. Additionally, in some countries, the five-year survival likelihood is as low as 2%. Pancreatic cancer is the 14th most common cancer globally, but the incidence rates are increasing by approximately 1.03% annually in the United States (U.S.) (Saad et al., 2018). With an increasing amount of the U.S. population experiencing pancreatic cancer diagnoses, the number of people seeking treatment for the disease is also increasing. The treatment options available for pancreatic cancer including the pancreaticoduodenectomy, or Whipple procedure, are complex and present numerous obstacles for both the patient and providers.

The development of Enhanced Recovery After Surgery (ERAS) protocols in surgery has dramatically altered how patients receive care before, during, and after a procedure. Altman et al. (2019) describe how in the early 2000s, Henrik Kehlet, a Danish colorectal surgeon, began challenging traditional surgical approaches with new techniques supported by high-level evidence. Kehlet led a new organization, The ERAS Society, comprised of surgeons, anesthesiologists, nurses, and other health professionals, to develop protocols for various procedures. These protocols aim to improve surgical quality and lower complication rates and lengths of stay by decreasing the stress of surgery and maintaining the patient's normal physiology as much as possible. (Altman et al., 2019). The implementation of ERAS guidelines

for Whipple procedures could greatly alter the success of the surgery as a treatment option in pancreatic cancer.

### **Background**

Treatment of pancreatic cancer includes surgery, chemotherapy, radiation, and palliative care. Surgery is the only curative treatment currently available in patients with pancreatic cancer (Brunner et al., 2019). Patients often develop vague symptoms during the early stages of the disease, and the cancer can progress quickly without detection. Aggravating the high mortality rates of the disease is the caveat that very few patients are eligible for surgery due to the strict eligibility criteria and the rapid disease progression that can make the primary tumor unresectable (Brunner et al., 2019). The surgical procedure of choice for resectable pancreatic tumors is the pancreaticoduodenectomy.

Although one of the only treatments for pancreatic cancer, the Whipple surgery is complicated for patients and providers. Improved by Dr. Allen Whipple in 1940, the Whipple procedure is a complex surgery that involves the removal of the pancreatic head, gallbladder, duodenum, a portion of the bile duct, and sometimes, a portion of the stomach (D’Cruz et al., 2022). The resection of such a large portion of the abdomen could lead to significant complications, extended hospital stays, and high costs. To ensure a better likelihood of a successful procedure and recovery, vigilant and highly educated interdisciplinary professionals must work together to utilize the best evidence available surrounding Whipple procedures.

### **Significance of the Problem to Nurse Anesthesia**

#### **Nurse Anesthesia and Enhanced Recovery After Surgery Protocols**

Before surgery, anesthesia and surgeons should work to optimize the patients medically. As a part of most ERAS protocols, the preoperative component consists of patient education,

fasting recommendations, bowel preparation, postoperative nausea and vomiting (PONV) prophylaxis, venous thromboembolism prophylaxis, and infection prevention (Tippireddy & Ghatol, 2023). Anesthesia teams can work with surgeons to ensure optimization before the day of surgery by facilitating clear communication between the patient and providers. The anesthetist can speak with the patient preoperatively to set realistic expectations regarding pain and the anesthetic plan. Although the surgeon will hold discussions regarding the surgery and postoperative goals, the anesthetist may also reiterate information and encourage patients about the procedure prior to relocating them to the operating room (OR).

Once in the OR, anesthesia providers will continue to impact the ERAS pathway directly. The intraoperative ERAS component includes providing multi-modal non-opioid pain medication, antiemetics, antibiotics, lung-protective ventilation, utilizing regional anesthesia, maintaining normothermia and euvolemia, and minimizing indwelling devices (Tippireddy & Ghatol, 2023). Using a multi-modal approach and limiting volatile anesthetics, the anesthetist can better prevent PONV and pain following surgery. Madrid et al. (2016) note that avoiding hypothermia reduces infection at surgical sites, cardiovascular complications, and surgical blood loss. Additionally, Tippireddy and Ghatol (2023) found that a euvolemic state decreases renal and pulmonary complications, accelerates bowel function return, and reduces infections. The anesthesia provider can positively affect the patient's postoperative status through the decisions made during the intraoperative phase.

The anesthesia team remains responsible for the patient after the surgery as well. Altman et al. (2019) summarize the postoperative components of the ERAS protocol to include early enteral feeding, early mobilization, and continued antiemetic and analgesic coverage. Although anesthesia providers do not routinely partake in the care of inpatients following surgery directly,

the decisions made preoperatively and intraoperatively last through this period as well. With controlled pain and nausea, patients will progress to mobilizing and eating quicker (Altman et al., 2019). Recent studies show that wound healing, infection rates, ileus rates, thromboembolic complications, and return of muscle function improve when patients meet these postoperative goals (Tippireddy & Ghatol, 2023). The anesthesia provider has a responsibility to properly implement many steps of an ERAS protocol to ensure positive outcomes.

### **Nurse Anesthesia and Pancreaticoduodenectomies**

Every surgery or procedure needing anesthesia requires vigilance and planning from the surgical team. However, some surgeries, such as the pancreaticoduodenectomy, are associated with increased morbidity and complexity despite proper preparation (Karim et al., 2018). D'Cruz et al. (2022) note that the considerable difficulties faced during a Whipple procedure are due to the intraabdominal dissection and repair of the digestive system that is necessary. Major complications stemming from this reconstruction include delayed gastric emptying (DGE) and surgical site infection (Karim et al., 2018). After the success of ERAS protocols in colorectal surgery, the ERAS Society expanded the protocols to include other procedures, such as the Whipple procedure, to decrease the morbidity of this complicated surgery (Altman et al., 2019).

Although no ERAS pathways are exactly alike, anesthesia providers are responsible for many of the same components before, during, and after a Whipple procedure as with any surgery. Avoiding hypothermia, using wound catheters in regional anesthesia, and preventing infections and thromboembolic events are just some of the examples of ERAS items that anesthesia can directly impact (Melloul et al., 2020). The full cooperation of the anesthesia team is necessary to improve outcomes with the ERAS protocol for pancreaticoduodenectomies.



## **Problem Identification**

### **Problem Statement**

In a population plagued with low survival rates, patients with pancreatic cancer are limited regarding treatment options. For patients with primary tumors eligible for resection, the Whipple procedure is an intricate surgery with many complications; nevertheless, it could extend the five-year survival rate, according to Poruk (2021). ERAS protocols are an evidence-based and multidisciplinary approach to improve complication rates, length of stay (LOS), and costs after various types of surgery (Altman et al., 2019). An ERAS protocol for pancreaticoduodenectomies, initially developed in 2012, gives a comprehensive and multifaceted approach to the best perioperative care for this population; however, not all institutions and providers are familiar with the approach (Lassen et al., 2012). When properly implemented, an ERAS guideline for pancreaticoduodenectomies, based off the official ERAS protocol, can lead to improved outcomes for patients and hospital systems.

### **PICO(T) Question**

Because patients with pancreatic cancer face immense difficulty during their treatment, improvements to the Whipple procedure can greatly contribute to a better quality of life following surgery. To find evidence supporting the implementation of ERAS guidelines for pancreaticoduodenectomies, the following PICO(T) question is utilized: In patients with pancreatic cancer undergoing a pancreaticoduodenectomy (**P**), how does the implementation of evidence-based practice ERAS guidelines (**I**), compared to traditional management (**C**), affect the length of hospital stay and rates of delayed gastric emptying and incisional infection (**O**)?

### **Project Objectives**

Evidence-based practice (EBP) requires the latest research to support clinical practice changes. In a complex surgical procedure such as the pancreaticoduodenectomy, current studies document the positive impact of EBP guidelines inspired by an ERAS protocol (Melloul et al., 2020). Initially, experts cautiously developed ERAS protocols for the Whipple because of the complexity of the surgery; however, early studies demonstrated its feasibility and safety (Li et al., 2021). A standardized ERAS guideline is essential to conduct further multicenter studies and use the most effective strategies to improve outcomes.

The overall goal of the Doctor of Nursing Practice (DNP) project is to encourage the implementation of EBP ERAS guidelines for the Whipple procedure based on the newest evidence-based research supporting its use. Additionally, the DNP project will compare the application of the guidelines to traditional methods of caring for patients undergoing the Whipple procedure to determine its clinical and financial value. The objectives of the doctoral paper are as follows:

1. Develop ERAS EBP guidelines in patients undergoing pancreaticoduodenectomy procedures;
2. Develop a comprehensive plan to implement the ERAS guidelines in patients undergoing pancreaticoduodenectomies;
3. Develop a comprehensive plan for how to monitor and measure compliance and the effectiveness of the implementation of the ERAS guidelines for eligible patient cases;
4. Develop a comprehensive plan for how to adjust the guidelines if the outcomes are less than desirable or expected.

## **Literature Search and Analysis**

A literature search is necessary to gather evidence supporting a practice change. In 2012, The Enhanced Recovery After Surgery Society, an international non-profit organization comprising various health professionals, published the first ERAS protocol for the pancreaticoduodenectomy (Lassen et al., 2012). Although clinical pathway programs for the Whipple procedure showed encouraging results in the past, they were all varying and did not report a comprehensive prospective protocol (Lassen et al., 2012). The development of the first ERAS protocol for the Whipple procedure allowed for unified guideline development and validation across hospital systems worldwide, with the hope that future studies would demonstrate the reduced morbidity, LOS, and hospital costs associated with its use. The literature search conducted for the project summarizes and analyzes the results of ERAS implementation for pancreaticoduodenectomy since its development in 2012.

### **Literature Search Strategy**

#### ***Databases***

Otterbein University's OneSearch database through the Courtright Memorial Library was utilized to begin the literature review. OneSearch allows the researcher to access the library's resources, including prominent databases such as Cumulative Index to Nursing and Allied Health Literature (CINAHL), the Cochrane Library, and PubMed, in one all-inclusive program (Otterbein University, 2023). OneSearch displays journals, books, and other multimedia and permits using keywords and Boolean operators to effectively narrow results to the desired topic. Using the aforementioned PICO(T) question to develop primary search terms, the project team skimmed and evaluated current evidence for its relevance and strength of contribution to the project matter.

### ***Search Terms***

The initial search using the key terms and Boolean operators “ERAS OR Enhanced Recovery After Surgery OR ERAS protocol AND pancreaticoduodenectomy OR Whipple” yielded 66,008 results on OneSearch. The researcher limited the literature to full-text versions to narrow it further, resulting in 33,859 results. Additionally, filtering to only English language articles displayed 29,423 articles. Due to a large number of articles and many that were irrelevant to the desired topic, the researcher limited the key terms to be included in the “subject” of each article. Doing so drastically reduced the total search results to 106 pieces.

Of the 106 articles discovered during the literature search, 26 were duplicate copies. One article did not include the trial results because the trial was still in process. After closer evaluation, 53 articles were deemed unrelated to the subject matter due to discussing surgeries other than the Whipple procedure or a lack of ERAS implementation. Nine articles were discarded as they provided suggestions for improvement to the ERAS protocol but did not disclose the implementation outcomes. Although they discussed the development of the ERAS protocol, two articles were eliminated because they were outdated recommendations compared to the newest 2019 protocol. Finally, seven articles were lower-level evidence or already included in more extensive systematic reviews. Therefore, their inclusion was not necessary. After reviewing the 106 original articles, eight articles were extensively analyzed and synthesized for evidence.

### **Literature Analysis**

#### ***ERAS Guideline Development***

Though the original ERAS protocol for pancreaticoduodenectomies were published in 2012, Melloul et al. (2020) updated the protocol more recently as part of the ERAS Society. The

article is a systematic review and expert opinion piece. The authors included 314 articles, all related to the Whipple procedure, in English, and either a meta-analysis, randomized controlled trial (RCT), or prospective cohort study. The original search resulted in 8,368 articles before the authors narrowed it for relevancy. The authors analyzed the selected studies and utilized them to develop an ERAS protocol for the pancreaticoduodenectomy consisting of 27 items and recommendations for each (see Appendix A).

Of the 27 items in the ERAS protocol, eight received a score classifying them as high-level evidence and strong recommendations. Therefore, it is pertinent to include these eight recommendations in any ERAS guideline for the Whipple procedure: avoid preoperative biliary drainage unless decompression is needed; preoperative nutrition counseling is only recommended for patients with severe weight loss; there is no need for perioperative oral immunonutrition; start low-molecular-weight heparin two to 12 hours following surgery and continue until discharge, or longer for those with cancer; give antibiotics less than 60 minutes before the incision; continuous wound infiltration is an acceptable alternative to an epidural; hypothermia should be avoided; and drain removal is appropriate after 72 hours for those with amylase levels less than 500 units per liter (Melloul et al., 2020). Many of the policies presented by the ERAS Society in this article align with previous ERAS protocols, highlighting the efficacy of implementation in seeing improved outcomes as previously studied in surgeries that have long utilized ERAS protocols.

### ***Outcomes***

After reviewing the newest ERAS protocol for the pancreaticoduodenectomy, the project team began to analyze the articles that included the ERAS implementation as an independent variable, compared to “traditional approaches.” Traditional approaches refer to the typical

management of a patient undergoing a pancreaticoduodenectomy without the hospital system adopting the standardized ERAS approach. The dependent variables often studied include rates of complications such as pancreatic fistula, DGE, and infection, length of hospital stay, mortality, and readmission and reoperation rates. The project focuses on how ERAS implementation will affect three specific outcomes: LOS, DGE, and incisional infection. Although the newest protocol of ERAS for the Whipple procedure came in 2019, a few of the meta-analyses and systematic reviews available were completed before 2019 using the 2012 protocol. The changes between the two editions were not drastic; therefore, studies from before 2019 were still accepted.

### **Length of Stay**

Staying in the hospital overnight or for multiple days is an unfortunate but often necessary result of surgery. In addition to the increased time spent in the hospital, a longer LOS will directly increase patient costs. Since their development, a mainstay of ERAS protocols has been the goal to reduce the LOS and hospital costs associated with surgery (Melloul et al., 2020). LOS is defined as the span between the day of surgery and discharge from the facility (Ji et al., 2018).

The evidence largely supports implementing an ERAS guideline for pancreaticoduodenectomies to decrease hospital LOS. Each article analyzed in the literature review found a statistically significant decrease in LOS for the patients that received the ERAS protocol compared to the existing variable techniques (Cao et al., 2019; Ji et al., 2018; Kuemmerli et al., 2022; Li et al., 2021; Noba et al., 2023; Sun et al., 2020; Wang et al., 2020). Additionally, hospital costs in facilities in the United States, China, Europe, and Canada, were

significantly reduced with the ERAS approach (Noba et al., 2023). The patient and providers would benefit greatly from reduced length of stay following the Whipple procedure.

### **Delayed Gastric Emptying**

DGE is a common complication of pancreaticoduodenectomy. The most used criteria to define DGE is the International Study Group of Pancreatic Surgery's (ISGPS) recommendation that "patients needing maintenance of a nasogastric tube (NGT) for greater than three days, needing to reinsert the NGT for persistent vomiting after postoperative day three, or unable to tolerate a solid diet by postoperative day seven, should be considered DGE" (Ji et al., 2018, p. 1668). DGE is a primary cause of delayed recovery, requiring further intervention and higher costs (Noba et al., 2023).

In previous studies, the evidence on whether an ERAS protocol for pancreaticoduodenectomy will lower rates of DGE is inconclusive. However, five of the seven articles in the literature review demonstrated reduced incidence (Ji et al., 2018; Kuemmerli et al., 2022; Noba et al., 2023; Sun et al., 2020; Wang et al., 2020). In the umbrella review by Li et al. (2021), the authors analyzed ten studies and found six that investigated delayed gastric emptying; although two of the articles included showed no difference between the two intervention groups, the other four showed a decreased rate of DGE. Cao et al. (2019) wrote one of the studies included in the umbrella review that demonstrated no significant difference ( $p = 0.36$ ). Overall, the evidence still favors DGE incidence decreasing with the Whipple procedure ERAS protocol.

### **Incisional Infection**

Following surgery, infection is a possible complication. Each study in the review used the author's own definitions to classify infection. The project team defines incisional infection to include an elevated white blood cell count and need for antibiotics with reasonable suspicion that

the surgical site is the culprit, confirmed by wound cultures. ERAS protocols aim to prevent infection by including antimicrobial prophylaxis.

Although the authors did not always explicitly state incisional infection as an outcome, there is still support for the reduced incidence of infection with the Whipple procedure ERAS protocol. Incisional infection rates were lowered in two studies (Cao et al., 2019; Wang et al., 2020). In the four remaining studies where incisional infection was not explicitly mentioned, overall complication rates were lowered (Ji et al., 2018; Kuemmerli et al., 2022; Li et al., 2021; Noba et al., 2023). Ji et al. (2018) did not define what “abdominal incision” referred to, whether it might be an intra-abdominal infection or an infection on the abdomen at the incision site; however, the rate of abdominal infection was shown to be lower in the ERAS group ( $p = 0.006$ ). Lastly, one of the articles found no statistical significance between the two groups regarding incisional infection (Sun et al., 2020). Although the studies could define the outcome of infection more clearly, the overall decreased complication rate and majority consensus on a reduced incidence of infection supports the use of an ERAS protocol for the Whipple procedure.

### **Summary of Literature Review**

For eligible pancreatic cancer patients, the Whipple procedure is a surgery that can significantly impact their quality and length of life. Unfortunately, the morbidity and mortality associated with the procedure make it a challenge for patients and providers alike. Introducing an ERAS guideline for pancreaticoduodenectomies can potentially improve patient outcomes, such as LOS, DGE incidence, and incisional infection rates. By conducting and analyzing the literature surrounding ERAS protocol effectiveness, researchers can conclude that the evidence supporting implementation is significant.



The ERAS Society supplies recommendations for 27 items, including preoperative, intraoperative, and postoperative tasks (Melloul et al., 2020). The literature search completed by the project team includes seven articles supporting the use of the recommendations included in the article by Melloul et al. (2020). All studies included in the review are level I evidence, and no article demonstrates a risk to implementation. Although the studies do not include many RCTs due to the subject nature and inability to blind the experiment correctly, the sample sizes are large and inclusive of the pancreaticoduodenectomy population. Implementing an ERAS guideline for the Whipple procedure will likely improve the outcomes of LOS, DGE, and incisional infection compared to traditional approaches.

### **Project Design**

#### **Evidence-Based Practice Model**

To successfully construct a doctorate-level final scholarly project, the project investigator chooses a model that helps guide the project. The model should focus variables and define a viewpoint utilized to analyze and interpret data and variable assumptions (Sacred Heart University, n.d.). The Johns Hopkins Evidence-Based Practice (JHEBP) model is a popular and significant tool for nurses that guides practitioners through the EBP process. The framework is frequently revised using feedback from clinical and academic users to highlight EBP as an activity to enhance patient care and team collaboration (Dang et al., 2022). Permission to use the Johns Hopkins model and tools was obtained via the Copyright Permission Form on June 29, 2023, as indicated in Appendix B. Appendix C depicts the most recent Johns Hopkins EBP model that emphasizes the importance of reflection and learning to inspire additional inquiry. Throughout the final scholarly project, the author and advisors continuously inquired, adopted

best known practices, and reflected; therefore, the JHEBP model is the most appropriate and helpful framework to adopt to establish an ERAS guideline for pancreaticoduodenectomies.

## **Methods**

The JHEBP model contains the PET process: Practice Question, Evidence, and Translation (Dang et al., 2022). Melnyk & Fineout-Overholt (2019) clarify that although this process and the steps within appear linear, discovery in one phase may lead to the adaptation and revision of work completed in a previous phase. Appendix D displays the specific steps in each part of the EBP procedure, and they are discussed in greater detail below.

### ***JHEBP: Practice Question***

The practice question is the foundation of an effective EBP project. Dang et al. (2022) describe the practice question phase and the steps necessary to facilitate success, including assembling a team, establishing leadership, describing the problem, and identifying stakeholders. For the final scholarly project, the clinical problem is the inconsistent compliance with EBP guidelines for patients undergoing pancreaticoduodenectomies at a level one trauma center in an urban setting. The leadership team for the project includes this graduate nursing student, a nurse anesthesia program director who will serve as a project team leader, and other nursing faculty from a graduate nursing program. Stakeholders for the clinical problem include the patients, hospital staff in the perioperative area and inpatient floors, hospital administration, and equipment and pharmaceutical supply coordinators.

### ***JHEBP: Evidence***

In the Evidence stage, project members search, appraise, summarize, and synthesize current and relevant literature pertaining to the clinical problem to develop best practice recommendations. Learning to do so effectively requires knowledge and an aptitude for locating

and retrieving nursing literature (Dang et al., 2022). The findings and summarization of the literature review of the outcomes associated with implementing an ERAS guideline for Whipple procedure patients are discussed extensively in the Literature Synthesis and Analysis portion of the paper and in Appendix A, the evidence review worksheet.

### ***JHEBP: Translation***

The final phase of the EBP PET process, according to the JHEBP model, is the translation into practice. An essential component of this stage is clinical reasoning; Dang et al. (2022) define clinical reasoning as a set of cognitive processes that require professionals to recognize the relevance of the evidence and how it relates to the specific patient population. The Translation and Action Planning Tool, shown in Appendix E, assists with creating specific recommendations and will be used to assess the feasibility and likelihood of acceptance within an organization (Dang et al., 2022). Additionally, project team leaders will use both quantitative and qualitative data collection to accurately audit outcomes and compliance with implementation.

### **Quantitative Data**

Similar to many of the studies included in the literature review, the quantitative data collected during the implementation process of the project will determine the ERAS guideline's success in improving the targeted outcomes of LOS, rates of DGE, and rates of incisional infection. Therefore, it is pertinent to collect information about the rates of complications and LOS both before and after implementation. Electronic healthcare records of patients undergoing pancreaticoduodenectomies will be analyzed before implementation and then again after implementation. After the results are compiled, the project team will compare the data to conclude whether the intervention was a worthwhile use of time and resources to improve patient

outcomes. Additionally, the medical records will be evaluated to track compliance with key components of the ERAS guideline to ensure that the data accurately represents the proposed items.

### **Qualitative Data**

Qualitative data is another valuable tool for assessing the advantages and disadvantages of a proposed change in practice. Those providing care and managing the patient during this time will greatly impact the project's success. Therefore, it is crucial to understand the thoughts and behaviors of those contributing their time and resources. If the qualitative data reveals that most stakeholders find the guidelines too taxing or they are not fully compliant, further education or adjustments will be necessary. The qualitative data will be collected using a Likert scale, as seen in Appendix F, allowing participants to rate statements from "strongly disagree" to "strongly agree."

### **Implementation Plan**

Project leaders assembled a three-part implementation plan. The three phases include pre-implementation, trial implementation, and post-implementation data collection. The primary project team developed the three stages of plan execution but will involve other stakeholders throughout.

#### ***Pre-Implementation Phase***

Before investing significant time and resources, the project team must gain approval to pursue a practice change. To obtain hospital administration consent, the clinical problem is identified and justified through EBP question refinement and research. Hospital administration must understand the benefits to the patient and hospital system, potential costs or savings, and what is expected of them throughout the project. Institutional Review Board (IRB) approval is

also necessary before further action. Once they grant approval, equipment and pharmaceutical supply coordinators are contacted to ensure proper supplies and medications will be available during implementation. Additionally, these stakeholders will agree to meet once every month with the project team during the pre-implementation phase to discuss developments and potential limitations.

The first phase of project implementation also includes the official development of a facility-specific ERAS guideline for pancreaticoduodenectomies. Although all 27 items supplied by Melloul et al. (2019) are evidence-based and expert-recommended, limiting the guideline to only the items with the strongest evidence and highest recommendations narrows the list to eight items. The official ERAS guidelines for the Whipple used in the project and submitted to the IRB are shown in Appendix G. Education regarding these items is provided for surgeons, nurses, and anesthesia providers prior to the beginning of the trial implementation phase.

A team of staff members from the Quality Improvement (QI) department is assigned to data retrieval before implementation. The quantitative data discussed previously, including LOS and DGE and infection rates, is noted from the medical records of the last 50 patients who have previously undergone Whipple procedures at the facility. The average LOS and complication rates are calculated and used to evaluate the effectiveness of the guideline following implementation.

### ***Trial Implementation Phase***

After adequate time for education, an implementation trial period date is decided upon. For every patient who undergoes a pancreaticoduodenectomy, the ERAS guidelines should be followed as closely as possible. Two items, avoiding preoperative biliary drainage and oral immunonutrition, require the doctors to omit an order they might have previously decided to

include in the plan of care. The other six items require the providers to place the correct orders, the nurses to execute the orders correctly, and the anesthesia providers or surgeons to use clinical judgment during the procedure. If a patient scenario warrants deviation from the provided ERAS policy, staff members are asked to provide documentation of why variation was necessary.

During this trial period, the stakeholders will meet monthly to discuss thoughts and observations on the process thus far. Trial implementation continues until at least 50 patients have received ERAS guideline care for their pancreaticoduodenectomy, or one year, if enough operations are not performed within that time. A 50 patient sample size was derived from the minimum number of participants included in previous meta-analyses.

### ***Post-Implementation Phase***

Following the trial phase, more data collection is necessary. ERAS guideline implementation for Whipple procedures will continue, but the QI department team will only review the charts of the first 50 patients during the trial period. The same quantitative data from the pre-implementation phase is collected. After the data is complete, average times for LOS and complication rates for DGE and incisional infection are compared, with the expectation and goal of the ERAS patients demonstrating a shorter LOS and fewer complications. Additionally, the qualitative data discussed previously, used to determine stakeholder acceptance and understanding of the guideline, is collected. Compliance is also documented for each of the eight ERAS items.

The project team will use the data to understand if the ERAS guideline successfully improved the desired outcomes. The project team determines a threshold of 75% compliance to be sufficient in validating the data based on the average compliance recorded in previous meta-analyses. If one item scores consistently lower in compliance, the project team can investigate

the cause. Additionally, staff responses to the Likert survey can help initiate discussions about necessary improvements. The findings of the project are disseminated throughout the facility using email, bulletins, and staff meetings. If the outcomes are less than desirable, the project team will reevaluate and identify the crucial next steps to adjust and improve the plan.

### **Budget and Timeline**

Although the new ERAS guideline brings attention to eight essential aspects of the surgical experience, the project does not require a substantial budget for preparation. To account for approximately 50 hours of planning and research at a rate of \$121 an hour, the nurse anesthetist project member will budget \$6,050 in operational costs (ZipRecruiter, n.d.). The meetings between the remaining project team and significant stakeholders will occur during regular business hours, so additional hourly pay is unnecessary for those involved. The QI department will also complete data collection during typical work hours. Education for the staff will occur during monthly staff meetings and through bulletins and emails. The capital costs of preparation include one ream of paper and one cartridge of ink necessary to print out education materials, priced at \$8.25 and \$51.89 respectively (Staples, n.d.). The total cost of preparation for ERAS implementation is \$6,110.14 and is displayed in Appendix H.

The ERAS guideline implementation itself is relatively inexpensive. During the trial implementation phase, supply coordinators will need to allow for the possibility of 50 patients needing an NGT and enteral nutrition if severe weight loss has occurred. The likelihood that all 50 of the patients in the trial will experience enough weight loss to qualify for preoperative nutrition is low, but the equipment must be available. Prices vary greatly on NGTs and tube feeding, but \$200 per tube and \$25 per bag of tube feed is plausible based on the prices listed by VitalityMedical (n.d.). For 50 patients, each receiving one bag prior to surgery, the total cost

could be up to \$11,250 in capital costs. However, the hospital supply will likely not be affected this drastically. With such a small sample size and by buying in bulk through typical medical suppliers, the actual need is probably much lower. Each of the remaining ERAS items requires either no cost, as orders are omitted, or does not add to the typical cost of patient care. Patients routinely receive antibiotics before surgery, low-molecular-weight or unfragmented heparin daily while in the hospital, and each OR is equipped with forced-air warming devices to prevent hypothermia. The proposed total budget necessary for the project is \$17,3601.14 or less, as indicated in Appendix H.

The timeline for all three phases of implementation will vary. The pre-implementation phase contains the project's research, analysis, and guideline development. Because these are already completed, the pre-implementation phase should be completed within two months. The timeframe will give the project team and stakeholders two months to meet and agree on expectations and limitations, as well as the QI department to investigate the charts of the last 50 patients who received Whipples at the facility. The trial implementation phase timeline is difficult to estimate as it depends mainly on the number of patients seeking the procedure. If fifty patients are not enrolled within one year, the project team can begin the post-implementation phase without reaching the patient goal. The post-implementation phase will also take place over two months. Although data collection and education should be completed within these two months, the refinement and reintroduction of the project may continue for some time after the initial completion. Collectively, the initial three-phase implementation plan should require, at most, 16 months to accomplish.



### **Outcomes and Analysis**

During the post-implementation phase, project investigators will use the data collected from the QI department chart review to determine the statistical significance of ERAS implementation on the outcomes of hospital LOS, DGE, and incisional infection rates. By comparing data from patients who did not receive the ERAS guideline prior to project implementation with the patients who were enrolled in the trial, a p-value can be computed. A p-value less than 0.05 rejects the null hypothesis and proves that a statistical significance in the two interventions does exist. Therefore, if the project investigators analyze the three outcomes listed above and discover p-values of less than 0.05 for them, the project supports the success of the ERAS implementation.

The data collected must be both reliable and valid. To ensure accuracy and consistency, project members will assess for compliance with each ERAS item. While collecting data regarding the outcomes from the medical charts, the QI department will be auditing the overall completeness of the ERAS guideline. If the 75% threshold is not met during the initial data collection period, additional patients will be enrolled until the compliance goal is met.

### **Recommendations and Conclusions**

#### **Limitations and Future Directions**

A few minor limitations to this project do exist. Unfortunately, the urban hospital where this project is centered is not a high-volume center for pancreaticoduodenectomies. The sample size of the study is substantially smaller than some of the multi-center studies utilized for research. Additionally, because of the nature of the study, project investigators cannot blindly randomize patients to a control and intervention group. Instead, it is a retrospective cohort study

with a lower level of evidence than if it were a randomized controlled trial. Lastly, there is a lack of implementation results, and outcome analysis is pending.

The project could be expanded in the future to include additional components. For example, with newer research, more elements of the ERAS protocol proposed by the ERAS Society might demonstrate considerable benefit to the patients and providers. Further, providers might become aware of complications frequently reoccurring in Whipple patients that did not appear to be as much of a concern as before. Project leaders at the facility can quickly adapt the implementation plan and design of this project to include other ERAS items and investigate new outcomes to continuously improve the guidelines.

### **Conclusion**

The pancreaticoduodenectomy is a complicated and taxing procedure for the patient and the provider. According to the supporting research, an EBP guideline utilizing an ERAS protocol for pancreaticoduodenectomies is likely to shorten the patient's length of stay, lower infection rates, and reduce DGE incidence. By implementing items from the ERAS Society's protocol for Whipple procedures that are highly recommended and supported with strong evidence, project leaders expect a statistically significant improvement in the outcomes investigated. The project team will continuously inquire about what will improve outcomes in the pancreatic cancer patient population, implement evidence-based practice changes, evaluate the effectiveness of adopting best practices in this facility, and support implementation in surrounding practice environments, as well.

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Appendix A

Evidence Review Worksheet

Kuemmerli, C., Tschuor, C., Kasai, M., Alseidi, A. A., Balzano, G., Bouwense, S., Braga, M., Coolsen, M., Daniel, S. K., Dervenis, C., Falconi, M., Hwang, D., Kagedan, D. J., Kim, S. C., Lavu, H., Liang, T., Nussbaum, D., Partelli, S., Passeri, M. J., ... M. A. H. (2022). Impact of enhanced recovery protocols after pancreatoduodenectomy: meta-analysis. *British Journal of Surgery*, 109(3), 256–266. <https://doi.org/10.1093/bjs/znac436>

Conceptual Framework or Model	Design or Method	Sample & Setting	Major Variables Studied & their Definitions, if any	Outcome Measurement(s)	Data Analysis	Findings	Level of Evidence	Quality of Evidence: Critical Worth to Practice
<b>Theoretical basis for the study:</b> N/A	Meta-analysis	<p><b>Inclusion Characteristics:</b></p> <ul style="list-style-type: none"> <li>Involves patients undergoing PD with 30 days of follow-up</li> <li>Includes ERAS</li> <li>ERAS characteristics: preoperative counseling, bowel preparation and fasting, antithrombotic and antimicrobial prophylaxis, PONV prophylaxis, postoperative fluid infusions, analgesia, mobilization, oral intake, NG tube, urinary catheter, abdominal drain removal, and discharge criteria</li> <li><b>31 studies comprising 5,844 patients undergoing PD. Individual data available for 17 studies and 3,143 patients.</b></li> </ul>	<p><b>Independent variables :</b></p> <p><b>IV1=</b> ERAS protocol implementation</p> <p><b>IV2=</b> Traditional approach</p> <p><b>Dependent variables :</b></p> <ul style="list-style-type: none"> <li>LOS</li> <li>Postoperative functional recovery elements: time to liquid intake, time to bowel movement, time to removal of NG tube, time to removal of last drain</li> <li>Postoperative morbidity</li> <li>Readmission</li> <li>Major complications (Dindo-Clavien grade IIIa or higher)</li> <li>Minor complications (Dindo-Clavien grade I or II)</li> </ul>	<p><b>Scale(s) used:</b></p> <ul style="list-style-type: none"> <li>reported in accordance with the Preferred Reporting Items for Review and Meta-analysis of Individual Participant Data statement</li> <li>RoB 2/ROBINS-I</li> </ul> <p><b>Reliability information (alphas, if any):</b> N/A</p>	<p><b>Statistical tests, if any:</b></p> <ul style="list-style-type: none"> <li>R version 3.6.1</li> <li>Point estimates = risk and mean differences</li> <li>Varmeta package to estimate sample mean and standard deviation</li> <li>I<sup>2</sup> statistic used to measure heterogeneity among trials</li> <li>Funnel plots &amp; Egger’s test to explore publication bias</li> <li>Priori-defined sensitivity analysis to assess impact of exclusion of most weighted study and lowest-quality study</li> <li>Post hoc analysis of differences</li> </ul>	<p><b>Statistical findings, if any:</b></p> <ul style="list-style-type: none"> <li>Time to liquid intake (P&lt;0.001), bowel movement (P&lt;0.001), and removal of NG tube (P=0.001) shorter in ERAS group</li> <li>Comparable time to removal of drains (P=0.051)</li> <li>Overall complication rate lower in ERAS group (P=0.015)</li> <li>Mortality comparable (P=0.996)</li> <li>LOS shorter in ERAS group (P=0.001)</li> <li>Readmission rate comparable (0.3)</li> <li>DGE less frequent in ERAS group (P &lt;0.001)</li> </ul>	Level I	<p><b>Strengths:</b></p> <ul style="list-style-type: none"> <li>Large sample size</li> <li>High level of evidence</li> </ul> <p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>few RCTs available</li> <li>Lack of blinding</li> <li>Heterogenous ERAS protocols</li> </ul> <p><b>Risk or harm if implemented:</b> N/A</p> <p><b>Feasibility of use in the project practice area:</b> Requires the cooperation of and coordination between many disciplines, but still supports implementation</p>

	<p><b>Exclusion Criteria:</b></p> <ul style="list-style-type: none"> <li>▪ studies reporting on four or fewer items as part of the ERAS</li> <li>▪ non-elective procedures</li> <li>▪ non-comparative studies with fewer than 20 patients per group</li> <li>▪ studies of distal or total pancreatectomies</li> </ul> <p><b>Attrition:</b> 31/1160 studies included</p> <p><b>Setting:</b> Any articles from The Cochrane Library, MEDLINE, EMBASE, Scopus, and Web of Science in English, French or German, published up until August 2020</p>	<ul style="list-style-type: none"> <li>▪ Rate of postoperative pancreatic fistula</li> <li>▪ DGE</li> </ul>		<p>between postoperative bleeding and pulmonary complications</p> <ul style="list-style-type: none"> <li>▪ P values</li> </ul> <p><b>Qualitative analysis, if any:</b> N/A</p>	<p><b>Qualitative findings, if any:</b> N/A</p>		
<b>Assignment E</b>							
<p><b>Annotated Bibliography statement:</b> Kuemmerli et al. (2022) conducted a meta-analysis involving 5,844 patients and 31 studies undergoing pancreaticoduodenectomies (PD). The goal of the meta-analysis was to analyze the efficacy of implementing an Enhanced Recovery After Surgery (ERAS) protocol in lowering outcomes such as length of stay (LOS), functional recovery elements, morbidity, readmission, and complications such as postoperative fistula and delayed gastric emptying (DGE), compared to traditional approaches. The study found that the ERAS protocol was significantly effective in lowering LOS, complications, DGE, and functional recovery elements. Although many of the studies included are not blinded or randomized controlled trials, this is a strong piece of evidence in support of ERAS implementation.</p>							
<p><b>Thematic Analysis</b>  <b>Key Themes or FSP related significance:</b></p> <ol style="list-style-type: none"> <li>1. ERAS shortens LOS</li> <li>2. ERAS lowers incidence of DGE</li> <li>3. ERAS lowers major complications</li> <li>4. Level I evidence</li> </ol>							

Key: N/A- not applicable; PD- pancreaticoduodenectomy; ERAS- Enhanced Recovery After Surgery; PONV- postoperative nausea and vomiting; NG- nasogastric; MEDLINE- Medical Literature Analysis and Retrieval System Online; EMBASE- Excerpta Medical Database; LOS- length of stay; DGE- delayed gastric emptying; RoB 2- risk of bias in randomized trials; ROBINS-I- Risk of Bias in Non-randomized Studies of Interventions; RCT- randomized controlled trial



Cao, Y., Gu, H.-Y., Huang, Z.-D., Wu, Y.-P., Zhang, Q., Luo, J., Zhang, C., & Fu, Y. (2019). Impact of enhanced recovery after surgery on postoperative recovery for pancreaticoduodenectomy: Pooled analysis of observational study. *Frontiers in Oncology*, 9, 1–14. <https://doi.org/10.3389/fonc.2019.00687>

Conceptual Framework or Model	Design or Method	Sample & Setting	Major Variables Studied & their Definitions, if any	Outcome Measurement(s)	Data Analysis	Findings	Level of Evidence	Quality of Evidence: Critical Worth to Practice
<p><b>Theoretical basis for the study:</b> N/A</p>	<p>Meta-analysis</p>	<p><b>Inclusion Characteristics:</b></p> <ul style="list-style-type: none"> <li>▪ Involves patients undergoing PD, PPPD, pancreaticojejunostomy, proximal pancreatic resection, or distal pancreatectomy</li> <li>▪ Includes ERAS and conventional</li> <li>▪ Reports ERAS outcomes</li> <li>▪ Most common ERAS interventions: preoperative counseling, antimicrobial prophylaxis, epidurals, postoperative artificial nutrition, earl mobilization, antithrombotic prophylaxis, PONV, and avoiding hypothermia</li> <li>▪ <b>19 studies (7 cohort studies, 12 case-controlled studies) comprising 3,387 patients</b></li> </ul> <p><b>Exclusion Criteria:</b></p> <ul style="list-style-type: none"> <li>▪ Not English</li> <li>▪ Repetitive studies</li> <li>▪ Unobtainable source literature or original data that is unobtainable</li> <li>▪ emergency operations</li> <li>▪ total pancreatectomy</li> </ul> <p><b>Attrition:</b> 19/976 articles included</p> <p><b>Setting:</b> Studies from Ovid MEDLINE, OVID EMBASE, The Cochrane Library, and ISIWeb of Science, in English, published up until May 1, 2018</p>	<p><b>Independent variables :</b> <b>IV1=</b> ERAS protocol implementation <b>IV2=</b> Traditional approach</p> <p><b>Dependent variables :</b></p> <ul style="list-style-type: none"> <li>▪ Mortality</li> <li>▪ Reoperation</li> <li>▪ Readmission</li> <li>▪ Postoperative complications (fistula, infection, DGE)</li> <li>▪ LOS</li> <li>▪ Hospitalization cost</li> </ul>	<p><b>Scale(s) used:</b></p> <ul style="list-style-type: none"> <li>▪ New-castle-Ottawa Scale to evaluate for bias</li> <li>▪ Used guidelines of Preferred Reporting Items for Meta-analysis</li> </ul> <p><b>Reliability information (alphas, if any):</b> N/A</p>	<p><b>Statistical tests, if any:</b></p> <ul style="list-style-type: none"> <li>▪ I<sup>2</sup></li> <li>▪ No P values</li> </ul> <p><b>Qualitative analysis, if any:</b> N/A</p>	<p><b>Statistical findings, if any:</b></p> <ul style="list-style-type: none"> <li>▪ ERAS is associated with a decreased incidence of pancreatic fistula</li> <li>▪ Lower rate of incisional infection in ERAS group</li> <li>▪ No significant difference for DGE</li> <li>▪ No significant difference in mortality</li> <li>▪ No significant difference in readmission</li> <li>▪ No significant difference in reoperation</li> <li>▪ Shorter LOS in ERAS group (3.12 days shorter)</li> <li>▪ Lower hospital costs in ERAS group</li> </ul>	<p>Level I</p>	<p><b>Strengths:</b></p> <ul style="list-style-type: none"> <li>▪ Large sample size</li> <li>▪ High level of evidence</li> </ul> <p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>▪ No blinded studies</li> <li>▪ Only 2 RCTs</li> </ul> <p><b>Risk or harm if implemented:</b> N/A</p> <p><b>Feasibility of use in the project practice area:</b> Requires the cooperation of and coordination between many disciplines, but still supports implementation</p>

						<b>Qualitative findings, if any:</b> N/A		
<b>Assignment E</b>								
<p><b>Annotated Bibliography statement:</b> Cao et al. (2019) published a meta-analysis comprising 19 studies and 3,397 patients undergoing various pancreatic procedures. The article studied whether traditional approaches or the Enhanced Recovery After Surgery (ERAS) protocol for pancreaticoduodenectomies would decrease rates of mortality, reoperation, readmission, postoperative complications such as infection, fistula or delayed gastric emptying, length of stay (LOS), and hospitalization costs. The authors found statistically significant data supporting that an ERAS protocol would lower pancreatic fistula rates, incisional infection rates, LOS, and hospital costs. The other data sets were comparable between the two groups. Despite that many of the studies that are included are not blinded or randomized controlled trials, this is a strong piece of evidence in support of ERAS implementation.</p>								
<p><b>Thematic Analysis</b>  <b>Key Themes or FSP related significance:</b></p> <ol style="list-style-type: none"> <li>1. ERAS lowers incision infection rates</li> <li>2. ERAS lowers pancreatic fistula rates</li> <li>3. ERAS shortens LOS</li> <li>4. ERAS lowers hospital costs</li> <li>5. Level I evidence</li> </ol>								

Key: N/A- not applicable; PD-pancreaticoduodenectomy; PPPD- pylorus-preserving pancreatoduodenectomy; ERAS- Enhanced Recovery After Surgery; PONV- postoperative nausea and vomiting; MEDLINE- Medical Literature Analysis and Retrieval System Online; EMBASE- Excerpta Medical Database; DGE- delayed gastric emptying; LOS- length of stay; RCT- randomized controlled trial;

Li, J., Lin, F., Yu, S., & Marshall, A. P. (2021). Enhanced recovery protocols in patients undergoing pancreatic surgery: An umbrella review. *Nursing Open*, 9(2), 932–941. <https://doi.org/10.1002/nop2.923>

<i>Conceptual Framework or Model</i>	<i>Design or Method</i>	<i>Sample &amp; Setting</i>	<i>Major Variables Studied &amp; their Definitions, if any</i>	<i>Outcome Measurement(s)</i>	<i>Data Analysis</i>	<i>Findings</i>	<i>Level of Evidence</i>	<i>Quality of Evidence: Critical Worth to Practice</i>
<b>Theoretical basis for the study:</b> N/A	Umbrella Review	<p><b>Number of Characteristics:</b></p> <ul style="list-style-type: none"> <li>Includes any elective pancreatic surgical procedure</li> <li>Involves ERAS elements</li> <li>Includes ERAS outcomes</li> <li>Systematic reviews</li> <li>English or Chinese</li> <li><b>10 systematic reviews</b></li> </ul> <p><b>Exclusion Criteria:</b></p> <ul style="list-style-type: none"> <li>Abstract of conference paper</li> <li>Unavailable as full text</li> <li>duplicate</li> </ul> <p><b>Attrition:</b> 10/129 studies included</p> <p><b>Setting:</b> Studies from PubMed, EMBASE, Cochrane Library, CINAHL, CNKI, Wan Fang, and VJIP up until October 2019</p>	<p><b>Independent variables:</b></p> <p>IV1= ERAS approach</p> <p>IV2= traditional approach</p> <p><b>Dependent variables:</b></p> <ul style="list-style-type: none"> <li>LOS</li> <li>Total complications morbidity</li> <li>Readmission rate</li> <li>Hospital costs</li> <li>Mortality</li> <li>Reoperation</li> <li>Pancreatic fistula</li> </ul>	<p><b>Scale(s) used:</b></p> <ul style="list-style-type: none"> <li>Followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guideline</li> <li>AMSTAR 2 tool to guide quality assessment of systematic reviews</li> </ul> <p><b>Reliability information (alphas, if any):</b> N/A</p>	<p><b>Statistical tests, if any:</b> N/A</p> <p><b>Qualitative analysis, if any:</b> N/A</p>	<p><b>Statistical findings, if any:</b> N/A</p> <p><b>Qualitative findings, if any:</b></p> <ul style="list-style-type: none"> <li>10 reviews reported decreased LOS</li> <li>7 reported decreased costs</li> <li>6 reported decreased complications rate</li> <li>No adverse effect incidents of ERAS</li> <li>No difference in mortality</li> <li>No difference in reoperation rate</li> <li>No difference in readmission</li> <li>No difference in pancreatic fistula</li> </ul>	Level I	<p><b>Strengths:</b> looks at many different systematic reviews</p> <p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>No specific data available</li> <li>Only three reviews included RCTs</li> <li>Quality of the 10 reviews was considered “critically low”</li> </ul> <p><b>Risk or harm if implemented:</b> N/A</p> <p><b>Feasibility of use in the project practice area:</b> Requires the cooperation of and coordination between many disciplines, but still supports implementation</p>

**Assignment E**

**Annotated Bibliography statement:** Li et al. (2021) created an umbrella review that analyzed 10 systematic reviews involving Enhanced Recovery After Surgery protocols in pancreatic procedures versus traditional approaches. They studied variables such as length of stay (LOS), morbidity from complications, readmission rates, hospital costs, mortality, reoperation rates, and pancreatic fistula occurrences. Their analysis demonstrated that every systematic review found a correlation between length of stay and ERAS implementation. Additionally, most articles also reported decreased costs and complication rates with ERAS. The other outcomes were not significantly different between the two groups. Unfortunately, this article did not provide specific data analysis.

**Thematic Analysis**

**Key Themes or FSP related significance:**

1. ERAS shortens LOS
2. ERAS lowers complication rates
3. ERAS lowers hospital costs
4. Level I evidence

*Key:* N/A- not applicable; ERAS- Enhanced Recovery After Surgery; EMBASE- Excerpta Medical Database; CINAHL- Cumulated Index to Nursing and Allied Health Literature; CNKI- China National Knowledge Infrastructure; VJIP- VIP Journal Integration Platform; PD- Pancreaticoduodenectomy; LOS- length of stay; AMSTAR- A Measurement Tool to Assess systematic Reviews; RCT- randomized controlled trial

Sun, Y.-M., Wang, Y., Mao, Y.-X., & Wang, W. (2020). The safety and feasibility of enhanced recovery after surgery in patients undergoing pancreaticoduodenectomy: An updated meta-analysis. *BioMed Research International*, 2020, 1–15. <https://doi.org/10.1155/2020/7401276>

Conceptual Framework or Model	Design or Method	Sample & Setting	Major Variables Studied & their Definitions, if any	Outcome Measurement(s)	Data Analysis	Findings	Level of Evidence	Quality of Evidence: Critical Worth to Practice
<b>Theoretical basis for the study:</b> N/A	Meta-Analysis	<p><b>Inclusion Characteristics:</b></p> <ul style="list-style-type: none"> <li>▪ RCTs or case control studies</li> <li>▪ English</li> <li>▪ Patients older than 18 who underwent elective PD</li> <li>▪ Involves ERAS elements (at least 9 of 27 elements)</li> <li>▪ <b>20 studies comprising 3,613 patients (N= 1,914 ERAS patients and N= 1,699 control patients ; 4 RCTs vs. 16 case-control studies)</b></li> </ul> <p><b>Exclusion Criteria:</b></p> <ul style="list-style-type: none"> <li>▪ Full text not available</li> <li>▪ Republished</li> <li>▪ Focus on palliative, emergency, or laparoscopic PD</li> <li>▪ Lower than 13 point quality score</li> <li>▪ Unextractable useful outcomes</li> </ul>	<p><b>Independent variables:</b></p> <p><b>IV1=</b> ERAS approach <b>IV2=</b> Traditional approach</p> <p><b>Dependent variables:</b></p> <ul style="list-style-type: none"> <li>▪ Overall postoperative complications</li> <li>▪ Rates of pancreatic fistula</li> <li>▪ DGE</li> <li>▪ Incision infections</li> <li>▪ Abdominal abscesses</li> <li>▪ Readmission</li> <li>▪ Reoperation</li> <li>▪ Mortality</li> <li>▪ LOS</li> </ul>	<p><b>Scale(s) used:</b></p> <ul style="list-style-type: none"> <li>▪ Followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guideline</li> <li>▪ Cochrane risk assessment tool to evaluate quality of RCTs</li> <li>▪ MINORS to evaluate nonrandomized controlled studies</li> </ul> <p><b>Reliability information (alphas, if any):</b> N/A</p>	<p><b>Statistical tests, if any:</b></p> <ul style="list-style-type: none"> <li>▪ Revman5.3 software to perform statistical analysis</li> <li>▪ Heterogeneity analyzed with chi-squared test</li> <li>▪ I<sup>2</sup> used to measure heterogeneity</li> <li>▪ Funnel plot to assess publication bias</li> <li>▪ P values</li> </ul> <p><b>Qualitative analysis, if any:</b> N/A</p>	<p><b>Statistical findings, if any:</b></p> <ul style="list-style-type: none"> <li>▪ Significantly lower overall postoperative complications in ERAS (P&lt; 0.00001)</li> <li>▪ no significant difference in pancreatic fistulas (P = 0.16)</li> <li>▪ DGE incidence lower in ERAS group (P &lt;0.00001)</li> <li>▪ Shorter LOS in ERAS (P &lt; 0.00001)</li> <li>▪ No significant difference in wound infections (P=0.36), abdominal abscesses (P=0.59), readmission (P=0.75), reoperation (P=0.81), and morbidity (P=0.12)</li> </ul> <p><b>Qualitative findings, if any:</b> N/A</p>	Level I	<p><b>Strengths:</b></p> <ul style="list-style-type: none"> <li>▪ Large sample size</li> <li>▪ High level of evidence</li> <li>▪ More RCTs than other reviews</li> </ul> <p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>▪ Majority of studies were retrospective case-control studies leading to possible bias</li> <li>▪ No blinding</li> <li>▪ Heterogeneity in ERAS protocols</li> </ul> <p><b>Risk or harm if implemented:</b> N/A</p> <p><b>Feasibility of use in the project practice area:</b> Requires the cooperation of and coordination between many disciplines, but still supports implementation</p>

		<p><b>Attrition:</b> 20/345 studies included</p> <p><b>Setting:</b> Studies from PubMed, EMBASE, and the Cochrane Library up until July 2019</p>						
<b>Assignment E</b>								
<p><b>Annotated Bibliography statement:</b> This study by Sun et al. (2020) investigated the difference in outcomes for patients undergoing an Enhanced Recovery After Surgery (ERAS) protocol approach to pancreaticoduodenectomy versus a traditional approach. It included 20 studies and 3,613 patients. The dependent variables they studied were overall complication rates, rates of pancreatic fistula, delayed gastric emptying (DGE), incisional infections, abdominal abscesses, readmission, reoperation, and mortality, and length of stay (LOS). The results included a lower incidence of overall complications and DGE and a shorter length of stay with an ERAS approach. Many of the studies included are not blinded or randomized controlled trials; however, this is a strong piece of evidence in support of ERAS implementation.</p>								
<p><b>Thematic Analysis</b></p> <p><b>Key Themes or FSP related significance:</b></p> <ol style="list-style-type: none"> <li>1. ERAS lowers DGE rates</li> <li>2. ERAS lowers overall complications</li> <li>3. ERAS shortens LOS</li> <li>4. Level I evidence</li> </ol>								

Key: N/A- not applicable; RCT- randomized controlled trial; PD- pancreaticoduodenectomy; ERAS- Enhanced Recovery After Surgery; EMBASE- Excerpta Medical Database; DGE- delayed gastric emptying; LOS- length of stay; MINORS- Methodological Index for Non-Randomized Studies

Ji, H.-B., Zhu, W.-T., Wie, Q., Wang, X.-X., Wang, H.-B., & Chen, Q.-P. (2018). Impact of enhanced recovery after surgery programs on pancreatic surgery: A meta-analysis. *World Journal of Gastroenterology*, 24(15), 1666–1678. <https://doi.org/10.3748/wjg.v24.i15.1666>

Conceptual Framework or Model	Design or Method	Sample & Setting	Major Variables Studied & their Definitions, if any	Outcome Measurement(s)	Data Analysis	Findings	Level of Evidence	Quality of Evidence: Critical Worth to Practice
<b>Theoretical basis for the study:</b> N/A	Meta-analysis	<p><b>Inclusion Characteristics:</b></p> <ul style="list-style-type: none"> <li>Includes patients undergoing pancreatic surgery</li> <li>ERAS implemented programs</li> <li>Measures in perioperative management described in both groups</li> <li>Reports at least measures of POPF, DGE, abdominal infection, mortality and LOS</li> <li><i>20 studies (all retrospective) with sample sizes greater than 100. A total of 3,694 patients included (N=1,886 ERAS and N= 1,808 control)</i></li> </ul> <p><b>Exclusion Criteria:</b></p> <ul style="list-style-type: none"> <li>Sample size less than 10</li> <li>Comments, guidelines, reviews, case reports, abstracts, letters, and non-</li> </ul>	<p><b>Independent variables:</b></p> <p><b>IV1=</b> ERAS approach <b>IV2=</b> Traditional approach</p> <p><b>Dependent variables:</b></p> <ul style="list-style-type: none"> <li>POPF</li> <li>DGE</li> <li>LOS</li> <li>Abdominal infection</li> <li>Mortality</li> <li>Readmission</li> <li>Reoperation</li> <li>Occurrence of complication within 30 days</li> </ul>	<p><b>Scale(s) used:</b></p> <ul style="list-style-type: none"> <li>MINORS to evaluate nonrandomized controlled studies (17 studies with scores greater than 12)</li> </ul> <p><b>Reliability information (alphas, if any):</b> N/A</p>	<p><b>Statistical tests, if any:</b></p> <ul style="list-style-type: none"> <li>RevMan5.3.5 software</li> <li>Chi-squared test for heterogeneity</li> <li>I<sup>2</sup> for evaluation of statistical heterogeneity</li> <li>Funnel plots to evaluate potential publication bias</li> </ul> <p><b>Qualitative analysis, if any:</b> N/A</p>	<p><b>Statistical findings, if any:</b></p> <ul style="list-style-type: none"> <li>POPF: no difference (P= 0.24)</li> <li>DGE: ERAS with lower incidence (P&lt; 0.00001)</li> <li>Overall postoperative complications: lower with ERAS (P&lt; 0.00001)</li> <li>Abdominal infection: lower in ERAS (P= 0.006)</li> <li>LOS: lower in ERAS (P&lt; 0.00001)</li> <li>Mortality: no difference (P= 0.51)</li> <li>Readmission: no difference (P= 0.75)</li> <li>Reoperation: no difference (P= 0.40)</li> </ul> <p><b>Qualitative findings, if any:</b> N/A</p>	Level I	<p><b>Strengths:</b></p> <ul style="list-style-type: none"> <li>Large sample size</li> <li>High level of evidence</li> </ul> <p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>Variable definitions of complications</li> <li>No RCTs</li> <li>Heterogeneity of ERAS protocols</li> </ul> <p><b>Risk or harm if implemented:</b> N/A</p> <p><b>Feasibility of use in the project practice area:</b> Requires the cooperation of and coordination between many disciplines, but still supports implementation</p>

		comparative studies ▪ Replications ▪ Incomplete data  <b>Attrition:</b> 20/159 studies included <b>Setting:</b> Studies from PubMed, Cochrane Library, and EMBASE, from January 1995- August 2017						
<b>Assignment E</b>								
<p><b>Annotated Bibliography statement:</b> A meta-analysis by Ji et al. (2018) summarizes the findings of 20 studies including 3,694 patients undergoing pancreatic surgery with an Enhanced Recovery After Surgery (ERAS) or traditional approach. The authors studied the dependent variables of pancreatic fistula, delayed gastric emptying (DGE), length of stay (LOS), abdominal infection, mortality, readmission, reoperation, and complications within 30 days of surgery. The findings indicated that ERAS was successful in lowering DGE, overall complications, abdominal infections, and LOS. Although many of the studies included are not blinded or randomized controlled trials, this is a strong piece of evidence in support of ERAS implementation.</p>								
<p><b>Thematic Analysis</b>  <b>Key Themes or FSP related significance:</b>                  1. ERAS lowers DGE                  2. ERAS lowers overall complications                  3. ERAS lowers rates of abdominal infections                  4. ERAS shortens LOS                  5. Level I evidence</p>								

Key: N/A- not applicable; ERAS- Enhanced Recovery After Surgery; POPF- postoperative pancreatic fistula; DGE- delayed gastric emptying; LOS- length of stay; EMBASE- Excerpta Medical Database; MINORS- Methodological Index for Non-Randomized Studies; RCT- randomized controlled trial



Noba, L., Rodgers, S., Doi, L., Chandler, C., Hariharan, D., & Yip, V. (2023). Costs and clinical benefits of enhanced recovery after surgery (eras) in pancreaticoduodenectomy: An updated systematic review and meta-analysis. *Journal of Cancer Research and Clinical Oncology*. <https://doi.org/10.1007/s00432-022-04508-x>

<i>Conceptual Framework or Model</i>	<i>Design or Method</i>	<i>Sample &amp; Setting</i>	<i>Major Variables Studied &amp; their Definitions, if any</i>	<i>Outcome Measurement(s)</i>	<i>Data Analysis</i>	<i>Findings</i>	<i>Level of Evidence</i>	<i>Quality of Evidence: Critical Worth to Practice</i>
<b>Theoretical basis for the study:</b> N/A	Meta-analysis	<p><b>Inclusion Characteristics:</b></p> <ul style="list-style-type: none"> <li>English</li> <li>Adult patients undergoing PD</li> <li>Compared ERAS and traditional care</li> <li>Reported at least one of the following outcomes: hospital costs, LOS, complications, compliance, DGE, mortality, readmissions, reoperations</li> <li><b>5,382 patients (N=2,776 ERAS and N=2,606 traditional)</b></li> </ul> <p><b>Exclusion Criteria:</b></p> <ul style="list-style-type: none"> <li>Non-elective or transplants</li> <li>Non-PD</li> <li>Non-English</li> </ul> <p><b>Attrition:</b> 31/835 studies included</p> <p><b>Setting:</b> Studies from Medline, EMBASE, PubMed, CINAHL, and the Cochrane Library between January 2000 and December 2021</p>	<p><b>Independent variables:</b></p> <p><b>IV1=</b> ERAS approach</p> <p><b>IV2=</b> Traditional approach</p> <p><b>Dependent variables:</b></p> <ul style="list-style-type: none"> <li>Hospital costs</li> <li>LOS</li> <li>Complication rates</li> <li>DGE</li> <li>Mortality</li> <li>Readmission</li> <li>Reoperation</li> </ul>	<p><b>Scale(s) used:</b></p> <ul style="list-style-type: none"> <li>Conducted in compliance with PRISMA</li> <li>Cochrane Collaboration’s risk of bias tool for quality of RCTs</li> <li>NOS for cohort studies quality</li> </ul> <p><b>Reliability information (alphas, if any):</b> N/A</p>	<p><b>Statistical tests, if any:</b></p> <ul style="list-style-type: none"> <li>Review Manager 5.4</li> <li>Chi-squared test for heterogeneity</li> <li>Funnel plots for publication bias</li> </ul> <p><b>Qualitative analysis, if any:</b> N/A</p>	<p><b>Statistical findings, if any:</b></p> <ul style="list-style-type: none"> <li>Hospital costs: significantly lower in ERAS group (P&lt; 0.00001)</li> <li>LOS: significant reduction in ERAS group (P&lt;0.00001)</li> <li>Complication rates: significant reduction in rates of complication in ERAS group (P &lt; 0.0001)</li> <li>DGE: significantly fewer cases of DGE in ERAS group (P=0.01)</li> <li>Mortality: significantly lower in ERAS group (P=0.05)</li> <li>Readmission: no difference (P=0.4)</li> <li>Reoperation: no difference (P=0.88)</li> </ul> <p><b>Qualitative findings, if any:</b> N/A</p>	Level I	<p><b>Strengths:</b></p> <ul style="list-style-type: none"> <li>Largest study to date on this topic as of publication</li> </ul> <p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>Heterogeneity in ERAS protocols</li> <li>Compliance is not well documented</li> <li>No surgical approach specified in most studies</li> </ul> <p><b>Risk or harm if implemented:</b> N/A</p> <p><b>Feasibility of use in the project practice area:</b> Requires the cooperation of and coordination between many disciplines, but still supports implementation</p>

**Annotated Bibliography statement:** Noba et al. (2023) study the relationship between an Enhanced Recovery After Surgery (ERAS) protocol approach in a pancreaticoduodenectomy procedure and hospital costs, length of stay (LOS), complication rates, delayed gastric emptying (DGE), mortality, readmission, and reoperation. Their meta-analysis included 5,382 patients, making it the largest study to date on the topic. When compared to traditional approaches, the authors found that ERAS protocols lower hospital costs, LOS, complication rates, DGE, and mortality. However, the compliance to ERAS within each article was not well documented. Despite missing audit information, this piece is still a strong piece of evidence.

**Thematic Analysis**

**Key Themes or FSP related significance:**

1. ERAS shortens LOS
2. ERAS lowers hospital costs
3. ERAS lowers complications
4. ERAS lowers DGE
5. ERAS lowers mortality
6. Level I evidence

*Key:* N/A- not applicable; PD- pancreaticoduodenectomy; ERAS- Enhanced Recovery After Surgery; LOS- length of stay; DGE- delayed gastric emptying; EMBASE- Excerpta Medical Database; CINAHL- Cumulated Index to Nursing and Allied Health Literature; PRISMA- Preferred Reporting Items for Systematic reviews and Meta-Analysis; RCT- randomized controlled trial; NOS- Newcastle-Ottawa Quality Assessment Scale

Wang, X.-Y., Cai, J.-P., Huang, C.-S., Huang, X.-T., & Yin, X.-Y. (2020). Impact of enhanced recovery after surgery protocol on pancreaticoduodenectomy: A meta-analysis of non-randomized and randomized controlled trials. *HPB*, 22(10), 1373–1383. <https://doi.org/10.1016/j.hpb.2020.07.001>

<i>Conceptual Framework or Model</i>	<i>Design or Method</i>	<i>Sample &amp; Setting</i>	<i>Major Variables Studied &amp; their Definitions, if any</i>	<i>Outcome Measurement(s)</i>	<i>Data Analysis</i>	<i>Findings</i>	<i>Level of Evidence</i>	<i>Quality of Evidence: Critical Worth to Practice</i>
<p><b>Theoretical basis for the study:</b> N/A</p>	<p>Meta-Analysis</p>	<p><b>Inclusion Characteristics:</b></p> <ul style="list-style-type: none"> <li>▪ Compares influence of ERAS with standard care</li> <li>▪ Includes at least 5 ERAS items</li> <li>▪ English</li> <li>▪ <b>22 studies (N=2008 ERAS patients and N=2139 control patients). 3 RCTs, 19 non-randomized comparative studies</b></li> </ul> <p><b>Exclusion Criteria:</b></p> <ul style="list-style-type: none"> <li>▪ Review articles, case reports, conference proceedings, letters, protocols, and animal experimental studies</li> <li>▪ Studies including patients undergoing procedures other than PD</li> </ul> <p><b>Attrition:</b> 22/487 articles included</p>	<p><b>Independent variables:</b> <b>IV1=</b> ERAS approach <b>IV2=</b> Traditional approach <b>Dependent variables:</b></p> <ul style="list-style-type: none"> <li>▪ Overall morbidity</li> <li>▪ POPF</li> <li>▪ DGE</li> <li>▪ Incision infection</li> <li>▪ Abdominal infection</li> <li>▪ LOS</li> <li>▪ 30-day readmission</li> <li>▪ Mortality</li> </ul>	<p><b>Scale(s) used:</b></p> <ul style="list-style-type: none"> <li>▪ Compliance with guidelines of the Cochrane Handbook of systematic Reviews and meta-analysis</li> <li>▪ Reported according to PRISMA-P</li> <li>▪ NOS for non-randomized studies</li> <li>▪ Cochrane Handbook for RCTs</li> </ul> <p><b>Reliability information (alphas, if any):</b></p> <ul style="list-style-type: none"> <li>▪ 14/19 articles scored above 6 on NOS= high quality</li> </ul>	<p><b>Statistical tests, if any:</b></p> <ul style="list-style-type: none"> <li>▪ RevMan 5.3</li> <li>▪ STATA 12</li> <li>▪ Mantel-Haenzel method</li> <li>▪ Chi-squared test for heterogeneity</li> <li>▪ I<sup>2</sup> for heterogeneity</li> <li>▪ Funnel plot for publication bias</li> <li>▪ Egger’s test</li> </ul> <p><b>Qualitative analysis, if any:</b> N/A</p>	<p><b>Statistical findings, if any:</b></p> <ul style="list-style-type: none"> <li>▪ Overall morbidity= significantly lower in ERAS (P&lt; 0.001)</li> <li>▪ POPF: no significant difference (P= 0.07)</li> <li>▪ DGE: significantly lower in ERAS (P= 0.002)</li> <li>▪ Incisional infection: markedly lower in ERAS (P= 0.01)</li> <li>▪ Abdominal infection: significantly lower in ERAS (P= 0.05)</li> <li>▪ LOS: significantly shorter in ERAS (P&lt; 0.001)</li> <li>▪ 30-day readmission: no difference (P= 0.71)</li> <li>▪ Mortality: no difference (P= 0.2)</li> </ul>	<p>Level I</p>	<p><b>Strengths:</b></p> <ul style="list-style-type: none"> <li>▪ Large sample size</li> <li>▪ High level of evidence</li> </ul> <p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>▪ Heterogeneity among ERAS protocols and outcomes</li> </ul> <p><b>Risk or harm if implemented:</b> N/A</p> <p><b>Feasibility of use in the project practice area:</b> Requires the cooperation of and coordination between many disciplines, but still supports implementation</p>

		<b>Setting:</b> Studies included from PubMed, Web of Science, and Cochrane Library from January 1990 to July 2019				<b>Qualitative findings, if any:</b>		
<b>Assignment E</b>								
<p><b>Annotated Bibliography statement:</b> A meta-analysis by Wang et al. (2020) summarizes the findings of 22 studies including 4,147 patients undergoing a pancreaticoduodenectomy. The independent variables were an Enhanced Recovery After Surgery (ERAS) protocol approach and a traditional approach, and the dependent variables were overall morbidity, pancreatic fistula, delayed gastric emptying (DGE), incision infections, abdominal infections, length of stay (LOS), 30-day readmission, and mortality. The results indicated a significantly lower rate of overall morbidity, DGE, incisional infections, abdominal infections, and LOS. The article is high-level evidence in support of ERAS implementation.</p>								
<p><b>Thematic Analysis</b>  <b>Key Themes or FSP related significance:</b>                      1. ERAS lowers morbidity                      2. ERAS lowers DGE rates                      3. ERAS lowers incisional infection and abdominal infection rates                      4. ERAS shortens LOS                      5. Level I evidence</p>								

Key: N/A- not applicable; ERAS- Enhanced Recovery After Surgery; RCT- randomized controlled trial; PD- pancreaticoduodenectomy; POPF- postoperative pancreatic fistula; DGE- delayed gastric emptying; LOS- length of stay; PRISMA-P- Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols; NOS- Newcastle-Ottawa Scale

Melloul, E., Lassen, K., Roulin, D., Grass, F., Perinel, J., Adam, M., Wellge, E. B., Kunzler, F., Besselink, M. G., Asbun, H., Scott, M. J., Dejong, C. H., Vrochides, D., Aloia, T., Izbicki, J. R., & Demartines, N. (2020). Guidelines for perioperative care for pancreatoduodenectomy: Enhanced Recovery After Surgery (ERAS) recommendations 2019. *World Journal of Surgery*, 44(7), 2056–2084. <https://doi.org/10.1007/s00268-020-05462-w>

Conceptual Framework or Model	Design or Method	Sample & Setting	Major Variables Studied & their Definitions, if any	Outcome Measurement(s)	Data Analysis	Findings	Level of Evidence	Quality of Evidence: Critical Worth to Practice
<b>Theoretical basis for the study:</b> N/A	Systematic Review and Expert Opinion/ Guidelines	<p><b>Inclusion Characteristics:</b></p> <ul style="list-style-type: none"> <li>English</li> <li>Meta-analyses, RCTs, or prospective cohort studies</li> <li>Related to PD</li> <li><b>314 articles used to develop 27 items</b></li> </ul> <p><b>Exclusion Criteria:</b></p> <ul style="list-style-type: none"> <li>Not English</li> <li>Not regarding PD</li> <li>Not high enough evidence</li> </ul> <p><b>Attrition:</b> 314/8368 articles included</p> <p><b>Setting:</b> Studies included from EMBASE, PubMed, Medline Ovid and Cochrane Library from January 2000 to December 2018</p>	<p><b>Independent variables:</b> IV1= N/A IV2= N/A</p> <p><b>Dependent variables:</b> N/A</p> <p><b>27 items developed include:</b></p> <ol style="list-style-type: none"> <li>Preoperative counseling</li> <li>Prehabilitation</li> <li>Preoperative biliary drainage</li> <li>Preoperative smoking and alcohol consumption</li> <li>Preoperative nutrition</li> <li>Perioperative oral immunonutrition</li> <li>Preoperative fasting and 43reoperative treatment with carbohydrates</li> <li>Pre-anesthetic medication</li> <li>Anti-thrombotic prophylaxis</li> <li>Antimicrobial prophylaxis and skin preparation</li> <li>Epidural analgesia</li> <li>Postoperative intravenous and per oral analgesia</li> <li>Wound catheter and TAP block</li> </ol>	<p><b>Scale(s) used:</b></p> <ul style="list-style-type: none"> <li>Endnote X8 used to manage citations</li> <li>CONSORT to assess quality of RCTs</li> <li>GRADE system to assess level of evidence of each item</li> <li>PRISMA guidelines for article selection</li> </ul> <p><b>Reliability information (alphas, if any):</b> N/A</p>	<p><b>Statistical tests, if any:</b> N/A</p> <p><b>Qualitative analysis, if any:</b> N/A</p>	<p><b>Conclusions for each item:</b></p> <ol style="list-style-type: none"> <li>Should receive (moderate evidence, weak recommendation) initiated 3-6 weeks before surgery reduces complications (moderate evidence, strong recommendation)</li> <li>Avoid unless decompression is needed (high evidence, strong recommendation)</li> <li>Abstain from smoking for at least four weeks. No alcohol abstinence benefit noted (moderate evidence for smoking, low for drinking, strong recommendation)</li> <li>Recommended for patients with severe weight loss only (high evidence, strong recommendation)</li> <li>Not recommended (high evidence, strong recommendation)</li> <li>Six hour solid fasting, two hour liquid fasting (moderate evidence, strong</li> </ol>	Level I	<p><b>Strengths:</b></p> <ul style="list-style-type: none"> <li>Lists every recommendation for ERAS</li> </ul> <p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>Some items do not have high quality evidence</li> </ul> <p><b>Risk or harm if implemented:</b> N/A</p> <p><b>Feasibility of use in the project practice area:</b> Requires the cooperation of and coordination between many disciplines, but still supports implementation</p>

			<p>14. PONV prophylaxis</p> <p>15. Avoid hypothermia</p> <p>16. Postoperative glycemic control</p> <p>17. NG intubation</p> <p>18. Fluid balance</p> <p>19. Perianastomotic drainage</p> <p>20. Somatostatin analogues</p> <p>21. Urinary drainage</p> <p>22. DGE</p> <p>23. Stimulation of bowel movement</p> <p>24. Postoperative artificial nutrition</p> <p>25. Early and scheduled mobilization</p> <p>26. Minimally invasive surgery</p> <p>27. Audit compliance</p>			<p>recommendation); carb loading is safe (moderate evidence, strong recommendation)</p> <p>8. Avoid anxiolytics as much as possible (moderate evidence, strong recommendation); opioid-sparing-use Tylenol 1g and gabapentinoid (moderate evidence, strong recommendation); NSAIDS after surgery (moderate evidence, strong recommendation)</p> <p>9. Start LMWH 2-12 hours before surgery and continue until discharge; four weeks for those with cancer (high evidence, strong recommendation); mechanical measures are good (low evidence, weak recommendation)</p> <p>10. ATB administered less than 60 minutes before incision, redosing dependent on half-life (high evidence, strong recommendation); alcohol preparation is first option (moderate evidence, strong recommendation)</p>	
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						<p>11. Thoracic epidural offers improved analgesia (moderate evidence, strong recommendation)</p> <p>12. Tailored postoperative multimodal opioid sparing strategy is optimal (moderate evidence, strong recommendation)</p> <p>13. Continuous wound infiltration through catheter is alternative to epidural (high evidence, strong recommendation)</p> <p>14. PONV prophylaxis- two or more risk factors should receive combination of two antiemetics, three or four risk factors should receive two to three drugs (moderate evidence, strong recommendation)</p> <p>15. Avoid it (high evidence, strong recommendation)</p> <p>16. Maintain glucose as close to normal as possible (moderate evidence, strong recommendation)</p> <p>17. Remove NG tube quickly (moderate evidence, strong recommendation)</p>	
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						<p>18. Use goal-directed therapy (moderate evidence, strong recommendation)</p> <p>19. Early drain removal at 72 hours for patients with amylase content &lt;500U/L on POD1 (high evidence, strong recommendation)</p> <p>20. Not recommended (moderate evidence, weak recommendation)</p> <p>21. Remove on POD1 or when patient ambulates for those with wound catheters; others can leave operating room with one (low evidence, strong recommendation)</p> <p>22. Administration of artificial nutrition can improve DGE outcome (low evidence, strong recommendation)</p> <p>23. Chew gum (moderate evidence, weak recommendation); drugs to treat (very low evidence, weak recommendation)</p> <p>24. Normal diet without restriction, artificial nutrition considered individually (moderate evidence, strong recommendation)</p>	
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						<p>25. Mobilization on POD0 if possible (low evidence, strong recommendation)</p> <p>26. LPD in centers with experience and strict protocols (moderate evidence, strong recommendation)</p> <p>27. Auditing improves compliance and outcomes (moderate evidence, strong recommendation)</p>		
<b>Assignment E</b>								
<p><b>Annotated Bibliography statement:</b> Melloul et al. (2020) constructed a systematic review and expert opinion piece to provide guidance on best practice regarding Enhanced Recovery After Surgery (ERAS) protocols in pancreaticoduodenectomies. The authors used 317 total articles to construct 27 items included in the protocol and rated the strength of evidence and recommendation for each one. Eight items were scored as high-level evidence and strong recommendations:</p> <ul style="list-style-type: none"> <li>▪ Avoid preoperative biliary drainage unless decompression is needed;</li> <li>▪ Preoperative nutrition counseling is recommended only for patients with severe weight loss;</li> <li>▪ There is no need for perioperative oral immunonutrition;</li> <li>▪ Start low-molecular weight heparin two to 12 hours following surgery and continue until discharge, or longer for those with cancer;</li> <li>▪ Give antibiotics less than 60 minutes before incision;</li> <li>▪ Continuous wound infiltration is an alternative to an epidural;</li> <li>▪ Hypothermia should be avoided;</li> <li>▪ Drain removal is appropriate after 72 hours for those with amylase levels less than 500 units per liter.</li> </ul> <p>This article is the foundation of each ERAS protocol instituted in the remaining articles included in the literature review.</p>								
<p><b>Thematic Analysis</b>  <b>Key Themes or FSP related significance:</b></p> <ol style="list-style-type: none"> <li>1. 27 items with recommendations for pancreaticoduodenectomy procedures</li> <li>2. Some are higher levels of evidence and stronger recommendations than others</li> <li>3. Authors looked at many articles and used a panel of experts to grade the evidence</li> <li>4. A successful ERAS protocol should include items from the list above</li> </ol>								

*Key:* N/A- not applicable; RCT- randomized controlled trial; PD- pancreaticoduodenectomy; EMBASE- Excerpta Medical Database; TAP- transversus abdominis plane; PONV- postoperative nausea and vomiting; NG- nasogastric; DGE- delayed gastric emptying; CONSORT- Consolidated Standards of Reporting Trials; GRADE- Grading of Recommendations Assessment Development and Evaluation; PRISMA- Preferred Reporting Index for Systematic reviews and Meta-Analyses; LMWH- low molecular weight heparin; ATB- antibiotic; POD- postoperative day; LPD- laparoscopic pancreaticoduodenectomy; ERAS- Enhanced Recovery After Surgery

## Appendix B

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# JOHNS HOPKINS EBP MODEL AND TOOLS- PERMISSION

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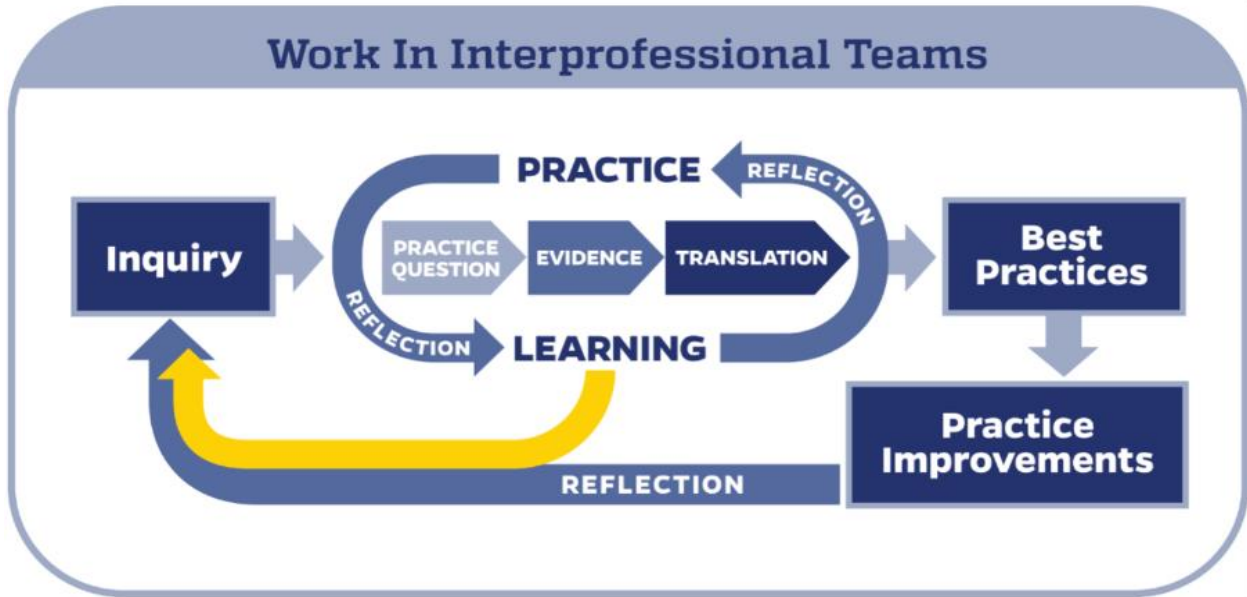
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Appendix C

Johns Hopkins Evidence-Based Practice Model



(Dang et al., 2022)



	17. If change is implemented, evaluate outcomes to determine if improvements have been made									
	18. Report results to stakeholders									
	19. Identify next steps									
	20. Disseminate findings									

**Appendix E**

**Translation and Action Planning Tool**

<b>Translation</b>	
<b>Select the statement that best describes the overall characteristics of the body of evidence from the team’s synthesis and recommendations (Appendix H):</b>	
<input type="checkbox"/> Strong & compelling evidence, consistent results <input type="checkbox"/> Good but conflicting evidence <input type="checkbox"/> Good & consistent evidence <input type="checkbox"/> Little or no evidence	
<b>What is the level of safety risk associated with the intervention?</b>	
<input type="checkbox"/> High <input type="checkbox"/> Low	
<b>Translation Assessment Flowchart:</b>	
<pre>                     graph TD                         Start[Start Here] --&gt; D1{Strong, compelling evidence. Consistent results?}                         D1 -- YES --&gt; A1[Change is indicated.]                         D1 -- NO --&gt; D2{Good and consistent evidence?}                         D2 -- YES --&gt; D3{What is the level of risk or potential for harm if implemented?}                         D2 -- NO --&gt; D4{Good but conflicting evidence?}                         D4 -- YES --&gt; D3                         D4 -- NO --&gt; D5{Little or no evidence?}                         D3 -- LOW --&gt; A2[Consider pilot of change or further investigation.]                         D3 -- HIGH --&gt; A3[No indication for change at this time.]                         D5 -- YES --&gt; A3                 </pre>	
<b>Based on the Translation Assessment, select the course of action:</b>	
<input type="checkbox"/> Change is indicated (system or process improvement, or practice), go to Section I <input type="checkbox"/> Consider a pilot of the change or further investigation for new evidence, go to Section I. <input type="checkbox"/> No indication for change or consider further investigation for new evidence, develop a research study or discontinue project, go to Section II.	

<b>Section I: If change is indicated, generate organization-specific recommendations by assessing the best-evidence recommendations for feasibility, fit, and acceptability:</b>	
<p><b>Feasibility</b> Extent to which the team evaluates and believes that the change is low risk, doable, and can be successfully implemented within a given organization or setting.</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> The change is low risk.</li> <li><input type="checkbox"/> Few, if any, barriers identified, and the time, effort, and resources to overcome them is reasonable.</li> <li><input type="checkbox"/> Sponsors or leaders share their point of view, endorse and support the change</li> </ul>
<p><b>Fit</b> Compatibility of a change with end-user workflow and consumer expectations; and/or the perceived relevance of the change in addressing the problem and in answering the PICO question within a given practice setting.</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> The change aligns with unit and/or departmental priorities.</li> <li><input type="checkbox"/> The change is suitable and seems like a good match with end-user workflow.</li> <li><input type="checkbox"/> The change is applicable to the problem and answers the PICO question.</li> </ul>
<p><b>Acceptability</b> Extent to which stakeholders and organizational leadership perceive the change to be agreeable, palatable, satisfactory, and reasonable.</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> The change aligns with organizational priorities.</li> <li><input type="checkbox"/> The change meets the approval of stakeholders and organizational leadership.</li> <li><input type="checkbox"/> Stakeholders and leaders like and welcome the change and find it appealing.</li> </ul>
<b>Organization-specific recommendations:</b>	
<b>Section II: When a change or pilot is not indicated, what, if any, next steps does the EBP team recommend?</b>	

<b>Action Planning</b>		
<b>Complete the following activities to ensure successful implementation:</b>		
<ul style="list-style-type: none"> <li><input type="checkbox"/> Secure a project leader</li> <li><input type="checkbox"/> Identify change champions</li> <li><input type="checkbox"/> Consider whether translation activities require different or additional members</li> <li><input type="checkbox"/> Identify objectives and related tasks</li> <li><input type="checkbox"/> Determine dates to complete tasks</li> <li><input type="checkbox"/> Identify observable pre and post measures</li> </ul>		
<b>Identify strengths that can be leveraged to overcome barriers to ensure the success of the change:</b>		
Resources or Strengths	Barriers	Plan to Overcome Barriers by Leveraging Strengths as Appropriate
<b>Which of the following will be affected by this change? (<i>Select all that apply</i>)</b>		
<input type="checkbox"/> Electronic health record <input type="checkbox"/> Workflow <input type="checkbox"/> Policies and/or procedures <input type="checkbox"/> Other _____		
<b>Identify and secure the resources and/or funding required for translation and implementation: (<i>Check all that apply</i>)</b>		
<input type="checkbox"/> Personnel costs <input type="checkbox"/> Supplies/equipment <input type="checkbox"/> Technology <input type="checkbox"/> Education or further training	<input type="checkbox"/> Content or external experts <input type="checkbox"/> Dissemination costs (conference costs, travel) <input type="checkbox"/> Other: _____	



**Appendix F**

**Staff Post-Implementation Survey**

*Post-Implementation Evaluation*

	1= Strongly Disagree	2= Disagree	3= N/A, neutral	4= Agree	5= Strongly Agree
The ERAS guidelines for pancreaticoduodenectomies are easy to understand					
I feel like I have the necessary resources to accurately complete the elements I am responsible for in the ERAS pathway					
Education on the ERAS guideline was helpful and thorough					
Overall, I would recommend keeping these guidelines in place					

Please leave any additional comments or concerns below:

---

**Appendix G**

**ERAS Guidelines for Pancreaticoduodenectomies**

<b>Enhanced Recovery After Surgery Evidence-Based Practice Guidelines for Use in Pancreaticoduodenectomies (2023)</b>	
<b>Developed Date:</b> 09/01/2023	<b>Effective Date:</b>
<b>Developed By:</b> Rebecca Wheeler, SRNA	<b>Reviewed Date:</b>
<b>Reviewed By:</b> Dr. Brian Garrett	<b>Approved by:</b> Dr. Brian Garrett

**STATEMENT OF PURPOSE:**

The implementation of Enhanced Recovery After Surgery (ERAS) guidelines for patients undergoing pancreaticoduodenectomies are evidence-based and effective in numerous facilities at lowering complication rates and length of stay following surgery. Having guidelines for ERAS use in place increases the likelihood of increased success following the Whipple procedure.

**POLICY:**

These guidelines are to be followed by all staff involved in the care of patients undergoing pancreaticoduodenectomies, whenever applicable. Most importantly, clinical judgment should be used to deviate from the policy when considering the safety of the patient, if necessary. However, compliance of key components of these guidelines will be audited, and clear communication should be given by any staff member if they are unable to follow the policy.

**GUIDELINES:**

- **Preoperative Components:**
  - Avoid preoperative biliary drainage, unless abdominal decompression is needed (bilirubin > 250 µmol/L, preoperative episodes of cholangitis, neoadjuvant treatment).
  - Patients with severe weight loss (>15%) should receive preoperative nutrition (e.g., nasogastric feeding tube).
  - It is not recommended to order oral immunonutrition prior to surgery.
  - Start low molecular weight heparin or unfragmented heparin 2-12 hours before surgery. Continue until hospital discharge or four weeks after surgery for those with cancer.
  
- **Intraoperative Components:**

- Single-dose intravenous antibiotics should be administered within 60 minutes of incision. Repeat doses are dependent on half-life of the drug and length of the procedure.
  - Continuous wound catheter infiltration through a preperitoneal catheter is an appropriate alternative to an epidural for pain control. However, there is no evidence for the efficacy of transversus abdominis plane (TAP) blocks in pancreatic surgery and therefore, they should not be used.
  - Forced-air or active warming measures should be initiated before induction of anesthesia if patient temperature is below 36°C and the temperature should be maintained above this threshold throughout the procedure and time in the post-anesthesia care unit.
- **Postoperative Components:**
    - Remove perianastomotic drains at 72 hours following surgery if amylase content in drain is <5000 U/L on post-op day one.

*Note:* Guidelines adapted from Melloul et al. (2020).

Melloul, E., Lassen, K., Roulin, D., Grass, F., Perinel, J., Adam, M., Wellge, E. B., Kunzler, F., Besselink, M. G., Asbun, H., Scott, M. J., Dejong, C. H., Vrochides, D., Aloia, T., Izbicki, J. R., & Demartines, N. (2020). Guidelines for perioperative care for pancreatoduodenectomy: Enhanced Recovery After Surgery (ERAS) recommendations 2019. *World Journal of Surgery*, 44(7), 2056–2084. <https://doi.org/10.1007/s00268-020-05462-w>

**Appendix H**

**ERAS Implementation Proposed Budget**

	<b>Cost</b>	<b>Quantity</b>	<b>Total</b>
<i>CRNA hourly wage</i>	<i>\$121</i>	<i>50 hours</i>	<i>\$6,050</i>
<b><u>Ream of paper</u></b>	<b><u>\$8.25</u></b>	<b><u>1 ream</u></b>	<b><u>\$8.25</u></b>
<b><u>Ink</u></b>	<b><u>\$51.89</u></b>	<b><u>1 cartridge</u></b>	<b><u>\$51.89</u></b>
<b><u>Nasogastric tube</u></b>	<b><u>\$200</u></b>	<b><u>50 tubes</u></b>	<b><u>\$10,000</u></b>
<b><u>Tube feeding bag</u></b>	<b><u>\$25</u></b>	<b><u>50 bags</u></b>	<b><u>\$1,250</u></b>
			<b><u>\$17,360.14</u></b>

\*Operational costs are *italicized*. Capital costs are underlined.

(ZipRecruiter, n.d.) (Staples, n.d.) (VitalityMedical, n.d.)