Regional Health Command-Central (RHC-C)
Institutional Review Board

HUMAN SUBJECTS RESEARCH
PROTOCOL APPLICATION – Part B

CLINICAL TRIALS: NCT02674711
4 May 2018

1. PROTOCOL TITLE: The Effect of a Pain Medication Educational Approach before Spinal Surgery on 6-month Post-Operative Use of Opioid Medication: A Randomized Clinical Trial

2. ABSTRACT

Background: Opioid-based pain medication use and prescription has increased dramatically in the last two decades, leading to high rates of overdose and utilization for patients with chronic non-cancer pain, despite lack of evidence to support its use. Very little research has looked at educational strategies to help address this problem.
Design: Randomized clinical trial
Methods: Subjects will be recruited from the pool of patients coming in for the pre-operative appointment prior to spine surgery. Patients that consent and enroll will be randomized to receive either a brief educational video at this appointment or usual care. Patients will be followed after surgery weekly for the first month, and then again at 6 months to determine their self reported opioid medication utilization patterns. Pain medication prescription and healthcare utilization will also be abstracted from the MDR healthcare database.
Summary: The results from this study will help inform and develop best practice for managing patients taking opioid medication for surgical pain.

3. OBJECTIVES/SPECIFIC AIMS/RESEARCH QUESTIONS.

This study is a continued project in a line of research aimed at improving the quality of spinal pain management. The purpose of this project is to assess the impact of an educational tool that addresses the latest evidence regarding the use of opioid medication in a patient-centric fashion. We will assess the impact this shared-decision making educational tool has on 12 month health care utilization post operatively and the self reported use of narcotic pain medication usage for the 6 months following lumbar spine surgery.

Specific Aim 1: Evaluate the differences in opioid medication use for the 12-month period after surgery in subjects that received the education prior to surgery compared to those that received usual care education.

Specific Aim 2: Compare the changes in self-reported outcome measures (pain, disability, and sleep) between groups over the 6-month period after surgery.

Specific Aim 3: Describe the sociodemographic factors and healthcare utilization in enrolled subjects for the 12 months leading up to a surgical procedure for the lumbar spine. Identify factors that could account for differences in opioid medication, and any potential interaction effect between intervention, opioid use, and clinical outcomes following surgery.

4. MILITARY RELEVANCE

The U.S. Armed Forces are experiencing alarming rates of post-war chronic pain related to musculoskeletal disorders.[1] Pain is reported by 40% of OIF/OEF/OND veterans.[2] Chronic pain after musculoskeletal injury is the leading cause of medical discharge from service[3] and a primary source of disability in the U.S. Military.[4,5] The costs of chronic pain related disability to the Department of Defense exceed $1.5 billion annually.[6] In 2007, musculoskeletal injuries resulted in approximately 2.4 million medical visits to military treatment facilities and accounted for $548 million dollars in direct patient care costs.[7] The cumulative incidence of injuries requiring an outpatient visit in U.S. Army entry-level training is about 25% for men and 55% for women.[8,9] Physical training and sports-related activities account for up to 90% of all injuries[8,10] and 80% of these injuries are considered overuse in nature.[11,12]

Military personnel are especially susceptible to the burden of chronic pain. Higher rates of chronic pain are observed in veterans compared to the general population.[13] Nearly 1 million veterans are prescribed opioids for musculoskeletal conditions, and over half of these individuals chronically use opioids.[14,15] Military personnel in combat settings are expected to perform duties in extreme operational environments that require very intense physical demands. The body armor and full combat load can be in excess of 120 pounds, which increases the physical demands even further and leaves military personnel at greater risk for back injury and other musculoskeletal disorders.[16] In a survey by Konitzer et al., U.S. Army soldiers reported an increase in the incidence of back, neck, and upper extremity pain during deployment.[16] Considering the demands of a combat load, the incidence of lower extremity musculoskeletal injury is also common among soldiers, which results in significant lost workdays.[17]

The U.S. Military faces a post-war chronic pain epidemic. Chronic pain after musculoskeletal injury is the leading cause of medical discharge and related to a growing rate of opioid addiction.[18-22] Traditional medical management has failed to correct this chronic pain epidemic.

5. BACKGROUND AND SIGNIFICANCE.

Historical Perspective:

Initial estimates of addiction risk based on data in the 1980s appear to have been very underinflated, and therefore the risk to benefit ratio for prescribing opioids for chronic non-cancer pain seemed acceptable.[23] Initially it was thought that less than 1% of patients would develop a dependency, but recent research shows that the actual number may be as high as 35%[24]. This has also led to a 10-fold increase in prescription of opioids in the last 2 decades, and the drug overdose death rates have tripled since 1990.[25] In fact, drug overdose is the 2nd highest cause of accidental death in North America after motor vehicle accidents.[25]

Economical Impact of Opioid Abuse:

The impact of opioid abuse is felt in various ways. While the effectiveness of opioids for chronic non-cancer pain is questionable, and not recommended for routine use in various clinical guidelines[26,27], prescription rates continue to rise,[28] at an alarming rate of 300-600% over the last 10-20 years. Despite there being almost 15,000 deaths due to prescription pain killer abuse in the U.S. in 2008[25], this only represents a fraction of the problem. For every one death, there are 10 treatment admissions for abuse,[29] 32 emergency department visits,[30] 130 people who abuse pain killers[31], and 825 non-medical users of opioids.[31] The chronic pain epidemic in the U.S. costs can also be measured indirectly by looking at the excess of $560 billion annually in healthcare expenses,

and lost productivity.[32] This epidemic is punctuated by escalating use of opioids leading to a reported 22.6 million addicted users.[26]
Musculoskeletal injury and disorders are the leading cause of chronic pain in the U.S.[32] Back pain is the most common of all of these musculoskeletal disorders.[33] In fact an increase of 423% in expenditures related to opioids for back pain has been recently seen.[33] Because of these factors, the costs associated with chronic pain disability continue to rise.[33]

Spine Surgery:
Data suggest that the rate of lumbar spine surgery in the United States has continually increased through the 1980's and 1990's [34,35]. Furthermore, there is significant geographic variation in rates of spine surgery within the United States [36] and between the United States and other developed countries [37]. Consistent with this, the postoperative recommendations provided to these patients vary widely and may not be based upon the best available evidence [38]. The observed variation in geographic differences in surgical rates and postoperative recommendations may adversely affect the clinical outcomes associated with lumbar spine surgery. Previous research has demonstrated that the clinical outcomes following lumbar disc surgery are suboptimal with many patients experiencing recalcitrant pain, disability and reduced quality of life [39-43]. Prolonged opiate use after cercvial surgery is also s problem.[75] Indeed, unsuccessful spine surgery has been described as a major health-care problem [44].

Opioid-based drugs are often used to help manage pain after spinal surgery.[19,45,46] However, it is also used often to manage spine pain in general, even prior to surgical interventions.[33] This is despite a recent systematic review that found only a very modest affect, and that was in the short term.[47] The outcomes for chronic pain, greater than 4 months, were not available.[47] Even the Cochrane collaboration back group has stated that "the benefit of opioids in clinical practice for the long-term management of chronic [low back pain] remains questionable."[48] Other studies show that when patients receive opioids for treatment of non-cancer pain, high levels of pain remain persistent and their quality of life decreases.[49]

Ironically, pre-operative use of opioid medications is actually a predictor of worse outcome after spine surgery.[50] Another study found that 1/3 of patients were still using opioid pain medication one year **after** their spine surgery.[51]

Opioid Abuse in the Military
Abuse of opioid pain medication may be even higher in the military.[18,20,21] The U.S. Military faces a post-war chronic pain epidemic. Chronic pain after musculoskeletal injury is the leading cause of medical discharge and related to a growing rate of opioid addiction. Traditional medical management has failed to correct this chronic pain epidemic.

Education Initiatives/Intervention
Most clinical guidelines recommend an informed decision process between the provider and the patient. Deyo and colleagues argue that patients need to be better social support and honest preparation to deal with their circumstances: "Patients need realistic expectations despite product marketing, media reports, and medical rhetoric that promise a pain-free life."[33]

The American Pain Society and the American College of Physicians has provided guidance on prescription of opioid therapy in patients with chronic, non-cancer pain.[52] They strongly recommend an educational approach,

with continuing discussion that should include goals, expectations, potential risks, and alternatives to an opioid trial. [52] In fact one of the critical research gaps identified by a panel of experts was further evidence on the utility and value of the informed consent process with patients.[53] This includes improving educational strategies and processes that can better inform patients about the true risks and dangers of opioid medication use.

Dr. Mike Evans is a physician-professor at the University of Toronto in Canada, and chaired the patient education committee for the College of Family Physicians of Canada. He runs the Evans Health Lab (evanshealthlab.com) which "fuses clinicians and creatives, filmmakers and patients, social entrepreneurs and best evidence to create "edutaining" healthcare information." His lab has developed an educational video titled "Best Advice for People Taking Opioid Medication" which is available open source on youtube.com. The video can be found at this link:
https://www.youtube.com/watch?v=7Na2m7lx-hU

This particular video has been endorsed by the Centre for Addiction and Mental Health and the Canada Health Infoway. It summarizes the state of the evidence, balancing the benefits and the dangers of opioid use, in a very user friendly and patient-centric manner. These types of educational tools have the potential to improve the shared decision making process between patients and providers about to prescribe a trial of opioid medications.

To date NO randomized clinical trials have specifically evaluated the effect of patient education on outcomes or modification of opioid usage post surgery.

6. **RESEARCH DESIGN** Randomized controlled trial with 2 intervention arms.

7. RESEARCH PLAN

7.1 Selection of Subjects

7.1.1. Subject Population. Subjects will be adults 18 years or older that are already scheduled for a spinal surgery in the neurosurgery or ortho spine clinic.

7.1.2. Source of Research Material.

Source of Research Material	Clinical Purposes (Y/N)	Research Purposes
Oswestry Disability Index	N	Y
Neck Disability Index	N	Y
Pain Catastrophizing Index	N	Y
Fear Avoidance Belief Questionnaire	N	Y

Numeric Pain Rating Scale	N	Y
Healthcare Utilization (MDR Healthcare Database)	Y	Y
The Opioid Risk Tool	N	Y
AHLTA	Y	Y

7.1.3. Inclusion and Exclusion Criteria.

Inclusion criteria (all of the following)

(a) Any patient currently scheduled for a pre-operative appointment with an orthopaedic spine surgeon or neurosurgeon specifically for a lumbar or cervical procedure.
(b) Surgery is taking place for a condition that has been ongoing for 6 months or longer (chronic)
(c) Between the age of 18 - 65 years
(d) Read and speak English well enough to understand the education, provide informed consent and follow study instructions (the surgeon, associate investigator, or research assistants will make this determination. Any patient that needs an interpreter will not be allowed to enroll).

Exclusion criteria (any of the following)

(a) Known aversion or allergy that would prevent the patient from taking any opioid-based pain medication

7.1.4. Description of the Recruitment and Prescreening Process. As we are targeting patients that have already made a decision to have surgery, they will already have been scheduled for a pre-operative visit that typically takes place 1-2 days before their surgical procedure. Before coming to this appointment, patients are typically told to set aside the entire morning (4-5) hours for the pre-operative planning procedures as standard of care. When they come in for this visit, the nurse or a research assistant will ask them if they would be interested in participating in the study. The current nurse that works in this department is not on active duty, and if any research assistants or investigators assist in this process, they will be in civilian clothing so their rank is unknown. Each week, the MSA in neurosurgery has a list of patients that are coming in for pre-operative appointments and she knows the procedures that they are scheduled to have. She will identify those that are having the procedure of interest, and remind the nurse seeing these patients to ask the patient if they would be interested in participating. Patients are always told to reserve the entire morning for pre-op as it can take several hours. Each patient will be told that this will add 20-30 minutes to their appointment. The MSA will also be able to notify a research assisting or associate investigator the week before of the days where there may be eligible patients coming in for a pre-operative appointments. These individuals will be available in the clinic on those days where a potential subject is coming in for a pre-operative appointment. As part of the pre-operative appointment that is usually taken care of by the nurse or physician's assistant, they will ask the patient if they are interested in participating and if they would like to know more about the study. . If they agree, they will be consented and if they meet the inclusion/exclusion criteria, they will be enrolled in the study.

7.1.5. Subject Screening Procedures. Screening will be performed by clinical members of the neurosurgery department, associate investigators, or research assistants listed on this protocol. In some cases it may be one of the surgeons if they are listed as an AI on this study. After providing informed consent, screening will occur by a brief interview and medical records review as a part of the patients normal pre-operative appointment. Essentially they will make sure that the patient meets the inclusion/exclusion criteria, and that they are scheduled for the surgical procedure of interest.

7.1.6. Consent Process. An investigator or research assistant will conduct the consent process for participation in this study, in the presence of a witness with the subject utilizing the approved informed consent and HIPAA documents in a private setting. The investigator will inform the subject that the study involves research and explain the purpose and procedures entailed in this study. Furthermore, the subjects will be informed of the approximate amount of subjects involved in the study. In addition, any foreseeable risks, discomforts, and benefits will be explained. The voluntary nature of the participation will be stressed, and subjects will be reminded by study personnel throughout their participation that they may elect to withdraw from the study at any time. Subjects will be assured that a decision not to participate will have no effect on their military status or ability to access health care; yet, if the subject chooses to participate he/she will be informed that all records identifying the subject are maintained confidentially by the PI in a password protected electronic file and all hard copies are maintained in a locked file cabinet that only the PI and study team have access to. Subjects electing to withdraw from the study will not participate in any data collection or other procedures associated with this study. The investigative team may terminate a subject's participation in the study at any time he/she feels this to be in the subject's best interest (i.e., safety, health, etc). Moreover, subjects will be provided with the appropriate contact information of whom to speak to about their rights and whom to speak with should the subject have any questions.

Subjects will be given ample time to ask questions, read and understand the consent form and take it home (if he/she chooses) so the research can be discussed with friends and family prior to participation. Upon completion of the informed consent process and after all concerns have been addressed the subject, the individual obtaining consent along with an impartial witness will sign the approved Institutional Review Board consent and HIPAA forms. A copy of the signed documents will be offered to the subject, and the original signed document will be placed in the subject's study record. The informed consent process will occur and the informed consent document will be signed by all parties prior to any/all study related procedures performed.

APRIL 2018: As part of an amendment extending collection of health care utilization to one year after study enrollment, we are requesting to collect this additional data under a waiver of informed consent and a waiver of HIPAA authorization. At the time of this amendment, all follow up with enrolled subjects has been completed and we are no longer in contact with participants. The research remains minimal risk to subjects and their privacy. The amendment does not adversely affect their rights and welfare since it is merely an extension of the healthcare utilization review for which they have already provided consent and authorized for collection of PHI. It is not practicable to contact all of the subjects and have them re-consent in order to obtain HIPAA authorization for this minor change in data collection (12 instead of 6 months).

7.1.7. Compensation for participation. None

7.2 Drugs, Dietary Supplements, Biologics, or Devices.

7.2.1 N/A

7.2.2 N/A

7.3. Study Procedures/Research Interventions.
After consenting, meeting inclusion criteria, and enrollment, all participants will complete several standard self-report questionnaires related to medical history, social demographic, and psychosocial variables that are related to low back pain, and often used in clinics as standard care in managing patients with spinal pain. Patients undergoing lumbar spine surgery will fill out the OSW and patients undergoing cervical spine surgery will fill out the NDI. They will then be randomized to either receive the education, or only usual care (which is the typical information the surgeon provides the patient verbally). All patients will receive the usual care education from their surgeon.

Randomization:
Subjects will then be randomized into one of two arms (Group I = Educational Video, Group II= Usual Care Education). The method of group assignment will be sequentially numbered opaque sealed envelopes (SNOSE). To minimize the risk of predicting the treatment assignment of the next eligible patient, randomization will be performed in permuted blocks of two or four with random variation of the blocking number.

Education Group:
The educational video chosen for this education is one created by Dr. Mike Evans, a physician and associate professor of Family and Community Medicine at the University of Toronto, CA, with a strong research focus on patient engagement. He runs the Health Design Lab which has produced several dozen patient engagement videos on a variety of public health topics. They are well-vetted, strongly based on evidence, and have been profiled by organizations such as the Journal of the American Medical Association (JAMA).

The video we are choosing for the educational intervention is titled: ***Best Advice for People Taking Opioid Medication*** and is available at the URL: http://www.youtube.com/watch?v=7Na2m7lx-hU

The content of the education focus on providing a historical perspective for opioid prescription from the time when the risk of dependence was highly underestimated. The video discusses the current evidence for the effect of opioid medications in non-cancer non-acute pain. It also discusses some of the dangers of long-term opioid usage. The video is 11 and ½ minutes long.

The consent, enrollment, and video education will take about 20-30 minutes for patients in this group, and occur at the end of their pre-operative visit. The patient will watch the video on a portable Tablet computer.

Usual Care Group: Patients that are randomized to usual care will only receive the regular instructions about opioid usage they typically receive from their surgeon. After they consent and are enrolled, they will fill out the questionnaires and then be done with the 1st visit of the study.

All Subjects:
All subjects will receive the usual care education that is typically given by their surgeon. That will be left up to the discretion of each surgeon. The screening and enrollment should take no more than 5-10 minutes, and then the filling out of self-report questionnaires should take approximately 5-7 minutes. Subjects in the group that is randomized to the education will take an additional 11 minutes to view the educational content.

All patients will proceed with the surgical procedure as planned. Each week during the 1-month period after the surgery, patients will be contacted (phone call, email, and text message - depending on what they consented to). They will be reached out to daily until contact is made. A voicemail will be left stating that "This is [name of person] from Brooke Army Medical Center calling in regards to a research study that an individual at this number is participating in. Please call us back at [number] at your convenience." They will be asked the following 6 questions:

1) "On a scale from 1 or 10, what has your average pain been like over the past week?"

2) 1) "On a scale from 1 or 10, what has your least and worst pain been like over the past week?"

3) "Approximately how many times have you taken opioid medication for pain (**Include types) over the past week?" [days, times per day]

4) "Approximately how many times have you taken other medication for pain (aspirin, Tylenol, ibuprofen) over the past week?"

5) How many days of narcotics pain medication were you prescribed? (# of days or unknown)

6) How much of that original prescription do you have remaining at this point? (estimate # of days or % left)

At the 1-month and 6-month time points they will be asked to fill out the additional clinical outcomes measures detailed below (ODI, PCS, PSQI, NPRS). These can be done in person with a visit to the clinic, over the telephone, or by email – depending on what they consented to. They will be reached out to daily until contact is made.

Assessment	**Visit / Follow Up (F/U) Interval**				
Study Day / period	12 months prior	Same Day	1 month	6 months	12 months after
Screening		X			
Informed Consent, discuss Plan, etc.		X			
Randomization		X			
Demographics, History & Physical		X			
Treatment (video education)		X			
Neck Disability Index (cervical surgery)		X	X	X	
Oswestry Disability Index (lumb surgery)		X	X	X	
The Opioid Risk Tool		X			
Pittsburg Sleep Quality Index		X	X	X	
Pain Catastrophizing Scale		X	X	X	
Medication use		X	X	X	
Numeric Pain Rating Scale		X	X	X	
Healthcare Utilization (MDR database)	X (entire 12 month period)				X (entire 12 month period)

7.3.1 Collection of Human Biological Specimens. N/A

7.3.1.1 Laboratory evaluations and special precautions. N/A

7.3.1.2 Specimen storage. N/A

7.3.2 Data Collection. Self-report measures (at baseline on paper forms) will be collected at the end of 1 and 6 months. Healthcare utilization will be collected at the end of 12 months.

Self-Report Measures:

Oswestry Disability Index (OSW): The Oswestry Disability Questionnaire, originally described by Fairbank et al[54] as a condition-specific measure of functional status for patients with LBP. The OSW is a 10-item scale with higher numbers indicating greater disability. We will use the modified version that replaces the sex life item with an employment/ homemaking item due to poor compliance with the former.[55,56] The OSW is widely used in research on non-operative management of patients with LBP.[57] Our previous research has found the modified OSW to be used in this study to have high levels of test-retest reliability among stable patients (ICC = 0.90), good construct validity, and responsiveness to change for patients with acute LBP, with a minimum clinically important difference of 6 points for patients with acute LBP receiving physical therapy.[55] It is a form often used as standard of care in physical therapy clinics.

Neck Disability Index(NDI):
The NDI was created to measure pain related disability associated with activities of daily living in people with neck pain.[76] The NDI contains ten focused sections. Seven items focus on activities of daily living. These sections include statements related to personal care, lifting, recreational activities, work, driving, and sleeping. Two items focus on the patient's pain. There is one section that evaluates pain directly. The NDI is easy to complete and score. Each item is scored on a 6-point scale and can reach a maximum score of 5; therefore, the maximum score is 50. Higher scores indicating higher levels of disability. Content, construct validity and reliability of the NDI has been previously shown in patients with neck pain.[76, 77] The MCID has been established as a change of 13% (or 6.5 points).[78]

The Opioid Risk Tool: The Opioid Risk Tool is a validated tool to assess the risk of narcotic abuse in patients with chronic pain. It stratifies risk based on age, gender, history of abuse, and psychological disease. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates a high risk for opioid abuse.[58] This tool, based on the way that the questions are asked, cannot imply whether the subject currently has a substance abuse issue or a history of one. Therefore, utilizing it as an outcome measure does not alter the current course of treatment from the neurosurgery staff. However, because the Army values the ability for service members to seek care for substance abuse, all subjects will be reminded that the army does have help for substance abuse with the Fort Sam Houston Alcohol and Drug Control Officer (ADCO): 210-295-6345 or Military OneSource at 1-800-342-9647.

Numeric Pain Rating Scale (NPRS): A 0-10 numeric pain rating scale ('0' indicating no pain, and '10' worst imaginable pain) will be used to assess LBP intensity. Numeric pain scales are known to have excellent test-retest reliability.[56] Our previous research has found the NPRS to be responsive to change, with a minimum clinically important difference of two points among patients with acute LBP receiving physical therapy.[9] It is a standard of care measurement taken in physical therapy clinics.

Pain Catastrophizing Scale (PCS): The PCS is a 13-item patient-report scale developed to measure the extent to which people catastrophize in response to pain.[60] Each item is scored from 0 ('not at all') to 4 ('all the time'). The PCS is reported as a total score, with higher scores indicating greater catastrophizing, and is composed of three sub-scales: Rumination (four items; e.g. 'When I am in pain, I keep thinking about how badly I want the pain to stop'), Magnification (three items; e.g. 'When I am in pain, I become afraid that the pain will get worse'), and Helplessness (six items; e.g. 'When I am in pain, I feel I can't go on') The PCS has been shown to have high levels of internal consistency and construct validity.[61] Pain catastrophizing has also

been found to play a role in the transition from acute to chronic LBP.[61] It is a form often used as standard of care in physical therapy clinics.

Pittsburg Sleep Quality Index (PSQI) The Pittsburg Sleep Quality Index (PSQI) is a self-rated questionnaire which assesses sleep quality and disturbances. Clinical properties provide utility in both psychiatric clinical pratices and research activities. Seven "component" scores including: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction are generated from 19 individual items.[63] Sleep quality may have a significant role in affecting outcomes of patients with low back pain as several studies have shown correlation between chronic back pain and quality of sleep.[70, 71]

Fear Avoidance Belief Questionnaire (FABQ): The [72] will be used to measure patients' beliefs about how physical activity and work may affect their pain and perceived risk for re-injury. The FABQ contains two subscales; a 7-item work subscale (FABQW), and 4-item physical activity subscale (FABQPA). Test-retest reliability of the FABQ subscales is high,[72,73] and validity is supported by associations with disability and work loss in patients with acute and chronic LBP,[74,75] Heightened fear-avoidance beliefs have been shown to be a risk factor for the development of chronic LBP following an acute episode.[62,76] Other research suggests it may be appropriate for other body regions, specifically evaluating its use in lower extremity injuries within a physical therapy setting.[77]

Healthcare Utilization

Finally, healthcare utilization data will be collected from the MHS Data Repository (MDR) database and will be confirmed via AHLTA. Healthcare utilization data will be used to determine any opioid medication use along with any subsequent medical utilization related to low back or neck pain. In order to collect this information a DUA will be completed between the researcher team and Patient Administration Systems and Biostatistics Activity (PASBA) and the Tricare Management Agency (TMA). Both of these agencies require a signed completed IRB protocol prior to submitting the DUA. However, this should not impact the timing of this study; as the data pull will be completed no sooner than December 2015. This will provide more than enough time to complete the DUA with both agencies and submit the signed DUA to the BAMC IRB prior to performing this analysis. Details for the determining healthcare utilization are outlined below:

The goal of the MDR database will be to determine the medication utilization for each of these subjects, as well as any other healthcare related to low back pain sought in the 12-month period after treatment in this study. This data (type, location, number of clinic visits, types of specialty clinic visits, imaging, and associated medication) will allow us to determine the extent of low back pain related healthcare utilization for each subject.

- Recording of Extracted Data with Identifiers:
  The data will be provided in a de-identified manner from PASBA. As they have done before with members of our team on prior project, they extract all the required data along with name, age and social security number in order to identify the correct subjects that were in our study. They will then assign a pseudo identification number and match that with the list of our subject identification numbers that we provide. Therefore, the final working set they provide us for analysis will not have any identifying PHI/PII associated with it. If additional follow-up is needed to clarify a healthcare utilization event in AHLTA, the research team can check the master subject record (stored on an encrypted government computer) in order to link the subject ID to SSN. Therefore, prior to analysis occurring, the identifiers will be eliminated. Confidentiality of protected health information will be maintained by the research staff at all times, however it should be minimal at this time. The final working database to be used in the data analysis will not include PHI information.

- Location of Extracted and Recorded Data:
  The healthcare utilization data will be primarily extracted from the MDR database and through AHLTA. Even though the data is now de-identified, the extracted data will still be maintained in an encrypted, password protected file kept at the Physical Therapy Clinic, Brooke Army Medical Center.

- Nature of Identifying Data
  Timeframes will be requested in reference to the baseline enrollment date rather than the actual date. For example, the date of appointment will be required initially to determine when the healthcare visit associated with the back pain occurred. However, this data will be coded differently in the working spreadsheet. The initial appointment will be recorded in weeks from the baseline date of enrollment. If multiple appointments exist, the range of dates will be recorded in the final spreadsheet (e.g. the patient was seen over a 4 week window) and the exact appointment days will not be included in the master spreadsheet. Analysis of the data will only occur in the de-identified spreadsheet.

- Status of the extracted data after completion of the research study:
  The de-identified spreadsheet outlined above will be stored indefinitely on a password-protected computer at the Physical Therapy Clinic, Brooke Army Medical Center.

- Redundancy:
  In addition to searching the MDR database, at each follow-up visit we will ask subjects if they have utilized healthcare resources since the last follow-up (4 and 26 weeks), specifically related to their LBP in 4 categories: visits to providers (traditional or complementary/alternative), medications (prescription or over-the-counter), interventions (injections, surgery, etc.), or testing (x-rays, MRI, etc.).

7.3.3. Human Biological Specimens/Tissue/Data Banking.

N/A

Statistical Consideration

7.4

7.4.1 *Sample Size Estimation*. Collection of healthcare utilization will occur in 100% of the subjects as no follow-up is required, and therefore no opportunities to collect data from a follow-up visit will be lost. Therefore the sample size estimation is based on the secondary outcome variable of self-reported pain and function (OSW). Assuming at least 85% of patients complete the OSW at 6 months, enrollment of 60 subjects per group (total sample size 120 subjects) will provide at least 84% power to detect a difference of 12 points (2 X MCID) on the change in OSW to 26 weeks, assuming a standard deviation in the change in OSW of 16 points (treatment effect = 43.8% of one standard deviation). The MCID for both the OSW and NDI has been estimated at 6 points.[55] Previous work with patients with acute LBP indicate that these estimates of anticipated effect size and standard deviation are realistic,[78-80] and would be consistent with detecting an effect that is at least slightly in excess of the threshold for seeing significant change. The NDI and OSW are similar in length and answer-type, and as we are expecting a higher number of lumbar patients, we will use the OSW to power this study.

Estimate Required Sample Size	**101**
Estimate Participant Drop Out / Withdrawal	**19**
Total Enrollment Requirement	**120**

Enrollment at Each Site	

BAMC	**120**

7.4.2 Primary (i.e., primary outcome variables) and secondary endpoints.
Primary Outcome Variable: Spinal pain healthcare utilization during the 1 year after enrollment understanding patients are likely still receiving care for their surgery at 6 months. This will include a comparison of imaging orders and types, specialty referrals, and medication use (pain and narcotics).

The self-reported outcome measures will also be taken at baseline, 1 month, and 6 months.

7.4.3 Data analysis.
All data will be analysed in IBM SPSS 21 (Chicago, IL). Descriptive statistics will be performed to describe the sociodemographic (age, sex, race, etc.) and health characteristics (disability, pain intensity, psychosocial factors, etc.) of the entire sample, and comparisons made between groups. Means and standard deviations will be computed for continuous data and frequency distributions will be analysed for categorical data.

Specific Aim #1 will be evaluated by determining the RR (risk ratio) for opioid medication use during the 1 year following surgery between both groups. Utilization reports will be broken down into the 1st week (expected to be the highest), 1st month, and then from 2 through 1 year. We will also look at all healthcare utilization events between patients associated with lumbar ICD-9 codes (Appendix A) in those randomized to also view the educational video.

Comparison of self-report outcomes between groups at baseline and 6 months will be performed using a linear mixed-effects model, which is flexible in accommodating data assumed to be missing at random (Specific Aim #2). The time points will be baseline, 1 month, and 6 months for the measures collected from the patient (self-report questionnaires). Significance is set at 0.05 and 95% confidence intervals will be reported for all relevant data. Sensitivity analysis will be run adjusting for other demographic and/or prognostic variables (PCS, pain intensity, ESS, etc) that may affect the outcome.

Specific Aim #3 will be determined by comparing the variables between each group and introducing them as covariates into the linear mixed-effects model to see if the adjustment influences the differences between each group.
Point estimates with 95% Confidence Intervals will be reported.

7.7 Confidentiality. The only document that will link the subject to the data indirectly is the master patient list. This document will have the patients name, social security number, and assigned subject ID number. This document will be encrypted, password protected, and kept on a CAC-enabled government computer in the BAMC physical therapy section, where only approved study personnel will have access to it. Each subject that consents to participate in the study, will also fill out a contact form that will have their name, email address, and phone number. These documents will be kept in a binder, locked in a research cabinet in a locked office. The master patient list will be referenced when a research team member needs to contact a subject to coordinate follow-up appointment, and needs to correlate the subject ID number with an actual patient. The master list is also needed for when healthcare utilization data is requested from PASBA. At that time, the encrypted file will be emailed to the analyst assigned to work on this project using a government email address, that is digitally signed and encrypted in order to be HIPAA compliance. In essence it will be an encrypted document, that is also being sent via encrypted email. When PASBA returns the healthcare utilization dataset, they will de-identify the data and it will only have a pseudo-ID assigned by the system, along with the subject ID that we had provided. The analysis of the data will

occur with a de-identified data set. The master patient list will be kept for 3 years after the study has been closed out, and then destroyed. The de-identified data will be kept indefinitely for any potential future secondary analysis.

7.7.1 Certificate of Confidentiality. N/A

8.0 RISKS/BENEFITS ASSESSMENT

8.1 Risks. Risks are unknown, but none are anticipated

There is always a potential risk for loss of confidentiality, but that risk is minimized because we are limiting access to to only members of the research team, and have protections in place as we have already outlines, to protect the information.

8.2 Potential Benefits. There are no direct benefits to the patient.

9.0 ADVERSE EVENTS, UNANTICIPATED PROBLEMS, AND DEVIATIONS

9.1 No adverse events are anticipated for this study as it is employing educational material, which is often used in some clinics, but using a novel deployment approach. There is the possibility that the screen from the tablet may be too bright and cause the patient to have to look away, although this would likely be very unlikely and the research assistant can step in and help dim the screen with the appropriate settings. There is also a very minor possibility that the patient may drop the tablet and the screen would shatter, sending sharp glass particles around. However, the tempered glass on the tablets makes this less likely, and the tablets will have cases which should protect them. None of these potential adverse events are serious, and have a very low likelihood of occurring.

In addition, a regular computer can be used to show the video if the tablet becomes a problem.

If an injury does occur, aid will be provided and the patient will be escorted to receive further medical care. The research assistant will help coordinate this with their PCP.

Deviations:
Minor protocol deviations will be reported to the IRB during annual review using the protocol deviation tracking log P53. Major deviations will be reported to the IRB within 48 hours by the primary investigator, in accordance with HRPP policy memo 5.4 on protocol deviations .

9.2 Reporting Unanticipated Problems Involving Risks to Subjects or Others, Serious Adverse Events and Deaths to the RHC-C IRB Office.

All unanticipated problems involving risk to subjects or others, unexpected serious adverse events, and all subject deaths related or possibly related to the study will be reported promptly providing initial notification of the event as quickly as possible after the research team's knowledge of the event, but within five (5) business days of identification by phone, by e-mail, by facsimile (210-916-1650) or via letter addressed to IRB Administrator). A complete written report will follow the initial notification within 10 working days.

9.3 Research Monitor. N/A

10.0 WITHDRAWAL FROM STUDY PARTICIPATION. Subjects may withdraw at any time by just notifying a member of the investigative team. As the primary outcome measure is healthcare utilization being collected through the MDR database, it will not be affected with patient withdrawal. However, self-report data will not be collected at the 4 and 26-week follow-up points if patients choose to withdraw and not make those follow-up appointments.

11.0 USAMRMC Volunteer Registry Database. N/A

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13.0 TIME REQUIRED TO COMPLETE THE RESEARCH (including data analysis).

With an anticipated surgical lumbar surgery load of approximately 20-25 patients per month and a conservative enrollment rate of 50%, we anticipate 1 year for the enrollment period.

- December 2014 – Protocol submitted to BAMC IRB
- April 2015 – Anticipate IRB approval
- March – April 2015 – Study staff training on study procedures
- May 2015 – Subject recruitment/enrollment begins
- May 2017 – Subject recruitment/enrollment end
- November 2017 – Last subject completes 6-month follow-up
- November 2017 – Healthcare utilization data requested from PASBA
- May 2018 – Data analysis and sub-analysis complete
- August 2018 – Publication submitted to appropriate journal

14.0 STUDY CLOSURE PROCEDURES

After all aims have been met, the PI will submit a protocol closure report through IRBNet. Study files will be kept for 6 years and then destroyed.

APPENDICES:

A. Oswestry Disability Index (OSW):
B. Numeric Pain Rating Scale (NPRS):
C. Pain Catastrophizing Scale (PCS):
D.The Pittsburg Sleep Quality Index (PSQI):
E. Fear Avoidance Belief Questionnaire (FABQ):
F. Opioid Risk Tool