Medical University of South Carolina
Protocol

An Equity Focused Intervention to Improve Utilization in Guideline Concordant Extended Venous Thromboembolism Prophylaxis After Major Cancer Surgery

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Project Summary/Abstract

Venous thromboembolism (VTE) following major cancer surgery is a significant contributor to morbidity and mortality. Extended VTE prophylaxis (ePpx) following major cancer surgery decreases the risk of post-hospital VTE and is recommended by professional societies. However, utilization of ePpx remains limited. Moreover, racial disparities exist for cancer associated outcomes including VTE and mortality. These inequities in broader cancer care suggest that disparities may exist related to the utilization of ePpx. This aspect of cancer care has not been studied through a lens of cancer health disparities. The reasons for low utilization of ePpx remain a significant knowledge gap. Electronic medical record (EMR)-based clinical decision support systems (CDSS) have been effective in improving adherence to *inpatient* VTE prophylaxis though has not been studied for *ePpx*. The overall objective of this work is to identify barriers and facilitators related to ePpx guideline adherence and convene stakeholders to develop and implement a multi-faceted educational intervention including an EMR-based CDSS for increasing guideline adherence in a diverse oncology population. Our central hypothesis is that modifiable patient and surgeon factors exist, which provide an explanatory mechanism for poor adherence to ePpx guidelines (both by the surgeon and patient) and that these factors may be overcome by the equity focused intervention described below. We will test our hypotheses through these specific aims:

Specific Aim 1: Characterize barriers and facilitators to ePpx guideline adherence as perceived by stakeholders via key informant interviews with a diverse group of patients and surgeons at four hospitals within the MUSC Health system that routinely perform abdominopelvic cancer surgery.

Hypothesis 1: Barriers and facilitators related to ePpx use exist that are not forthcoming from clinical data; once uncovered, these factors will inform the educational interventions in Aims 2.1 and 2.2.

Specific Aim 2.1: Conduct a stepped-wedge randomized trial including multi-faceted surgeon-focused education and academic detailing to evaluate the impact of an EMR-based CDSS to increase adherence to ePpx guidelines at the three selected hospitals.

Hypothesis 2.1: The intervention will increase ePpx following abdominopelvic cancer surgery.

Specific Aim 2.2: Evaluate the impact of VTE related pre-discharge education on patient adherence to ePpx via a pre-post study of patients undergoing abdominopelvic cancer surgery at the three selected hospitals.

Hypothesis 2.2: Focused VTE related education will improve patient adherence.

The application of rigorous qualitative research methodology to this clinical context will elucidate mechanisms to improve administration of guideline concordant ePpx. Pairing these data with a multi-faceted, stakeholder informed educational intervention, this work has the potential to significantly impact cancer care and mitigate cancer health disparities.

The above study is funded by the National Cancer Institute through the Early-Stage Surgeon Scientist Program. The protocol below pertains to Aim 2.

TABLE OF CONTENTS

A. SPECIFIC AIMS

This protocol will only discuss Aim 2 as the focus of this IRB submission.

Specific Aim 2.1: Conduct a stepped-wedge randomized trial including multi-faceted surgeon-focused education and academic detailing to evaluate the impact of an EMR-based CDSS to increase adherence to ePpx guidelines at the three selected hospitals.

Hypothesis 2.1: The intervention will increase ePpx following abdominopelvic cancer surgery.

Specific Aim 2.2: Evaluate the impact of VTE related pre-discharge education on patient adherence to ePpx via a pre-post study of patients undergoing abdominopelvic cancer surgery at the three selected hospitals.

Hypothesis 2.2: Focused VTE related education will improve patient adherence.

B. BACKGROUND & SIGNIFICANCE

B.1. Venous thromboembolism (VTE) is highly morbid and costly in cancer patients. *Among abdominopelvic (gastrointestinal (GI), gynecologic (GYN), and urologic (GU)) cancer patients, those with VTE, including pulmonary embolism (PE) and deep vein thrombosis (DVT), had a 1.5 to 11.2 times increased risk of death within one year after controlling for age, cancer stage, and race.(22)* VTE is also a leading cause of death after cancer surgery accounting for 46 percent of deaths within 30-days in a large prospective study of surgical oncology patients.(23) In addition to the nearly one-third of PE patients who present with sudden death,(24) a national study of surgical oncology patients showed a nearly ten percent mortality among those readmitted with postoperative VTE.(25) These entities come at a substantial financial cost. VTE nearly doubles the cost of care over five years in patients with cancer or those having surgery.(26, 27)

B.2. In hospital and post-discharge VTE are common among surgical cancer patients. Cancer related hypercoagulability increases VTE risk 4-fold.(28) Compared to surgery for benign indications, abdominopelvic surgery for cancer has a 2- to 3-fold increased risk of VTE.(29) The Caprini model for 30-day postoperative VTE risk considers a score of 5 or greater to be "high risk." Based on this model, any patient age 41-60 undergoing abdominopelvic surgery for cancer is "high risk" with a minimum estimated 30-day VTE risk of 1.33%.(30) Across commonly performed major cancer surgical resections, the median length of hospital stay ranges from 4 to 10 days in national observational series.(31) It is thus unsurprising that post-hospital VTE accounts for 18% to 47% of VTE following abdominopelvic cancer surgery.(31-34)

B.3. Extended VTE prophylaxis effectiveness and guidelines. Post-hospital extended VTE prophylaxis (ePpx) after major cancer surgery is safe and effective with a 2009 Cochrane review of randomized trials showing a reduction from 14% to 6% in any VTE and 1.7% to 0.2% in symptomatic VTE.(35) Since 2012, the American Academy of Chest Physicians,(36) the National Comprehensive Cancer Network,(37) the American Society of Clinical Oncology,(38) the European Association of Urology,(39) American College of Obstetricians and Gynecologists,(40) and the American Society of Colon and Rectal Surgery(41) have recommended consideration of ePpx after abdominopelvic cancer surgery using low molecular weight heparin (LMWH). A 2019 Cochrane review evaluating an additional three randomized trials reaffirmed the safety and efficacy of ePpx.(42)

B.4. Extended VTE prophylaxis utilization remains low. Yet, uptake of these recommendations has been limited. Across multiple sources including statewide surgical quality collaboratives, national administrative data and surgeon survey, ePpx ranged from thirteen to forty percent.(43-47) The reasons for low utilization have not been forthcoming from existing data and remain a significant knowledge gap; one we intend to bridge with the proposed study. Concerns for adverse bleeding events, cost, perceived limited evidence, surgeon awareness of guidelines, and patient adherence have been put forward as reasons for poor surgeon guideline adherence.(48)

B.5. Racial disparities in cancer outcomes and cancer associated VTE. Decreased survival has been observed for Black patients across abdominopelvic cancers.(49-51) This phenomenon is likely multifactorial with environmental, societal, and genetic contributing factors. In conceptual support of this, racial residential segregation is associated with increased stage at presentation and decreased cancer specific survival for Black patients with colorectal cancer.(52) In the Southern US in particular, rural populations have shown higher stage at presentation for cancers with preventive opportunities.(53) Black patients with abdominopelvic malignancy are 40 to 60 percent more likely to suffer VTE overall,(54) and 56 percent more likely to suffer VTE after cancer surgery than White patients.(55) These inequities in broader cancer care suggest that disparities may exist related to the utilization of ePpx. Indeed, this aspect of cancer care has not been studied through a lens of cancer

health disparities. Inequities related to socioeconomic status and geography (*i.e*., rural area of residence) may be considered in addition to race related disparities to examine the intersection of these characteristics.

B.6. Electronic medical record (EMR) based interventions to improve *inpatient* VTE prophylaxis. Computerized clinical decision support systems (CDSS) have been deployed in a variety of clinical contexts to improve healthcare quality.(56) A Cochrane review of 13 randomized controlled trials (RCTs) evaluating human or EMR-based alerts to improve *inpatient* VTE prophylaxis showed a 21% increase in VTE prophylaxis utilization with a further 4% increase observed with multi-faceted interventions such as academic detailing.(57) A meta-analysis of eleven non-randomized trials evaluating EMR-based decision support tools to improve *inpatient* VTE prophylaxis in surgical patients showed a 2.35 times increased odds of appropriate VTE prophylaxis being ordered with EMR-based decision support and a 0.78 relative risk of VTE.(58) Despite robust evidence in favor of EMR-based decision support in the *inpatient* setting, this approach has not been applied to *post-discharge* VTE prophylaxis in surgical patients. Educational interventions to improve prescription of ePpx have shown promise but have been limited to small, single institution studies.(59-61)

B.7. Innovation. *The proposed research program is aligned with the missions of the National Cancer Institute (NCI) Division of Cancer Control and Population Sciences, NCI Center to Reduce Cancer Health Disparities, and National Institute on Minority Health and Health Disparities (NIMHD). It is highly innovative in the following ways*:

1. The proposed multi-site RCT represents **a novel application of an EMR-based CDSS aimed at improving utilization of ePpx after abdominopelvic cancer surgery**. This will be the **first stakeholder informed intervention in a broad surgical oncology population and the first to have an underlying theoretical framework**. This intervention has the potential to be deployed across the Accrual to Clinical Trials (ACT) network, an existing clinical trial infrastructure, as part of an extramural grant.
2. This trial will be the first to evaluate the utilization of ePpx from a health equity perspective. The patient population of South Carolina (SC), described in detail below, is unique in its **large proportion of Black, rural, and economically disadvantaged patients**, populations which have been significantly underrepresented in the surgical literature to date. Although the SC population is unique, it has the potential to provide generalizable data for use in improving the care of vulnerable populations in a wide variety of settings.

C.1. Preliminary Data. Our multi-disciplinary research team has a strong track record of collaboration in health equity research. Drs. Curran and Ford published on the association of tumor microenvironment immune signatures with racial disparities in colon cancer.(14) In Dr. Curran's role as the MUSC surgical lead for the South Carolina Surgical Quality Collaborative (SC SQC), for which Dr. Mauldin is the data lead, Dr. Curran led a study that showed an association with improvement in racial disparities in surgical morbidity over time across the SC SQC.(13) Drs. Ford and Lenert have implemented a statewide genomic screening initiative across the diverse SC population, (62, 63) and Drs. Lenert and Mauldin have evaluated the role of a health information exchange to improve emergency department care of patients in SC.(64, 65)

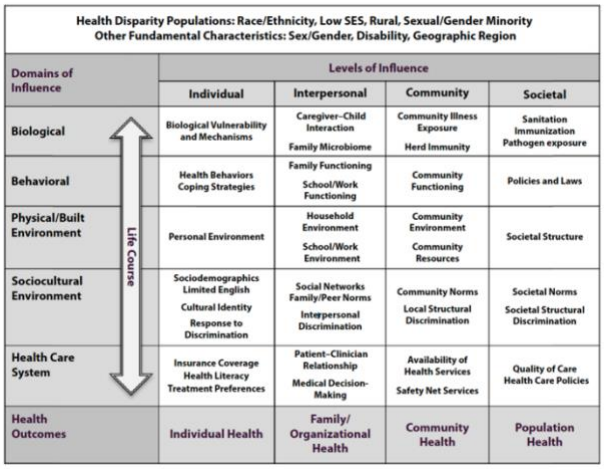
In an abstract recently submitted to the American Society of Colon and Rectal Surgeons Annual meeting and in preparation for publication, Drs. Curran and Mauldin characterized the utilization of ePpx after abdominopelvic cancer surgery at MUSC Charleston from 2014 to 2021. In 3,874 patients, we identified an overall guideline concordant utilization rate of 22.9% which is consistent with published data as above. On multivariable logistic regression, we noted that Black race (OR 0.79; 95%CI: 0.65-0.96), as compared to White race, and poverty (OR: 0.77; 95CI: 0.64-0.93) were independently associated with non-receipt of ePpx. Among colorectal cancer patients, rural patients were less likely to receive ePpx (OR: 0.70; 95%CI: 0.50-0.97). Dr. Curran has also been awarded a pilot grant through the American Cancer Society to evaluate racial disparities in ePpx using national Surveillance, Epidemiology, and End Results (SEER)/Medicare data. Unpublished preliminary analysis of these data shows poor adherence to guidelines with only five percent of colorectal cancer patients receiving a prescription for ePpx from 2016 to 2019. While the SEER/Medicare analysis is ongoing, these institutional data suggest the presence of disparities with the potential for amelioration through focused intervention.

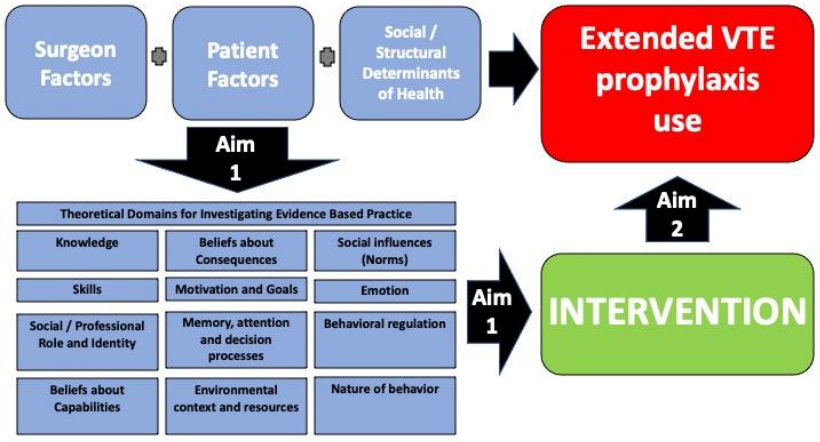
Seeking to augment both the training and intervention aspects of the mentorship team, Dr. Curran has recently collaborated with Drs. Phillips, Lenert and Deshmukh. Dr. Phillips has specific expertise in identification of barriers and facilitators to guideline-based care in sickle cell disease, which has directly informed the development of

Aims 1 and 2.2.(66) Dr. Lenert is the PI of a U01 award to pioneer an EMR-based CDSS to identify cases of opioid overdose and improve emergency department physician adherence to guideline-based naloxone adherence. The CDSS improved prescription of naloxone 4-fold at MUSC,(67) and will now be deployed to four centers as part of the U01 funded RCT. This experience in EMR-based CDSS will be leveraged to complete Aim 2.1. Dr. Deshmukh's expertise in trial design and data analytics demonstrated in a diverse anal cancer population will add further depth to the mentorship team. Dr. Curran's clinical and research expertise as a surgeon paired with the mentorship of this talented multi-disciplinary team makes him uniquely qualified to conduct the work described here.

D. RESEARCH DESIGN & METHODS

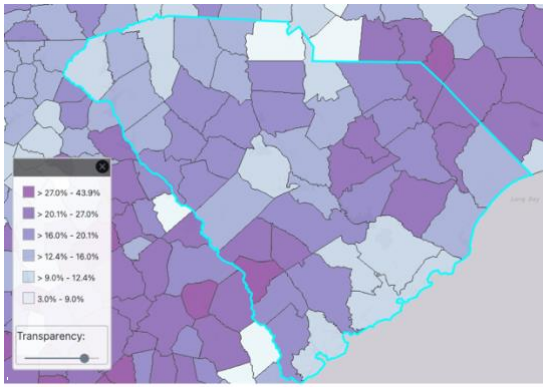
D.1. Overview and Conceptual Model. The over-arching goal of this research is to improve the utilization of ePpx following abdominopelvic cancer surgery and mitigate observed disparities. As put forward by the NIMHD





Research Framework, multiple domains and levels of influence may be implicated in disparate health outcomes (**Figure D1**).(68) With that in mind, barriers and facilitators of ePpx may exist among surgeons and patients that are not forthcoming from clinical data and these barriers/facilitators may vary depending on the specific patient and surgeon (Aim 1). The information gleaned from patient and surgeon interviews will inform a multi-faceted, EMR-based CDSS trial to improve surgeon adherence to guideline recommended ePpx across a variety of practice settings (Aim 2.1) and educate patients to improve adherence (Aim 2.2).

The above hypotheses will be tested through a prospective, multiple methods study including direct patient and surgeon interviews using purposive sampling to obtain representative perspectives. The multiple methods approach is advocated to maximize the effectiveness of RCTs by incorporating stakeholder feedback at the design and delivery phases.(16-19) The Theoretical Domains Framework (TDF) will inform the patient and surgeon interviews to maximize the effect of our patient and surgeon focused interventions. In a review evaluating the use of theory to evaluate guideline implementation among physicians, the TDF was among the most commonly used methods to identify barriers, select/tailor interventions, and evaluate intervention impact.(69) The TDF identifies 12 domains with associated component constructs and elicits questions for investigating the implementation of evidence-based practice.(70) The domains associated with the TDF will be used to inform the key informant and focus group interviews (Aim 1) by specifically identifying NIMHD-defined domains and levels of influence (surgeon factors, patient factors, and SSDH) associated with prescription of ePpx after cancer surgery. These findings will then shape the intervention deployed in Aim 2 to improve equitable and guideline concordant ePpx use. *The intersection of the NIMHD research framework and the TDF is highlighted in **Figure D2** above.*



D.2. Study Setting and Data Sources.
South Carolina. SC presents a unique opportunity to impact disparities in the utilization of ePpx following abdominopelvic cancer surgery owing to a *large disadvantaged and underserved population*. Foremost, SC has a high degree of racial/ethnic diversity with 28% of residents of Non-Hispanic Black race according to 2019 US census data.(71) As of 2018, 15% of SC residents lived below the Federal Poverty Level (FPL) and 20% lived between 100%-199% of the FPL, higher than the national average of 13% and 17%, respectively (**Figure D3**).(72) Further contributors to disparity include healthcare access, as 34% of SC residents reside in rural areas, which is seventeenth among US states.(73) Finally, SC ranks 40th in the rate of uninsured nonelderly individuals (13.1%, US average 10.9%).(72) The demographics of the MUSC Hollings Cancer Center patients mirror the population of the state closely.
MUSC Regional Health Network. Three of eleven MUSC hospitals routinely perform abdominopelvic cancer surgery. These include an urban academic tertiary care center (MUSC Charleston, 865 beds), an urban private hospital (MUSC Columbia Downtown, 258 beds) and a rural private hospital (MUSC Florence, 396 beds). As of January 2022, the entire health system adopted a common electronic medical record (EMR; Epic).

D.3. Prospective study design and implementation.
Specific Aim 2.1: *Conduct a stepped-wedge randomized trial including multi-faceted surgeon focused education and academic detailing to evaluate the impact of an EMR-based decision support tool to increase adherence to ePpx guidelines at four hospitals (six clinics) within the MUSC Health system.*

Aim 2.1. Intervention Design and Population. Surgeons performing cancer surgery within the MUSC system will be identified. Patients undergoing surgery for included cancers in the four hospitals will be identified using inclusion/exclusion criteria as follows. “Abdominopelvic cancer surgery” includes esophagectomy, gastrectomy, pancreatectomy, small bowel resection, colectomy, proctectomy, cystectomy, nephrectomy and hysterectomy / oophorectomy performed for a diagnosis of cancer as identified by Current Procedural Terminology (CPT) code and International Classification of Diseases, Tenth Revision (ICD-10) diagnosis code. See Appendix 1 for code listings. We will exclude patients receiving preoperative therapeutic anticoagulation within 30 days preoperatively, patients initiating therapeutic anticoagulation postoperatively and patients with chronic kidney disease grade 3 or higher. Patients with postoperative length of stay 30 days or greater will be excluded as ePpx duration is for 30 days postoperative.

Human Subjects Involvement, Characteristics, and Design

Aim 2.1. Surgeons performing the relevant surgical oncology operations at the four sites within the MUSC Enterprise will be the focus of the multi-faceted educational intervention.

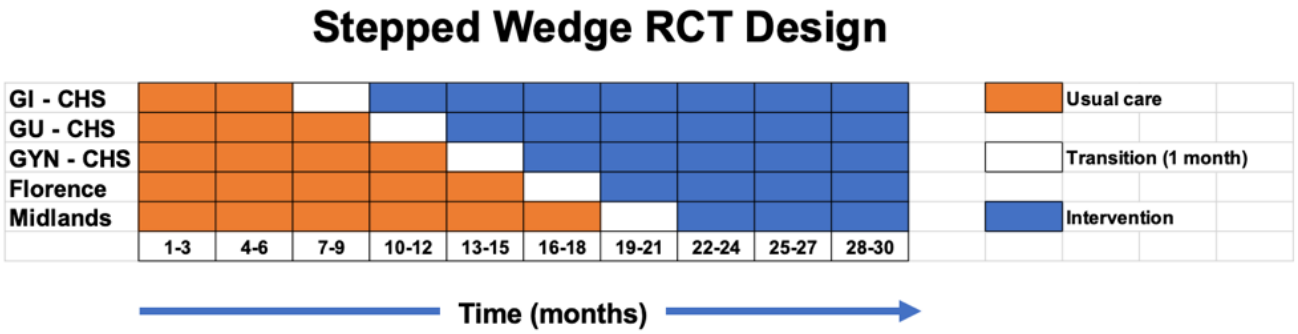
Recruitment.
Specific Aim 2.1. Surgeons performing cancer surgery within the MUSC Enterprise will be identified. There are approximately 30 surgeons across the 3 identified sites who routinely perform the relevant oncologic operations. The surgeon focused intervention will involve a combination of: (1) small group education at multi-disciplinary tumor board; (2) on-site academic detailing performed by the PI; and (3) an EMR-based CDSS. Academic detailing has been advocated by the Agency for Healthcare Research and Quality, and will be conducted in accordance with expert consensus best practices. Interventions 1-3 will take place during the one month transition period during of the stepped wedge study design. Surgeon re-engagement will take place at 3-month intervals via presentations at presentations at multi-disciplinary tumor board or individually.

Retention.
Specific Aim 2.1. Surgeon engagement will occur through regularly occurring Departmental activities including morbidity and mortality conference and multi-disciplinary tumor board. Attendance at these meetings are an integral part of surgeon clinical and academic responsibilities. Attendance at these events is monitored by the

department via pre-existing processes. Individual engagement may occur as needed for those surgeons not participating in the above conferences. The electronic medical record is necessarily used in all aspects of patient care and as a result, all providers performing clinical care of included patients will be exposed to the electronic medical record based clinical decision support system.

Aim 2.1. Intervention. The surgeon focused intervention will involve a combination of: (1) small group education at multi-disciplinary tumor board; (2) on-site academic detailing performed by the PI; and (3) an EMR-based CDSS. Academic detailing has been advocated by the Agency for Healthcare Research and Quality,(77) and will be conducted in accordance with expert consensus best practices.(78) The educational intervention will be specifically tailored to address barriers identified in Aim 1 (*i.e.,* risks, benefits of ePpx) and/or leverage facilitators. As noted above, Dr. Lenert has pioneered an EMR-based CDSS for prescription of naloxone in the emergency department management of opioid overdose.(67) This CDSS utilized a novel two-step non-interruptive approach 1) insertion of a reminder to access a template for documentation of emergency department-based opioid overdose care into providers' notes based on the patient's chief complaint, and 2) a corresponding documentation template for the overdose care, that when inserted into the note, provided support to help providers capture critical aspects of the history, physical exam, and to take actions to mitigate future risk. Dr. Lenert has collaborated with Dr. Curran to develop the CDSS, which will be automatically triggered by the patient's cancer diagnosis and surgical procedure. On postoperative day 1, the progress note will automatically incorporate the Caprini model for VTE risk stratification into the assessment and plan portion of the note.(30) The risk stratification will be used to recommend guideline based strategies for pharmacologic ePPx which may be utilized at the discretion of the clinician. A second notification will occur at the "medication reconciliation" portion of the discharge process with a remind of the patient's Carpini model derived risk and a recommendation for consideration of ePPx at the discretion of the clinician. The CDSS will be refined by the surgeon interviews in Aim 1 to optimize the timing (*i.e*., at admission, discharge, etc.) and location(s) of the CDSS (*i.e.,* in progress notes, discharge summary, medication reconciliation, etc.).

Aim 2.1. Prospective Study Design and Data Retrieval. We will deploy the intervention described above, including physician education and EMR-based CDSS in a stepped wedge RCT. The five clusters (six clinics) within the four hospitals for randomization include (1) MUSC Florence, (2) MUSC Midlands/Lancaster, and (3) GI, (4) GU, and (5) GYN surgical oncology at MUSC Charleston. We propose a prospective, stepped-wedge, cluster RCT with an open cohort design to study the implementation of an EMR-based CDSS. The stepped-wedge design permits all clinics to receive the intervention at some point during the study period. Each clinic will spend study time in the control phase before transitioning to the intervention phase, enabling the evaluation of the intervention within and between clinics. All clinics will begin the study in the control, or usual care, phase. The intervention will be

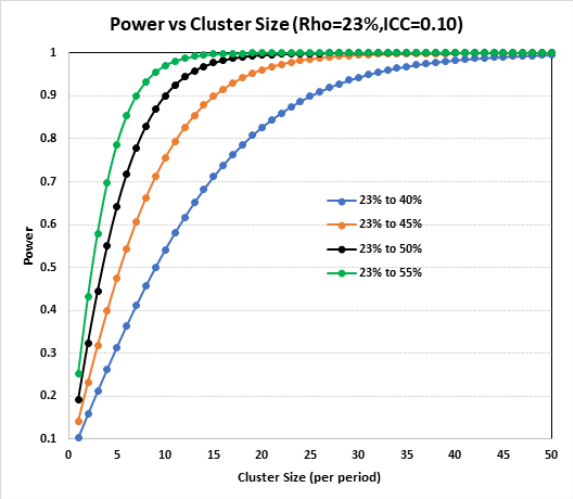


introduced in 5 steps with 1 clinic per step at intervals of 3 months (**Figure D4**). The transition phase from the control period to the intervention period will last 1 month and provide time for rolling out the education and EMR CDSS access. A computer-generated randomization program will assign clinics to one of the 5 pre-defined transition steps (months 7, 10, 13, 16, and 19). Clinicians implementing the intervention cannot be blinded to the clinic's assignment group, but the extraction outcome measures will be performed by the study team blinded to the intervention groups. Only the statistical programmer on the study will be unblinded to the outcomes.

Primary outcome: The primary outcome will be the proportion of patients prescribed ePpx at discharge. This will be assessed at the clinic level. Patients receiving a postoperative prescription for LMWH, the standard ePpx, or apixaban, an alternative ePpx, will be identified through the EMR.
Secondary outcome: The secondary outcomes will be (a) association of ePpx at the patient level with race and SSDH and (b) the rate of VTE or major bleeding at 30 and 90 days postoperative.

Aim 2.1. Covariates.

- Patient Data: Defined comorbid conditions will be retrieved from the EMR and include the components of the Caprini Score for risk stratification.(30) Socio-demographic information including age, sex, and insurance status will be retrieved. Race will be retrieved and categorized as Black/non-Black. Urban/rural geographic residence status will be determined using the FORHP Rural Areas crosswalk of ZIP Codes. Area deprivation index will be applied by zip code to assess SSDH.(79)
- Procedural and Postoperative Data: Procedure data including procedure type by CPT code, operative time, length of stay, and postoperative complications will be retrieved from EMR.



Aim 2.1. Statistical analysis. Univariate analyses with descriptive statistics and frequency distributions will be calculated for patient and clinic variables and primary implementation outcomes. Counts and proportions of eligible patients in each clinic receiving the EMR tool will be calculated for adoption outcomes. All variables will be compared between unexposed control periods and exposed intervention periods. The intent-to-treat (ITT) population, comprising all eligible patients according to randomized clinic crossover time (from control phase to intervention phase of the study), regardless of the availability of outcome data, will be used for the analyses. We will develop multivariable regression models using a generalized linear mixed modeling (GLMM) framework to evaluate the association of the intervention with outcomes while adjusting for potentially confounding covariates. Predictors will be pre-specified and include patient age, sex, race, and comorbidities. We will also choose variables using clinical relevance and results from the descriptive univariate analyses. We will use GLMM with random effects to account for the correlation between individuals within the same clinic). The GLMM will account for confounders and interaction terms producing robust estimates. We will include an interaction term between the intervention and race indicator to be followed by an interaction term of the intervention with the SSDH indicator. We will also use Generalized Estimating Equations (GEE) for additional analyses as GEE can handle normal or non-normal endpoints and GEE can be more robust than GLMM to misspecification of the variance structure since “sandwich” type variance estimates are used. Models will be assessed for collinearity and goodness of fit using residual analysis. Additional model diagnostics will be performed using SAS tools that detect outliers and influential data points. We will examine variance inflation factor (VIF) by checking if VIF >5 which implies collinearity and predictive accuracy (measured by the concordance index/c-statistics). Significance will be determined at the 0.05 level, and SAS 9.4 (SAS, Cary, NC) will be used for the statistical programming.

Aim 2.1. Sample Size and Power. Sample size estimation for stepped-wedge trials was performed using the SWSamp RPackage. We based the sample size on a binary outcome of the proportion of patients prescribed ePpx at discharge. Our preliminary data demonstrate that 22.9% of patients with abdominopelvic cancer surgery have been prescribed ePpx at discharge. We expect to increase the proportion of patients with prescribed ePpx at discharge from 22.9%% to 50% based on effect sizes for prior studies noted in section C6. We computed the power using the following assumptions: an intra-cluster correlation (ICC) of 0.10; type-I error of 5%. Given these, for a total of 5 clusters (clinics) transitioned from control to intervention at each of the 5 steps, the total sample size required to provide at least an 80% likelihood of detecting a 27% difference is 7.5 patients per step per cluster (clinic), or a total of 37.5 patients per clinic during the intervention period (**Figure**

D5). This amounts to a total of 188 study patients. Based on our institutional audit, each clinic has monthly volumes in excess of this threshold.

Specific Aim 2.2: *Evaluate the impact of dedicated VTE related pre-discharge education on patient adherence to ePpx via a pre-post study of patients undergoing abdominopelvic cancer surgery at four hospitals within the MUSC Health system.*

Aim 2.2. Intervention and Population. Utilizing the insights gained in Aim 1, a one-page education sheet will be created to educate patients on the risks of VTE and importance of ePpx. This will be included with the patient's hospital discharge information and reviewed with each patient prior to discharge by the discharge coordinator or nurse. This will be a pre-post study. The pre-intervention period will consist of the six months during which Aim 1 is taking place. The post-intervention will be after the implementation of the educational intervention and last 18 months. The patient population is defined in Aim 2.1. A REDCap survey will assess adherence to ePpx and health literacy as measured by the validated 3-item Brief Health Literacy Screening,(80, 81) and adverse events.

Human Subjects Involvement, Characteristics, and Design

Aim 2.2. Patients undergoing the relevant surgical oncology operations at the four sites within the MUSC Enterprise will be the focus of the patient educational intervention.

Recruitment.

Specific Aim 2.2. Patients will be identified prospectively using ICD-10 cancer diagnosis codes matched with the corresponding current procedural terminology (CPT) code. They will be a one-page education sheet will be created to educate patients on the risks of VTE and importance of ePpx. This will be included with the patient's hospital discharge information and reviewed with each patient prior to discharge by the discharge coordinator or nurse. At 30-days postoperatively, patients will be sent a link to a REDCap survey via the EMR integrated MyChart platform or their designated, preferred email address. Patients without access to electronic communication may be contacted by telephone. REDCap survey included as Appendix 2.

Retention.

Aim 2.2. Identification of patients meeting inclusion criteria will be automated through the EMR. Audits to assess accuracy of identification will be manually performed or cross referenced with an institutional cancer registry.
Primary outcome: The primary outcome will be adherence to ePpx as assessed by REDCap survey at 30-days postoperative. Adherence will be defined as the percentage of days covered with treatment during the prescription period (i.e. duration at discharge) which has been used previously to assess ePpx.(82) This will include filled prescription and approximate number of doses administered out of number of doses prescribed. Patients without access to electronic mail will be contacted by telephone.
Secondary outcomes: Patient reported reasons for non-adherence, bleeding events, or VTE.
Aim 2.1. Covariates. These are as defined in Aim 2.1.
Aim 2.1. Statistical analysis. We will compare the proportion of patient's adherent to ePpx before and after the educational intervention. Sub-group analyses will compare adherence by procedure, sociodemographic characteristics, health literacy, and SSDH. Proportions will be compared using Fisher's exact test.
Aim 2.2 Sample Size & Power. Prior estimates in the orthopedic, gynecologic oncology and urologic oncology populations demonstrated ePpx adherence of 75% to 85%.(20, 21, 82) Assuming a baseline adherence rate of 80%, a sample size of 199 patients in each group would provide 80% power at a type I error rate of 5% to detect an improvement in adherence to 90%. Assuming a survey response rate of 40%, our monthly volume of over 50 surgical oncology patients per month should provide adequate power to identify a difference in our primary outcome. Sub-group analyses will be exploratory in nature.

Study Procedures and Materials

D.4. Limitations, Alternative Approaches.
Aim 2.1. The ability of the CDSS to algorithmically identify appropriate surgical oncology patients will be assessed via comparison with an institutional cancer registry.

Aim 2.2. Survey response may be lower than expected and responders may be non-representative. This can be addressed by comparison of respondents to overall demographics and targeted outreach.

E. DATA MANAGEMENT

Participant Screening and Enrollment. All data will be entered into an electronic study database. Designated research staff will collect, gather, and enter required data from the EMR (Aim 2.1: demographics, clinical data) and study surveys (Aim 2.2) onto study data forms. The collected data will be helpful in examining the patient population and feasibility of enrollment criteria and will include gender, age, race and reason for exclusion. All dates will be shifted and other Personal Health Information (PHI) will be removed from the study database upon study completion. All data obtained from this study will be used for research purposes only and will comply with Federal HIPAA regulations. Master Screening and Enrollment Logs will be maintained electronically and will be used to prepare reports.

Data Security. Ensuring data security, compliance with 45 CFR 46 and maintaining the integrity of PHI is a top priority. MUSC has Standard Operating Procedures (SOP) to ensure a high level of data security while coordinating electronic and paper data management activities for clinical research trials. This study will use Research Electronic Data Capture (REDCap) for data capture and management. REDCap is a software toolset and workflow methodology for the electronic collection and management of research and clinical trials data. REDCap provides secure, web-based, flexible applications, including real-time validation rules with automated data type and range checks at the time of data entry. Exports are made available for several statistical packages including SPSS, SAS, SATA, R and Microsoft Excel. The study-specific REDCap electronic database will be designed and developed by the data manager. The provision of REDCap is made available through the South Carolina Clinical & Translational Research (SCTR) Institute at MUSC with NIH Grant awards UL1RR029882 and UL1TR000062. The REDCap study database will be hosted in the Biomedical Informatics secure data center at MUSC, a secure environment for data systems and servers on campus, and includes firewall, redundancy, failover capability, backups and extensive security checks. The secure data center has strict access control; only authorized core personnel may access the facility un-escorted. Only authorized users are allowed to connect to the network, and the security of the network is actively monitored. Power and environmental controls have several layers of backups, from interruptible power supplies to alternate and redundant feeds to the local utility company. The REDCap system administrator contributes to the maintenance of institutional disaster recovery and business continuity plans. Load balancers and a highly fault tolerant SAN infrastructure contribute to high availability. The REDCap system itself has several additional layers of protection including password protection. Access to the data and its security is managed institutionally by sponsored login IDs through a Shibboleth login with an MUSC issued NetID and features a user account management filter that controls who can access the data and to what degree. All personnel must pass an employment background check before being issued an ID. Data Entry. Only MUSC IRB approved study personnel that are authorized to have access to the REDCap study database will be granted password access. Study personnel using computers that are connected to the Internet will directly enter data into the remotely housed database. As such, no electronic study data will be stored on hard drives and/or any portable electronic devices. Additionally, all personnel with access to the database will have current University of Miami CITI training in the Conduct of Human Subject Protections, and their respective institution's HIPAA and Information Security trainings that are completed annually. Each participant will be assigned a unique study identifier, all PHIs will be masked, and data exports will be limited to the study team for generating reports and the conduct of statistical data analysis.

F. PROTECTION OF HUMAN SUBJECTS

1. RISKS TO THE SUBJECTS

a. Human Subjects Characteristics

Aim 2.1. Surgeons performing the relevant surgical oncology operations at the four sites within the MUSC Enterprise will be the focus of the multi-faceted educational intervention.

Aim 2.2. Patients undergoing the relevant surgical oncology operations at the four sites within the MUSC Enterprise will be the focus of the patient educational intervention.

INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN
Aim 2.1. All surgeons and hospital-based providers are adults. There will be no maximum age.

Aim 2.2. Adult patients (ages 18 and over) will be eligible to receive the survey. Children and adolescents under the age of 18 are excluded from this study because these cancers are rare in children. There will be no maximum age.

INCLUSION OF WOMEN AND MINORITIES
Planned Distribution of Subjects by Sex/Gender, Race, and Ethnicity
Aim 2.1. Surgeons and hospital-based providers have pre-established profile according to sex/gender, race and ethnicity. We will work to engage all surgical oncologists and team members performing the relevant surgical procedures.

Aim 2.2. The source of recruitment will be from the Medical University of South Carolina (MUSC) patient population. The strengths of MUSC catchment area relate to the ability to recruit Black, white, and Hispanic participants. We anticipate a slightly higher distribution of females (60%) given that patients with uterine and ovarian cancers are eligible for inclusion. The primary source of recruitment will be from the MUSC-Charleston which serves as the major statewide tertiary care oncology facility. The inclusion of smaller regional hospitals recently added to the MUSC network will facilitate recruitment of a more geographically diverse cohort. This will also increase the generalizability of the study through added representation of care in the community setting.

MUSC: Catchment Area and Population Served
MUSC serves the entire state of South Carolina. The racial composition of the MUSC catchment area is 68% White, 27% Black/Africa American, Mixed Race 2%; 1% Native American, <1% Asian; the ethnic composition is 6% Latin-X/Hispanic. There are socioeconomic and complex cultural, geographic and potentially biological factors related to cancer incidence, diagnosis, and surgical outcomes. Among all South Carolinians, up to 75 percent of new cancer cases and cancer deaths are caused by preventable factors such as tobacco use, poor diet, lack of exercise and limited access to health care. South Carolina leads the Nation in cancer disparities.

2. **Potential Risks**
Aim 2.1. The intervention directed toward surgical oncology providers within the MUSC health system includes education regarding current standard of care practice and an electronic medical record clinical decision support system intended to improve adherence to existing standard of care practice. The only potential risks include time spent reviewing educational materials and inconvenience associated with the electronic medical record.

Aim 2.2. Participation and response to the electronic survey is at the discretion of the patient.

3. Adequacy of Protection Against Risks

a. Recruitment, Informed Consent and Assent
Aim 2.1/2.2. Given the nature of the proposed intervention, a waiver of informed consent is requested from the IRB.

Subjects will be recruited as described above in Research Design and Methods.

We will also take extensive precautions to protect the privacy of the participants. Personal health identifiers (e.g., name, address) will not be used to identify participants in study databases. This study will use Research Electronic Data Capture (REDCap) for data capture and management. REDCap is a software toolset and workflow methodology for the electronic collection and management of research and clinical trials data. REDCap provides secure, web-based, flexible applications, including real-time validation rules with automated data type

and range checks at the time of data entry. Exports are made available for several statistical packages including SPSS, SAS, SATA, R and Microsoft Excel. The study-specific REDCap electronic database will be designed and developed by the data manager. We will use a confidential subject identification number to identify all participant data in research databases and on study documents. A hard copy of the key containing each participant's name, study identification number, and telephone number will be kept in a locked file cabinet until study procedures have been completed and the data have been checked for completeness and accuracy. At that time, this identifying information will be destroyed. Thus, we will retain no identifying information in the study data files. Moreover, all computerized study databases for questionnaire data will be housed on a secure, password-protected network server. All personal contact information will be kept in a database that will be housed separately from the database containing questionnaire data. There will be limited access to study files and study databases throughout the duration of the study; only pertinent study staff will have access to study information. Securing of participant identifying information will be accomplished through several means. All study documents including screeners, consents, assessments and call logs will be kept in a locked file cabinet in a locked office.

b. Protections Against Risk

The data management system for the proposed research will be designed to achieve the major elements of the study including: (1) determination of study eligibility, (2) monitoring recruitment and accrual, (3) generation of study materials, and (4) storage of data from survey responses. This type of system has been developed as part of Dr. Ford's previous studies and we will use these existing data management systems as the model for developing the data management system for the proposed study. All data collected as part of this study will be stored on a secure password-protected network server. Moreover, access to the server will be monitored by the PI and limited to pertinent study personnel.

Protection against Adverse Reactions. As described above, study data will be entered into research databases using a confidential subject identification number.

Handling Incidental Findings and Adverse Effects. In the event of any unexpected events related to incidental findings, safety concerns, and adverse effects, the PIs and/or study staff will contact the MUSC IRB (IRB of record) to discuss appropriate action.

c**. Vulnerable Subjects**
Pregnant Women, Fetuses, and Neonates or Children. This study does not involve the recruitment of children or the collection of specimens from fetuses or neonates. As the educational interventions are at the surgeon-level, there are no additional risks posed to pregnant women.

Prisoners. This study does not involve the recruitment of prisoners.

4. Potential Benefits of the Proposed Research to Research Participants and Others
Aim 2.1 of the study has the potential to benefit the participating surgeons by educating them on existing evidence-based guidelines related to extended VTE prophylaxis after abdominopelvic cancer surgery. The patients treated by these providers may also benefit by improving the likelihood of extended VTE prophylaxis, a treatment with demonstrated benefit in Level 1 evidence. The potential risks associated with study participation are minimal. Aim 2.2 has the potential to benefit patients by receiving education related to blood clot recognition and prevention after abdominopelvic cancer surgery (the intervention). The risks of survey response are minimal.

5. Importance of Knowledge to be Gained
Venous thromboembolism (VTE) following major cancer surgery is a significant contributor to patient morbidity and mortality. Extended VTE prophylaxis following major cancer surgery has been shown to decrease the risk of post-hospital VTE and is recommended by a number of professional societies. However, utilization of extended VTE prophylaxis remains limited. Moreover, racial disparities exist for cancer associated outcomes such as morbidity, including VTE, and mortality. These inequities in broader cancer care and the lack of guideline concordant care for Black patients suggests that disparities may exist related to the utilization of extended VTE prophylaxis as well. Indeed, this aspect of cancer care has not been studied through a lens of cancer health

disparities. The reasons for low utilization have not been forthcoming from existing data and remain a significant knowledge gap; a gap we intend to bridge with the proposed study. The application of rigorous qualitative research methodology to this clinical context will elucidate mechanisms to improve administration of guideline concordant extended VTE prophylaxis. Pairing these data with validated intervention development methodology, the intervention implemented through this work has the potential to significantly impact cancer care and mitigate cancer health disparities.

The proposed work also opens the door for the principal investigator to pursue future cancer health equity focused interventions. This methodology may be used to improve adherence to guideline concordant care across the continuum of cancer care in light of previously noted racial disparities in guideline concordant treatment. The methodology and lessons learned in this work will inform the investigator's K23 grant proposal to evaluate cancer care guideline concordance within a multi-center clinical trial by an equity focused, multiple methods intervention.

Data and Safety Monitoring Plan

Aim 2.1, 2.2: Considering the study rationale, population, procedures, and the risk benefit profile, the overall risk level for participation in this study is classified as: Minimum risk.

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APPENDIX 1: Procedure/Diagnosis Codes

Organ site	ICD10	Procedure
Stomach	C16	43620
Stomach	C16	43621
Stomach	C16	43622
Stomach	C16	43631
Stomach	C16	43632
Stomach	C16	43633
Stomach	C16	43634
Stomach	C16	43659
Stomach	C16	96446
Stomach	C16	49203
Stomach	C16	49204
Stomach	C16	49205
Esophagus	C15	43107
Esophagus	C15	43108
Esophagus	C15	43112
Esophagus	C15	43113
Esophagus	C15	43116
Esophagus	C15	43117
Esophagus	C15	43118
Esophagus	C15	43121
Esophagus	C15	43123
Esophagus	C15	43124
Esophagus	C15	43122
Esophagus	C15	43287
Esophagus	C15	43288
Esophagus	C15	43286
Small intestine	C17	44120
Small intestine	C17	44121
Small intestine	C17	44125
Small intestine	C17	44202
Small intestine	C17	96446
Small intestine	C17	49203
Small intestine	C17	49204
Small intestine	C17	49205
Colorectal	C18, C19, C20	44140
Colorectal	C18, C19, C20	44143
Colorectal	C18, C19, C20	44160
Colorectal	C18, C19, C20	44145
Colorectal	C18, C19, C20	44150
Colorectal	C18, C19, C20	44141
Colorectal	C18, C19, C20	44144
Colorectal	C18, C19, C20	44146
Colorectal	C18, C19, C20	44155
Colorectal	C18, C19, C20	44157
Colorectal	C18, C19, C20	44158

Colorectal	C18, C19, C20	44205
Colorectal	C18, C19, C20	44204
Colorectal	C18, C19, C20	44207
Colorectal	C18, C19, C20	44210
Colorectal	C18, C19, C20	44208
Colorectal	C18, C19, C20	44212
Colorectal	C18, C19, C20	44206
Colorectal	C18, C19, C20	45110
Colorectal	C18, C19, C20	45123
Colorectal	C18, C19, C20	45111
Colorectal	C18, C19, C20	45113
Colorectal	C18, C19, C20	45395
Colorectal	C18, C19, C20	45126
Colorectal	C18, C19, C20	45119
Colorectal	C18, C19, C20	45397
Colorectal	C18, C19, C20	44147
Colorectal	C18, C19, C20	44151
Colorectal	C18, C19, C20	44156
Colorectal	C18, C19, C20	45112
Colorectal	C18, C19, C20	45114
Colorectal	C18, C19, C20	44211
Colorectal	C18, C19, C20	44640
Colorectal	C18, C19, C20	44650
Colorectal	C18, C19, C20	44661
Colorectal	C18, C19, C20	96446
Colorectal	C18, C19, C20	49203
Colorectal	C18, C19, C20	49204
Colorectal	C18, C19, C20	49205
Biliary	C22, C23, C24	47120
Biliary	C22, C23, C24	47122
Biliary	C22, C23, C24	47125
Biliary	C22, C23, C24	47130
Biliary	C22, C23, C24	47600
Biliary	C22, C23, C24	47605
Biliary	C22, C23, C24	47610
Biliary	C22, C23, C24	47612
Biliary	C22, C23, C24	47620
Biliary	C22, C23, C24	47711
Biliary	C22, C23, C24	47712
Biliary	C22, C23, C24	47562
Biliary	C22, C23, C24	47563
Biliary	C22, C23, C24	47564
Biliary	C22, C23, C24	48150
Biliary	C22, C23, C24	48152
Biliary	C22, C23, C24	48153
Biliary	C22, C23, C24	47579
Pancreas	C25	48120
Pancreas	C25	48140
Pancreas	C25	48145
Pancreas	C25	48146
Pancreas	C25	48148

Pancreas	C25	48150
Pancreas	C25	48152
Pancreas	C25	48153
Pancreas	C25	48154
Pancreas	C25	48155
Pancreas	C25	48160
Pancreas	C25	48999
GYN	C53, C54, C55, C56	49203
GYN	C53, C54, C55, C56	49204
GYN	C53, C54, C55, C56	49205
GYN	C53, C54, C55, C56	58150
GYN	C53, C54, C55, C56	58152
GYN	C53, C54, C55, C56	58180
GYN	C53, C54, C55, C56	58200
GYN	C53, C54, C55, C56	58210
GYN	C53, C54, C55, C56	58240
GYN	C53, C54, C55, C56	58260
GYN	C53, C54, C55, C56	58262
GYN	C53, C54, C55, C56	58263
GYN	C53, C54, C55, C56	58267
GYN	C53, C54, C55, C56	58270
GYN	C53, C54, C55, C56	58275
GYN	C53, C54, C55, C56	58280
GYN	C53, C54, C55, C56	58285
GYN	C53, C54, C55, C56	58290
GYN	C53, C54, C55, C56	58291
GYN	C53, C54, C55, C56	58293
GYN	C53, C54, C55, C56	58292
GYN	C53, C54, C55, C56	58294
GYN	C53, C54, C55, C56	58541
GYN	C53, C54, C55, C56	58542
GYN	C53, C54, C55, C56	58543

GYN	C53, C54, C55, C56	58544
GYN	C53, C54, C55, C56	58548
GYN	C53, C54, C55, C56	58550
GYN	C53, C54, C55, C56	58552
GYN	C53, C54, C55, C56	58553
GYN	C53, C54, C55, C56	58554
GYN	C53, C54, C55, C56	58570
GYN	C53, C54, C55, C56	58571
GYN	C53, C54, C55, C56	58572
GYN	C53, C54, C55, C56	58573
GYN	C53, C54, C55, C56	58575
GYN	C53, C54, C55, C56	58661
GYN	C53, C54, C55, C56	58662
GYN	C53, C54, C55, C56	58700
GYN	C53, C54, C55, C56	58720
GYN	C53, C54, C55, C56	58940
GYN	C53, C54, C55, C56	58943
GYN	C53, C54, C55, C56	58951
GYN	C53, C54, C55, C56	58953
GYN	C53, C54, C55, C56	58954
GYN	C53, C54, C55, C56	58956
GYN	C53, C54, C55, C56	96446
GYN	C53, C54, C55, C56	58950
GYN	C53, C54, C55, C56	58952
GYN	C53, C54, C55, C56	58957
GYN	C53, C54, C55, C56	58958
GYN	C53, C54, C55, C56	58960
Kidney/Ureteral	C64, C65, C66	50220
Kidney/Ureteral	C64, C65, C66	50230
Kidney/Ureteral	C64, C65, C66	50240
Kidney/Ureteral	C64, C65, C66	50234

Kidney/Ureteral	C64, C65, C66	50225
Kidney/Ureteral	C64, C65, C66	50236
Kidney/Ureteral	C64, C65, C66	50545
Kidney/Ureteral	C64, C65, C66	50543
Kidney/Ureteral	C64, C65, C66	50546
Kidney/Ureteral	C64, C65, C66	50548
Kidney/Ureteral	C64, C65, C66	50225
Kidney/Ureteral	C64, C65, C66	50234
Kidney/Ureteral	C64, C65, C66	50236
Kidney/Ureteral	C64, C65, C66	50549
Bladder	C67	51595
Bladder	C67	51590
Bladder	C67	51596
Bladder	C67	51575
Bladder	C67	51585
Bladder	C67	51570
Bladder	C67	51550
Bladder	C67	51565
Bladder	C67	51555
Bladder	C67	51530
Bladder	C67	51580
Bladder	C67	51597
Prostate	C61	55810
Prostate	C61	55840
Prostate	C61	55845
Prostate	C61	55821
Prostate	C61	55831
Prostate	C61	55815
Prostate	C61	55801
Prostate	C61	55842
Prostate	C61	55866
Prostate	C61	55812
Prostate	C61	55815
Prostate	C61	55865
Testes	C62	54530
Testes	C62	54535
Testes	C62	38780

APPENDIX 2: RedCAP Survey

Many patients have trouble understanding the medical information they receive at the hospital or doctor's office.

1. How confident are you filling out medical forms by yourself?

Extremely, quite a bit, somewhat, a little bit, not at all

2. How often do you have someone help you read hospital materials?

All of the time, most of the time, somewhat, a little of the time, none of the time

3. How often do you have problems learning about your medical condition because of difficulty understanding written information?

All of the time, most of the time, somewhat, a little of the time, none of the time

4. Were you sent home with a prescription or over-the-counter medicine to prevent blood clots?
   a. Yes b. No (end survey)
5. Did you take all of the prescribed doses?
   a. Yes (skip to q8) b. No (q6)
6. How many blood thinner doses did you miss in 30 days after surgery?
   a. Less than 3 b. 3 to 6 doses c. 7 to 10 doses d. More than 10 doses
7. Check all reasons for missing doses:
   a. I forgot b. Ran out of medicine; too expensive to refill c. Did not have enough help available to give the medicine d. Did not like taking the medicine e. Had a complication (like bleeding) and was instructed to stop taking the medicine f. Was readmitted to the hospital g. Never filled the prescription (free text – why) h. Other (free text)

8. Did you develop a blood clot during the post-operative period? a. Yes b. No
9. Did you have any major bleeding during the post-operative period? a. Yes b. No

APPENDIX 3: IRB Approval

Institutional Review Board for Human Research (IRB)
Office of Research Integrity (ORI)
Medical University of South Carolina

South Park Plaza
1 South Park Circle, Bldg. 1, Suite 401
Charleston, SC. 29407
Federal Wide Assurance # 1888

APPROVAL:
This is to certify that the research proposal **Pro00130488** entitled:
A stepped-wedge randomized trial using multi-faceted surgeon-focused education to evaluate the impact of a decision support tool and VTE-related pre-discharge education to increase adherence to guideline-concordant extended venous thromboembolism prophylaxis after major abdominopelvic cancer surgery.

submitted by: **Thomas Curran**
Department: **GI / LAPAROSCOPIC SURGERY - MUSC**
Sponsor: NCI

for consideration has been reviewed by **IRB-II - Medical University of South Carolina** and approved. In accordance with 45 CFR 46.104(d), the referenced study is exempt from Human Research Subject Regulations. The IRB has approved the request for a Waiver of HIPAA Authorization, after determining that the waiver of authorization satisfies the criteria set forth in the HIPAA Privacy Rule at 45 CFR 164.512(i)(2). The waiver of authorization was reviewed and approved by the IRB. The IRB has determined that the protected health information necessary to be used/accessed is as outlined in the protocol and/or IRB application.

No further action or IRB oversight is required, as long as the project remains the same. However, you must inform this office of any changes in procedures involving human subjects. Changes to the current research protocol could result in a reclassification of the study and further review by the IRB.

Approval Date: **7/24/2023**
Approval Expiration: **7/24/2028**

Type: **Exempt**
Category: **2**

Administrator, - Medical University of South Carolina
Summer Young, MPH, CIP∗

∗***Electronic Signature****: This document has been electronically signed by the IRB Administrator through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*

Important Note: Approval by the Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Other MUSC clearances and approvals or other external agency or collaborating institutional approvals may be required before study activities are initiated. Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the University and the entity.

TO PRINCIPAL INVESTIGATOR

The IRB approval for your study has been released. Please see below for helpful reminders.

IRB POLICIES AND PROCEDURES

The link below will connect you to all IRB all IRB policies and procedures:
http://academicdepartments.musc.edu/research/ori/irb/policies.html
Here you will find important policy information regarding items such as: amendments, continuing reviews, protocol deviations, unanticipated problems and adverse events, etc.

INFORMED CONSENT AND HIPAA

Use only stamped IRB approved consent(s) and HIPAA. As the Principal Investigator, you are also required to make sure each person obtaining consent is approved and listed on your protocol and uses the most currently approved version of the consent(s)/HIPAA.

COMPLIANCE AUDITS FOR HUMAN RESEARCH STUDIES

The MUSC Compliance Office will randomly select human research studies for routine audit. Audits "for cause" will be conducted as necessary. The checklist used by the Compliance Auditor is located on the compliance website at:
https://horseshoe.musc.edu/everyone/compliance/univ-compliance/research/human-subject-audits/checklists

SUCCESS CENTER

The SUCCESS Center provides a variety of resources at no charge for PIs and study teams at any point in the research process including individualized training and consultation for regulatory submissions and documentation. Contact SUCCESS at:
843-792-8300 or success@musc.edu
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