Spring 2018

The Impact of Digital Education Delivery on Postoperative Pain Outcomes

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The Impact of Digital Education Delivery on Postoperative Pain Outcomes

Presented to the Faculty of the School of Nursing

The George Washington University

In partial fulfillment of the

requirements for the degree of

Doctor of Nursing Practice

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Spring 2018

Abstract

Background. Advances in technology and communication tools offer new, innovative methodologies for delivering information to patients. Research is needed to understand the clinical effectiveness of different education delivery methods on outcomes and comprehension.

Purpose. Compare the effects of digital education with conventional, written and verbal instructions on patients' pain outcomes, knowledge attainment, and treatment participation.

Methods. A quasi-experimental design evaluated outcomes in 133 patients undergoing major hip (n=73) and knee (n=60) arthroplasty who received point-of-care pain education delivered via a dynamic mobile-computing (iPad) platform (n=65) or by conventional education (n=68). The significance level was set at 0.05. Person's *r* and independent t-tests were calculated to evaluate the pre-post intervention pain knowledge scores and post-intervention pain outcomes.

Results. Following point-of-care education, all patients, regardless of delivery methodology demonstrated improvements in pain knowledge ($p<.001$). Overall, patient education demonstrated positive correlations between time spent and the number of education interactions ($r=.365$; $p<.000$) and the pain experience ($r=.211$; $p= .015$). Patients who received the digital education program spent significantly more time engaged in education ($p=.009$) yet required less provider directed education ($p=.003$). There were no significant differences in post-intervention pain knowledge, outcomes ($p=.501$), treatment participation ($p=.806$), and opioid requirements ($p=.366$) between groups.

Conclusions. Dynamic digital programs for self-directed, modular education at the point-of-care are equally as effective as conventional education in maintaining high quality education to achieve knowledge acquisition and positive pain outcomes. A digital education platform is a viable learning methodology that can be used to deliver effective patient education for pain management.

Acknowledgements

I would like to express my appreciation to a number of individuals and teams who were instrumental in the completion of this study. My primary advisor, Dr. Karen Whitt and secondary advisor, Dr. Laurie Posey offered a wealth of knowledge, experience, and meaningful inquiry to guide me through this study and analysis. My study staff, Carol Eggum, Mary Schwartz, Erin Verdoorn, and Rebecca Jirsa, each dedicated an untold amount of time and energy, assisting at all levels of implementation and coordination. The dedicated staff and leadership team on Eisenberg Nursing Station 8-2 and 9-2 and the Department of Orthopedic Surgery who continually strive to improve the care for the orthopedic patient. Their dedication to their patients, professionalism, and commitment to quality was evident through their unfettered engagement in this study. This interdisciplinary team strives every day to improve the quality care through initiatives such as this. My administrative Assistants, Melynda Wirt and Katie Grunloh provided essential clerical support to keep the study on track. Shauna Schad and Sherry Wolf, my Supervisor and Nurse Administrator, have supported my work time and efforts in completing this study. The Department of Patient Education, the Department of Social Media, CareHubs©, and usability lab were instrumental in the development and testing of the educational content, web-based platform, and digital application. The Center for Innovation (CFI) team and the 2015 CoDE (Connect Design Enable) Innovation Award funding was instrumental in the development of the dynamic, modular education platform tested in this study. Without the assistance of these individuals and teams this research study would not have been possible. It takes a village, and this is my village.

The study protocol was listed on the *NIH National Library of Medicine*. ClinicalTrials.gov Identifier: NCT03301610

Table of Contents

Problem Statement

Societal, environmental, and organizational influences have created a paradigm shift in the way health information is received and delivered. The effectiveness of patient education is dependent on information delivery methodologies, individual needs of the patient, and applicability of the content, necessitating the need to explore novel delivery methodologies and develop more effective educational interventions (Leino-kilpi, 2009). Rapid advancement and proliferation of technology in society and healthcare has created a strong potential for the integration of information technology (IT) into health information delivery and patient education. Digital education offers a highly dynamic and consumable deliverable for adaptive content, accessible regardless of literacy or learning preference. Research is needed to understand the effectiveness of digital educational delivery methods on associated outcomes, knowledge attainment, patient engagement, and medication management (National Institutes of Health [NIH], 2016; Gordon, Leon-Casasola, Wu, Sluka, Brennan, & Chou, 2016).

Background

According to the National Center for Health Statistics (2016), just over eight million inpatient surgical procedures are performed annually in the United States. The inpatient surgical population has unique patient engagement needs and education barriers. Rapid patient turnover and shortened lengths of stay necessitate patient empowerment and activation in self-care management (Organisation for Economic Co-operation and Development [OECD], 2014; European Patients Forum, 2015). One major self-care challenge in the post-surgical population is pain management.

Pain Management

Despite the multitude of available analgesics, novel anesthetics, modern devices (i.e. electrical nerve stimulation, peripheral nerve blockade, virtual reality), and nonpharmacological

interventions, pain in the acute postoperative period remains a prominent issue and effective management has remained elusive. It is estimated that anywhere from 50% to 75% of surgical patients experience inadequate pain relief (Huang, Cunningham, Laurito, & Chen, 2001; Apfelbaum, Chen, Mehta, & Gan, 2003; Sommer, de Rijke, van Kellef, et al., 2008), often due to delayed intervention (Sinatra, Torres, & Bustos, 2002; Hayes & Gordon, 2015). The inadequacy of pain management is multifactorial, stemming from individual (patient and provider), organizational, and system influences (Hayes & Gordon, 2015) including, (1) substandard pain assessment (Michales, Hubbartt, Carroll, & Hudson-Barr, 2006), (2) limited clinician knowledge to manage pain effectively (Bedard, Purden, Sauve-Larose, Certosini, & Schein, 2006), (3) reluctance to report pain (Stalnikowics, Mahamid, Kaspi, & Brezis, 2005), (4) poor patient engagement and education (Innis, Bikaunieks, Petryshen, Zellermeyer, & Ciccarelli, 2004), (5) population demographics (Rakel & Herr, 2004), (6) chronic pain, and (7) poor perioperative medical optimization (Pan, Coghill, Houle, et al., 2006; Herr, Titler, & Schilling, 2004). The failure to mitigate these factors has led to an overall under treatment of pain in the postsurgical setting.

From the patient perspective, effective pain management is reliant on knowledge, engagement, and the ability to effectively report pain symptoms. Patient reported dissatisfaction and poor pain outcomes have been linked to insufficient pain assessment, management, education, and patient-provider communication (The Joint Commission, 2009; Reynolds, 2009; Aubin, et al. 2006; Subramanian, Ramasamy, Hoong, Chinna, & Rosli, 2016; Smith, Rhodes, Paciotti, et al., 2015; Helfand & Freeman, 2009). Education and communication deficiencies have resulted in misconceptions about pain, increased opioid use, and adverse side effects (Helfand & Freeman, 2009; Morrison, Meier, & Fischberg, 2006). Clinical outcomes and

influential factors attributed to pain management, including knowledge, pain reporting, opioid management, pain scores, and satisfaction may be mitigated through focused patient education and knowledge acquisition (Mularski, White-Chu, Overbay, Miller, Asch, & Ganzini, 2006; Zoega et al., 2014; Allard, Maunsell, Labbe, & Dorval, 2001). The need for improved pain education is further reinforced by the American Pain Society (APS) and the American Anesthesia Association which made the following recommendation "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).

Patient Education

Effective education is a requisite for positive outcomes and the ability to influence the way in which patients engage as a learner, acquire knew knowledge, and alter behavior patterns. When effective, education can improve patients' self-esteem, sense of control, confidence, self-efficacy, and comprehension (Bridges, Cox, Lucas, & Perry, 2013; Johansson, Katajisto, Nuutila, Salanterä, & Virtanen, 2005). These benefits serve to empower patients and subsequently influence outcomes, including anxiety (McDonald, Page, Beringer, Wasiak, & Sprowson, 2014; Prouty, Cooper et al., 2006), pain (Thomas & Sethares, 2008), satisfaction (McDonald et al., 2014), quality of life (Leino-Kilpi, Johansson, Heikkinen, Kaljonen, Virtanen, & Salanterä, 2005), functional ability, self-management, adherence, and discharge planning (Siggeirsdottir, Olafsson, Jonsson, Iwarsson, Gudnason, & Jonsson 2005; Johansson, Katajisto et al., 2005).

Organizations, providers, and patients are subject to a variety of requirements and contingencies which may influence the effectiveness of education. In conventional patient education, health information is delivered by means of written material and verbal instruction. Both methods independent of one another or in combination are effective patient education

strategies, yet are time and labor intensive, time sensitive, limited in scope, and influenced by external variables. Written material is sensitive to readability, and the concomitant influences of baseline knowledge, language proficiency, and health literacy (Johansson, Salantera, Katajisto, & Leino-Kilpi., 2004). Verbal instruction is reliant not only on these receiver variables but also the provider's skill, knowledge, motivation, availability, and confidence (Marcus, 2014; Costello, Thompson, Aurelien, & Luc, 2016). This variability among providers results in inconsistent education delivery and messaging. The potential shortcomings of each method promote the use of the two delivery methods simultaneously. However, conventional approaches and generalized education material may still be insufficient in meeting the needs of the individual patient. Designed for the general populous, a "one-size-fits-all" approach to learning assumes that all learners have a similar base of knowledge and proficiencies and retain and recall information in the same way. This universalization leads to education that may be overwhelming for some and unnecessary for others.

Novel Approach

Newer progressive methodologies are incorporating information technology (IT) into education delivery. Learning can be facilitated through the use of various digital technology platforms (i.e. multimedia, social media, secure portals). Technological advances and the proliferation of technology have prompted a paradigm shift at both the organization and community level. This shift has resulted in high satisfaction with and a preference for technology-supported or digital learning (Yin, Goldsmith, & Gambardella, 2015; Vawdrey, Wilcox, Collins et al., 2011; Marble, Loescher, Lim, & Hiscox, 2010; Ranney, Choo, Wang et al., 2012). The transition from conventional education delivery to digital methods removes traditional barriers to education delivery (e.g. access, cost, and resources) to better meet individual patient needs, mitigate concomitant influences, and address system and patient level

barriers that hinder effective knowledge acquisition (Saidinejad & Zorc, 2014; Sorrentino, Berger, Wardian, & Pattrin, 2002).

Education delivery has the potential to be transformed into real-time, interactive, modular, and customizable programs using digital and mobile-computing platforms. Digital education is highly consumable and effective with dynamic capabilities which allow for independent navigation and interaction with personalized education that meets the individual's needs (Fredericks, Martorella, & Catallo, 2015). The integration of media through the use of images, animations, and video can improve outcomes, engagement, and empowerment by offering individualized content in a format that is accessible and understandable to all learning styles and literacy levels (Greyson et al., 2014; Fredericks, Beanlands, Spalding, & Da Silva, 2010; van Dijk, van Wijk, Kappen, Peelen, Kalkman, & Schuurmans, 2015). Founded on adult learning principles, digital and mobile technologies have the potential to support adaptive problem solving and active participation, which builds on the lived experience and provides a means of positive reinforcement and continuous feedback (Bastable, 2008; Knowles, Holton, & Swanson, 2015). These principles incorporated into education delivery enhance engagement and participation, both of which have been fundamentally linked to health outcomes, assessment accuracy, treatment efficacy, and medication safety (Gordon, Dahl, Miaskowski et al, 2005; McTier, Botti, & Duke, 2014). Strong evidence for digital education delivery is still developing, but early findings have demonstrated positive outcomes associated with enhanced knowledge, decreased anxiety (Friedman, Cosby, Boyko, Hatton-Bauer, Turnbull, 2011; Fredericks et al., 2010), increased satisfaction, and improved resource utilization (Dykes, Rozenblum, Dalal et al, 2017).

Although there is an established awareness and recognition of the positive influence of high quality education, gaps in available evidence still exist surrounding pain management and

the ideal educational delivery strategies to improve associated outcomes. In the evolving healthcare system that is influenced by the proliferation of technology and individualized patient needs, conventional and digital education delivery methods need to be explored to learn about their effects on pain outcomes. This exploration will aide in the optimization and design of future patient education.

Purpose

Purpose Statement

The purpose of this study was to compare the effects of digital patient education with conventional, written and verbal instructions in patients undergoing major hip (THA) and knee (TKA) arthroplasty.

Hypothesis and Study Aims

It was hypothesized that point-of-care pain management education delivered via a digital mobile-computing (iPad) platform would be more effective than verbal and written delivery in improving patients' pain management outcomes, knowledge attainment, treatment participation, and medication (i.e. opioid) requirements when compared to standard education delivery. The aims were as follows:

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

Review of the Literature

Health information technologies such as mobile applications, digital media, patient portals, and tablets are progressive and useful applications for information delivery. A systematic review of 16 studies concluded that utilizing electronic (i.e. computer programs, videos, and/or animation) instruction methodology for education resulted in patients having greater knowledge and understanding of their surgery and hospitalization (Muslow, Feeley, & Tierney, 2012). Although the exact delivery methodology varied between studies, the knowledge attainment correlated positively or remained at baseline when implementing technology-supported educational interventions. Across the 16 studies, pre-surgical understanding ranged from 59% - 82% with a 13.6% improvement in knowledge overall. The use of various technology platforms in practice can support education delivery and facilitate patient learning.

A primary goal and measure of the effectiveness of an educational intervention is knowledge retention and recall. Knowledge acquisition (i.e. recall and retention) is influenced by the presentation of the information specific to the mode of delivery, timing, and access (i.e. repetition) (Fredericks, Guruge, Sidani, & Wan, 2010). A pilot study of computer-based education delivered to 64 surgical patients found that compared to standard education, web-based education was more effective in improving patients' knowledge of the perioperative experience (Hering, Harvan, D'Angelo, & Jasinski, 2005). Similar positive results were demonstrated in larger scale studies. Edward, Naald, Oort, et al. (2011) studied the use of preoperative education and anesthesia using a web-based program in 893 elective surgical patients. Approximately, half (n=477) of the patients were sent a link to access the information prior to their perioperative clinical assessment visit. The other half (n=416) of patients received standard education using a pamphlet. Patients who completed the web-based education demonstrated greater gains in knowledge when compared to those who received only written

material or written material combined with spoken information. The authors concluded that a multimedia, interactive website was an effective means of health information delivery (Edward et al., 2011). A learners' engagement and knowledge acquisition are directly influenced by the necessity and value of information delivered at a time of need (Knowles, 1990; Cook, Moradkhani, Vickers Douglas, Prinsen, Fischer, & Darrell, 2014). A self-paced and readily available format creates a flexible and continuous learning environment for patients to engage with based on their individual needs. Education which is reliant on a provider hinders this flexibility as availability and patient readiness are often misaligned.

A unique benefit of digital delivery is the ability to present content in a variety of ways to support multiple learning needs. Any one program could potentially offer, media in various forms to support the visual and auditory learner; active participation (i.e. interactive functionality) to satisfy the experimental learner; and/or written text for the visual learner (i.e. readers) and as a mechanism to reinforcement of the other delivery methods. Tait, Voepel-Lewis, Chetcuti, Brennan-Martinez, & Levine (2014) explored a comprehensive multimedia approach among adult patients undergoing cardiac catheterization. The perioperative education program used a dynamic, modular interface consisting of 2D and 3D models and animations of anatomical structures; narrations (written and auditory) to supplement theses visual effects; and 26 interactive exercises to test comprehension. Despite wide variability in correct response rate (24.3% - 100%) among the study participants using the iPad-based informational program, those in the study arm had significantly higher understanding and recall of their medical procedure compared to those who received the standard education.

Many of the studies examined here compared one form of digital delivery with conventional delivery, including a component of provider delivered verbal instruction. The risk

of variability and poor consistency in verbal instruction has the potential to influence the results of studies of this design. Azem, Benington, Kahambay, & Ayoub (2014) controlled for this variability through the use of an audio recording in the control sample compared to an interactive program that used a combination of graphics, text, and audio. The use of an animated modular program presented on a tablet-computer was superior, improving information recall significantly when compared to the audio recording ($P<0.001$). These results further support the need for dynamic programs that use variable strategies to meet the needs of all learners. More than 52% of adults are experimental learners (SDS, 2014). These learners acquired knowledge and skills through active participation, hands-on training, and interactions. This dynamic and multifaceted program served a variety of learning styles. The highly adaptive nature of the program served the greater populous, lending to its success.

Simpler variations of multimedia delivery using video content have also demonstrated learning effectiveness. Yin, Goldsmith, & Gambardella (2015), examined a 20-minute perioperative information internet tutorial with a broad curriculum of relevant anatomical structures, pathophysiology, and perioperative instructions applicable for surgical patients undergoing an elective arthroscopy of the knee. Patients who completed this multimedia program felt more informed about their upcoming procedure; clearly understood the risks, benefits, and alternative treatment options; reported higher satisfaction with pre-surgical planning; and were better able to articulate the post-surgical expectations and details. Similarly, multimedia video delivered via a DVD demonstrated improved perioperative knowledge and preparedness which stemmed from increased patient and family access to necessary perioperative information (Ong, Miller, Appleby, Allegretto, & Gawlinski, 2009). Simple multimedia (i.e. video) programs like those studied by Yin et al. and Ong et al. do not offer an outlet for direct participation or

experimental learning. However, this gap did not impact the positive results of education on knowledge outcomes. This may be associated with learning's reliance on the effectiveness of the delivery. Multimedia in any form offers a degree of continuity, consistency, and accessibility that is limited with conventional learning methods.

Although technology-supported education has demonstrated evidence to support a positive impact on learning, the questions of utility and feasibility in practice remain. A prototype program called 'i engaging' was intended to engage patients in their care to reduce the risk and incidence of falls in the hospital (Tzeng, Yin, Fitzgerald, & Grahm, 2015). The feasibility results of this study examined benefits from the perspective of 23 patients and 10 healthcare providers'. Patients who used the device found it to be (1) easy to use, (2) an effective self-management tool, and (3) customizable to individual needs (Tzeng, et al. 2015). Providers expressed that the tool was comprehensive and a non-confrontational means of delivering education (Tzeng, et al. 2015). Although this study did not link the intervention to the outcome and further research is needed, strong consideration should be given to similar tools related to the feasibility results that demonstrated ease of use, effectiveness, and practicality in clinical practice.

Mobile technologies such as tablets (e.g. iPads) are of simple design with a familiar interface making it easy to use and learn. Feasibility pilots have tested tablet-computing in a variety of settings and populations. The use of such technologies at the point-of-care has been effective regardless of age, hospitalization, acuity, and surgical procedure (Dalal, Dykes, Collins et al. 2015; Cook et al., 2014; Kim, Mohammad, Coley, & Donihi, 2015). However, age and gender may influence learning preference and computer literacy. Kim et al. (2015) found that the female participants and those under the age of 65 were more likely to prefer tablet-based

education and report higher usability. Despite demographic variability patients of divergent age groups, even the frailest elderly, can quickly adapt and engage in education using tablet-computing (Cook et al., 2014). Overtime demographic variables and barriers to digital learning will recede, making digital education the preferred means of delivery.

Significance

The available research indicates a strong positive correlation between patient education and clinical outcomes, decision making, empowerment, and comprehension (Bridges et al., 2013; McDonald et al., 2014; Thomas & Sethares, 2008). The influence of patient education and knowledge acquisition is dependent on patients' access to quality information. Recent and progressive advancements in healthcare delivery models, technology, and information systems has allowed for the proliferation of novel information delivery programs and strategies to increase access and the success of education.

The use of technology for patient education and information delivery has evolved rapidly over the last five to ten years. Although the use of technology is growing, the body of research available on novel delivery methodologies is still in its infancy. The delivery methodologies, content, and results in this area have been broad and mixed. Overall, evidence suggests that novel approaches to education delivery are an effective means of delivering a wide variety of health information that improves knowledge and outcomes.

There has been no research on the direct influence of post-operative pain management education delivered using novel methodologies and the effect on hospital recovery including pain outcomes, engagement, and knowledge. These gaps are consistent with those identified by the National Institutes of Health (NIH) and APS (NIH, 2016; Gordon, et al., 2016). Further research is needed to understand the effectiveness, barriers, and use of digital delivery models. This research study sought to understand the difference and effectiveness of educational methods and

delivery mechanisms using a point-of-care digital patient education program compared to standard education delivery (verbal and written) and their impact on pain outcomes, pain experience, patient participation, and opioid requirements.

Theoretical Framework

Adult Learning Theory

First proposed by Malcom Knowles in 1968, andragogy refers a set of assumptions and principles that define the art and science of adult learning. The adult learning theory assumes that learning among this demographic is influenced by the (1) learner's need to know, (2) self-concept and (3) past learning experience of the learner, (4) readiness to learn, (5) orientation to learning, and (6) motivation to learn (Knowles et al., 2015). These assumptions underscore the importance of providing education that directly engages adult learners in problem-centered, relevant learning that draws on and fosters their lived experiences.

Digital learning offers a unique means of translating these concepts into the modern learning experience. The adult learner has a need for control and personal responsibility. The integration of technology into education delivery promotes an autonomous and flexible learning environment that maximizes individual motivation and ownership (i.e. motivation to learn and self-concept). Motivation and ownership are often enhanced when there is eminent need for the information. The autonomous learning style allows the individual to obtain and absorb the information based on need, relevance, and application (i.e. orientation and readiness). The flexibility of such dynamic platforms also allows for a variety of instructional delivery methods that appeal to a variety of learning styles, experience levels, and backgrounds (i.e. experience). Digital applications have the potential to transform education deliverables in a meaningful way to support any learning environment, including the hospital.

Study Variables

The independent variable was the type of education delivery, group A (study group, digital, mobile-computing education program) and group B (control group, conventional education). The dependent variables were 1) patient reported pain outcomes, 2) pain knowledge; 3) Patient reported participation in pain treatment plans, and 4) Total post-operative opioid consumption (Appendix A).

Method

Design

This study was designed as a quasi-experimental study. Study participants were assigned into an intervention or control arm based on bed assignment to one of two designated inpatient surgical units. Researchers and participants were blinded to the assigned study arm until postoperative, inpatient bed placement occurred.

Study Population

The target population was adult patients undergoing elective, lower extremity total joint arthroplasty (TJA). Eligible candidates were enrolled if they were 18 years of age or older at the time of consent, English speaking, and undergoing surgical intervention with planned 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 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 a hip fracture were excluded. Patients were also excluded if they presented with, or had a documented history of, preexisting physical or cognitive limitations that would hinder their ability to use the mobile application (e.g. blindness).

Sample Size

Assuming a moderate effect size and a coefficient variant of 0.50 (Cohen's d), a power of 80% (0.80) to detect 30% difference in scores utilizing an independent t-test, and a type 1 error rate (alpha) of 0.05, 64 participants were needed in each study arm (Polit, 2010).

Recruitment

Eligible patients were identified using the surgeon referral and/or electronic surgical listing reports. Patients were recruited at the time of perioperative phone consultation with nursing. This consultation occurred approximately two weeks prior to the scheduled surgical procedure. At this time, patients were introduced to the study and consented by the Institutional Review board (IRB) approved consent designees. Consent designees read the consent script (Appendix B) and provided adequate time to answer questions. Study enrollment was finalized when participants completed the HIPAA Authorization to Use and Disclose Protected Health Information (Appendix C) at the pre-operative visit.

Setting

The intervention and data collection was completed on two inpatient orthopedic care units at a large academic medical center in the upper Midwest. Between the two units there were 50 dedicated orthopedic beds that admit more than 9,000 orthopedic patients annually. Included in the annual orthopedic admissions are approximately 4,000 major total joint arthroplasties. Based on historical admission data and patient volumes the desired sample size was feasible. Patients relocated to non-orthopedic units' due to high patient census or clinical needs were removed from the study at the time of admission.

Intervention

In current practice, adult orthopedic surgical patients at our organization receive a minimum of two pamphlets specifically targeted to address pain communication and

management. Additionally, these patients receive a 40-page book covering numerous post-surgical topics inclusive of additional pain content. Verbal instruction and additional materials are determined based on nursing or provider appraisal of the patients' needs.

For the purpose of testing digital education delivery, a web-based education program was developed to be delivered using either a computer or mobile-computing (i.e. tablet such as an iPad) interface. Using human centered design principles, a transdisciplinary team of nurses and physicians, along with experts' in the fields of service design, project management, patient education, social media, graphic design, healthcare innovation, videography, and information technology, worked collaboratively to develop the education program. Built as a subsidiary site within the organizations existing social media platform, this web-based program was designed based on standards and recommendations from the Web Accessibility Initiative, National Institute for Literacy, and The Joint Commission. Prior to implementation, several program iterations were reviewed and adapted for accuracy and utility in practice. The prototype was tested for usability by 10 lay individuals who assessed the programs flow of information, ease of navigation, language, and formatting.

The asynchronous program offered self-directed, self-paced modular education using a combination of static and interactive methods. The curriculum, segmented into discrete learning components, used a combination of written text, video, interactive modules, illustrated graphics and guides, supplementary resources, virtual tours, printable materials, and frequently asked questions. For the purposes of this study, expanded post-operative pain management content was made available to supplement the identified gaps in pain management education.

The program and pain content was loaded onto ten mobile-computing tablets to be used in the hospital setting. The delivery of the program using a tablet computer offered an accessible

and simple interface that was familiar for most patients and nurses. The large screens allowed for easy viewing and readability. This accessible format is convenient and simple to use, allowing the content to be delivered at the point-of-care or when most appropriate, based on the patient condition. The curriculum and program design was intended to be comprehensive yet adaptive and customizable so that the content may be differentiated based on the individual patient's need. Screen shots of the web application may be found in Appendix D.

Study group. The participants in the study arm received digital pain management education delivered using mobile-computing tablets at the point-of-care. The education modules included information about the use of the pain assessment; pain expectations; pharmacologic and non-pharmacologic management options; medication side effects and safety; communicating with providers; and discharge instructions. The program also included an interactive pain rating scale, pain descriptor radial buttons, pain and discomfort management menu, media, and progress tracker. The digital application covered a curriculum of the most common concerns and questions faced by individuals experiencing pain (Gifford, 2014; Horwitz et al., 2013; AJN, 2015; and Chou et al., 2016). The content presented within the application was comprehensive and inclusive of all appropriate material for the post-surgical, orthopedic patient. The content presented as written text and video media within the interactive modules was based on previously developed education materials.

Patients enrolled in the study arm were given a tablet with an instruction sheet on admission to the postoperative unit. The RN instructed the patient on how to use the tablet and the pain education program. The device remained with the patient until discharge. The patient, independently or with the RN, used the program throughout their inpatient experience. The RN used the tablet to

engage patients in their pain management and followed-up to address any questions. The tablets were configured and secured, limiting patients' access to only the education program.

Control group. The control group received the current standard of care using conventional education delivery consisting of verbal instruction and a series of standard pain management pamphlets. The patient received two educational pamphlets titled *Your Pain and Discomfort Management Menu* (Appendix E) and *Communicating About Your Pain* (Appendix F). The pain management menu was designed to provide the patient with basic pain information with a focus on non-pharmacologic pain interventions. The pain communication pamphlet offered a more comprehensive explanation of the pain experience, pain rating scale, communication, and management options. At a minimum, the nurse was instructed to provide the two pamphlets to the patient and follow-up with the patient to address any questions. The content of these two standard documents were identical but not inclusive of the education in its entirety that was received by the study patients using the mobile device. However, all information delivered via the digital intervention was available to the control group. Based on an individual patient's needs, additional materials and/or verbal instruction were provided.

Management of interventions and study participants. All educational content for both study arms was developed using existing 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 implementation of the interventions in the study and control arm was closely monitored by the researcher. Nurses participated in multiple in-service educational sessions and received reference packets outlining the research protocol, roles and expectations, goals, mobile tablet use, and data collection procedures. The PI made daily rounds, conducted

random care observations, sent weekly e-mail updates, and offered just-in-time education as needed.

To control for fidelity of the intervention and avoid potential behavior changes in the control sample, the intervention the patient received was determined by the location during their stay in the hospital. Orthopedic TJA patients were assigned at random and based on bed availability to one of two patient care units. One of the two patient care units offered the standard education and the other unit provided digital education. The unit assigned to the study arm was selected by random draw. This study design helped minimize the risk of selection bias, increase fidelity of the intervention, and increased the probability that the differences demonstrated between the study groups was attributed to the actual intervention under study. The implementation of the study interventions and data collection procedures were monitored and assessed using a fidelity checklist (Appendix G).

Instruments

Patient demographics and clinical characteristics. Patient demographics and past medical history data was collected (Appendix H) including patient age, race, education level, marital status, and employment status. Data related to specific confounding variables associated with the type of intervention and outcome was collected including patients' preferred learning style, comfort level with technology, and anxiety associated with anticipated pain. Preferred learning styles were assessed using the three styles of learning; seeing, doing, or listening (Bastable, 2008). Comfort level with technology was assessed using a five-point Likert scale with zero being, "not comfortable at all" and five being "very comfortable." Anxiety associated with anticipated pain was assessed on a ten-point scale with zero being, "not anxious at all" and ten being "extremely anxious". Relevant past medical and surgical history was collected

including past major orthopedic surgeries, chronic pain, preoperative use of opioids, and mental health conditions.

Pain outcomes. The Revised American Pain Society Patient Outcome Questionnaire (APS-POQ-R) was used to evaluate the patients' perception of their pain management experience and outcomes (Appendix I). 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). The tool employs variable response measurements based on the intended purpose for each question subset. Pain experience here is assessed by generalized satisfaction with pain relief and participation in treatment decisions. These data points helped determine the influence of pain education on satisfaction with educational material/delivery and participation. The reported participation score was used to measure the degree to which the patient was engaged by a means of active participation in care and treatment. 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 et al., 2010). This tool was open source and available for application without further permission (Gordon et al., 2010).

Pain knowledge. The Patient Pain Questionnaire (PPQ) was used to evaluate pain knowledge post intervention (Appendix J). The16-item questionnaire measured both pain knowledge and actual experiences with pain. This study used only nine of the items targeted at pain knowledge and beliefs. Using a ten-point (0-10) ordinal scale the tool assessed 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. Scoring was dependent on the intended purpose of each individual statement; a higher score may indicate either agreement or disagreement with the statement. However, all items have been formatted so that zero indicates the most positive outcome and a ten indicates the most negative outcome. These nine items have been 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 was revised, as in the study conducted by Reynolds (2009) and reference to chronic cancer pain was 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; Measurement Instrument Database for the Social Sciences [MIDSS], n.d.).

Chart audit. Chart audits of the electronic health record were conducted after discharge to collect the remaining clinical data (Appendix K). Data collected included 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 obtained from quality data specialists.

Data Management

Data Collection Procedure

Data was collected at three points in time using paper and pencil survey's and chart audits. The data collection protocol can be found in Appendix L. The patient demographic and the pre-intervention revised PPQ survey were administered in the perioperative orthopedic ambulatory setting, one to five days prior to the scheduled surgery. Post-intervention and at the time of discharge participants completed the APS-POQ-R and repeated the revised PPQ surveys. It took participants approximately ten minutes to complete the two surveys. All study materials and instruments were administered using paper and pencil and took no more than ten minutes to complete. The pre-intervention and post-intervention paper surveys were returned to the study staff. Following discharge, the researcher and study staff conducted chart audits to collect clinical data including opioid consumption totals during the hospital stay, past medical history, anesthesia type, and length of stay. The collected data from all forms was collated and entered into SPSS by study staff and confirmed for accuracy by the primary investigator prior to analysis.

Data Analysis Plan

This study used a revised adaption of the Patient Pain Questionnaire (PPQ) survey. The use of the revised version necessitated an evaluation of the internal reliability and validity of the nine knowledge-based questions using Cronbach's α and factor analysis. Psychometric analysis of the revised PPQ demonstrated internal consistency with a Cronbach α of 0.79. This is consistent with the original PPQ internal consistency of 0.71 (Ferrel & Rivera, 1997).

Descriptive statistics were performed to analyze patient demographic data and to quantify usage and pain outcomes. Continuous variables were reported using a mean and standard

deviation. A one-way ANOVA was calculated to compare continuous variables between all patient enrolled by type of intervention (p-value<0.05 was considered significant). Categorical variables, including patient characteristics, were reported as frequencies and percent occurrence. A Pearson's r correlation coefficient was calculated to examine relationship between all patient enrolled by type of intervention (p-value<0.05 was considered significant).

Patient education usage and engagement was calculated based on the patient and nursing report. Patient reported participation in treatment decisions was calculated using a 10-point Likert scale. The number of times patients accessed pain education material and the time spent reviewing content and discussing pain management was determined by the care-team per individual patient. The difference amongst the two study groups was analyzed using an independent sample t-test. Additional analysis of pain knowledge and participation was conducted using an ANCOVA to examine the influence of covariates such as pre-intervention pain knowledge, age, and engagement.

Ethical Considerations

The study was reviewed by Nursing Research Review and approved by Mayo Clinic's IRB (Appendix M). Internal policies and procedures for nursing research and the IRB were adhered to. Oral consent was obtained, documented, and maintained as part of the research records. HIPAA authorization was signed to finalize the participant's enrollment prior to data collection. Data was de-identified following initial data collection and entry. The only identifiable information collected and retained was the study identification number and clinic number. There was a risk for disclosure of personal protected information. The electronic data was stored on an internal secure server and if transport of data was necessary an encrypted storage device was used. Paper and pencil surveys were stored in a locked cabinet in a secure

office. Access to the data was restricted to only research personnel approved by the organization's IRB. Data was de-identified following data collection and entry.

Enrollment into the study was completely voluntary. Participation posed minimal risk to the participants; all patients received the necessary education to meet their care needs and the minimum standard of practice. The potential risk was that the mode of information/education delivery did not meet the patients' needs particularly in the instance 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 remained the same; no changes were made to the process for treating pain using either non-pharmacologic or pharmacologic interventions. Medication orders, medication administration, and pain treatment plans were not affected by participation in the study. As the standard, pain management was customized to meet the needs of the individual patient.

Results

Patient Characteristics

Between October 20, 2017 and January 26, 2018, 167 patients were enrolled in the study. Thirty-four patients did not complete the study, eight voluntarily unenrolled, eighteen were removed due to breakdowns in the study protocol, two were admitted to off service units for care, and six canceled or rescheduled the surgical procedure. In total, 133 patients completed the study, 65 in the digital education group and 68 in the standard education group. Patient demographics were similar in age (p=.477), sex (p=.322), race (p=.177), educational level (p=.112), employment status (p=.797), marital status (p=.366), and past medical history (i.e. surgical [p=.907], chronic pain [p=.385], opioid use [p=.325], and mental health [p=.659]) between groups. Hospital and surgical characteristics were similar in surgical procedure (p=.101), regional anesthesia (p=.416), length of stay (p=.623), and discharge disposition (p=.688). Learning characteristics were similar

for computer literacy (p=.569), perioperative education class attendance (p=.358), and preferred learning style between groups (p=.644). It is important to note that 78.2% of patients reported a preference for learning that incorporated all styles of learning (i.e. listening, reading, seeing, and doing). (Appendix N, Tables 2, 3, and 4).

Education Use, Satisfaction, and Treatment Participation

Overall, 97.5 % (n=117) of participants reported having received information about pain treatment options (50.8% control; 46.7% intervention) and the mean (SD) patient reported helpfulness of the education materials was 8.4 (+/-1.9). The mean (SD) helpfulness score was higher in the intervention group, yet the result was not statistically significant at 8.7 (+/-1.6) vs. 8.1 (+/-2.1) (p=.095). Overall, there was a positive correlation between time (in minutes) and the number of direct patient-provider interactions with or without the use the materials (r=.365*; P*= <.000). The number of times patients engaged in education with the nurse was significantly higher among the conventional education patients (8.31 [+/-5.1] vs. 6.1 [+/-]; 3.1 p=.003). However, patients using the digital education program spent significantly more time (in minutes) engaging in pain education (31.1 [+/-16.5] vs. 40.1 [+/-22.4]; p=.009) (Appendix N, Table 5 and Figure 7). The mean (SD) patient reported participation in pain treatment decisions was not statistically significant (p=.806) (Appendix N, Table 5). The significance remained unchanged when patient participation was adjusted for use (F=.040; p=.842) and time (F=.211; p=.647).

Pain Knowledge

The pre-PPQ knowledge scores were not significantly different between the two study arms. The highest (negative outcome, indicating lower knowledge) scoring items included pain medications are dangerous and may interfere with breathing (M=6.2; SD+/-2.9), important to give lowest amount of medicine possible (M=5.9; SD+/-3.4), and patients are often given too much pain medicine (M=5.5; SD+/-2.9). Overall patients had a strong understanding and

expectation that pain can be effectively relieved (M=2.9; SD+/-2.7) even when using non-pharmacologic treatments (M=2.7; SD+/-2.8).

ANOVA demonstrated no statistically significant difference in post-intervention PPQ scores between the intervention and control groups for any of the nine knowledge items (Appendix N, Table 6). Similarly, an ANCOVA between groups (standard, digital education) with pre-PPQ scores, education use, and time covariates revealed no effect on post-intervention PPQ scores. However, there was a significant difference in pre- and post-PPQ scores when the whole study sample was evaluated regardless of type of intervention (Table 7); with the exception of "pain medications are dangerous and may interfere with breathing" which demonstrated an increase in score from 6.2 (+/-2.9) pre- intervention to 6.3 (+/-3.2) (p=.806) post-intervention.

Pain Outcomes

Pain outcome results were similar. Patient reported worst pain experience and time spent in severe pain was higher in the intervention group, yet the results were not significant at p=.501 and p=.417 respectively. Regardless of education intervention, there was a positive correlation between severity of the worst pain experience and the use (in minutes) engaged in education (r=.211; p= .015). Despite higher reports of negative outcome variables there were no statistically significant differences in opposing pain variables including lowest pain experience (p=.928), experienced pain relief (p=.646), and satisfaction with pain treatment results (p=.280), which trended more positively for the intervention group. Additionally, the mean (SD) 48-hour oral morphine requirements were lower in the intervention patients, yet remained not statistically significant at 71.3 (+/-67.2) vs. 82.3 (+/-72.0); p=.366 (Appendix N, Table 8).

Discussion

Education, an augment to medical practice, empowers patients with information as a means of becoming an active member in their healthcare team (Hibbard, Mahoney, Stock, &

Tussler, 2007; Coulter & Ellins, 2007) which has been fundamentally linked to health outcomes, assessment accuracy, treatment efficacy, and medication safety (Gordon et al, 2005; McTier et al., 2014). The ability for information to be retained and recalled is dependent on effective and appropriate delivery. Patient centric and individualized, verbal instruction is provider dependent resulting in inconsistencies and inefficiencies (Marcus, 2014; Costello et al., 2016). This limited methodology is associated with poor memory recall (Knowles et al., 2015). Acquisition is strengthened when verbal instruction used in conjunction with written material (Johansson et al., 2004). Conversely, digital education platforms are easily accessible, adaptable, and dynamic with build potential for interactive learning (Knowles et al., 2015). This dynamic delivery method presents the greatest degree of versatility and utility for a wide range of patients with varying baseline knowledge, learning preferences, and language skills. Among all learners, 78.2% reported a preference for a dynamic (i.e. reading, seeing doing, listening) approach to learning. The fundamental principles and capabilities of digital education serve the dynamic learner well by offering an equally effective alternative or augment to conventional learning as a means of engaging patients in treatment decisions and care participation.

This study demonstrated that education as an intervention influences patient knowledge regardless of the mode of delivery. Hospitalized patients who received a mobile-computing tablet loaded with an interactive digital education program had no significant improvements in pain knowledge, outcomes, or participation in pain treatment decisions. This contrasts with ample literature supporting various adaptations of digital education as superior to conventional strategies, yet aligns strongly with the established premise that patient education is a means of influencing knowledge of disease and treatment (Johansson et al., 2005); intrinsic and extrinsic

motivators (Bridges, Cox, Lucas, & Perry, 2013); treatment participation, and clinical outcomes (Thomas & Sethares, 2008; Leino-Kilpi et al., 2005; Siggeirsdottir et al., 2005).

Meaningful patient learning depends on the efficacy of the delivery method and teaching strategies that may occur asynchronously and synchronously between patient and provider. The efficacy of this relationship is essential for successful clinical outcomes. Traditionally, education in the health care setting is time and labor intensive for staff as learning is a cyclical process and effective knowledge acquisition is dependent on timing, mode, and consistency (Fredericks et al., 2010; Cook et al., 2014). Digital education platforms offer a more flexible and continuous means of learning. When utilized asynchronously, self-directed education may reduce direct care team involvement and the time required to support patients in the learning process (Fox, 2009). This may explain the difference in time and direct nursing involvement between the two groups. Participants who completed education using the mobile application spent significantly more time (in minutes) engaging and interacting with the educational material, yet the nurses reported a higher frequency of direct education interactions with patients receiving standard education. Historically the patient-nurse relationship has been a principal component in patient education. While digital delivery may reduce direct interactions, the education format can be an effective means of supporting patient engagement, informed decision making, and enable self-care management (Taylor, 2015). This study demonstrated consistency between the study arms in treatment participation and satisfaction with both pain management and education, suggesting that digital education and the subsequent reduction in nurse directed education did not negatively impact the overall pain and education experience.

The increased flexibility and access to content afforded by the digital technology platform allowed participants to spend more time engaged in self-directed learning. Suggesting

that patients in the study arm may have been better able to self-direct and manage their learning needs. The digital program placed the learner in control of their education and offered unconstrained access to information without inhibiting opportunities for provider-patient interactions. The versatility and availability of content also provided a platform conducive to facilitating customized teaching between the patient and provider. These three aspects (i.e. control, access, and facilitation) offered by digital learning make this delivery methodology well suited for adult learning (Knowles et al., 2015). Despite variability in time and direct patient-provider interaction the knowledge and outcome variables remained unaltered by the intervention method.

This study found no difference between education groups in knowledge attainment, treatment participation, or pain associated outcomes. However, the results demonstrated the positive effects of both forms of education as an intervention to assist patients in managing post-surgical pain. The study participants from both groups demonstrated 26.6% improvement in knowledge scores at the time of discharge from the hospital. The consistency and overall improvement in knowledge and outcomes is reflective of the quality of the standard education provided directly by the RN and the existing pamphlet-based material, as well as the quality of the digital education.

The intent of both education interventions was to dispel individual's preconceptions and misconceptions about pain and pain management. Preconceived knowledge, attitudes, and expectations result in common unsubstantiated or misguided fears of addiction and tolerance, medication administration and safety, and awareness of medications and associated side effects (Aranda, et al. 2004; Helfand & Freeman, 2009). Improvement was noted in all knowledge questions but opportunities for further development are needed in medication safety and dosing.

Patient knowledge related to these topics demonstrated the least degree of improvement following education.

The population was a representative group of elective orthopedic patients with participants being on average 63.7 years of age and a greater frequency of females. Historically, the adoption to digital education and learning has been limited due to acceptance and use of technology in the elderly population. 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 inhibited 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). The utilization of digital and mobile health platforms for a variety of applications is anticipated to continue across all populations (Visiongain, 2013; Taylor, 2015). The anticipated growth in technology consumption along with continued technological advancement and utility will continue to make technology less of a challenge in health information delivery. When the data was adjusted for age, there was no difference in knowledge, outcomes, or use of materials.

Limitations

This study design presented a number of limitations. At the time of the study, the Department of Orthopedic Surgery was undertaking a Manage to Reimbursement (MTR) initiative that was designed to standardize practice (e.g. pain), improve efficiencies, and reduce length of stay. The breadth and scope of the intermittent trials that took place at various points were not able to be fully controlled for. All attempts were made to identify antecedents that impacted pain and pain outcomes to adjust for accordingly during data analysis. Despite attempts to control the standard verbal and written education, variability in RN practice and skill still existed. Additionally, knowledge of the objective of the study increased awareness of pain

education and gaps, potentially leading to an inadvertent practice change among the RNs administrating the standard of care.

The final assessment of effectiveness on knowledge attainment was limited. The retest of pain knowledge occurred shortly after or near the completion of patient education in the hospital setting. The completion of the retest at the time of discharge allowed for assessment of immediate knowledge acquisition. The ability to have added a second retest several weeks post discharge would have allowed for a greater analysis and understanding of the education's impact on long-term retention and recall.

Despite internal analytic capabilities within the digital intervention, data abstraction directly from the program was not feasible. The investigators did not employ the use of the applications' internal analytic capabilities in efforts to avoid different data collection procedures between the two groups. The use of such analytics in future studies would allow for a more in-depth analysis of use and engagement with the education. In its current iteration, as an anonymous user, there was a high risk of data loss and errors. Future builds will require adjustments for the utility of tracking and data collection.

This study did not focus on usability and feasibility. The program was originally tested using a computer interface in the usability lab and then was made available for 200 patients to access in from home devices. The tablet interface in the inpatient setting was not previously tested. With the proliferation and widespread use of mobile devices in the community and the easy to use interface of tablet devices, this was not perceived as a barrier. However, the study did not collect any direct feedback or usability findings from patients enrolled in the study arm. The investigators did not want to detract patients from completing the study surveys that were required for the objectives of the study. Indirect feedback was collected from the RN staff and

patients who voluntarily provided feedback. Occasional technical challenges were reported from both patients and nurses but were attributed to user error or planned outages. No significant delays in care or education delivery were noted due to these gaps. Overall, patients and nurses responded positively to the digital program although some opportunities for enhancements and content development were noted. Adjustments will be made accordingly to enhance the utility of the web-based, digital education for patients and nurses.

Implications and Recommendations

Despite a lack of significant findings to demonstrate a benefit of digital education over paper and provider delivered education, this study provides evidence to indicate that patients would not be negatively impacted by the implementation of education delivered digitally by mobile platforms. Additionally, the ability to increase patient access to information and reduce the need for direct patient-provider interactions while maintaining effective, quality education makes digital education a superior option in terms of efficiency. In practice, digital delivery of educational content should be considered a complementary approach to conventional methods and used to augment the learning process. Digitally delivered education should not replace nurse-patient interactions and education but rather used as a supportive tool to enhance patient's learning.

Depending on an organization's technological capabilities, web-based education may not be attainable due to technical limitations and cost (Knowles et al, 2015). However, content management capabilities may out-weigh the upfront cost of program build and design (Cook et al., 2014; Suhling, Rademacherm, Zinowsky et al., 2014). Written education allows for mass distribution of educational content but is associated with printing expenses and low patient compliance (Knowles et al., 2015). Digital delivery offers greater manipulability of educational content. Adaptive digital platforms allow for easy and timely access to alter content to align with

practice and information changes. Once established in practice, these technologies can be adapted and used for other specialties and other aspects of patient education.

Conclusions

The use of digital education delivery and learning methodologies, such as the one studied here, are not inferior to conventional approaches to education. Dynamic digital programs for self-directed, modular education at the point-of-care are equally as effective as conventional education in maintaining high quality education to achieve knowledge acquisition and positive pain outcomes. Used synchronously or asynchronously as a complimentary tool for patient education, this method of delivery offers an innovative means of informing and engaging patients in their care.

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Appendix A

Table 1. Study Variables

Variable Type	Variable	Measurement Tool
Independent	Pain education delivery	n/a
Dependent	Patient reported pain outcomes	Revised APS patient Outcomes Questionnaire (APS-POQ-R) Chart Audits
	Pain Knowledge	Revised/adapted Patient Pain Questionnaire (PPQ)
	Patient reported participation in pain treatment plans	Revised APS patient Outcomes Questionnaire (APS-POQ-R)
	Total post-operative opioid consumption	Chart Audits
Extraneous	Characteristics of the population & past medical history	Demographic form Chart Audits
	Use of non-pharmacologic interventions	Revised APS patient Outcomes Questionnaire (APS-POQ-R)

Appendix B

Oral Consent Script

Protocol Title: The Impact of Mobile Education Delivery on Postoperative Pain Outcomes
IRB #: 17-004771
Principal Investigator: Amber Stitz

You are being asked to participate in a research study that will evaluate different ways of delivering pain management education and the effect that it has on pain outcomes such as pain scores, participation in treatment, and pain knowledge.

If you agree to participate you will be asked at the start of the study to fill out 2 questionnaire forms one will ask you some demographic and health status questions and the other will assess your knowledge of pain and treatment. These surveys will only take 5 minutes to complete. After surgery, in the hospital, you will receive pain education using either written pamphlets with verbal instruction or an interactive mobile program using an iPad. The type of education you receive will be determined by your location in the hospital after surgery. Before you leave the hospital, you will receive two questionnaires. One will ask you questions about your pain experience while in the hospital. The second survey will assess your knowledge of pain and treatment. This study will not change how your healthcare team will manage your pain after surgery. All study forms will have a unique identifying number so that your information will be kept confidential. Your name and any other identifying information will not be used in the research reports or any related publications. Only your immediate medical records related to this hospital stay and surgery will be accessed by the identified researchers.

If you decide to participate, you will need to read and sign the Authorization to Use and Disclose Protected Health Information (HIPAA) form and return it with the questionnaire. We are not allowed to use the answers without your signature on the HIPAA form. An extra copy is included for your records.

There is minimal risk to you by taking part in this research study. The potential for risk is that the way we deliver the education may not meet your needs. If this should happen we will change the education delivery to ensure that you receive all the information the way that best works for you. Additionally, you may feel uncomfortable talking about your pain or other topics included in this study. If you are uncomfortable at any time, you may choose to not answer specific questions or withdraw from study participation.

The benefits which may reasonably be expected to result from this research study are that your overall pain may be lower and you may increase your ability to make informed decisions about your health care and pain treatment options. Other benefits may include less time in the hospital, more satisfaction with your care, and increased self-esteem. However, you may not benefit from participating in this study.

Please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty. Specifically, your current or future medical care at the Mayo Clinic will not be jeopardized if you choose not to participate.

If you have any questions about this research study you can contact Amber Stitz at 507-266-3384. If you have any concerns, complaints, or general questions about research or your rights as a participant, please contact the Mayo Institutional Review Board (IRB) to speak to someone independent of the research team at 507-266-4000 or toll free at 866-273-4681.

Appendix C

HIPAA Authorization to Use and Disclose Protected Health Information

MAYO CLINIC

HIPAA Authorization to Use and Disclose Protected Health Information

Name and Clinic Number

Approval Date: **August 10, 2017**
Not to be used after: **August 9, 2018**

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

IRB#: 17-004771

Principal Investigator: Amber Stitz and Colleagues

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission. You will be given a copy of this form.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

This information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Your health information may be used or shared with:

- Mayo Clinic research staff involved in this study.
- George Washington University Faculty staff involved in this study

Your health information may also be shared with:

- The Mayo Clinic Institutional Review Board that oversees the research.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

Protection of your health information after it has been shared with others:
Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

MAYO CLINIC

HIPAA Authorization to Use and Disclose Protected Health Information

Name and Clinic Number

Approval Date: August 10, 2017
Not to be used after: August 9, 2018

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study. Your decision won't change the access to medical care or any other benefits you get at Mayo Clinic now or in the future.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

Your signature documents your permission to use your protected health information for this research.

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Appendix D

Figure 1. Screen Shot of Digital Pain Education Application

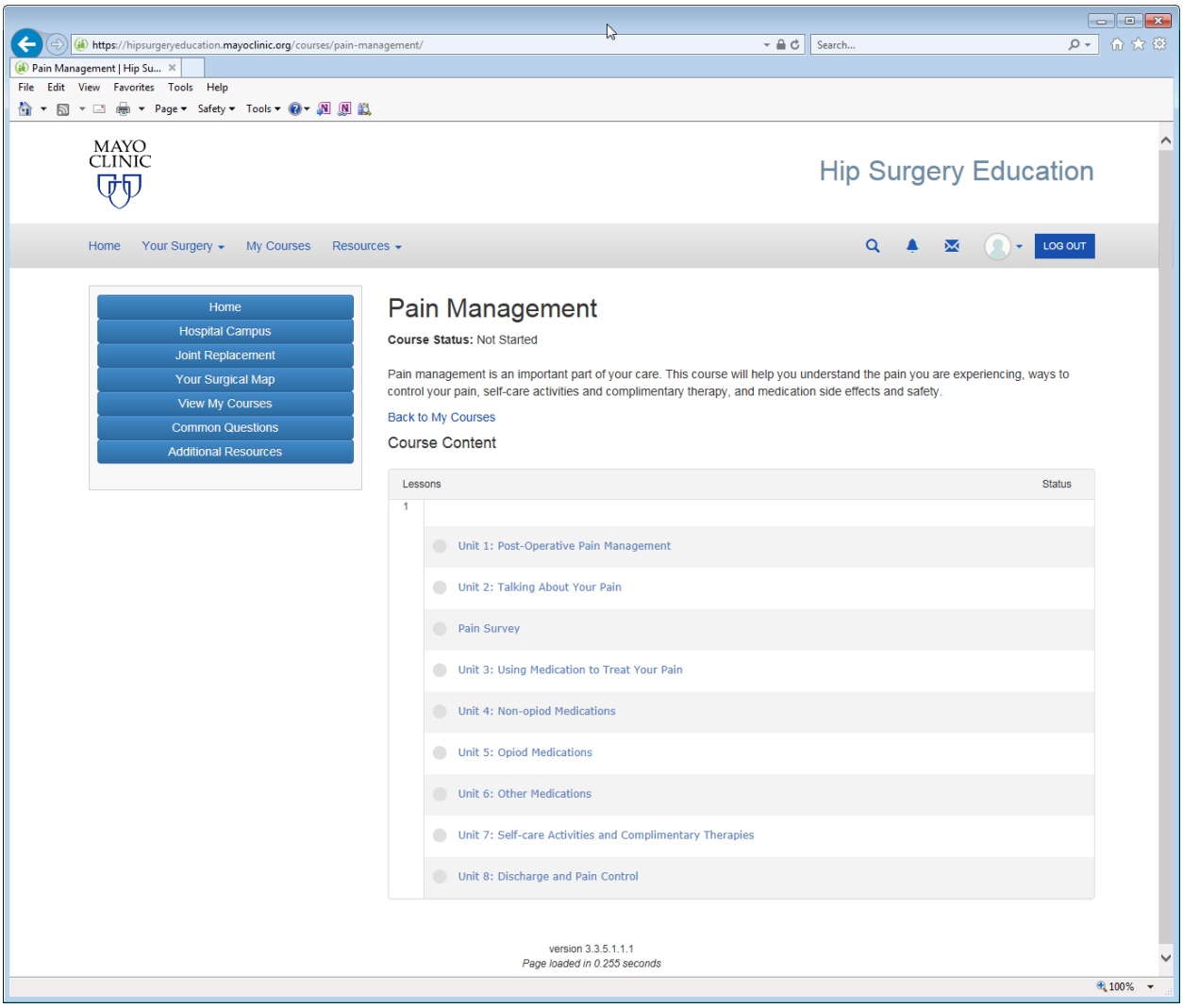


Figure 2. Screen Shot of Digital Pain Education Unit

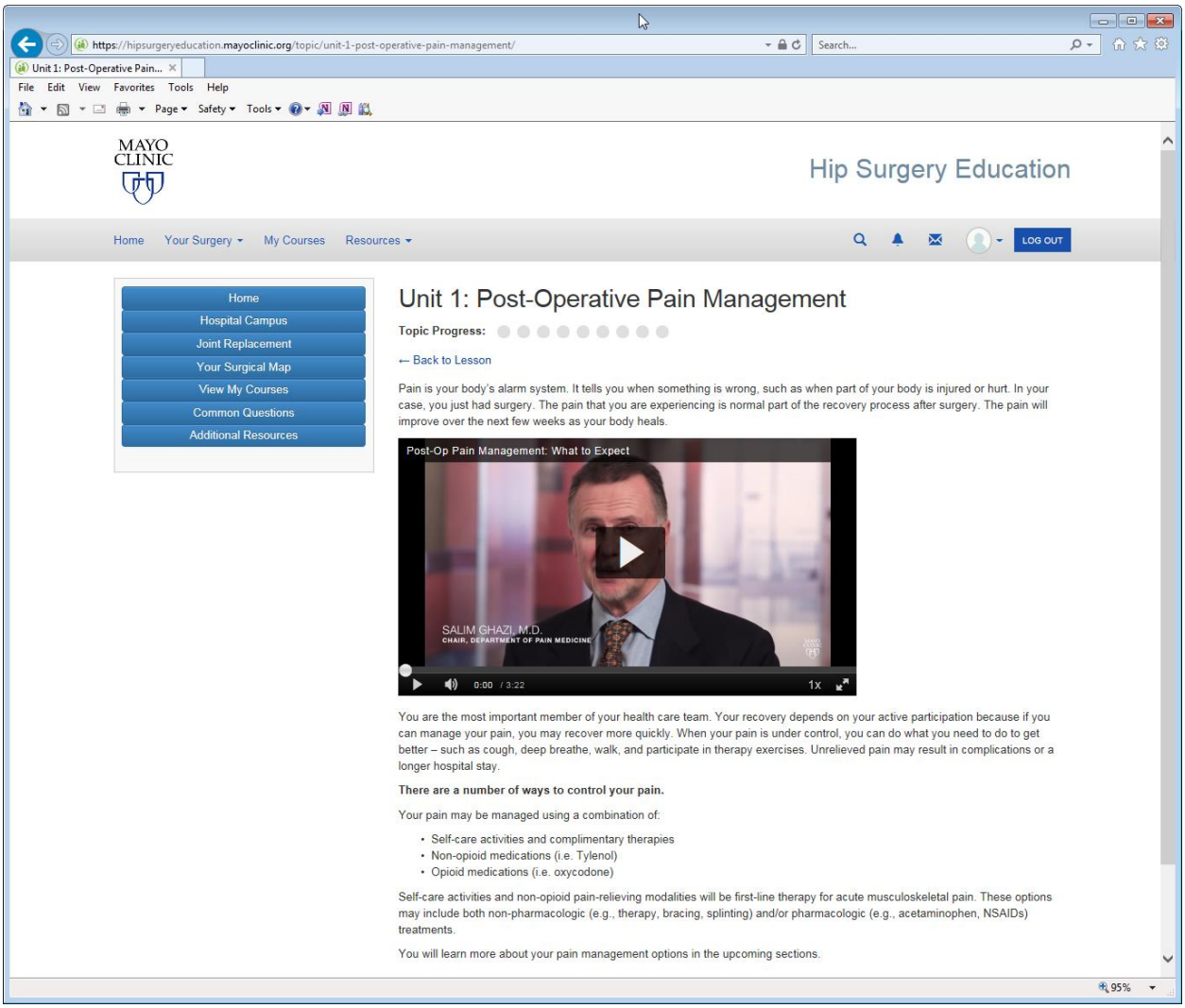


Figure 3. Screen Shot of Interactive Pain Assessment

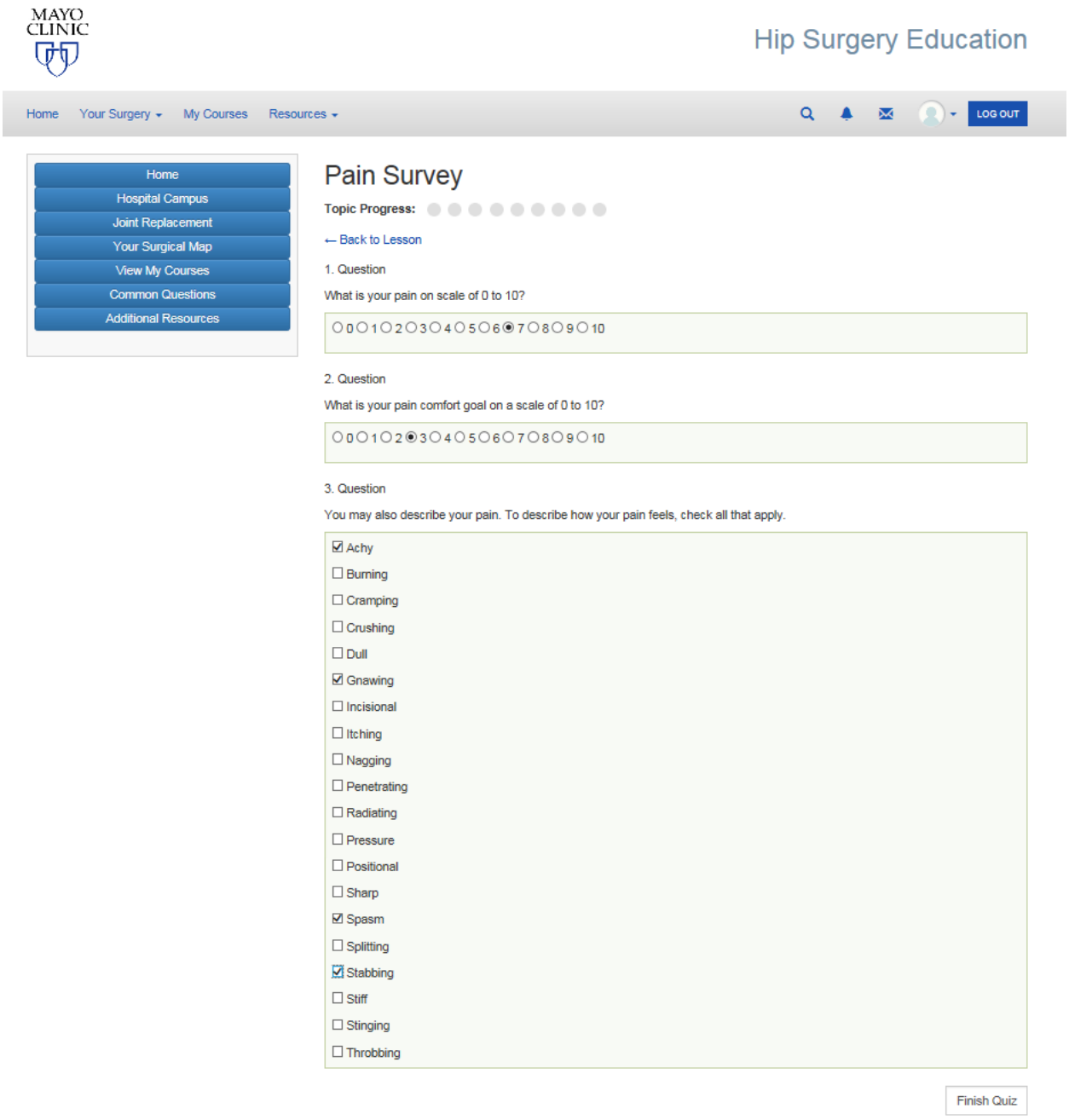
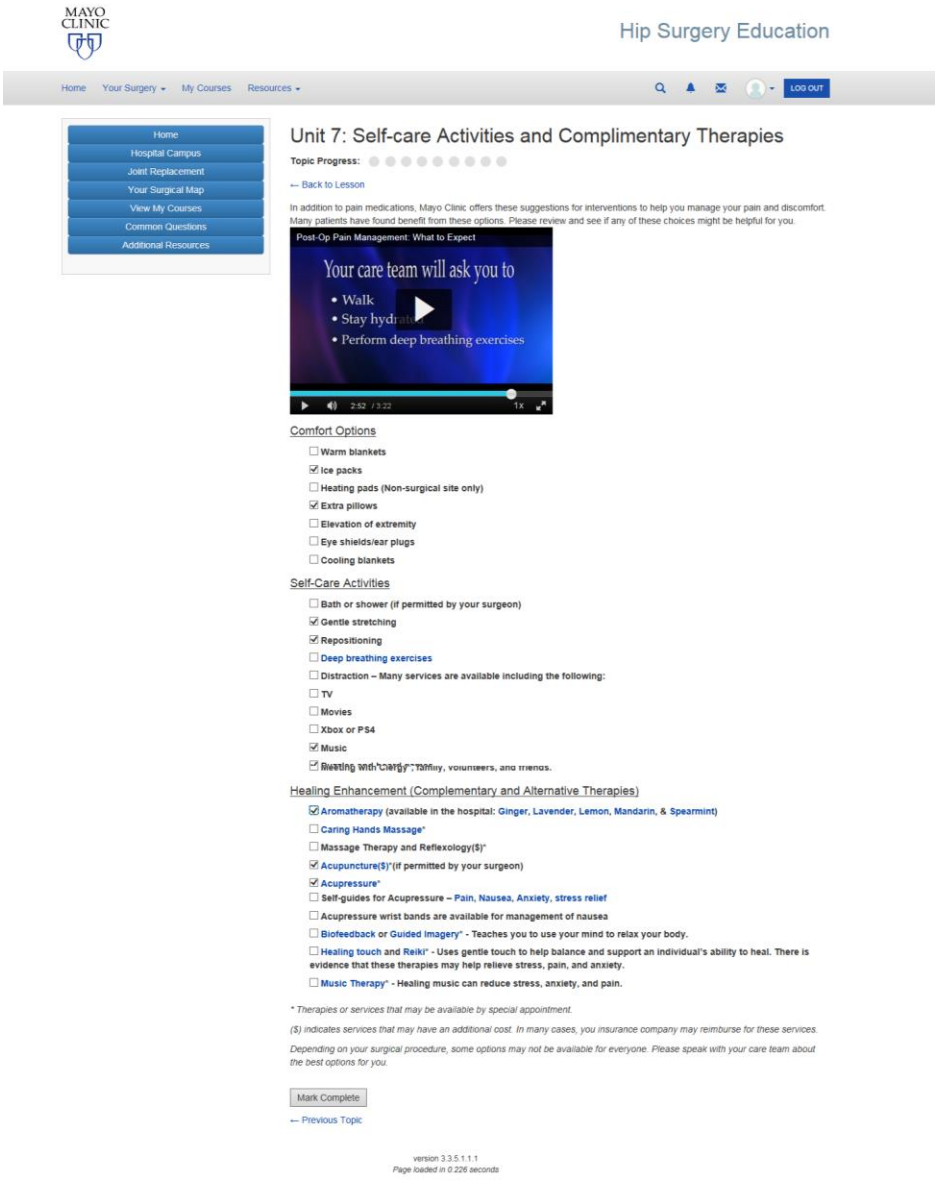
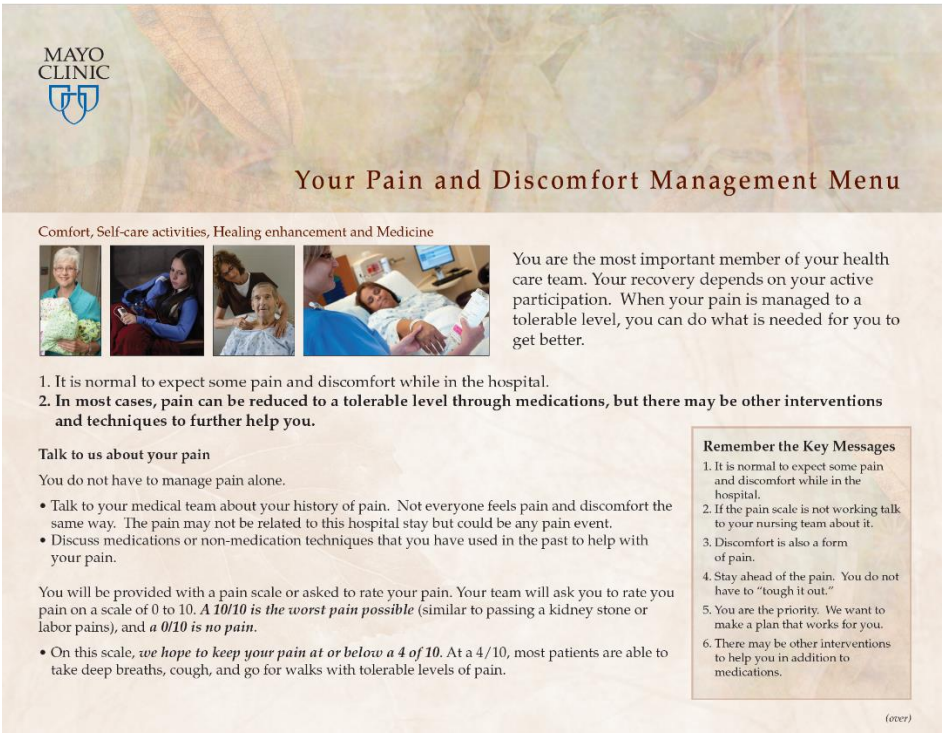


Figure 4. Screen Shot of Interactive Digital Pain Management Menu



Appendix E

Figure 5. Your Pain and Discomfort Management Menu



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Your Pain and Discomfort Management Menu

Comfort, Self-care activities, Healing enhancement and Medicine

You are the most important member of your health care team. Your recovery depends on your active participation. When your pain is managed to a tolerable level, you can do what is needed for you to get better.

1. It is normal to expect some pain and discomfort while in the hospital.
2. **In most cases, pain can be reduced to a tolerable level through medications, but there may be other interventions and techniques to further help you.**

Talk to us about your pain

You do not have to manage pain alone.

- Talk to your medical team about your history of pain. Not everyone feels pain and discomfort the same way. The pain may not be related to this hospital stay but could be any pain event.
- Discuss medications or non-medication techniques that you have used in the past to help with your pain.

You will be provided with a pain scale or asked to rate your pain. Your team will ask you to rate you pain on a scale of 0 to 10. ***A 10/10 is the worst pain possible*** (similar to passing a kidney stone or labor pains), and ***a 0/10 is no pain.***

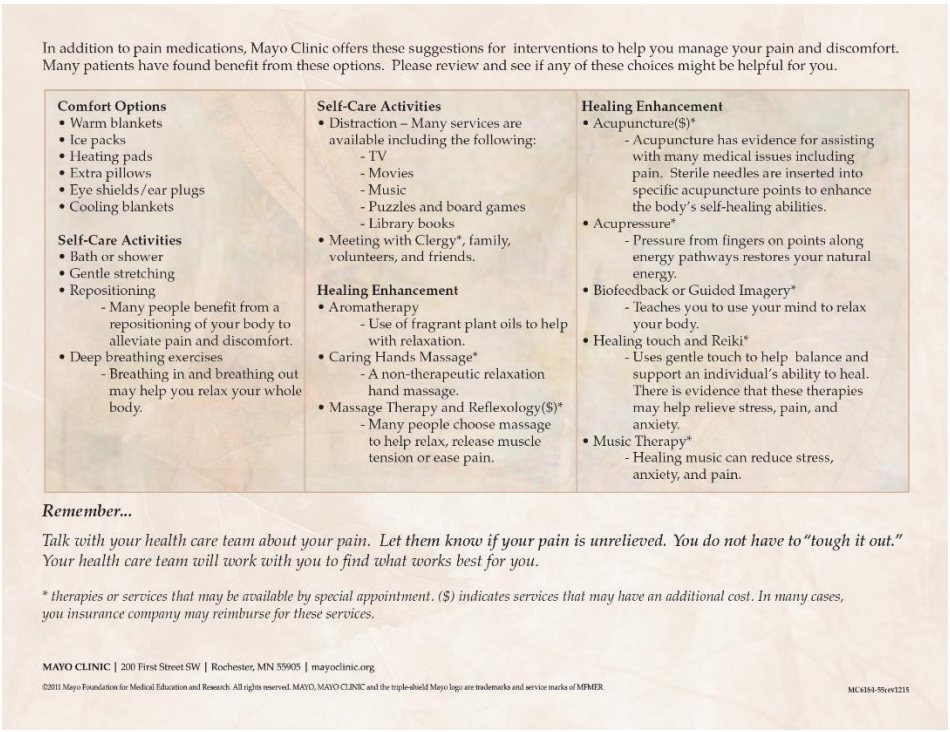
- On this scale, ***we hope to keep your pain at or below a 4 of 10.*** At a 4/10, most patients are able to take deep breaths, cough, and go for walks with tolerable levels of pain.

Remember the Key Messages

1. It is normal to expect some pain and discomfort while in the hospital.
2. If the pain scale is not working talk to your nursing team about it.
3. Discomfort is also a form of pain.
4. Stay ahead of the pain. You do not have to "tough it out."
5. You are the priority. We want to make a plan that works for you.
6. There may be other interventions to help you in addition to medications.

(over)

(Front)



In addition to pain medications, Mayo Clinic offers these suggestions for interventions to help you manage your pain and discomfort. Many patients have found benefit from these options. Please review and see if any of these choices might be helpful for you.

Comfort Options
- Warm blankets
- Ice packs
- Heating pads
- Extra pillows
- Eye shields/ear plugs
- Cooling blankets

Self-Care Activities
- Bath or shower
- Gentle stretching
- Repositioning
  - Many people benefit from a repositioning of your body to alleviate pain and discomfort.
- Deep breathing exercises
  - Breathing in and breathing out may help you relax your whole body.

Self-Care Activities
- Distraction – Many services are available including the following:
  - TV
  - Movies
  - Music
  - Puzzles and board games
  - Library books
- Meeting with Clergy*, family, volunteers, and friends.

Healing Enhancement
- Aromatherapy
  - Use of fragrant plant oils to help with relaxation.
- Caring Hands Massage*
  - A non-therapeutic relaxation hand massage.
- Massage Therapy and Reflexology($)*
  - Many people choose massage to help relax, release muscle tension or ease pain.

Healing Enhancement
- Acupuncture($)*
  - Acupuncture has evidence for assisting with many medical issues including pain. Sterile needles are inserted into specific acupuncture points to enhance the body's self-healing abilities.
- Acupressure*
  - Pressure from fingers on points along energy pathways restores your natural energy.
- Biofeedback or Guided Imagery*
  - Teaches you to use your mind to relax your body.
- Healing touch and Reiki*
  - Uses gentle touch to help balance and support an individual's ability to heal. There is evidence that these therapies may help relieve stress, pain, and anxiety.
- Music Therapy*
  - Healing music can reduce stress, anxiety, and pain.

Remember...

Talk with your health care team about your pain. Let them know if your pain is unrelieved. You do not have to "tough it out." Your health care team will work with you to find what works best for you.

** therapies or services that may be available by special appointment. ($) indicates services that may have an additional cost. In many cases, you insurance company may reimburse for these services.*

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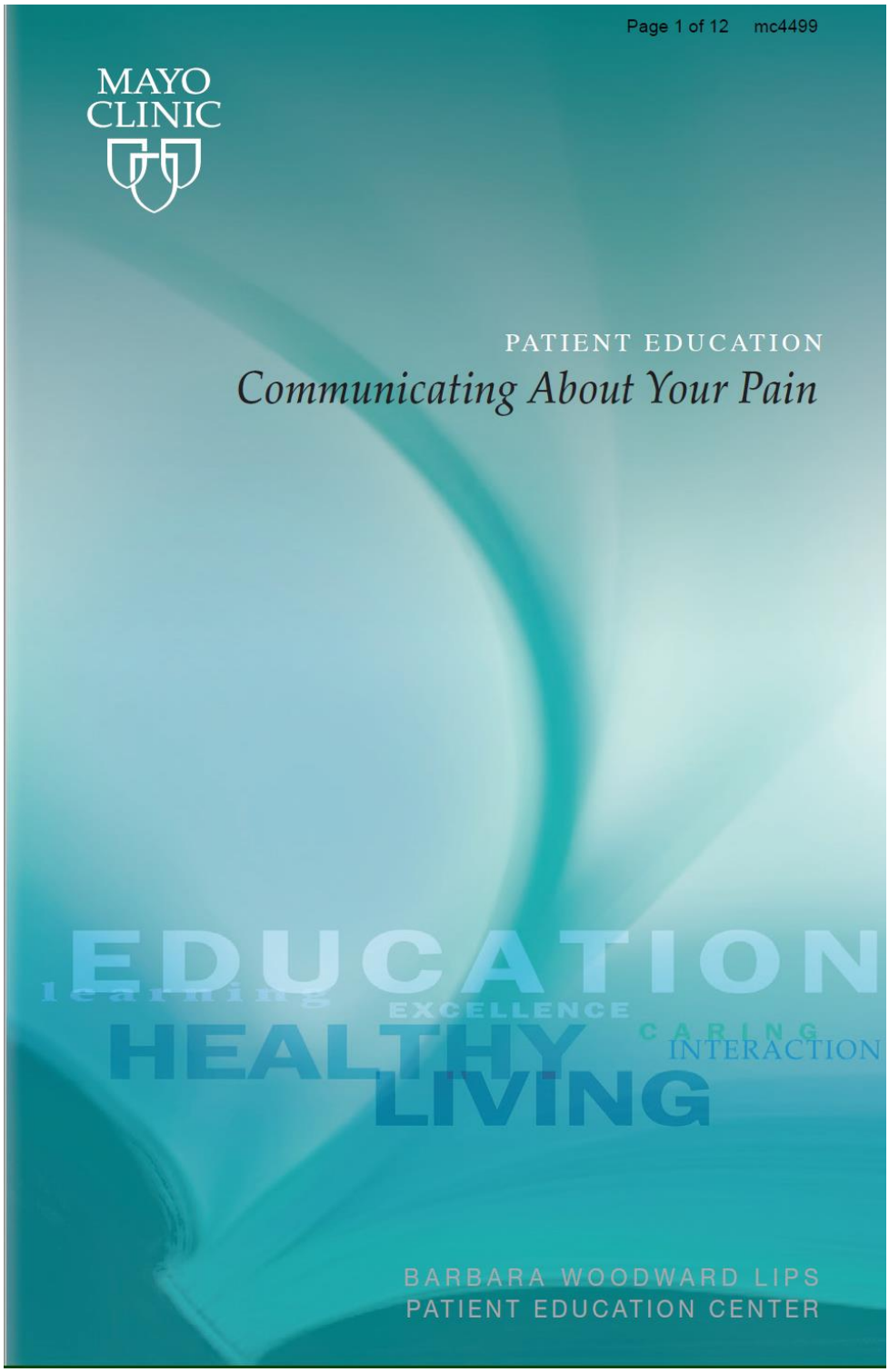
MC6184-55rev1215

(Back)

Appendix F

Figure 6. Communicating About Your Pain



Appendix G

Study (Fidelity) Checklist

Study Enrolment:

- ☐ Oral Consent Obtained
  Date: _____ Obtained by: _____
- ☐ HIPAA Signed and returned
  Date: _____

Pre-Intervention Paperwork:

- ☐ Patient Demographics and Past Medical History Form
- ☐ Revised Patient Pain Questionnaire (PPQ)

Intervention:

The PI or other study staff will notify nursing, HUCs, and bed control of patients' participation in the study and study arm enrolment.

- ☐ Study Arm: iPad given directly to patient or to assigned RN (nursing and/or study PI/staff)
  Assigned iPad number: _____
- ☐ Control Arm: Standard of Care, minimum education given to patient includes: Pain education pamphlets [*Your Pain and Discomfort Management Menu* and *Communicating About Your Pain*] (nursing)
- ☐ **Ongoing** for both study arms, complete the chart on the reverse side to indicate when and how the pain education and engagement were provided/done.

Post-Intervention Paperwork and Processes:

Direct care nursing staff to administer and collect the 2 surveys prior to patient discharge from the hospital. Place all completed surveys and forms in the individually marked folder and return both the packet and the iPad (study arm only) to the designated area.

- ☐ Revised Patient Pain Questionnaire (PPQ)
- ☐ Revised American Pain Society Patient Outcome Questionnaire (APS-POQ-R)
- ☐ Chart Audit complete (study PI/staff)
- ☐ Study Arm: iPad returned and checked into designated area or the study PI/staff
- ☐ Complete the quality improvement staff survey on the back of this form

	Day shift (0700-1530)					Evening shift (1500-2330)					Night Shift (2300-0730)				
Post-op day (POD)	**Did you…**			How many times did the patient actively engage with you & participate in pain treatment, education, w/ o w/o the use of materials? **	Estimate how much time was spent total for pain education ? (minutes)	**Did you…**			How many times did the patient actively engage with you & participate in pain treatment, education, w/ o w/o the use of materials? **	Estimate how much time was spent total for pain education ? (minutes)	**Did you…**			How many times did the patient actively engage with you & participate in pain treatment, education, w/ o w/o the use of materials? **	Estimate how much time was spent total for pain education ? (minutes)
	Treat the patient for pain? (Y/N)	Provide any education / instruction on pain or pain treatment ? (Y/N)	Directly provide pain education using the designated pain education inter-vention* (Y/N)			Treat the patient for pain? (Y/N)	Provide any education / instruction on pain or pain treatment ? (Y/N)	Directly provide pain education using the designated pain education inter-vention* (Y/N)			Treat the patient for pain? (Y/N)	Provide any education/ instruction on pain or pain treatment? (Y/N)	Directly provide pain education using the designated pain education inter-vention* (Y/N)		
POD 0 Day of Surgery															
POD 1															
POD 2															
POD 3															

* Use of the appropriate designated pain education intervention is based on the study arm that the patient is enrolled in (either use of the pamphlet education with verbal instruction or use of the mobile (iPad) application with verbal instruction)

** Engagement/participation can be defined as direct engagement with you as the RN or provider and/or independently using educational materials.

For nurses caring for the patients using the mobile iPad pain education program:

Did you like providing and offering education using the iPad? **Yes** **No** Comments:_____

On a scale of 0-5, how satisfied are you with the iPad device and pain education? Circle your answer on the scale below.

0 **1** **2** **3** **4** **5**

(Not satisfied at all) (Highly satisfied)

On a scale of 0-5, how easy (user-friendly) was it to use the iPad device and program? Circle your answer on the scale below.

0 **1** **2** **3** **4** **5**

(Not easy to use at all) (Very easy to use)

Comments:_____

Do you feel that the use of the device and/or the content helped you to better engage your patients in pain management? **Yes** **No**

Comments:_____

Would daily bedside mobile education fit into your patient care routine? **Yes** **No**

Outside of the pain education, what other benefits and/or uses do you see if made available in your practice area? _____

_____

How could it be in improved? _____

Appendix H

Patient Demographics and Past Medical History Form

1. Age: _____

2. Sex: (circle one) Male (1) Female (2)

3. Which of the following best describes your educational background? (circle one)
   1=8th Grade or Less
   2=Some High School
   3=High School Graduate or GED
   4=Some College
   5=College Graduate, AA degree
   6=College Graduate, BA degree
   7=Any Post Graduate Work

4. Which of the following best describes your racial background? (circle one)
   1=White/Caucasian
   2=Black/African-American
   3=Spanish or Hispanic/Latino
   4=Asian or Pacific Islander
   5=American Indian or Alaskan Native
   6=Other

5. Which of the following best describes your marital status? (circle one)
   1=Married
   2=Widowed
   3=Separated
   4=Divorced
   5= Never Married/single

6. Which of the following best describes current employment status? (circle one)
   1=Employed
   2=Unemployed
   3=Disabled
   4=Retired

7. When being given new information, how do you best learn? (circle one)
   1=Seeing
   2=Doing
   3=Listening
   4= Seeing, doing, and listening

8. On a scale of 0 to 5, how comfortable are you using technology such as the internet, computers, or tablet devices?

0	1	2	3	4	5
Not comfortable at all					Very comfortable

9. How anxious are you about pain after surgery?

0	1	2	3	4	5	6	7	8	9	10
Not anxious at all										Extremely anxious

10. Have you ever had any major orthopedic surgery in the past? (circle one)
    Yes (1) No (0)

11. Do you have a history of or have you ever been diagnosed with chronic pain or a chronic pain syndrome? (circle one)
    Yes (1) No (0)

12. Prior to coming into for this surgical procedure were you taking any opioids (narcotics) to control your pain? (circle one)
    Yes (1) No (0)

    If so, what medications?_____
    how much?_____

13. Do you have a history of or ever been diagnosed with any mental health conditions (examples may include: depression, anxiety, autism, mood disorders, Schizophrenia, Substance abuse)? (circle one)
    Yes (1) No (0)

    If so, what condition(s)?_____

Appendix I

Revised American Pain Society Patient Outcome Questionnaire (APS-POQ-R)

The following questions are about pain you experienced after your joint replacement surgery.

P1. On this scale, please indicate the **least** pain you had in the first 24 hours:

0 1 2 3 4 5 6 7 8 9 10
No pain — Worst pain possible

P2. On this scale, please indicate the **worst** pain you had in the first 24 hours:

0 1 2 3 4 5 6 7 8 9 10
No pain — Worst pain possible

P3. How often were you in **severe** pain in the first 24 hours?

Please circle your best estimate of the percentage of time you experienced severe pain:

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
Never in severe pain — Always in .

P4. Circle the one number below that best describes how much pain **interfered or prevented you from**

a. Doing **activities in bed** such as turning, sitting up, repositioning**:**

0 1 2 3 4 5 6 7 8 9 10
Does not interfere — Completely interferes

b. Doing **activities out of bed** such as walking, sitting in a chair, standing at the sink:

0 1 2 3 4 5 6 7 8 9 10
Does not interfere — Completely interferes

c. **Falling asleep**

0 1 2 3 4 5 6 7 8 9 10
Does not interfere — Completely interferes

d. **Staying asleep**

0 1 2 3 4 5 6 7 8 9 10
Does not interfere — Completely interferes

P5. Pain can affect our mood and emotions.

On this scale, please circle the **one** number that best shows how much the pain caused you to feel:

a. **Anxious** 0 1 2 3 4 5 6 7 8 9 10 (Not at all — Extremely)

b. **Depressed** 0 1 2 3 4 5 6 7 8 9 10 (Not at all — Extremely)

c. **Frightened** 0 1 2 3 4 5 6 7 8 9 10 (Not at all — Extremely)

d. **Helpless** 0 1 2 3 4 5 6 7 8 9 10 (Not at all — Extremely)

P6. Have you had any of the following side effects?

Please circle **"0" if no**; if yes, circle the **one** number that best shows the severity of each

a. **Nausea/ Vomiting**	0 None	1	2	3	4	5	6	7	8	9	10 Severe
b. **Drowsiness**	0 None	1	2	3	4	5	6	7	8	9	10 Severe
c. **Itching**	0 None	1	2	3	4	5	6	7	8	9	10 Severe
d. **Dizziness**	0 None	1	2	3	4	5	6	7	8	9	10 Severe

P7. Since Surgery, how much pain **relief** have you received?
Please circle the one percentage that best shows how much relief you have received from all of your pain treatments combined (medicine and non-medicine treatments):

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
No relief Complete relief

P8. Were you **allowed to participate in decisions** about your pain treatment as much as you wanted to?

0 1 2 3 4 5 6 7 8 9 10
Not at all Very much so

P9. Circle the one number that best shows how **satisfied** you are with the results of your pain treatment while in the hospital:

0 1 2 3 4 5 6 7 8 9 10
Extremely **dissatisfied** Extremely **satisfied**

P10. Did you receive any **information** about your pain treatment options? ___ No, ___ Yes.
a. If yes, please circle the number that best shows **how helpful** the information was:

0 1 2 3 4 5 6 7 8 9 10
Not at all helpful Extremely helpful

P11. Did you use any **non-medicine methods** to relieve your pain? _____ No _____ Yes.
If yes, **check all** that apply:

_____cold pack	_____massage therapy	_____meditation
_____deep breathing	_____caring hands massage*	_____prayer
_____distraction (such as watching TV, reading)	_____reflexology*	_____aromatherapy*
	_____listen to music	_____acupuncture*
_____heat	_____relaxation	_____acupressure*
_____guided imagery or visualization	_____walking	_____healing touch or reiki*

P12. How often did a nurse or doctor **encourage you to use** non-medicine methods?
_____ never _____ sometimes _____ often

Thank you for your time and feedback

P13 ☐Tick here if the patient received help in filling-in the questionnaire

Appendix J

Revised Patient Pain Questionnaire (PPQ)

1. Pain can be effectively relieved

0 1 2 3 4 5 6 7 8 9 10
Agree Disagree

2. Pain medicines should be given only when pain is severe

0 1 2 3 4 5 6 7 8 9 10
Disagree Agree

3. Most patients on pain medicines will become addicted to the medicines over time

0 1 2 3 4 5 6 7 8 9 10
Disagree Agree

4. It is important to give the lowest amount of medicine possible to save larger doses for later when the pain is worse

0 1 2 3 4 5 6 7 8 9 10
Disagree Agree

5. It is better to give pain medications around the clock (on a schedule) rather than only when needed

0 1 2 3 4 5 6 7 8 9 10
Agree Disagree

6. Treatments other than medications (such as massage, heat, relaxation) can be effective for relieving pain

0 1 2 3 4 5 6 7 8 9 10
Agree Disagree

7. Pain medicines can be dangerous and can often interfere with breathing

0 1 2 3 4 5 6 7 8 9 10
Disagree Agree

8. Patients are often given too much pain medicine

0 1 2 3 4 5 6 7 8 9 10
Disagree Agree

9. If pain is worse, I must be getting worse

0 1 2 3 4 5 6 7 8 9 10
Disagree Agree

Appendix K

Chart Audit Form

Primary surgical procedure:

- ☐ 1=Primary THA
- ☐ 2=Bilateral THA
- ☐ 3=Revision THA
- ☐ 4=Primary TKA
- ☐ 5=Unicompartmental TKA
- ☐ 6=Bilateral TKA
- ☐ 7=Revision TKA

Regional Anesthesia:

- ☐ 1=Continuous infusion nerve block
- ☐ 2=Single injection nerve block
- ☐ 3=Epidural

Length of stay: _____

Preoperative Education Class:

- ☐ 0=NO
- ☐ 1=Yes

EMR Pain Education Documentation

- ☐ 0 = No
- ☐ 1= Yes

Patient Engagement Time:_____

- ☐ 0 = ≤ 5 times
- ☐ 1 = 6 – 11 times
- ☐ 2 = 12 – 17 times
- ☐ 3 = 18 – 23 times
- ☐ 4 = 24 – 29 times
- ☐ 5 = ≥ 30 times

Discharge disposition:

- ☐ 1=Home self-care
- ☐ 2=Home with homecare
- ☐ 3=Skilled nursing facility
- ☐ 4=Swing bed

Opioid Administration:

POD 0: Calculated morphine equivalency (mg)

Total Oxycodone (mg): _____ = _____
Total Tramadol (mg): _____ = _____
Total Morphine (mg): Oral_____ = _____
IV_____=_____
Total Hydromorphone (mg): Oral_____=_____
IV_____=_____
Total morphine equivalency = _____

POD 1: Calculated morphine equivalency (mg)

Total Oxycodone (mg): _____ = _____
Total Tramadol (mg): _____ = _____
Total Morphine (mg): Oral_____ = _____
IV_____=_____
Total Hydromorphone (mg): Oral_____=_____
IV_____=_____
Total morphine equivalency = _____

POD 2: Calculated morphine equivalency (mg)

Total Oxycodone (mg): _____ = _____
Total Tramadol (mg): _____ = _____
Total Morphine (mg): Oral_____ = _____
IV_____=_____
Total Hydromorphone (mg): Oral_____=_____
IV_____=_____
Total morphine equivalency = _____

POD 3: Calculated morphine equivalency (mg)

Total Oxycodone (mg): _____ = _____
Total Tramadol (mg): _____ = _____
Total Morphine (mg): Oral_____ = _____
IV_____=_____
Total Hydromorphone (mg): Oral_____=_____
IV_____=_____
Total morphine equivalency = _____

Total morphine equivalency (mg) for hospital stay = _____

Appendix L

Data Collection - Study Protocol

Study Aims

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. 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. The aims are as follows:

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

Study Population/Sample

This study will include adult patients over the age of 18 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) The patient must be able to read and speak English.

Study Interventions

- Study arm: mobile education delivery using iPads at the point of care.
- Control arm: standard written and verbal education.

Instruments

Study participants will be enrolled into one of two study arms, intervention or control based on random assignment to one of two patient care units. All data collection instruments are labeled with the corresponding identification number and the date.

The following data collection instruments will be used:

- HIPAA Authorization to Use and Disclose Protected Health Information: This form is for internal use only, and will not be submitted to the aggregate data pool. This form will be kept in a separate locked file cabinet. A copy will also be provided to the patient.
- Patient Demographics and Past Medical History Form: The demographic and clinical data on this form must be collected for descriptive data analysis. This form also includes

preferred learning style, comfort with technology, and anxiety. This form will be completed by the patient at the perioperative visit.

- Revised American Pain Society Patient Outcome Questionnaire (APS-POQ-R): This form assesses the patients' perception of their overall satisfaction and pain experience, care, and treatment while hospitalized. This form will be completed by the patient at the time of discharge from the hospital, post education delivery for both study arms.
- Revised Patient Pain Questionnaire (PPQ): This form uses nine knowledge based questions 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. This form will be completed by the patient at the time of discharge from the hospital, post education delivery for both study arms.
- Pain Outcome Questionnaire (POQ): This form documents the patient's overall satisfaction and pain experience while hospitalized, and will be documented on the day of discharge.
- Chart Audit Form: This form documents pain assessment and interventions from the medical record, as well as surgical information. This form will be filled out by the investigator.

Data Collection Procedures

The time frames for data collection will be as follows:

1. Perioperative surgical visit in the ambulatory setting, typically occurs 1-5 days before scheduled surgical procedure.
2. Day of Discharge
3. Post-discharge chart audit

Forms to be completed at each collection point:

1. Perioperative surgical visit
   - Patient: HIPAA Authorization
   - Patient: Personal Characteristics Form
   - Patient: Pain Outcome Questionnaire (POQ)
2. Day of Discharge
   - Patient: Revised American Pain Society Patient Outcome Questionnaire (APS-POQ-R)
   - Patient: Pain Outcome Questionnaire (POQ)
3. Post Discharge

- Researcher: Chart Audit Form

Important Note:

A cover letter will be included as part of each patient packet that provides the descriptions and purpose of the study and provides instructions to the patient for correctly and accurately completing the patient questionnaire. If the patient requires assistance, the questions should be

read rather than interpreted. If the patient refuses to complete the questionnaires, record the reason on the form. Refusals should be recorded as follows:

- Time: Patient does not have time
- Read: Patient could not read the form
- Conf: Patient perceived violation of confidentiality
- Unab: Patient unable to complete
- Other: Any other stated reason (e.g. altered mental status)

Appendix M

IRB Approval Letter

MAYO CLINIC

Principal Investigator Notification:

From: Mayo Clinic IRB
To: Amber Stitz
CC: Amber Stitz
Re: IRB Application # 17-004771

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

Please note that all correspondence (modifications, continuing reviews, reportable events) related to this application must be submitted electronically in the IRBe system.

The following is an excerpt from the minutes of the Mayo Clinic Institutional Review Boards (IRB Thursday) meeting dated 8/10/2017 :

DECISION: The Committee reviewed and approved the above referenced application and noted that all requirements for approval of research (45CFR46.111) were met. This approval is valid for one year unless during that time the IRB determines that it is appropriate to halt or suspend the study earlier. IRB approval will expire on August 9, 2018. The Committee approved the accrual of 128 male and female adult subjects from a screening population of 150. The Committee approved the following site to conduct this study: Mayo Clinic in Rochester, Minnesota.

REVIEW: The Committee noted receipt of the protocol, Version 1 dated May 2, 2017. The Committee noted the letters of support dated June 6, 2017 and April 25, 2017.

CONTACT MATERIALS: The Committee approved the contact letter, questionnaires, and education materials as submitted.

CONSENT: The Committee noted that oral consent with HIPAA authorization is appropriate for this study. The oral consent script was reviewed and approved with minor edits. The written HIPAA form was reviewed and approved as written. The Committee approved waiver of the requirement for the Investigator to obtain a signed consent form in accordance with 45 CFR 46.117 as justified by the Investigator.

REMINDERS: The Committee:

- Reminds the investigator to submit a continuing review report prior to the expiration date (reminder will be sent prior to expiration).
- Refers this study to the expedited review procedures for continuing review, in accordance with 45CFR46.110, items 5 and 7.

Attachments (if applicable):
name

Schwartz, Gary L. M.D., Chair
Heidi Hanf , Correspondent
Mayo Clinic Institutional Review Boards

IRB Closure Letter

MAYO CLINIC

Principal Investigator Notification:

From: Mayo Clinic IRB
To: Amber Stitz
CC: Amber Stitz
Re: **Continuing Review #:** PR17-004771-02
Title: The Impact of Mobile Education Delivery on Postoperative Pain Outcomes

IRBe Protocol Version: 0.04
IRBe Version Date: 4/9/2018 9:01 AM

IRB Approval Date: 4/9/2018
IRB Expiration Date: 8/9/2018

The Investigator's final report and request for closure of the above referenced application has been processed and the application status changed to "Completed".

Mayo Clinic Institutional Reviewer

Appendix N

Results

Table 2. Demographic Variables (Mean)

Demographic Variable

	Mean			*p Value*
	Total (n=133)	Conventional Education (n=68)	Digital Education (n=65)	
Age	63.7 (133)	64.34 (68)	62.97 (65)	.477
Perioperative Anxiety	4.7(128)	4.29 (67)	5.13 (61)	.066
Computer Literacy	3.7 (132)	3.64 (67)	3.97 (65)	.569
Length of Stay (LOS)	2.0 (133)	1.9(68)	2.0 (65)	.623

Table 3. Demographic Variables (Frequency)

Demographic Variables

	% (Frequency)			*p Value*
	Total	Conventional Education	Digital Education	
Gender	(n=133)	(n=68)	(n=65)	.322
Male	44.4% (59)	24.8% (33)	26.3% (26)	
Female	55.6% (74)	19.5% (35)	29.3% (39)	
Racial/Ethnic group				.177
Caucasian/White	96.2% (128)	48.1% (64)	48.1% (64)	
Black/African American	2.3% (3)	2.3% (3)	0.0% (0)	
Hispanic	0.8% (1)	0.8% (1)	0.0% (0)	
Other	0.8% (1)	0.0% (0)	0.8% (1)	
Education level				.112
Some High School	0.8% (1)	0.0% (0)	0.8% (1)	
High school Graduate	13.5% (18)	3.8% (5)	9.8% (13)	
Some College	24.1% (32)	13.5% (18)	10.5% (14)	
College Graduate- AA Degree	12.0% (16)	6.0% (8)	6.0% (8)	
College Graduate - BA Degree	19.5% (26)	13.5% (18)	6.0% (8)	
Any Post-Graduate Work	30.1% (40)	14.3% (19)	15.8% (21)	
Employment Status				.797
Employed	44.4% (59)	21.1% (28)	23.3% (31)	
Unemployed	1.5% (2)	0.8% (1)	0.8% (1)	
Disabled	3.8% (5)	1.5% (2)	2.3% (3)	
Retired	50.4% (67)	27.8% (37)	22.6% (30)	
Marital status				.336
Married	73.7% (98)	39.1% (52)	34.6% (46)	
Widowed	9.0% (12)	3.8% (5)	5.3% (7)	
Separated	0.8% (1)	0.8% (1)	0.0% (0)	
Divorced	9.8% (13)	3.0% (4)	6.8% (9)	
Never Married/Single	6.8% (9)	4.5% (6)	2.3% (3)	

Demographic Variables

	% (Frequency)			*p Value*
	Total	Conventional Education	Digital Education	
Preferred Learning Style				.644
Reading/Seeing	11.3% (15)	4.5% (6)	6.8% (9)	
Doing	10.5% (14)	5.3% (7)	5.3% (7)	
Listening	0.0% (0)	0.0% (0)	0.0% (0)	
Reading, Doing, Listening	78.2% (103)	41.4% (54)	36.8%(49)	
History of Major Orthopedic Surgery	(n=127)	(n=66)	(n=61)	.907
Yes	67.7% (86)	35.4% (45)	32.3% (41)	
No	32.3% (41)	16.5% (21)	15.7% (20)	
History of Chronic Pain	(n=128)	(n=67)	(n=61)	.385
Yes	12.5% (16)	7.8% (10)	4.7% (6)	
No	87.5% (112)	44.5% (57)	43.0% (55)	
Pre-operative Opioid Use	(n=127)	(n=67)	(n=60)	.325
Yes	15.0% (19)	9.4% (12)	5.5% (7)	
No	85.0% (108)	43.3% (55)	41.7% (53)	
History of Mental Health Condition	(n=126)	(n=67)	(n=59)	.659
Yes	16.5% (21)	9.4% (12)	7.1% (9)	
Depression	9.5% (12)	7.1% (9)	2.4% (3)	
Anxiety	2.4% (3)	0.0% (0)	2.4% (3)	
Depression/Anxiety	4.0% (5)	2.4% (3)	1.6% (2)	
No	83.5% (106)	43.3% (55)	40.2% (51)	

Table 4. Hospital Admission and Discharge Variables

Hospital Admission and Discharge Variables

	% (Frequency)			*p Value*
	Total (n=133)	Conventional Education (n=68)	Digital Education (n=65)	
Surgical Procedure				.101
Primary THA	53.4% (71)	3.0% (4)	28.6% (38)	
Bilateral THA	1.5% (2)	0.8% (1)	0.8% (1)	
Primary TKA	41.4% (55)	22.6% (30)	18.8% (25)	
Unicompartmental TKA	1.5% (2)	1.5% (2)	0.0% (0)	
Bilateral TKA	2.3% (3)	2.3% (3)	0.0% (0)	
Regional Anesthesia				.416
Continuous Infusion Nerve Block	8.3% (11)	3.0% (4)	5.3% (7)	
Single Injection Nerve Block	1.5% (2)	0.8% (1)	0.8% (1)	
Arthroplasty Block	18.0% (24)	11.3% (15)	6.8% (9)	
Spinal	1.5% (2)	0.8% (1)	0.8% (1)	
Spinal with Arthroplasty Block	36.1% (48)	18.0% (24)	18.0% (24)	
Spinal with Continuous Infusion Nerve Block	17.3% (23)	6.0% (8)	11.3% (15)	
Spinal with Single Injection Nerve Block	2.3% (3)	0.8% (1)	1.5% (2)	
Spinal with Arthroplasty and Continuous Infusion Blocks	11.3% (15)	8.3% (11)	3.0% (4)	
Continuous with Arthroplasty Block	3.8% (5)	2.3% (3)	1.5% (2)	
Preoperative Education Attendance				.358
Yes	65.4% (87)	35.3% (47)	30.1% (40)	
No	34.6% (46)	15.8% (21)	18.8% (25)	
Discharge Disposition				.688
Home Self Care	84.2 (112)	44.4% (59)	39.8% (53)	
Home with Home Care	0.0% (0)	0.8% (1)	0.8% (1)	
Skilled Nursing Facility	13.5% (18)	6.0% (8)	7.5% (1)	
Swing Bed	1.5% (2)	0.8% (1)	0.8% (1)	

Table 5. Education Outcomes

Education Outcomes

	Conventional Education (n=68)		Digital Education (n=65)		
	M	SD	M	SD	***p* Value**
Time spent reviewing/completing pain education	31.1	16.5	40.1	22.4	.009
Use (reported in number)	8.3	5.1	6.1	3.1	.003
Helpfulness of Pain Information (education)	8.1	2.1	8.7	1.6	.095
Participation in pain treatment decisions	8.9	2.1	9.0	1.8	.806

Figure 7. Time Engaged to Provider-Patient Interactions

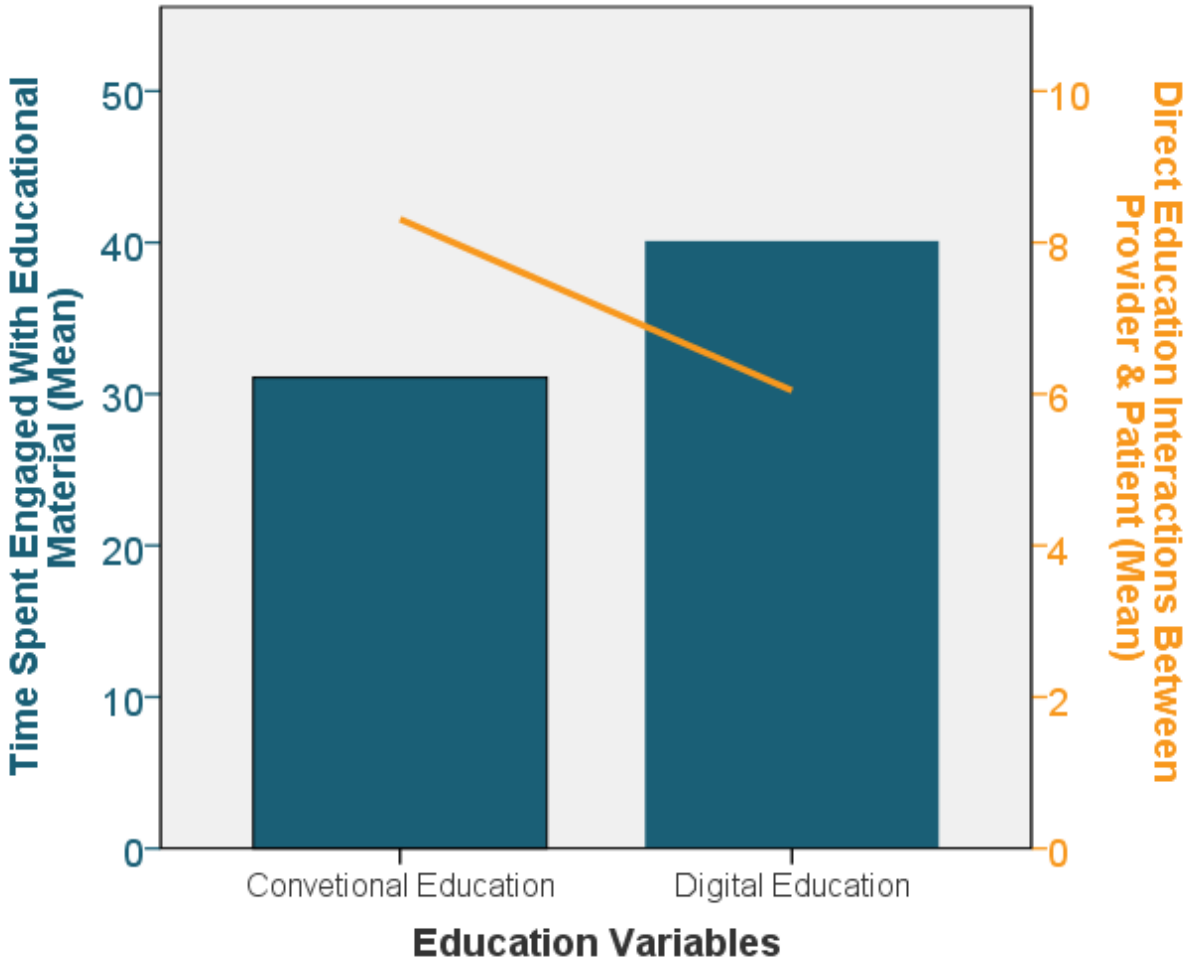


Table 6. Post-Test Pain Knowledge Comparison By Intervention

Post-Test Pain Knowledge Comparison By Intervention

	Conventional Education (n=67)		Digital Education (n=64)		
Knowledge Question	M	SD	M	SD	***p* Value**
Pain can be effectively relieved	2.25	3.0	1.80	2.2	.321
Pain medicines should be given only when pain is severe	2.4	2.9	2.72	2.6	.509
Most patients on pain medicines will become addicted to the medicines over time	3.1	3.5	3.6	3.5	.456
It is important to give the lowest amount of medicine possible to save larger doses for later when the pain is worse	4.1	3.8	5.1	3.5	.118
It is better to give pain medications around the clock (on a schedule) rather than only when needed	2.8	3.2	2.5	3.1	.598
Treatments other than medications (such as massage, heat, relaxation) can be effective for relieving pain	1.9	2.3	1.9	2.2	.977
Pain medicines can be dangerous and can often interfere with breathing	5.8	3.2	6.7	3.3	.136
Patients are often given too much pain medicine	3.9	3.3	4.1	3.2	.688
If pain is worse, I must be getting worse	1.7	2.3	2.1	2.2	.258

Table 7. Pain Knowledge Comparison Scores for All Study Participants

Pre- and Post- Pain Knowledge Comparison Scores for All Study Participants

	Pre-test (n= 131)		Post-test n= 131		
Knowledge Question	M	SD	M	SD	***p* Value**
Pain can be effectively relieved	2.9	2.7	2.0	2.6	.004
Pain medicines should be given only when pain is severe	4.9	3.3	2.6	2.7	<.001
Most patients on pain medicines will become addicted to the medicines over time	4.3	3.4	3.3	3.5	.001
It is important to give the lowest amount of medicine possible to save larger doses for later when the pain is worse	5.9	3.4	4.6	3.7	<.001
It is better to give pain medications around the clock (on a schedule) rather than only when needed	4.5	3.3	2.7	3.1	<.001
Treatments other than medications (such as massage, heat, relaxation) can be effective for relieving pain	2.7	2.8	1.9	2.2	.007
Pain medicines can be dangerous and can often interfere with breathing	6.2	2.9	6.3	3.2	.937
Patients are often given too much pain medicine	5.5	2.9	4.0	3.2	<.001
If pain is worse, I must be getting worse	3.0	2.6	1.9	2.2	<.001

Table 8. Pain Management Outcomes

Pain Management Outcomes

	Conventional Education (n= 68)		Digital Education (n= 65)		
	M	SD	M	SD	***p* Value**
Lowest pain experience	2.3	2.0	2.3	2.0	.928
Worst pain experience	6.3	2.5	6.6	2.1	.501
Percent of time severe pain was experienced	23.0	23.8	26.4	24.1	.417
Percent of pain relief experienced since surgery	73.6	20.9	75.2	16.1	.646
Overall satisfaction with pain treatment and results	8.8	2.0	9.1	1.3	.280
48-hour Oral Morphine Requirements	82.3	72.0	71.3	67.2	.366
Length of stay (LOS)	1.9	.86	2.0	.88	.623