The Impact of Mobile Education Delivery on Postoperative Pain Outcomes

Study Protocol

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IRB Minimal Risk Protocol Template

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1. Open your study in IRBe. Click on the study 'Documents' tab and select the most recent version of the protocol. Save it to your files.
2. Open the saved document and activate "Track Changes".
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General Study Information

Principal Investigator: Amber Stitz

Study Title: The Impact of Mobile Education Delivery on Postoperative Pain Outcomes

Protocol version number and date: Version #1 May 2, 2017

Research Question and Aims

Hypothesis: It is hypothesized that a real-time, interactive, mobile education system will demonstrate improved pain associated outcomes, and higher patient participation when compared to the current standard education delivery method.

Aims, purpose, or objectives: This study seeks to understand the difference between two different education delivery methodologies and the effect on the postoperative pain experience, including participation in treatment plan, knowledge, pain outcomes, and opioid requirements.

- Evaluate the difference in patients' self-reported pain experience according to the type of education delivery methods.
- Determine if there are significant differences in patients' knowledge of pain, medications, and side effects according to the type of education delivery methods.
- Evaluate the difference in patients' self-reported participation in pain management according to the type of education delivery methods.
- Determine if there is a significant difference in opioid requirements in the first 48 hours according to the type of education delivery methods.

Background (*Include relevant experience, gaps in current knowledge, preliminary data, etc*.):

Despite all the available analgesic, modern devices, and nonpharmacological interventions, pain in the acute post-surgical period remains a prominent issue and effective management has remained elusive with significant gaps in care. Early estimates suggest that anywhere from 50% to 75% of surgical patients experience inadequate pain relief (Huang et al., 2001), often due to delayed intervention (Sinatra, Torres, & Bustos, 2002). A National Survey of patients who had undergone non-specific surgical care demonstrated occurrence of acute pain in 80% of patients and moderate to severe pain in approximately 86% of those who experienced acute pain (Apfelbaum, Chen, Mehta, & Gan, 2003). A 2008 study of 1,490 surgical inpatients, 41% of patients reported severe pain in the first 24 hours after surgery (Sommer, de Rijke, van Kellef, et al., 2008). Watt-Watson, Stevens, Garfunkel, Steiner, & Gallop (2001) found severe pain in 86% of coronary artery bypass patient 24 hours after surgery. A chart review revealed that 80% of these patients experiencing severe pain received <16 mg of morphine over the previous 24 hours and two had no analgesia orders in the medical record (Watt-Watson eat al., 2001). Ineffective pain management effects recovery, complications, cost (Gordon, Dahl, & Stevenson, 2000), patient satisfaction (Garimella & Cellini, 2013), length of stay (Joshi, Beck, Emerson, et al., 2014), readmissions (ASA, 2012), quality of life (Ersek, 2001), and chronic postsurgical pain (O'Brien, Pergolizzi, van de Laar, et al, 2103; Barrington, Halaszynski, & Sinatra, 2014).

Effective pain management is the use of appropriate pain modalities to improve the pain experience while balancing the goal of optimal pain relief with patient safety to prevent adverse outcomes (Hayes & Gordon, 2015). In the surgical setting, effective and safe pain management poses significant challenges for nurses, providers, and healthcare organizations. This is due in part to the multifactorial influences that result in inadequate pain management including substandard assessment of pain (Michales, Hubbartt, Carroll, & Hudson-Barr, 2006), limited clinician knowledge to manage pain effectively, and poor patient engagement (Innis, Bikaunieks, Petryshen, Zellermeyer, & Ciccarelli, 2004). From the patient perspective, effective pain management is reliant on their knowledge, engagement, and the ability to effectively report pain symptoms (The Joint Commission, 2009). Patient reported dissatisfaction and poor pain outcomes have been linked to insufficient education and limited patient-provider communication (Subramanian, Ramasamy, Hoong, Chinna, &Rosli, 2016; Smith, Rhodes, Paciotti, et al., 2015; Helfand & Freeman, 2009). These gaps faced by patients result in misconceptions about pain, opioid use, and side effects (Helfand & Freeman, 2009; Morrison RS, Meier DE, Fischberg et al., 2006). Clinical outcomes, including pain reporting, opioid management, pain scores, and satisfaction may be improved with focused patient education and knowledge acquisition (Mularski, White-Chu, Overbay, Miller, Asch, & Ganzini, 2006). The literature suggests that patients lack the needed knowledge to effectively manage opioid analgesic medications safely and effectively (Horwitz et al., 2013; AJN, 2015). Lack of knowledge, medication safety concerns (misuse), and risk for adverse effects are most prominent in the opioid naïve patient experiencing acute pain (AJN, 2015). A panel of clinical experts from the APS and the American Anesthesia Association made the following recommendations "clinicians provide patient and family-centered, individually tailored education to the patient (and/or responsible caregiver), including information on treatment options for management of postoperative pain, and document the plan and goals for postoperative pain management" (Chou et al., 2016, pg. 133) followed by an adjustment by the clinician in the "pain management plan on the basis of adequacy of pain relief and presence of adverse events" (Chou et al., 2016, pg. 135).

In 2016, the NIH and the American Pain Society (APS) both issued gaps in research to guide clinical practice. Research gaps exist in nearly every aspect of pain management. One gap of note is the role of pain management patient education and engagement on recovery, pain relief, adverse effects, safety, and long term outcomes in patients undergoing major joint arthroplasty (TJA) (NIH, 2016; Gordon, Leon-Casasola, Wu et al., 2016). Research is needed to understand the effectiveness of educational methods, delivery mechanisms, and

intervention timing to determine the impact on pain outcomes, patient engagement in the shared-decision making process, safety, and post-discharge medication management.

Significance

The available research indicates a strong positive correlation between patient education and outcomes. However, there is limited literature on the direct influence of pain management education on patients' recovery, engagement, pain relief, adverse effects, safety, and long term outcomes. These gaps are consistent with the identified research gaps from the NIH and APS. The use of technology in clinical practice and patient education, such as mobile applications, patient portals, and iPads, are only just beginning to be explored in the last five to ten years. Further research is needed to understand the effectiveness, barriers, and use of eHealth delivery models. One barrier to eHealth delivery is adoption and use of technology in the elderly populations. The elderly population has lagged in the acceptance and adaptation to technology. Only 59% of seniors use the internet and computer, compared to 86% of all adults (Smith, 2014). The adoption of technology in this population is potentiated by physical challenges (arthritis, and vision changes), skeptical attitudes about the benefits of technology, and difficulty with learning how to use digital devices. However, a paradigm shift is occurring with a 6% annual increase in the number of seniors using technology (Smith, 2014). This trend is anticipated to continue, making technology less of a challenge in health information delivery. The average age of patients undergoing TJA surgery is 67years of age. As such, consideration and further research into the adoption of eHealth delivery in this population is necessary. Additionally, each education delivery method poses several advantages and disadvantages. Verbal 1:1 education is patient centered and allows for direct interaction and questions yet is costly, time consuming, and is associated with limited memory recall (Knowles, Holton, Swanson, 2011). This style of education is often used in conjunction with written text in the form of booklets or pamphlets. Written education allows for mass distribution of educational content but is associated with printing expenses and low patient compliance (Knowles, Holton, Swanson, 2011). Conversely, internet based education is interactive, easily accessible, simple, and visually appealing (Knowles, Holton, Swanson, 2011). Depending on an organization's technological capabilities, internet based education may not be attainable due to technical limitations and cost (Knowles, Holton, Swanson, 2011). The research study proposed here seeks to understand the difference and effectiveness of educational methods and delivery mechanisms using mobile applications compared to standard education delivery (verbal and written) to determine the impact on pain outcomes, pain experience, patient participation, and opioid requirements.

Study Design and Methods

Methods: *Describe, in detail, the research activities that will be conducted under this protocol*:

Variables

The independent variable is the type of patient education deliverable given to the two study arms, group A (experimental group, real-time, interactive, mobile education system) and group B (control group, standard of care). The dependent variables are 1) patient knowledge, 2) patient perceived participation in pain management, 3) high and low pain scores, and 4) total opioid consumption. A simple table of the independent, dependent, and additional variables are presented in Appendix B. A detailed accounting of all data points including variable type, theoretical definitions, and operational definitions can be found in the detailed code book.

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Method

Design

This prospective study has been designed as quasi-experimental study. This study design was selected for several reasons. This study seeks to explore both a treatment and control group in efforts to compare outcomes which are dependent on the type of intervention. To control for fidelity of the intervention and avoid cross over, behavior changes from nurses providing the intervention, the intervention the patient receives will be determined by the location they are bedded in hospital. Orthopedic TJA patients are assigned at random and based on bed availability to one of two patient care units. One of the two patient care units will offer standard education the other unit will offer the mobile, iPad based education. The patient care unit to offer the mobile, iPad based education will be selected at random. This study design will help minimize will reduce the risk of selection bias, increase fidelity of the intervention, and increases the probability that the differences demonstrated between the study groups will be attributed to the actual intervention under study.

Study participants will be assigned into one of two study arms, intervention or control, based on random assignment to the two designated units. At the time of consent, patients will be informed that there are two study arms and that some subjects will receive enhanced pain management education; however, subjects will not explicitly be informed if they are in the intervention or control arm of the study. Participants who have verbally consented will receive a HIPAA authorization form accompanied by a letter reminding them of the study and their consent to participate at the time of the preoperative visit. This typically occurs one to two days before surgery. Participants will be asked to sign the HIPAA authorization form and return the clinical staff. Participants will be provided an extra copy for their records. No Patient data will be collected prior to this. Once HIPAA has been signed participants will complete the intake survey provided with the packet of information.

Researchers are blinded to the study arm the participant was enrolled in until after consent has been obtained, the patient is enrolled in the study, and has been admitted to the hospital and assigned a bed. Once enrolled and consented, bed control will be notified to assign the patient(s) to one of the two designated patient care units with no specific direction offered on which unit the patient(s) should be assigned to. The only direction provided will be to split the patients evenly between the two units. Only ten study arm participants may be enrolled and active at one time. This is limited based on the number of available iPad devices for the purposes of this study.

Study Population

The target population is adult patients undergoing elective, lower extremity total joint arthroplasty (TJA). Candidates for inclusion are adult patients over the age of 18 years undergoing surgical intervention and inpatient care for one of the following procedures, total hip arthroplasty (THA) (primary, bilateral, and revision) and total knee arthroplasty (TKA) (primary, bilateral, unicompartmental, and revision). Patients must be fluent in the English language. Patients will be excluded if they are undergoing more complex hip and knee procedures such as implant resections with or without spacer placement, liner exchange, or THA or unipolar hip arthroplasty related to repair of hip fracture. Patients will also be excluded if there are preexisting physical or cognitive limitations that would hinder their ability to use the mobile application.

Sample Size

Assuming a moderate effect size 0.50 (Cohen's d), a power of 80% (0.80), and an alpha of 0.05, 64 participants are needed in each study arm (Polit, 2010). Due to limited time scope, a minimum of 150 patients will be approached for potential participation. If time allows and additional subjects are needed to achieve the desired sample size, additional candidates will be approached to reach the recommended total of 128 patients, divided between the two study arms.

Recruitment and Consent

Eligible patients will be identified using surgeon referral and/or electronic surgical listing reports. Enrollment into the study is completely voluntary. Patients will be recruited at the time of perioperative phone consultation with nursing. This consultation occurs approximately two weeks prior to their scheduled surgical procedure. At this time patients will be introduced to the study by the RN or APRN. If the patient expresses interest, verbal consent will be obtained and documented at the time of the call by the IRB approved consent designees. Consent designees will read the consent script and provide any necessary time to answer the patients' questions. At the time of consent, patients will be informed that there are two study arms and that some subjects will receive enhanced pain management education; however, subjects will not explicitly be informed if they are in the intervention or control arm of the study.

Enrollment into the study is completely voluntary. Participating in this study poses minimal risk to the participants; all patients will receive the necessary education to meet their care needs and the minimum standard of practice. The potential for risk is that the mode of information/education delivery does not meet the patients' needs and the risk of low acceptance of technology use. In this case, patients in the study arm would be removed from the study and would receive standard education. Pain management in both arms will remain the same; no changes will be made to the process for treating pain using either non-pharmacologic or pharmacologic interventions. Medication orders, medication administration, and pain treatment plans will not be affected by participation in study. As care is today, pain management will be customized to meet the needs of the individual patient.

Oral consent will be obtained, documented, and maintained as part of the research records. No identifiable patient information will be maintained. The only identifiable information collected will be the patients' clinic number. It will be used for tracking purposes only until the data collection process is complete. When the chart audit is complete, the clinic numbers will be removed from the data set and only the predesignated subject number will be used and maintained. At the start of the study the patient will be asked to complete the HIPAA Authorization to Use and Disclose Protected Health Information. The researcher will remain blinded to the type of education delivery that the patient will receive until after enrolment and bed assignment. This will prevent potential bias with inadvertently assigning patients to groups based on characteristics, like age.

There is a risk for disclosure of personal protected information. The electronic data will be stored on an internal secure server. If transport of electronic data is necessary for any reason an encrypted storage device will be used. Paper and pencil surveys will be stored in a locked cabinet, in a locked and secure office. The researcher and the RN will be responsible to data entry into SPSS. The RN will be trained by the researcher on SPSS data entry. Access to the data will be restricted to only research personnel approved on the IRB application. The RNs will complete the institution's IRB education requirements for staff assisting with research data. Limiting the number of staff involved will reduce the potential for data entry errors.

Setting

The intervention and data collection will be collected on orthopedic patients admitted to two orthopedic inpatient care units who have undergone major joint replacement surgery at a large academic medical center in the upper Midwest. Between the two units there are 50 dedicated orthopedic beds that admit more than 9,000 orthopedic patients annually. Included in the annual orthopedic admits are approximately 4,000 major total joint arthroplasties. Based on historical admission data and patient volumes the desired sample size is feasible. Patients relocated to non-orthopedic units due to high patient census will not be included in the study. The goal is to recruit 20 patients on a weekly basis, ten in each arm of the study. Due to the restricted number of iPads

available, only ten patients may be enrolled in the study arm at any point in time. The total divided sample of 124 patients should be achievable within ten weeks from the start of the study.

Intervention

Study group. The participants in the study arm will receive comprehensive pain management education delivered using mobile iPads at the point of care. The mobile based education modules will be inclusive of the use of the pain rating scale and assessment of pain; communication with healthcare providers; daily expectations for pain and pain management; pharmacologic and non-pharmacologic treatment options; medication side effects and safety; and discharge instructions including safe handling of opioids, disposal, tapering, and when to call the provider. It will also include an interactive pain and discomfort menu, knowledge based questions, and medication tracking log. The content has been developed using existing Mayo Clinic patient education materials (videos and written text) developed by the Department of Anesthesia and Pain Service in conjunction with the Department of Patient Education. The mobile application covers a curriculum of the most common concerns and questions individual experiencing pain have as presented by Gifford (2014), Horwitz et al. (2013), AJN (2015), and Chou et al. (2016). The content presented in the application is comprehensive, compiling the content of several standard Mayo Clinic education pamphlets and videos in an easily accessible, comprehensive, and convenient way. The mobile application uses multiple teaching methodologies to accommodate different learning needs, including written text; short videos; illustrated graphics, pictures, and guides; interactive checklists; knowledge based questions; and frequently asked questions. The program was developed using Mayo Clinic Care Connect as the build platform in collaboration with the Department of Social Media. The Web-based platform where this pain program is housed was successfully trialed in 2016 by providing perioperative education to TJA patients. The iPads for use in the hospital have been configured and secured in such a way that patients will only have access to this program.

Patients enrolled in the study arm will be given an iPad on admission to the post-surgical unit. The RN will instruct the patient on how to use the iPad and the program. The device will remain with the patient until discharge. The patient, independently or with the nurse, may use the program at any point during the inpatient care experience. The RN will use the iPad to engage patients in their pain management and care. Intervention fidelity will be monitored by requiring the RN to indicate when and how often they observed and/or directly engaged the patient in pain education using the mobile device. A checklist will be available on the patients chart for the RN to complete at the end of each shift through the duration of the patients hospital stay.

Control group. The control group will receive the current standard of care which consists of verbal instruction and pain management pamphlets. At a minimum, the patients will receive two educational pamphlets titled *Your Pain and Discomfort Management Menu* and *Communicating About Your Pain*. The pain management menu is designed to provide the patient with basic pain information with a focus on non-pharmacologic pain interventions. The pain communication pamphlet offers a more comprehensive explanation about pain, assessment of pain (0-10 scale), communicating with the healthcare providers, and pain management options. The content of these two documents is a portion of the education the study patients will receive using the mobile application. These two documents are existing educational material available through the Department of Patient Education. These educational materials were developed by the Department of Anesthesia and Pain Service in conjunction with the Department of Patient Education. Verbal instruction is inconsistent and is nurse dependent. At a minimum the nurse is instructed to provide the two pamphlets to the patient and follow-up with the patient to address any questions. Additional printed education materials are available through the department of patient education and verbal instruction may be tailored based on nursing assessment and patient need. It is important to note that all educational content available to the study participants is available to the control group in different forms or functions. Fidelity to standard of care will be

monitored by requiring the RN to indicate when and how often they observed and/or directly engaged the patient in pain education using standard pamphlet educational material. A checklist will be available on the patients chart for the RN to complete at the end of each shift through the duration of the patients hospital stay.

Management of interventions and study participants. The implementation of the interventions in the study and control arm will be closely monitored by the researcher. Educational in-services for all shifts will be held on various days. Education will include the research protocol, goals of the study, use of the mobile iPad patient education in practice, and data collection procedures. To ensure all staff have access to the education, a brief video will be disseminated via e-mail to be viewed at staff convenience prior to the start of the study. Participants in the study will be denoted by a specific color coded label at the door. This will notify and flag direct care staff to ensure that the appropriate study protocol is followed. The research protocol for each arm of the study and instructions for the mobile education application will be placed in the research reference book, located at each nursing sub-station. For participants whom are enrolled in the study arm, the researcher will deliver the iPad either directly to the patient or to the bedside RN caring for the patient. The RN will receive one-on-one, just in time education at the point of device delivery. The researcher will also make daily rounds and random care observations with nurses caring for participants enrolled in the study. Additional education and reminders will be offered at the point of care and as needed.

Instruments

Patient demographics and clinical characteristics. Patient demographics and past medical history will be collected as part of the study (Appendix D). Patient demographic variables to be collected include age, race, education level, marital status, and employment status. Specific confounding variables associated with the type of intervention and outcome will be collected including patients' preferred learning style, comfort level with technology, and anxiety. Preferred learning style will be assessed using the three styles of learning reading, seeing, doing, or listening (Bastable, 2008). Comfort level with technology will be assessed using a five-point Lickert scale with zero being, "not comfortable at all" and five being "very comfortable." Anxiety associated with anticipated pain will be assessed on ten-point. Relevant past medical and surgical history will also be collected including past major orthopedic surgeries, chronic pain, preoperative use of opioids, and mental health conditions. The patient demographic collection form will be administered using paper and pencil survey. The patient will be given the form when they arrive to the ambulatory orthopedic clinic for their perioperative visit, one to two days prior to their scheduled surgery. It will take participants approximately five minutes to complete the survey.

Pain outcomes. The Revised American Pain Society Patient Outcome Questionnaire (APS-POQ-R) will be used to evaluate the patients' perception of their pain management experience and outcomes (Appendix E). The APS-POQ-R is a 23-item, two-page questionnaire measuring five subscales of the patient experience and one aspect measuring non-pharmacologic management. These 6 aspects include (1) pain severity and relief; (2) impact of pain on activity, sleep, and negative emotions; (3) side effects of treatment; (4) helpfulness of information about pain treatment; (5) ability to participate in pain treatment decisions; and (6) use of nonpharmacological strategies (Gordon, Polomano, Pellino et al., 2010). There are 14 symptom-based questions to indicate symptom severity using a ten-point scale (0-10). The higher the score, the more severe the symptom experience. Two additional symptom-based questions explore severity of pain over time and pain relief using a ten-point scale with a range of 0% to 100%. For pain severity over time, a higher score indicates a higher incidence of severe pain in 24 hours. For pain relief, a higher score indicates a more positive response to pain relief. These data points will help determine the effectiveness of the intervention on pain outcomes (pain scores). Three questions are associated with the pain education experience. Using a ten-point scale (0-10), the higher response scores indicate a more positive experience rating. Pain experience here is assessed by

generalized satisfaction with pain relief and participation in treatment decisions. These data points will help determine the influence of pain education on satisfaction with educational material/delivery and participation. The reported participation score will be used to measure the degree to which the patient is engaged by a means of active participation in care and treatment. The remainder of the survey questions use a single word association to answer the question rather than a measurable scale. The APS-POQ-R has demonstrated adequate psychometrics, construct validity, reliability, and clinical feasibility. Internal consistency reliability was acceptable with a Cronbach α of 0.86. The individual subscales were also assessed for reliability with the resulting Cronbach α as follows affective subscale, $\alpha = 0.82$; pain severity and sleep interference subscale, $\alpha = 0.83$; perceptions of pain care subscale, $\alpha = 0.70$; interference with activity, $\alpha = 0.82$; and adverse effects subscale, $\alpha = 0.63$ (Gordon, Polomano, Pellino et al., 2010). This tool is open source and available for application without further permission (Gordon, Polomano, Pellino et al., 2010).

Pain knowledge. The Patient Pain Questionnaire (PPQ) will be used to evaluate pain knowledge post intervention (Appendix F). The PPQ is a 16-item questionnaire measuring both pain knowledge and actual experiences with pain. This study will use only nine of the items targeted at pain knowledge and beliefs. The nine knowledge-based questions use a ten-point (0-10) ordinal scale to assess patients' agreement or disagreement with statements about pain relief, medication administration, addiction, dosing, timing, non-pharmacologic management, side effects, beliefs about pain medications, and changes in the pain experience. Depending on the statement a higher score may indicate either agreement or disagreement with the statement. All items have been formatted so that zero indicates the most positive outcome and a ten indicates the most negative outcome. These nine items are primarily used for chronic cancer pain; however the PPQ has been and can be adapted to assess general pain knowledge and experiences. Psychometric analysis of the PPQ demonstrated content validity of 0.90 (content validity index), construct validity of <0.05 variance, concurrent validity ($r=0.60$; $p<0.05$), test-retest reliability ($r=0.80$), and internal consistency with a Cronbach α of 0.71 (Ferrel & Rivera, 1997). The language will also be revised, as in the study conducted by Reynolds (2009) and reference to chronic cancer pain will be removed from the original question. This tool is open source and available for application without further permission and may be utilized by clinicians or researchers (City of Hope Pain and Palliative Care Resource Center, 2017; MIDSS, n.d.).

At the start of the study and at the time of discharge the patient will complete the APS-POQ-R and the revised knowledge-based PPQ surveys. It will take participants approximately 10 minutes to complete the two surveys. The use of these two widely used instruments will ensure that the information being collected is highly reliable and valid, truly measuring what the study is seeking to evaluate. These paper and pencil surveys will be provided to the patient prior to discharge and collected from the patient by the staff registered nurse (RN) and/or charge nurse. In addition to training and education on the intervention, staff will receive direction on the data (survey) collection process and requirements.

Chart audits. Chart audits of the electronic health record will be conducted after discharge to collect the remaining clinical data. Data to be collected will include total opioid requirements as indicated by the medication administration record; primary surgical procedure as reported in the surgical listing and the operative report; type of regional anesthesia as indicated in the anesthesia record; length of stay; and discharge disposition as reported in the hospital dismissal summary. Additionally, the past medical history will be reviewed to confirm patient reported history of chronic pain, preoperative use of opioids, and mental health conditions. The researcher and a staff RN will conduct these chart audits.

Limitations

The design of this study does present some limitations. Participants in the study group will receive enhanced pain content that is delivered using an alternative method, ultimately testing both the delivery method and the content. The duality of the study intervention is a confounding variable and may make differentiating

the cause of the outcome difficult. Another limitation is that preoperative educational classes are available to patients to attend if they choose. All patients receive the same pamphlets and information in the mail when surgery is scheduled. An in-person didactic class is optional for patients. Some pain education is offered in this class. Currently only 49% of patients attend these classes. It is anticipated that some patients enrolled in the study will have received varying levels of education prior to their hospital admission. This is an antecedent variable that will be collected as part of the chart audit and accounted in the data analysis. The two nursing units involved in the study are located within the same hospital. It is possible that nursing staff from the intervention unit may float to the control unit and educate study patients using content from the expanded education from the intervention on the iPads. Pre-testing knowledge of pain and measured again at the end of the intervention (prepost) using a paired t-test analysis will strengthen the design of the study. Only opioid use for pain control is being measured.

Data Management

Data Collection Procedure

Data will be collected at three points in time using paper and pencil survey's and chart audits. The data collection protocol can be found in Appendix G. After completion of the HIPAA form, demographic and past medical history information and pain knowledge survey will be administered in the ambulatory clinic at the time of the perioperative surgical visit. A paper and pencil survey/form will be provided to the patient when they arrive in the clinic for their perioperative appointment and returned to the desk staff when completed.

The intervention will occur on the postoperative inpatient care unit (PCU) starting at the time the patient arrives on the unit from the post anesthesia care unit (PACU). The intervention will continue through the course of care until discharge. At the time of discharge the patient will complete the Revised American Pain Society Patient Outcomes Questionnaire (APS-POQ-R) (Gordon et al., 2010) and the revised knowledge-based Patient Pain Questionnaire (PPQ) (Ferrell &Rivera, 1997; Reynolds, 2009). The use of these two widely used instruments will ensure that the information being collected is highly reliable and valid, truly measuring what the study is seeking to evaluate. These paper and pencil survey's will be provided to the patient prior to discharge and collected from the patient by the staff registered nurse (RN) and/or charge nurse. In addition to training and education on the intervention, staff will receive direction on the data (survey) collection process and requirements. The administration of the post-intervention surveys at the point of care, before the patient has left the study environment, will help to prevent the loss of study participants due to non-response or failure to complete follow-up surveys.

After discharge the researcher will conduct a chart review to collect clinical data including opioid consumption totals, past medical history, anesthesia type, and length of stay. The researcher in addition to one RN will be responsible for chart audit data collection. The RNs will be trained by the researcher on chart audit processes. The RNs will complete the institutions IRB education requirements for staff assisting with research data. A tentative timeline has been developed as a GNATT chart in Appendix H. All collected data from the paper surveys' and chart audits will be entered in to SPSS for analysis. Data storage and management is discussed further under ethical considerations.

Resources: *Describe the available resources to conduct the research (personnel, time, facilities, mentor commitment, etc.)*:

This study has no financial implications or budget associated with implementation or data analysis. Equipment being used in this study was paid for using previous allocated grant funds. Statistical analysis will be conducted by the primary investigator with assistance from program advisor listed in the IRB application.

The primary researcher will have at a minimum a 0.1 - 0.2 FTE to dedicate towards research activities. An additional 0.1 - 0.2 FTE of staff RN time will be dedicated towards research activities once the data collection and intervention implementation is underway. The RNs to assist is an inpatient staff RN, Erin Verdoorn and Ben Schmidt. The process of identifying patients and consent will be built into the ambulatory nurses existing work at the time of the preoperative phone consultation. Ten iPads have been purchased and the platform setup to conduct this study using grant funds from the Center for Innovation.

☐ (1a) This is a multisite study involving Mayo Clinic and non Mayo Clinic sites. *When checked, describe in detail the research procedures or activities that will be conducted by Mayo Clinic study staff.*

☐ (1b) Mayo Clinic study staff will be engaged in research activity at a non Mayo Clinic site. *When checked, provide a detailed description of the activity that will be conducted by Mayo Clinic study staff.*

Subject Information

Target accrual is the proposed total number of subjects to be included in this study at Mayo Clinic. A "Subject" may include medical records, images, or specimens generated at Mayo Clinic and/or received from external sources.

Target accrual: Due to limited time scope, a minimum of 150 patients will be approached for potential participation. If time allows and additional subjects are needed to achieve the desired sample size, additional candidates will be approached to reach the recommended total of 128 patients, divided between the two study arms.

Subject population (children, adults, groups): adult patients undergoing elective lower extremity total joint arthroplasty (TJA).

Inclusion Criteria: Adult patients over the age of 18 years undergoing surgical intervention and inpatient care for one of the following procedures, total hip arthroplasty (THA) (primary, bilateral, and revision) and total knee arthroplasty (TKA) (primary, bilateral, unicompartmental, and revision). Patients must be fluent in the English language.

Exclusion Criteria: Pediatric patients under the age of 18; undergoing more complex hip and knee procedures such as implant resections with or without spacer placement, liner exchange, or THA or unipolar hip arthroplasty related to repair of hip fracture; preexisting physical or cognitive limitations that would hinder their ability to use the mobile application.

Research Activity

Check all that apply and complete the appropriate sections as instructed.

1. ☐ **Drug & Device**: Drugs for which an investigational new drug application is not required. Device for which (i) an investigational device exemption application is not required; or the medical device is

cleared/approved for marketing and being used in accordance with its cleared/approved labeling. (Specify in the Methods section)

2. ☐ **Blood**: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.

3. ☐ **Biological specimens other than blood**: Prospective collection of human biological specimens by noninvasive means that may include: urine, sweat, saliva, buccal scraping, oral/anal/vaginal swab, sputum, hair and nail clippings, etc.

4. ☐ **Tests & Procedures:** Collection of data through noninvasive tests and procedures routinely employed in clinical practice that may include: MRI, surface EEG, echo, ultrasound, moderate exercise, muscular strength & flexibility testing, biometrics, cognition testing, eye exam, etc. (Specify in the Methods section)

5. ☐ **Data** (medical record, images, or specimens): Research involving use of existing and/or prospectively collected data.

6. ☐ **Digital Record**: Collection of electronic data from voice, video, digital, or image recording. (Specify in the Methods section)

7. ☒ **Survey, Interview, Focus Group:** Research on individual or group characteristics or behavior, survey, interview, oral history, focus group, program evaluation, etc. (Specify in the Methods section)

☐ NIH has issued a *Certificate of Confidentiality* (COC). *When checked, provide the institution and investigator named on the COC and explain why one was requested*. _____

Biospecimens – Categories 2 and 3

(2) Collection of blood samples. When multiple groups are involved copy and paste the appropriate section below for example repeat section b when drawing blood from children and adults with cancer.

a. **From healthy, non-pregnant, adult subjects who weigh at least 110 pounds**. For a minimal risk application, the amount of blood drawn from these subjects may not exceed 550ml in an 8-week period and collection may not occur more frequently than 2 times per week.
   Volume per blood draw: _____ml
   Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) _____

b. **From other adults and children considering age, weight, and health of subject.** For a minimal risk application, the amount of blood drawn from these subjects may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period, and collection may not occur more frequently than 2 times per week.
   Volume per blood draw: _____ml
   Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) _____

(3) Prospective collection of biological specimens other than blood: _____

MAYO CLINIC

Review of medical records, images, specimens – Category 5

For review of existing data: provide a date range or an end date for when the data was generated. The end date can be the date this application was submitted to the IRB. Example: *01/01/1999 to 12/31/2015* or all records through *mm/dd/yyyy*.

Date Range:

Check all that apply (data includes medical records, images, specimens).

☐ (5a) Only data that exists before the IRB submission date will be collected.

☐ (5b) The study involves data that exist at the time of IRB submission **and** data that will be generated after IRB submission. Include this activity in the Methods section.
Examples

- The study plans to conduct a retrospective chart review and ask subjects to complete a questionnaire.
- The study plans to include subjects previously diagnosed with a specific disease and add newly diagnosed subjects in the future.

☐ (5c) The study will use data that have been collected under another IRB protocol. Include in the Methods section and enter the IRB number from which the research material will be obtained. *When appropriate, note when subjects have provided consent for future use of their data and/or specimens as described in this protocol*.

Enter one IRB number per line, add more lines as needed

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ (5d) This study will obtain data generated from other sources. Examples may include receiving data from participating sites or an external collaborator, accessing an external database or registry, etc. Explain the source and how the data will be used in the Methods section.

☐ (6) Video audio recording: *Describe the plan to maintain subject privacy and data confidentiality, transcription, store or destroy, etc.*

HIPAA Identifiers and Protected Health Information (PHI)

Protected health information is medical data that can be linked to the subject directly or through a combination of indirect identifiers.

Recording identifiers (including a code) during the conduct of the study allows you to return to the medical record or data source to delete duplicate subjects, check a missing or questionable entry, add new data points, etc. De-identified data is medical information that has been stripped of all HIPAA identifiers so that it cannot be linked back to the subject. De-identified data is **rarely** used in the conduct of a research study involving a chart review.

Review the list of subject identifiers below and, if applicable, check the box next to each HIPAA identifier being recorded at the time of data collection or abstraction. Identifiers apply to any subject enrolled in the study including Mayo Clinic staff, patients and their relatives and household members.

Internal refers to the subject's identifier that will be recorded at Mayo Clinic by the study staff.
External refers to the subject's identifier that will be shared outside of Mayo Clinic.

Check all that apply:	INTERNAL	EXTERNAL
Name		
Mayo Clinic medical record or patient registration number, lab accession, specimen or radiologic image number	X	
Subject ID, subject code or any other person-specific unique identifying number, characteristic or code that can link the subject to their medical data	X	
Dates: All elements of dates [month, day, and year] directly related to an individual, their birth date, date of death, date of diagnosis, etc. **Note:** Recording a year only is not a unique identifier.		
Social Security number		
Medical device identifiers and serial numbers		
Biometric identifiers, including finger and voice prints, full face photographic images and any comparable images		
Web Universal Resource Locators (URLs), Internet Protocol (IP) address numbers, email address		
Street address, city, county, precinct, zip code, and their equivalent geocodes		
Phone or fax numbers		
Account, member, certificate or professional license numbers, health beneficiary numbers		
Vehicle identifiers and serial numbers, including license plate numbers		
Check 'None' when none of the identifiers listed above will be recorded, maintained, or shared during the conduct of this study. (exempt category 4)	☐ None	☐ None

Data Analysis

Power analyses and study endpoints are not required for minimal risk research, pilot or feasibility studies.

☐ No statistical information. *If checked, please explain*:

Power Statement: N/A

Data Analysis Plan

The pre-intervention and post-intervention, paper surveys' will be returned to the researcher for data entry and storage. The collected data will be collated and entered by the researcher into SPSS for data analysis. A detailed code book has been developed to include specific information on the type of variable and the theoretical and operational definitions. Data entry will be double-checked for accuracy by one of the staff trained staff RNs participating in data collection and chart audits. Descriptive statistics will be performed on each study variable. Continuous variables, including pain scores, pain knowledge, and opioid requirements, will be reported using a mean and standard deviation. Categorical variables, including patient characteristics and education engagement, will be reported as frequencies and percent occurrence. The data will be examined for any baseline differences between the groups to identify characteristics that may confound results and require control in the analysis. Data will be examined to assure that it meets the assumptions of normality required for parametric analysis. If data does not meet normality assumptions, nonparametric analyses will be used. This study uses a revised adaption of the Patient Pain Questionnaire (PPQ) survey. For this reason, the reliability and validity of the nine knowledge based questions will be evaluated using Cronbach's alpha and factor analysis.

This study will explore the difference between two types of education delivery methods and the effect on pain scores, participation, knowledge, and opioid requirements. The difference amongst the two study groups will be analyzed using an independent *t*-test. Using the population mean of each group a *t* statistic will be computed. The independent *t*-test was selected because this statistical test is appropriate when there are two groups that are not the same people and are not connected to one another in any other systematic way (Polit, 2010). Additionally, the requirements for the *t*-test fit with the design of the study and variables. The independent variable must be dichotomous nominal level indicating a participants' status in one of the two groups and the dependent variable must maintain the characteristics of interval-scale or ratio (Polit, 2010).

Endpoints
Primary: N/A
Secondary: N/A