ENHANCED RECOVERY PATHWAY FOR COLORECTAL SURGERY IMPROVES OUTCOMES IN PRIVATE AND SAFETY NET SETTINGS

By

Taylor Roberts, B.S.

DISSERTATION

Presented to the Faculty of the Medical School

The University of Texas Southwestern Medical Center at Dallas

In Partial Fulfillment of the Requirements

For the Degree of

DOCTOR OF MEDICINE WITH DISTINCTION IN QUALITY IMPROVEMENT AND PATIENT SAFETY

The University of Texas Southwestern Medical Center

Dallas, Texas

© Copyright by Taylor Roberts 2018

All Rights Reserved

ACKNOWLEDGMENTS

Special thank you to Dr. Gary Reed, Patty Brown, Eleanor Phelps, Mary Baldwin and Virginia Pineda-Dow of the UT Southwestern Office of Quality Improvement and Patient Safety. Your unwavering support and guidance have tremendously benefited my education and happiness.

Thank you to my inspiring mentors Dr. Jennifer Rabaglia and Dr. Joselin Anandam for helping me grow as a person and as a future physician.

ABSTRACT

ENHANCED RECOVERY PATHWAY FOR COLORECTAL SURGERY IMPROVES OUTCOMES IN PRIVATE AND SAFETY NET SETTINGS

The University of Texas Southwestern Medical Center, 2018
Supervising Professor: Jennifer Rabaglia, M.D.

BACKGROUND: Although it is known that Enhanced Recovery Pathways (ERP) decrease length of stay (LOS) and improve outcomes in colorectal surgery, these studies predominantly represent the private health care setting. There is a paucity of information regarding the effectiveness of ERP in the public arena, comprised of the under and uninsured who may have different social determinants of health. This study aims to compare the effect of an ERP on LOS and readmission for colorectal surgery across the private and safety-net settings in a large urban academic medical center.

METHODS: A multidisciplinary panel of experts utilized professionally recognized standards and evidence-based best practice to create a comprehensive ERP for elective colorectal surgery. The ERP included standardization of patient education, optimization of co-morbidities, multimodal analgesia, carbohydrate loading, intraoperative goal-directed fluid therapy, minimization of opioids, and early ambulation, removal of urinary catheter, and resumption of diet. There were no social interventions. The ERP was implemented in the safety-net hospital (SNH) in September 2014 and the private hospital (PH) in December 2014. Process and outcome metrics from 100 consecutive patients having surgery in the 18 months prior to ERP at each

institution were compared to a similar group post ERP. Surgeons and discharge criteria remained constant. Primary endpoints were LOS and readmissions.

RESULTS: Patients in the post-ERP cohorts at both facilities were significantly older than pre-ERP (p=0.047, 0.034), with no significant difference in gender and BMI. The rate of open versus minimally invasive was similar at SNH (p=0.067), while more post-ERP patients at PH underwent open surgery (p=0.002). 96% of PH patients were funded through private insurance or Medicare, verses only 6% at the SNH. ERP implementation reduced total LOS at both facilities, while readmission and reoperation remained constant. LOS at PH fell from 8.1 to 5.9 days (p=0.028), and at SNH from 7.0 to 5.1 days (p=0.004). 30-day all-cause readmission and return to surgery were stable (PH p=0.634; SNH p=1) and (PH p=0.610; SNH p=0.066) respectively. Surgical site infection rate was unchanged at PH (p=0.485) and significantly reduced at SNH (p=0.021, OR 0.39). Mean time to ambulation and mean time to first bowel movement were reduced at SNH (p=0.002, 0.001). Mean time to resumption of solids was reduced at both PH and SNH (p<0.001).

<u>CONCLUSIONS</u>: Implementation of ERP is similarly effective across private and safety net settings, without interventions to address social determinants of health. Both cohorts experienced reduced LOS without increasing readmission or reoperation. The data suggest ERP may have a more dramatic impact on outcomes in the safety net setting, perhaps through standardization in a group with more varied baseline health status. Utilization of ERP appears to be advantageous for all populations regardless of funding.

TABLE OF CONTENTS

Introduction	7
Problem Description.	7
Available Knowledge	8
Rationale	10
Specific Aims	11
Methods	11
Context	11
Interventions	12
Study of the Interventions	14
Measures	19
Analysis	20
Ethical Considerations	20
Results	20
Conclusion	26
Discussion	26
Limitations	30
Conclusions	30
Disclosures	31
Bibliography	31
Supplemental Appendix	33
Vitae	36

PROBLEM DESCRIPTION

There is an overwhelming amount of underlying variability inherent to surgical practice, and many believe that this is at least in part, or perhaps largely to blame for such variability in outcomes. Clinicians encounter variation at every level – physician preference both in and out of the operating room, nursing practices, system level issues including infection control, antibiotic policies and discharge patterns, as well as patient level issues including social factors, living environment, and support.

Under the traditional care model, where physician preference directs patient care, variation between surgeons leads to hospital environments without reliable routines and without set expectations for postoperative recovery. Additionally, it is known that traditional clinical practice is slow to respond to new evidence, and often fails to incorporate updated best-practices into patient care [1, 2]. The variable degree to which evidenced-based treatments are applied contributes to an unpredictable care environment and variable outcomes.

Increasing emphasis on elimination of medical errors and control of rising healthcare costs has prompted investigation into which areas of medicine would benefit most from quality improvement initiatives. Within General Surgery, colectomy procedures have become an important target for such efforts. Using the National Surgical Quality Improvement Program database, Schilling et al. found that, among the thirty-six most frequently performed general surgery procedures, colectomy had the highest number of adverse events, and was the greatest contributor to excess hospital length of stay. On average, colectomy comprises roughly 10% of all general surgical procedures but is responsible for over 25% of all operative complications [3]. Colectomy also has a relatively high readmission rate. For these reasons, colectomy at the

University of Texas Southwestern Medical Center was identified as the target for the current quality improvement project.

AVAILABLE KNOWLEDGE

To address variability in care, an innovative strategy is transforming surgical practice across a range of disciplines and settings. An Enhanced Recovery Pathway (ERP) is a set of standardized, evidence-based perioperative care components that have been shown to improve outcomes and accelerate postoperative return to function. ERP provide predictable algorithms for perioperative care, reducing system and practice variability, which results in fewer errors and higher quality care. The Enhanced Recovery After Surgery Society has outlined recommendations for key pathway elements, including standardized patient education, preoperative comorbidity optimization, carbohydrate loading, proper antibiotic use, multimodal pain control with minimization of opioids, avoidance of fluid overload, and early return to diet and ambulation [4]. There is ample evidence that implementing ERP safely decrease complications, hospital length of stay (LOS) and costs in a range of surgical subspecialties, including colorectal surgery [5-12]; A meta-analysis of thirteen randomized controlled trials by Zhuang et al. showed that ERP implementation decreased mean hospital LOS by approximately 2.5 days, reduced complication risk (RR 0.68), without affecting readmission rates or mortality [5]. Despite these benefits, ERP is underutilized in surgical practice across the United States [2]. One explanation for underutilization is uncertainty regarding the applicability of ERP in certain settings. Existing studies supporting the use of ERP predominantly represent the private healthcare setting. To our knowledge, there are no publications studying the implementation of an ERP in the safety-net setting.

The Institute of Medicine defines safety-net providers as: "Those providers that organize and deliver a significant level of health care and other health-related services to uninsured, Medicaid, and other vulnerable patients" [13]. It is known that such patient populations are at a higher risk for poor surgical outcomes and longer hospital stays due to a variety of factors including limited resources and various social determinants of health [14-16]. A patient's access to outpatient care, social support, stable housing, food, transportation, and medications are only few of the potential challenges to a typical safety-net patient's health. Consequently, these patients tend to present with more advanced disease, be less adherent to treatment regimens, and receive less postoperative care. In a nationally representative survey of patients admitted for surgery for colorectal carcinoma, Kelz et al. found that uninsured and Medicaid patients were more likely to have emergent admissions and comorbid diseases than patients with private insurance. This study also found that Medicaid patients were 22% more likely to develop a complication during admission and 57% more likely to die postoperatively compared to patients with private insurance [14]. In addition to socioeconomic determinants of health and issues of healthcare access, another factor that could contribute to worse outcomes in this vulnerable patient population is the quality of care they receive.

The comparative performance of safety-net facilities and private institutions remains a controversial topic. Several studies have suggested that safety-net hospitals, in general, perform lower on quality metrics than private institutions [17-19]. Goldman et al. used Hospital Compare data to evaluate adherence to best-practices at high Medicaid (hospitals with >40% Medicaid patients) and other hospitals for three common medical conditions: myocardial infarction, congestive heart failure, and community acquired pneumonia [17]. Among the 2874 participating non-teaching hospitals, high Medicaid hospitals had lower adherence on all 10 quality indicators

compared to other hospitals. However, this difference was not found between teaching hospitals. In 2008, Rhoads et al. showed that high-Medicaid hospitals have higher mortality after colon surgery than other hospitals [16]. Whether these worse outcomes result from patient factors, lower quality of care delivery, or both, it remains to be shown if an ERP can be equally effective in the safety-net setting [20].

RATIONALE

It is important to determine the applicability of ERP in the safety-net for two key reasons. First, the unique obstacles faced by safety-net facilities and their patient populations challenge the very concept of an enhanced recovery with shortened hospital stay. In theory these patients present with poorer health at baseline, making them less suited for quick recovery, and are more likely to lack social and financial resources conducive to expedited discharge. For these reasons, the success of ERP at private institutions primarily serving insured patients by no means guarantees equivocal results in the safety-net setting. Second, while there are presumably greater challenges to success in the safety-net setting, there are also greater potential rewards. By improving patient outcomes in the safety-net setting, an ERP would decrease healthcare disparities for this vulnerable patient population. By optimizing adherence to best-practices and quality performance metrics, an ERP would increase the benefits a safety-net hospital could receive from pay-for-performance reimbursement systems and avoid penalties. By decreasing direct costs of care, an ERP would liberate funds for other uses in the often cost-constrained safety-net environment. For these reasons, there is a need to evaluate the utility of ERP in the safety-net setting. To our knowledge, no studies have investigated ERP in the safety-net setting.

By design, the ERP in our study included best-practice medical components of perioperative care but specifically did not include interventions to address socioeconomic

barriers to care. This was done in order to avoid high financial costs of pathway implementation and thereby ensure the generalizability of the intervention.

SPECIFIC AIMS

The aim of this study is to determine the impact of an ERP on LOS and patient outcomes for elective colorectal surgery at a safety-net hospital compared to a private hospital. We devoted attention to pathway implementation and compliance barriers in order to ensure adherence. Implementation of the ERP began in 2014 at both a safety-net hospital and private hospital within a large, urban academic medical center. We retrospectively reviewed the medical records of patients undergoing elective colorectal surgery prior to and following ERP implementation at each hospital.

CONTEXT

Parkland Memorial Hospital is a 862-bed academic county hospital that primarily serves the residents of Dallas County and is associated with the University of Texas Southwestern Medical Center in Dallas, Texas. Parkland surgeons conduct over 17,000 surgeries annually. This hospital serves as the safety-net hospital in our study, as the majority of its patients are funded by charity. The two Parkland Hospital colorectal surgeons performed all safety-net hospital cases in our study and remained consistent across the pre-implementation and post-implementation groups.

William P. Clements Jr. University Hospital is a 460-bed private, academic, tertiary referral hospital affiliated with the University of Texas Southwestern Medical Center. This hospital served as the private hospital in our study, as the majority of its patients are funded by

private insurance or Medicare. The two University Hospital colorectal surgeons (different from those at Parkland) performed all private hospital cases in our study and remained consistent across the pre-implementation and post-implementation groups.

Prior to our intervention, the colorectal surgery faculty and care staff at both the safetynet and private hospitals functioned under the traditional care model, meaning that physician preference directed patient care on a patient-by-patient basis. No clinical pathways for colorectal surgery existed at either institution prior to our project.

INTERVENTIONS

The steps of this quality improvement project were organized using the Plan-Do-Act-Study (PDSA) model as depicted in **Figure 1**.

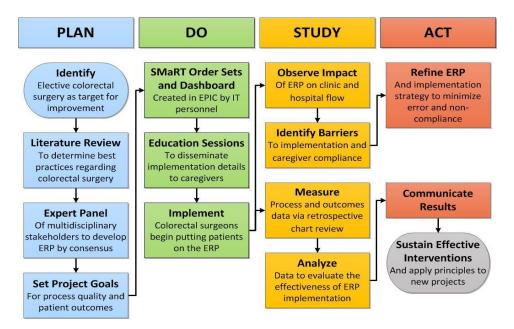


Figure 1. Flowchart depicting the major steps of the project within the PDSA framework.

PATHWAY DEVELOPMENT

A thorough literature search was performed to identify consensus "best practices" related to colorectal surgery. A multidisciplinary panel of experts and direct caregivers from within the institution was convened with representation from all facets of surgical care delivery, including colorectal surgeons, anesthesiologists, OR nursing, floor nursing, infection control, nutrition, enterostomal therapy, physical therapy, social work, and electronic medical record (EMR) specialists. The fishbone diagram shown in **Figure 2** was created to organize all factors that could potentially contribute to poor surgical outcomes. With these components in mind, the group generated the ERP using an iterative process until consensus was reached regarding the final pathway construct. Key elements of the pathway were in accordance with guidelines published by the Enhanced Recovery After Surgery Society in 2013 [4]. Complete details of the pathway can be found in the Supplemental Appendix.

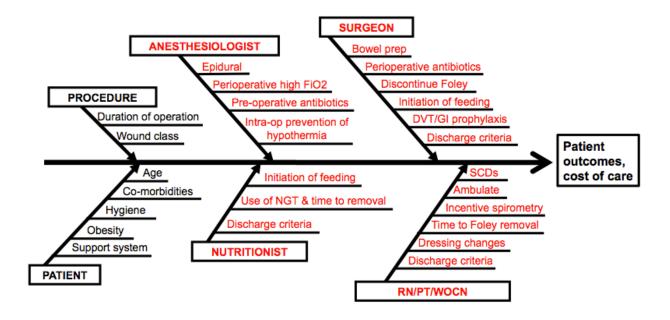


Figure 2. Fishbone diagram depicting factors that contribute to patient outcomes organized by provider type. Factors in red were considered modifiable and under the scope of the ERP.

To facilitate pathway adherence, IT personnel created order sets in the EMR of both hospitals that standardized perioperative phases of care for elective colorectal surgeries based on identified diagnosis and procedure codes.

PATHWAY IMPLEMENTATION

The pathway was implemented beginning in September 2014 at Parkland Memorial Hospital, a large safety-net hospital, and in December 2014 at Clements University Hospital, a large private hospital, both within the UT Southwestern academic medical center in Dallas, Texas. Details of the ERP and its implementation were disseminated to caregivers via specific educational sessions for nursing, ancillary staff, and physicians. The pathway and its associated order sets are directly initiated by the surgeon prior to admission. A nursing template within the EMR provides clear and easily accessible documentation of the timeline and milestones related to pathway components. Copies of the pathway were kept in the anesthesia area of the operating room for quick reference.

STUDY OF THE INTERVENTION

Direct observation of patient flow through the clinics and hospitals was performed to identify barriers to successful pathway implementation. Flowcharts detailing the impact of pathway components on the different phases of care are shown in **Figures 3 through 6**. As indicated by the red arrows, a recurrent barrier to implementation was identified at both institutions: resident surgeons were not reliably activating the preoperative and postoperative phases of care order sets for all pathway-eligible patients. To address this issue, targeted education is now provided to resident surgeons beginning their rotation on the colorectal service and faculty surgeons are responsible for overseeing pathway activation.

University Hospital Colorectal Clinic Patient Flow

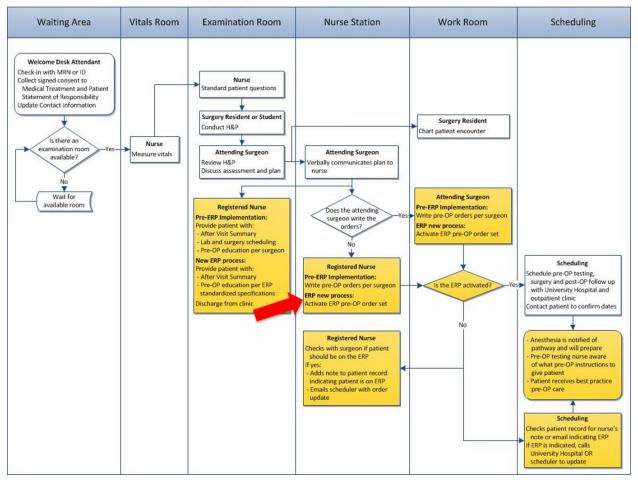


Figure 3. The University Hospital Colorectal Clinic Patient Flow diagram is representative of the pre-operative patient clinic flow at the private institution. Yellow icons show where the enhanced recovery pathway altered existing patient care in order to standardize best practices. The red arrow indicates a recurrent barrier to implementation when residents are required to manually initiate the pre-operative pathway.

Parkland Colorectal Clinic Patient Flow

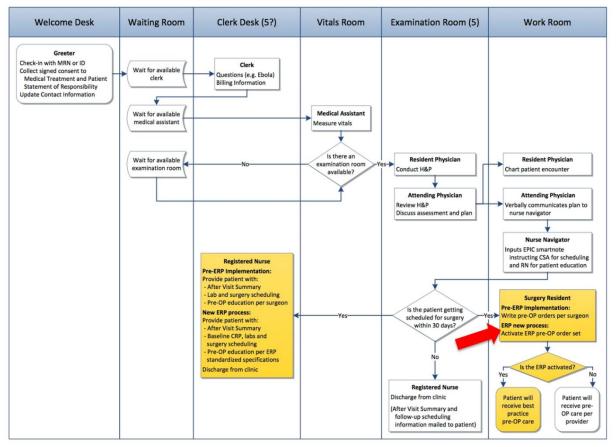


Figure 4. Parkland Colorectal Clinic Patient flow diagram is representative of the pre-operative patient clinic flow at the safety-net institution. Yellow icons show where the enhanced recovery pathway altered existing patient care in order to standardize best practices. Similar to the red arrow in Figure 3, the red arrow here indicates a recurrent barrier to implementation when residents are required to manually initiate the pre-operative pathway.

Pre-Implementation Hospital Patient Flow

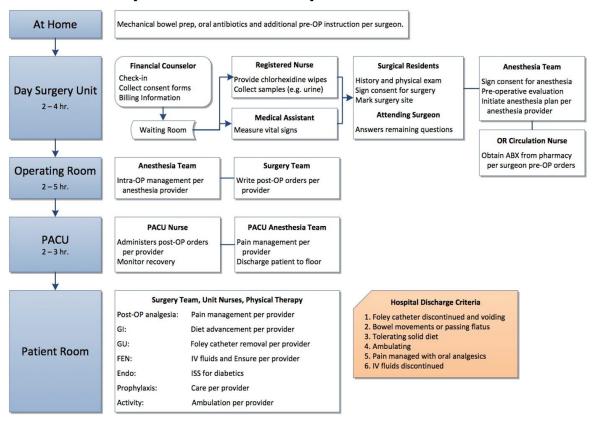


Figure 5. Pre-Implementation Hospital Patient Flow diagram depicts the pre-implementation care algorithm for colorectal surgery patients at both the private and safety-net institutions. Of note, treatment is guided by individual physicians and there is no predictable care pathway.

Post-Implementation Hospital Patient Flow

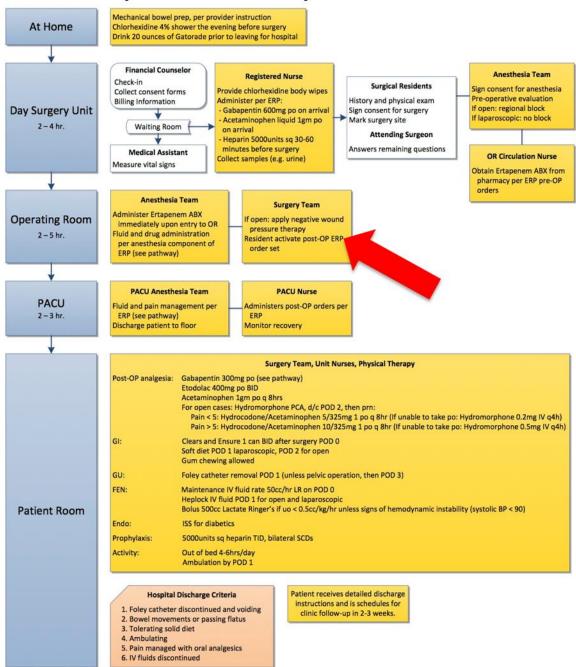


Figure 6. Post-Implementation Hospital Patient Flow diagram depicts the course of colorectal surgery patient care following enhanced recovery pathway implementation. Yellow icons show where the pathway standardized patient care and provided a predictable treatment course. The red arrow, like that seen in Figures 3 and 4, highlights a recurrent barrier to implementation when residents are required to manually initiate the intraoperative and postoperative pathway phases.

MEASURES

Process and outcomes metrics from 100 consecutive patients who underwent elective colorectal surgery in the 18 months prior to ERP implementation at each institution were compared to a similar group post implementation. Surgeons and discharge criteria at each institution remained the same throughout.

Using appropriate ICD-9-CM procedure codes, patients aged 18 to 65 undergoing the following procedures were eligible for inclusion: right hemicolectomy, left hemicolectomy, ileocecectomy, transverse colectomy, sigmoid colectomy, low anterior resection, total abdominal colectomy, abdominoperineal resection, pouch/ileoanal pull through, and proctectomy. Patients with urgent or emergent indications for surgery were excluded from this study, due to inability to complete the preoperative pathway components. Patients undergoing re-operative laparotomy were also excluded due to higher baseline morbidity.

Several process quality measures were collected to assess adherence to the pathway.

These included time to removal of indwelling urethral catheter, to ambulation, and to resumption of diet. These are periodically assessed via the EMR for continued monitoring of pathway adherence.

Outcome quality measures were collected to evaluate pathway impact on patient recovery. Primary outcome endpoints were LOS and readmissions. Length of stay reflects how quickly patients achieve recovery milestones and the variability of care delivery. Readmission rate (defined as any emergency readmission within 30 days of initial hospital discharge) has several functions. A decreased readmission rate reflects improved patient outcomes, as well as cost avoidance, whereas an increased readmissions rate reflects worse outcomes, and may suggest an inappropriately early hospital discharge.

Secondary outcome endpoints served as additional markers of patient recovery and included time to return of bowel function, surgical site infections (SSI), and return to surgery.

ANALYSIS

At each hospital, the pre-implementation group was compared to the post-implementation group to determine the impact of the pathway at each institution independently. For univariate analyses, the 2-tailed t-test and chi-square test were applied. Hospital LOS, time to return of bowel function, to removal of indwelling urinary catheter, to ambulation, to resumption of diet, and to return of bowel function were treated as continuous variables and analyzed using the 2-tailed t-test. Readmission, SSI, and return to surgery were treated as dichotomous variables and analyzed using the chi-square test. For both tests, alpha was set to p<0.05.

ETHICAL CONSIDERATIONS

Data were obtained in a retrospective manner from the Parkland Memorial Hospital EMR and Clements University Hospital EMR with Institutional Review Board approval. Patient-identifying information was hidden in accordance with the Health Insurance Portability and Accountability Act. Only the individuals involved in data collection had temporary access to protected health information, and data was collected and stored on secure campus computers.

RESULTS

STUDY SAMPLE

Table 1 shows the demographic data for patients at the SNH and PH. Patients in the post ERP cohorts at both facilities were significantly older than pre ERP (p=0.047, 0.034), with no

significant difference in gender and BMI. The rate of open versus minimally invasive surgery was similar at SNH (p=0.067), while more post ERP patients at PH underwent open surgery (p=0.002).

Patient and Operation	Sat	Safety Net Hospital			Private Hospital		
Characteristics	Pre	Post	P Value	Pre	Post	P Value	
Male Sex	54	46	0.108	48	51	0.548	
Age	50.4	51.2	0.034*	51.2	55.7	0.047*	
ВМІ	29.1	29.1	0.956	28.0	28.6	0.516	
Surgery							
Lap	59	68	0.067	65	44	<.001*	
Open	41	32		23	36		
Robotic	-	-		12	20		

Table 1. Patient Demographics. Within each institution, pre and post implementation groups had no significant differences in sex or body mass index (BMI). At both the safety-net and private institutions, patients in the post-implementation group tended to be older. More patients in the post-implementation group at the private hospital underwent open surgery compared to pre-implementation patients.

Figure 7 depicts the funding sources for patients at each institution. 96% of PH patients were funded through private insurance or Medicare, verses only 6% at the SNH. The majority of patients at the SNH were funded through charity, which is typical for a safety-net hospital.

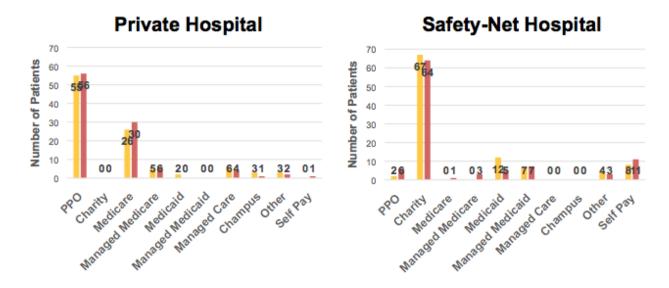


Figure 7. Funding Sources. The majority of patients at the safety-net hospital were funded by charity. In contrast, the majority of patients at the private institution were funded by a Preferred Provider Organization (PPO) or Medicare. These trends were consistent across pre and post-implementation groups.

PROCESS QUALITY ENDPOINTS

Mean time to ambulation (shown in **Figure 8**) was significantly reduced at the SNH from 2.14 to 1.48 days (p=0.002), but not reduced at the PH (1.78 to 1.79 days, p=0.759). Mean time to resumption of solids was significantly reduced at SNH from 4.59 to 2.56 days (p<0.001), and at PH from 4.76 to 2.65 days (p<0.001). Mean time to first bowel movement (shown in **Figure 9**) was reduced at SNH from 3.39 to 2.51 days (p=0.001), but not reduced at the PH (2.98 to 2.96 days, p=0.944). Time to removal of indwelling urethral catheter was not significantly reduced at either institution. Indwelling urethral catheter was removed on postoperative day 1.68 and 1.88 at the SNH (p=0.407), and 2.10 and 1.94 at the PH (p=0.708). **Table 2** summarizes the process quality results.

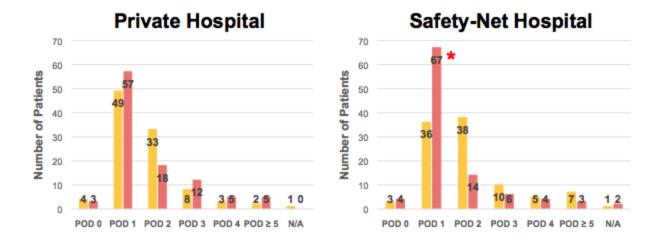


Figure 8 (above). Mean Time to Ambulation was significantly reduced at the Safety-Net Hospital from 2.14 to 1.48 days (p=0.002), but not reduced at the Private Hospital (1.78 to 1.79 days, p=0.759) following pathway implementation.

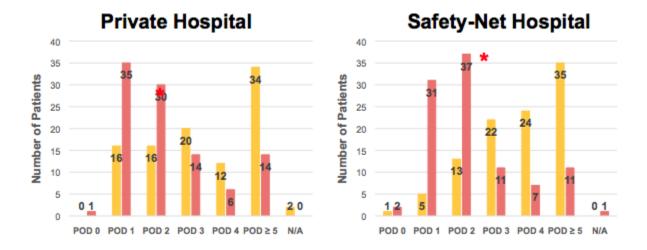


Figure 9 (above). Mean Time to Return to Bowel Function was significantly reduced at the Safety-Net Hospital from 4.59 to 2.56 days (p<0.001) and at the Private Hospital from 4.76 to 2.65 days (p<0.001) following pathway implementation.

Process Measures (Days)	Safety Net Hospital			Private Hospital		
	Pre	Post	P Value	Pre	Post	P Value
Foley removal	1.68	1.88	0.407	2.10	1.94	0.708
Time to ambulation	2.14	1.48	0.002 *	1.78	1.79	0.759
Time to solid food	4.59	2.56	<.001 *	4.76	2.65	<.001 *

Table 2 (above). Process Quality Endpoints. Time to removal of indwelling urethral catheter (Foley removal) was not significantly changed. Mean time to ambulation was reduced at the Safety-Net Hospital (SNH). Mean time to resumption of solid food was reduced at both the SNH and Private Hospital.

OUTCOME QUALITY ENDPOINTS

ERP implementation reduced total LOS at both facilities, while readmission and reoperation remained constant. LOS at PH fell from 8.1 to 5.9 days (p=0.028), and at SNH from 7.0 to 5.1 days (p=0.004). 30-day all-cause readmission remained stable at SNH (22% and 22%, p=1, OR 1) and at PH (23% and 21%, p=0.635, OR 0.89).

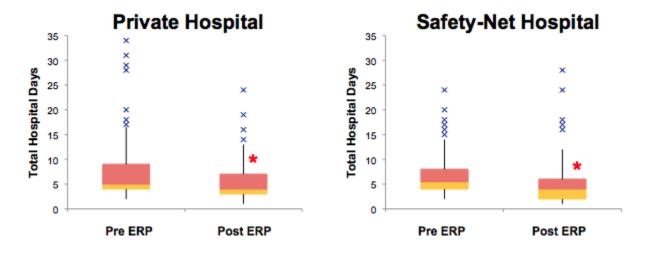


Figure 10. Average Hospital Length of Stay was significantly reduced at both the Private Hospital (8.1 to 5.9 days (p=0.028)), and at the Safety-Net Hospital (7.0 to 5.1 days (p=0.004)) following pathway implementation.

There was a non-significant trend toward reduced return to surgery at the SNH (5% to 1%, p=0.066, OR 0.19). Return to surgery at PH was unchanged (4% to 5%, p=0.61, OR 1.26). Surgical site infection rate was significantly reduced at SNH (14% to 6%, p=0.021, OR 0.39) and unchanged at PH (9% to 7%, p=0.485, OR 0.76). **Table 3** summarizes key outcome quality results.

Outcomes Measures	Safety Net Hospital			Private Hospital		
	Pre	Post	P Value	Pre	Post	P Value
Length of Stay	7.03	5.12	0.004 *	8.12	5.89	0.028 🖈
Readmissions	22	22	1 (1)	23	21	0.635 (0.89)
Return to surgery	5	1	0.066 (0.19)	4	5	0.61 (1.26)
SSI	14	6	0.021 (0.39) *	9	7	0.485 (0.76)
Time to return of bowel function	3.39	2.51	0.001 *	2.98	2.96	0.944

Table 3. Outcome Quality Endpoints. Length of stay was significantly reduced at both institutions following pathway implementation. There was no change in readmissions or return to surgery. There was favorable decrease in surgical site infections (SSI) at the Safety-Net Hospital, as well as decreased time to return of bowel function.

UNINTENDED CONSEQUENCES

Following pathway implementation, there was an unforeseen increase in blood transfusions within the first 24 hours after surgery. We hypothesized that the increase was due to one of the following pathway components: preoperative heparin administration, toradol given at the end of surgery, or scheduled postoperative NSAID use. By withholding one of these treatments at a time and monitoring transfusion requirements, we concluded that the preoperative heparin, intended for venous thromboembolism prophylaxis, was the cause of bleeding.

We searched the literature for reports of increased bleeding following ERP implementation and found none. It remains unclear if the bleeding resulted from an issue with administration route, dosage, or chance. We have reviewed the preoperative order set, and intend

to restart preoperative subcutaneous heparin on an individual patient basis, in accordance with ERAS Society guidelines, and monitor closely for bleeding.

DISCUSSION

To our knowledge, this study is the first to compare the effect of an ERP for elective colorectal surgery in the private and safety-net settings. We found the ERP was similarly effective across both settings in regards to the primary outcomes of LOS and 30-day all-cause readmissions. Consistent with prior studies, the ERP significantly reduced LOS by approximately 2 days at each institution (p<0.001) without increasing readmission rate or return to surgery [5, 6, 8]. This was achieved without any interventions to address social determinants of health.

Furthermore, our data suggest that ERP may have a more pronounced impact in the safety-net setting, as demonstrated by greater improvements in SSI rate, time to ambulation and time to return of bowel function at the safety-net hospital compared to the private hospital. We postulate this may be due to standardization of care in a patient population with more varied baseline health status.

A major strength of our intervention is its generalizability. The key elements of our ERP align with ERAS Society international guidelines and do not include interventions to address social determinants of health, such as hiring perioperative navigators and preoperative disposition planning staff. Such interventions can be costly barriers to implementation at many safety-net hospitals. The success of our ERP without any social interventions may be explained by the findings of a 2016 study by Alawadi et al. This study found that safety-net care providers perceived lack of social support as a barrier to ERP implementation, whereas most patients

welcomed the use of a pathway and reported adequate social support [20]. In light of the current evidence that ERP can work in the safety-net, it is important that we elicit patient perspectives to learn what discrepancies exist between the challenges our specific population faces and those we perceive them to face. This will inform further refinements to the pathway and the addition of social interventions in the future. Additionally, our study shows that ERP is applicable in a resident training environment provided that residents are educated on proper pathway application.

It is interesting to note that LOS prior to and after pathway implementation was approximately one day shorter at the safety-net hospital than the private hospital. We believe there are several factors to explain this counterintuitive finding. For one, the private hospital is a tertiary referral center and receives patients from a wide geographic area, whereas the safety-net hospital primarily serves Dallas County residents. Physicians at the private hospital may be more hesitant to discharge patients who live far from the hospital. As a tertiary referral center, the private hospital cares for patients who often have more advanced disease and complex comorbidities that delay discharge. Additionally, our particular safety-net hospital has social work staff devoted to coordinating discharge planning during the postoperative period, which likely prevented discharge delays that these patients would have otherwise experienced. This unanticipated finding presents an opportunity to investigate common causes for prolonged LOS at each institution.

The 30-day all-cause readmission rate did not increase following ERP implementation at either hospital, which reassures us that patients are not being prematurely discharged or discharged without appropriate social support. With the improved patient education and decreased infection rate, we might have even expected the readmission rate to decrease.

However, this was not the case, and in fact, the readmission rate at both institutions (22%) remained unchanged at a rate higher than the national average (13.5%)[21]. We observed that the most common reasons for readmission did not change following pathway implementation, and at both hospitals included ileus, infection, and dehydration. We postulate that patients at the safetynet hospital may have a lower threshold for admission because these patients tend to have greater difficulty completing postoperative follow-up, and may have insufficient social support to handle minor issues [22]. For example, patients who are discharged to homeless shelters face increased challenges with wound or ostomy care and medication compliance. Patients at the private hospital may have a high readmission rate due to the high level of disease complexity and comorbidities. Further investigation into the circumstances of each readmission is needed to identify "preventable" readmissions and develop methods to reduce these.

The analysis of this project provides valuable process quality data, which allows us to interpret the outcomes in light of pathway compliance. The reduced time to ambulation and to resumption of diet show improved adherence to important best practices, and support our assertion that the observed improvement in outcomes were indeed due to pathway implementation. There remains, however, room for improved pathway adherence through earlier ambulation and return to diet, as well as other pathway components that we did not directly measure. Studies have shown that ERP compliance improves over time, and outcomes improve as adherence increases in a dose-dependent relationship [23, 24]. To ensure the sustainability of our intervention, we periodically monitor process quality metrics, address areas of poor adherence, and train incoming residents and staff on pathway application. We are currently building a dashboard within the EMR that will display process and outcomes metrics in real-

time, so that providers will be up-to-date on pathway adherence and outcomes, and can then target areas for continued improvement.

Our results support the notion that patient outcomes can be improved by increasing adherence to best practices, despite the socioeconomic challenges this patient population faces. Hospitals serving a high proportion of Medicaid patients have been shown to perform below average on evidenced-based quality process measures, suggesting that poor patient outcomes at these institutions may be, at least in part, attributable to deficits in quality of care at these institutions [17, 23, 25]. In contrast, studies in 2012 by Marshall et al. and Ross et al. show equivalent performance at safety-net hospitals and non-safety-net hospitals [26, 27]. Regardless of baseline performance, safety-net hospitals are an important target for addressing healthcare disparities [19, 28], and our study shows that the implementation of ERP can effectively improve outcomes for this patient population.

ERP is beneficial both for patient care and for financial interests of safety-net hospitals. Werner et al. theorized that safety-net hospitals are particularly vulnerable to pay-for-performance medicine for three reasons: these institutions may (1) lack sufficient resources to invest in quality improvement efforts and data collection for reporting, (2) be penalized for lower performance on quality measures, (3) not receive as many benefits from reporting due to higher portion of uninsured patients [25]. Therefore it is especially urgent for safety-net hospitals to implement cost-effective interventions that will improve their performance baseline, and thereby increase their ability to compete for reimbursements. ERP not only improves adherence to best-practices but also reduces cost of care by decreasing complications and LOS [9, 11]. The potential for increased admissions financially benefits hospitals and decreases patient waiting time for surgery. Safety-net hospitals, in general, are known to have longer waiting times for

surgery following diagnosis, and shortening this period by freeing up hospital beds for additional admissions increases access to care for this underserved population [12, 29].

LIMITATIONS

There were several limitations to our study. First, this was a nonrandomized study, as all eligible patients participated in the ERP following implementation. Randomization is particularly difficult to achieve in clinical pathway studies due to the effect of "contamination bias," which occurs when patients in the non-treatment group unintentionally receive some aspects of treatment [30]. However, the study groups at each institution were acceptably similar. Second, the data was collected in a retrospective manner, which limits our ability to conclude a causal relationship between the ERP and improved outcomes. Third, the small sample size per patient group did not allow for the evaluation of outcomes in subgroups; for example, by individual insurance status and surgical pathology. However, the purpose of our study was to determine whether an ERP would be equally effective in the safety-net setting and private setting regardless of other factors, which we accomplished with our sample size.

CONCLUSIONS

Enhanced recovery pathways for elective colorectal surgery can be similarly effective at decreasing length of stay without increasing readmissions across private and safety-net hospital settings, even without special interventions to address socioeconomic barriers to health. The cost of ERP implementation is minimal, and there is significant potential for cost savings based on reduced length of stay and decreased complications. Thus, it would be advantageous for safety-net facilities to consider adopting ERP.

There is a need for future studies to test the effectiveness of ERP in other surgical subspecialties in the safety-net setting. There is great potential for addressing healthcare disparities and cost-savings at these institutions. Further engagement with patients at our institution is also needed to identify what social interventions would most effectively address patient needs and further improve ERP outcomes.

DISCLOSURES

The author and supervising faculty have no conflicts of interests to disclose.

BIBLIOGRAPHY

- 1. Grol, R. and J. Grimshaw, From best evidence to best practice: effective implementation of change in patients' care. Lancet, 2003. **362**(9391): p. 1225-30.
- 2. Kehlet, H., et al., Care after colonic operation--is it evidence-based? Results from a multinational survey in Europe and the United States. J Am Coll Surg, 2006. **202**(1): p. 45-54.
- 3. Schilling, P.L., J.B. Dimick, and J.D. Birkmeyer, *Prioritizing quality improvement in general surgery*. J Am Coll Surg, 2008. **207**(5): p. 698-704.
- 4. Gustafsson, U.O., et al., Guidelines for perioperative care in elective colonic surgery: Enhanced Recovery After Surgery (ERAS((R))) Society recommendations. World J Surg, 2013. **37**(2): p. 259-84.
- 5. Zhuang, C.L., et al., *Enhanced recovery after surgery programs versus traditional care for colorectal surgery: a meta-analysis of randomized controlled trials.* Dis Colon Rectum, 2013. **56**(5): p. 667-78.
- 6. Adamina, M., et al., Enhanced recovery pathways optimize health outcomes and resource utilization: a meta-analysis of randomized controlled trials in colorectal surgery. Surgery, 2011. **149**(6): p. 830-40.
- 7. Varadhan, K.K., et al., *The enhanced recovery after surgery (ERAS) pathway for patients undergoing major elective open colorectal surgery: a meta-analysis of randomized controlled trials.* Clin Nutr, 2010. **29**(4): p. 434-40.
- 8. Lv, L., Y.F. Shao, and Y.B. Zhou, *The enhanced recovery after surgery (ERAS) pathway for patients undergoing colorectal surgery: an update of meta-analysis of randomized controlled trials.* Int J Colorectal Dis, 2012. **27**(12): p. 1549-54.
- 9. Kulkarni, R.P., et al., *Clinical pathways improve hospital resource use in endocrine surgery*. J Am Coll Surg, 2011. **212**(1): p. 35-41.
- 10. Archer, S.B., et al., *Implementation of a clinical pathway decreases length of stay and hospital charges for patients undergoing total colectomy and ileal pouch/anal anastomosis.* Surgery, 1997. **122**(4): p. 699-703; discussion 703-5.

- 11. Debarros, M. and S.R. Steele, *Perioperative protocols in colorectal surgery*. Clin Colon Rectal Surg, 2013. **26**(3): p. 139-45.
- 12. Thiele, R.H., et al., Standardization of care: impact of an enhanced recovery protocol on length of stay, complications, and direct costs after colorectal surgery. J Am Coll Surg, 2015. **220**(4): p. 430-43.
- 13. Institute of Medicine Committee on the Changing Market, M.C. and P. the Future Viability of Safety Net, in *Americas's Health Care Safety Net: Intact but Endangered*, M. Ein Lewin and S. Altman, Editors. 2000, National Academies Press (US) Copyright 2000 by the National Academy of Sciences. All rights reserved.: Washington (DC).
- 14. Kelz, R.R., et al., *Morbidity and mortality of colorectal carcinoma surgery differs by insurance status.* Cancer, 2004. **101**(10): p. 2187-94.
- 15. Zak, Y., K.F. Rhoads, and B.C. Visser, *Predictors of surgical intervention for hepatocellular carcinoma: race, socioeconomic status, and hospital type.* Arch Surg, 2011. **146**(7): p. 778-84.
- 16. Rhoads, K.F., et al., *Quality of colon cancer outcomes in hospitals with a high percentage of Medicaid patients.* J Am Coll Surg, 2008. **207**(2): p. 197-204.
- 17. Goldman, L.E., E. Vittinghoff, and R.A. Dudley, *Quality of care in hospitals with a high percent of Medicaid patients*. Med Care, 2007. **45**(6): p. 579-83.
- 18. Hasnain-Wynia, R., et al., *Disparities in health care are driven by where minority patients seek care: examination of the hospital quality alliance measures.* Arch Intern Med, 2007. **167**(12): p. 1233-9.
- 19. Jha, A.K., et al., Concentration and quality of hospitals that care for elderly black patients. Arch Intern Med, 2007. **167**(11): p. 1177-82.
- 20. Alawadi, Z.M., et al., Facilitators and barriers of implementing enhanced recovery in colorectal surgery at a safety net hospital: A provider and patient perspective. Surgery, 2016. **159**(3): p. 700-12.
- 21. Lawson, E.H., et al., *Identification of modifiable factors for reducing readmission after colectomy: a national analysis.* Surgery, 2014. **155**(5): p. 754-66.
- 22. Kangovi, S. and D. Grande, *Hospital readmissions--not just a measure of quality*. Jama, 2011. **306**(16): p. 1796-7.
- 23. Pedziwiatr, M., et al., Early implementation of Enhanced Recovery After Surgery (ERAS(R)) protocol Compliance improves outcomes: A prospective cohort study. Int J Surg, 2015. 21: p. 75-81.
- 24. Gustafsson, U.O., et al., *Adherence to the enhanced recovery after surgery protocol and outcomes after colorectal cancer surgery.* Arch Surg, 2011. **146**(5): p. 571-7.
- Werner, R.M., L.E. Goldman, and R.A. Dudley, *Comparison of change in quality of care between safety-net and non-safety-net hospitals*. Jama, 2008. **299**(18): p. 2180-7.
- 26. Marshall, L., et al., Safety net hospital performance on national quality of care process measures. J Healthc Qual, 2012. **34**(2): p. 21-31.
- 27. Ross, J.S., et al., *Based on key measures, care quality for Medicare enrollees at safety-net and non-safety-net hospitals was almost equal.* Health Aff (Millwood), 2012. **31**(8): p. 1739-48.
- 28. Mouch, C.A., et al., *The quality of surgical care in safety net hospitals: a systematic review.* Surgery, 2014. **155**(5): p. 826-38.

- 29. Bradley, C.J., et al., Surgery wait times and specialty services for insured and uninsured breast cancer patients: does hospital safety net status matter? Health Serv Res, 2012. 47(2): p. 677-97.
- 30. Ronellenfitsch, U., et al., *The effect of clinical pathways for bariatric surgery on perioperative quality of care.* Obes Surg, 2012. **22**(5): p. 732-9.

SUPPLEMENTAL APPENDIX

ENHANCED RECOVERY PATHWAY FOR ELECTIVE COLORECTAL SURGERY

Initial Pre-op Visit (1-4 weeks prior to surgery)

- Pre-operative nurse and patient education.
- Optimization of co-morbid conditions (e.g. hypertension, diabetes, malnutrition)
- No oral pre-operative sedatives/analgesics
- Smoking cessation for 2-4 weeks
- Limit alcohol consumption to <2 glasses of wine/day or <2 beers/day
- Enterostomal therapist consult for ostomy marking/teaching
- Baseline CRP with pre-operative labs
- Provider will initiate the pathway via EMR order (Surgery C phases of care order set)

Day Before Surgery

- Mechanical bowel prep per attending surgeon
- Chlorhexidine 4% shower evening before surgery, instructions regarding no shaving and no lotion/perfume afterwards

Pre-operatively on Day of Surgery

- Carbohydrate loading: Gatorade, 20 ounces, at home just prior to leaving for the hospital. If patient does not have Gatorade, drink at least one full glass of water before leaving home.
- Gabapentin 600mg po on arrival to the day surgery
- Acetaminophen liquid 1gm po on arrival to the day surgery
- Heparin 5000units sq 30-60 minutes before surgery

Intra-operatively

- Ertapenem 1gm IV 30-60 minutes before surgery; if penicillin allergy, give metronidazole 500mg IV x 1 and ciprofloxacin 500mg IV x 1
- Bilateral SCDs
- Maintenance of GA: O₂ + N₂O (if no contraindications) + desflurane or sevoflurane
- Minimize intraoperative opioid dose [e.g., fentanyl less than ~2-3 mcg/kg/h + hydromorphone at the end of surgery (NOT during) ~10-15mcg/kg (IBW) for

laparoscopic/superficial (e.g., colostomy closure) cases and ~15-20 mcg/kg (IBW) for open cases titrated approximately 20-30 min prior to expected time of extubation.

- Fluid therapy: Avoid fluid overload.
 - For open procedures: Goal directed fluid therapy using stroke volume variation (SVV). If arterial line is placed use FloTrac and if no arterial line-use Nexfin to guide fluid therapy.
 - Algorithm: If baseline SVV >14% administer 200mL of crystalloid, repeat until SVV <14%. Do not depend solely on SVV. Also use other parameters (e.g., urine output, hemodynamics) in conjunction with SVV.
 - For laparoscopic procedures: Use of FloTrac and Nexfin have not been studied, thus no guidance can be provided.
- Dexamethasone 8mg IV after induction of anesthesia
- Acetaminophen 1gm, IV [ONLY if not given orally preoperatively]
- Ondansetron 4mg IV at end of case
- Ketorolac at end of surgery: 30mg IV for healthy patients and 15mg, IV for elderly >65 years or if renal dysfunction [avoid ketorolac in patients with creatinine clearance <30 mL/min].
- Local/Regional Analgesia Technique
 - For open procedures: TAP block at the end of the case or in the PACU. If TAP block is not possible, wound infiltration by surgeon.
 - For laparoscopic procedures: Wound infiltration by surgeon.
- Reversal of neuromuscular blockade: neostigmine dose based upon train-of-four response
- Normothermia (core body temperature of 36-38°C).
- Discontinue nasogastric tube at end of case.
- Incisional negative pressure wound therapy for open clean-contaminated colorectal surgery per guidelines listed under Parkland policy manager.

Postoperatively

- Reversal of neuromuscular blockade: neostigmine dose based upon train-of-four response
- Normothermia (core body temperature of 36-38°C).
- Provider will initiate the pathway via EMR order (Surgery C post-operative order set)
- CBC, BMP on POD 1
- CRP on POD 2
- Physical therapy consult
- Out of bed every 4-6hrs/day
- Discontinue Foley on POD 1 except for pelvic operations (proctectomy, LAR, APR), then discontinue on POD 3
- Maintenance IV fluid rate 50cc/hr Lactate Ringer's on POD 0

- Heplock IV fluid POD 1 for open and laparoscopic cases, bolus 500cc Lactate Ringer's if urine output <0.5cc/kg/hr unless signs of hemodynamic instability (systolic blood pressure <90)
- Clears and Ensure 1 can BID after surgery POD 0
- Soft diet POD 1 laparoscopic, POD 2 for open cases
- Gum chewing allowed

Postoperative Medications

- Gabapentin 300mg po TID until discharge if CrCl >60ml/min, Gabapentin 300mg po BID until discharge if CrCl 30-60mL/min, and Gabapentin 300mg po Daily until discharge if CrCl <30mL/min
- Etodolac 400mg po BID
- Acetaminophen 1gm po q 8 hours
- Heparin 5000units sq TID, bilateral SCDs
- Insulin Sliding Scale for diabetics
- Hydromorphone PCA (patient controlled analgesia); no PCA for laparoscopic cases, discontinue PCA on POD 2 for open cases, then prn meds:
 - If pain < 5, Hydrocodone/Acetaminophen 5/325mg 1 po q 8 hours prn pain, Hydromorphone 0.2mg IV q4h prn pain (if unable to take po)
 - If pain > 5, Hydrocodone/Acetaminophen 10/325mg 1 po q 8 hours prn pain, Hydromorphone 0.5mg IV q4h prn pain (if unable to take po)

Discharge Criteria

- Surgeon discretion (in general: tolerating diet, has return of bowel function, has mobility)
- Detailed discharge instructions given
- Scheduled to return to clinic in 2-3 weeks

This protocol provides recommendations that are supported by analysis of current literature and by a synthesis of expert opinion. This guideline has been reviewed and approved by Dr. Joselin Anandam, Dr. Babatunde Ogunnaike, Dr. Girish Joshi, Carol Chamberlain, PharmD, and Maria Casco RN. This Protocol will be reviewed once every two years.

Abbreviations:

sq = subcutaneous

IV = intravenous

CBC = complete blood count

BMP = basic metabolic panel

CRP =c-reactive protein

POD = post-operative day

po = per oral

TID = three times a day

BID = twice daily

SCD = sequential compression devices

prn = as needed

CrCl = creatinine clearance

q = every

VITAE

Taylor Roberts (January 1st 1992 – present) was born in Metairie, Louisiana and was raised in Kingwood, Texas by her parents Debbie and Jim Roberts. In 2014, she graduated from the University of Notre Dame in South Bend, Indiana with degrees in Biological Sciences and International Peace Studies. She attends the University of Texas Southwestern Medical Center for medical school, and will continue her training there in the Internal Medicine residency program in July 2018.

Permanent Address: 4819 Linnet Lane

Dallas, Texas 75209