A Video Intervention Targeting Opioid Disposal After General Surgery: A Feasibility Study

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A Video Intervention Targeting Opioid Disposal After General Surgery: A Feasibility Study

A Dissertation Presented By

Joanne Lewis

Submitted to the Graduate School of Nursing
University of Massachusetts Medical School

In partial fulfilment of the requirements for the degree of
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Nursing

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Abstract

PURPOSE: The purpose of this feasibility study was to explore the use of an online video intervention to prepare surgical patients to properly dispose of unused opioids.

SPECIFIC AIMS:

1. Describe the feasibility of recruiting, enrolling, randomizing and retaining participants who recently had a general surgery into the study.
2. Describe the differences in opioid disposal by age, sex, education, and type of surgery for the entire sample and by treatment assignment.
3. Describe the preliminary change in knowledge, behavioral beliefs, normative beliefs and disposal of opioids from baseline to post-intervention by group.
4. Describe the relationship between social desirability and behavioral beliefs, normative beliefs and disposal of opioids.

FRAMEWORK: The Theory of Reasoned Action was used to guide both the intervention and the measures.

DESIGN: This study used a randomized controlled feasibility study to explore a novel video intervention to teach safe storage and disposal of unused opioids after general surgery.

RESULTS: A total of 40 participants were enrolled in the study, average age was 44.7 (range 21-75 years), most were White, educated and employed. Recruitment took 11 weeks and the retention rate was excellent at 85%. Differences in opioid disposal was not significantly different by age, sex, education or type of surgery. The video intervention was positively received, but the majority (80%) still stored their pills unsecured.

CONCLUSION: The results demonstrate that a video intervention addressing safe storage and disposal practices of unused opioids is feasible and more research is needed to determine efficacy in increasing rates of secure storage and disposal of unused opioid pills.

KEYWORDS: Opioids, opioid disposal, general surgery, video education
Proposal

Introduction

More Americans died from drug overdoses (70,237) in 2017 than the number of American lives lost in the entirety of the Vietnam War (58,200) (CDC, 2019). Currently the most widely prescribed class of drugs in the United States, an estimated 245 million prescriptions (not including refills) for opioids were dispensed in 2014 (Volkow & McLellan, 2016). The diversion and misuse of prescription opioids, a resurgence in heroin use, and the recent increase in the abuse of illicit, high-potency synthetic opioids such as fentanyl have fueled what is now generally known as the opioid epidemic. Both the magnitude and the manifestations of this epidemic are startling. In 2016, an estimated 48.5 million persons in the U.S., or 18.0% of persons aged 12 years and older, reported use of illicit drugs or misuse of prescription drugs in the past year (Hoots et al., 2018). This estimate includes the use of marijuana, cocaine (including crack), heroin, hallucinogens, inhalants, and methamphetamines, and the misuse of prescription drugs (Hoots et al., 2018). Sixty percent of people who use prescription opioids without being under the care of a provider received these pills for free from family and friends (Rudd RA, 2016).

Initiatives throughout the country, such as prescription monitoring programs and educating prescribers, have sought to decrease the number of opioids prescribed for postoperative pain (Reifler et al., 2012). However, there is a paucity of information on how patients store unused opioids, and a few small studies have shown that proper, timely disposal of excess opioids is a rarity (Bartels et al., 2016). Currently, there are no guidelines or standard of care for prescribers to educate their patients on disposal practices of unused opioids (Costello,
2015). Given the high percentage of prescription opioids that are used by someone other than for whom they were prescribed, it is imperative that we try to decrease their availability.

The purpose of this feasibility study is to explore the use of an online video intervention to prepare patients to properly dispose of unused opioids in an effort to reduce the misuse of these drugs. The specific aims of the study are as follows:

1. Describe the feasibility of recruiting, enrolling, randomizing and retaining participants who recently had a general surgery into the study.
2. Describe the differences in opioid disposal by age, sex, education, and type of surgery for the entire sample and by treatment assignment.
3. Describe the preliminary change in knowledge, behavioral beliefs, normative beliefs and disposal of opioids from baseline to post-intervention by group.
4. Describe the relationship between social desirability and behavioral beliefs, normative beliefs and disposal of opioids.

**Background and Significance**

The practice of prescribing opioids for pain has increased dramatically over the past two decades, particularly in the United States and Canada. This has been accompanied by a marked increase in opioid-related morbidity and mortality (Alam & Juurlink, 2016). The US Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) have declared that overdose deaths involving prescription opioids constitute an epidemic, a decree that has prompted multijurisdictional initiatives (Barnett, Olenski, & Jena, 2017). In the late 1990s, healthcare systems in the United States, including the Department of Veterans Affairs (VA), jointly proclaimed the routine assessment of pain as a necessary intervention. This led to widespread national recognition of pain as a “5th vital sign” (Johnson, 2016). In 2001, the Joint
Commission on Accreditation of Healthcare Organizations (JCAHO) established the mandatory early recognition and management of pain as a standard of care (Baker, 2017). It is also noteworthy that at least two pharmaceutical companies were involved in funding and providing educational videos and materials for JCAHO regarding the need for better pain management (Fleming et al., 2017). As a result, various guidelines were instituted that compelled prescribers to dispense opioids for all types of pain syndromes and as a result, the sales of opioid analgesics quadrupled in the US between 1999 and 2010. Specifically, from 2002 to 2009, the number of prescriptions for extended-release opioids increased from 9.3 to 22.9 million, a 146% increase (Leece et al., 2017). It is frequently argued that the prescribing behavior of physicians has been one of the drivers of the opioid epidemic (Alam & Juurlink, 2016; Bicket et al., 2018; Hasak et al., 2018; M. V. Hill, McMahon, Stucke, & Barth, 2017). Other specialty groups are also involved with prescribing opioids in the United States such as dentists, nurse practitioners, and physician assistants. Between July 1, 2016 and June 30, 2017, nurse practitioners made up 15.8% of opioid prescribers and dispensed 9.9% of all opioids (Guy & Zhang, 2018). Prescribing has increased to the point that in 2010, enough opioids were prescribed in the United States to provide every American adult with 5 mg of hydrocodone every 4 hours for a month (Mertl, 2016).

Most of the efforts to combat the opioid epidemic has been about decreasing the number of opioids prescribed as well as treating those with addiction (Alam & Juurlink, 2016). Lacking is research on prevention of opioid misuse by encouraging timely disposal. This study seeks to focus on the disposal of unused opioids to prevent potential misuse. One aspect of the opioid crisis we have come to understand has to do with the misuse of opioids that are stored in the home (Jones, 2013). However, there is a lack of education for patients around disposal of excess
medications that they are no longer taking (M. V. Hill et al., 2017). Recent studies regarding opioid prescriptions after general surgery have concluded that many patients do not take all of the opioid pills that are prescribed, resulting in excess opioids available in the community (Bicket et al., 2018; Fujii et al., 2018; M. V. Hill et al., 2017). Studies suggest that the majority of patients with excess opioids store them in the home unlocked (de la Cruz et al., 2017; Hasak et al., 2018; Neill et al., 2017). The proposed study seeks to educate surgery patients to dispose of extra opioid pills after they are no longer needed so the pills are not available for misuse.

Currently, there is no mandated standard of care around education for opioid disposal. The American College of Surgeons did announce an initiative for opioid education and alternative analgesics perioperatively in 2016 (Maureen V Hill, Stucke, Billmeier, Kelly, & Barth Jr, 2018; Saluja, Selzer, Meara, Heneghan, & Daly, 2017) . However, the initiative did not include education around opioid disposal. Upwards of 60% of patients who are addicted to heroin state they started with opioid pills they either got free or stole from family and friends (Jones, 2013). Decreasing the number of opioid pills stored in the home is one step to preventing misuse. If educating patients to safe and timely disposal of their excess opioid pills is shown to be effective, this inexpensive modality can be translated to other patient populations making an even greater impact on the epidemic.

The American Nurses Association (ANA) issued a brief to provide an overview of the role of nurses as it relates to the opioid epidemic (Association, 2018). Because nurses’ practice in a variety of direct-care, care-coordination, leadership, and executive roles, they are often in key positions to educate patients and families on pain management, and safe storage and disposal of opioids. In order to prevent prescription opioids from reaching unintended individuals, storage and disposal techniques should be addressed at the time of prescribing, disbursement, and during
follow-up care planning. Nurses are most often the providers at the bedside who educate patients and families throughout the healthcare process and are in a unique role to provide information on storage and disposal techniques. Proper storage and timely disposal of unused opioids can decrease the number of pills that are available to unintended users.

The American Medical Association opioid task force also issued a progress report in 2018 entitled “Physicians Progress to Reverse the Nations Opioid Epidemic” (AMA, 2018). Opioid prescriptions have decreased across the nation. Between 2013 and 2017, the number of opioid prescriptions decreased by more than 55 million, which is a 22.2% decreased nationally (AMA, 2018). All 50 states saw a decrease in opioid prescriptions over the last five years. Prescription drug monitoring programs (PDMPs) are databases that prescribers are obligated to check prior to writing opioid prescriptions to ensure patients are not receiving multiple opioid prescriptions from other providers. There are over 1.5 million registered providers using PDMP’s as of 2017 (AMA, 2018). Providers made more than 300.4 million PDMP queries in 2017 which is a 121% increase from 2016 (AMA, 2018). The AMA opioid task force along with the US Surgeon General’s public health advisory urged greater use of naloxone to save lives from opioid overdose. Naloxone is a medication used to reverse the effects of opioid overdose. Naloxone prescriptions more than doubled in 2017, and between January 2018 in April 2018 naloxone prescriptions reached a record high in the United States of more than 11,600 prescriptions (AMA, 2018). Despite all of these amazing efforts, deaths related to heroin, illicit fentanyl, and prescription opioids continue to rise. These statistics suggest that decreasing prescriptions alone will not end the epidemic. Opioid disposal is one more piece in this complex puzzle that can help combat opioid abuse and decrease rates of addiction.
Patients will continue to have pain that requires treatment after surgery. Opiates are often needed to provide relief for acute postoperative pain. The exact number of pills to prescribe remains elusive and can vary greatly by type of surgery, individual pain threshold and physiologic response to opioids. Therefore, opiates will continue to be prescribed, leftover opiates will continue to be an issue, so disposing of unused pills is an important area of scientific inquiry.

**Use of Online Video Intervention Approaches**

Videos have been shown to be valuable resources for assisting in educating patients in today’s changing healthcare environment. They can be an effective teaching tool for patients by facilitating knowledge acquisition, as well as enhancing self-care behaviors. They incorporate both visual and auditory information into a teaching modality that can be easy for individuals to understand and retain. Twenty eight studies comprising of 12,703 participants were included in a systematic review examining the effectiveness of videos and modifying health behaviors in 2016 (Tuong, Larsen, & Armstrong, 2014). Video interventions were found to be effective in breast self-examination, prostate cancer screening, sunscreen adherence, self-care of patients with heart failure, HIV testing, treatment adherence, and female condom use. They also found that videos had increased effectiveness when they were tailored to the patient’s as well as being framed with positive messages (Tuong et al., 2014).

**Theoretical/Conceptual Framework**

The reasoned-action approach (RAA) is an integrative framework for the prediction (and change) of human social behavior (Fishbein & Ajzen, 1975). The reasoned-action approach states that attitudes towards the behavior, perceived norms, and perceived behavioral control determine people's intentions, while people's intentions predict their behaviors (Fishbein &
Ajzen, 1975) (see Figure 1). The reasoned-action approach is the latest version of the theoretical ideas of Martin Fishbein and Icek Ajzen, following the earlier theory of reasoned action and the theory of planned behavior (Ajzen & Fishbein, 2010). Those theoretical ideas have, since 1975, resulted in over a thousand empirical studies in behavioral science journals (McEachan et al., 2016).

The Theory of Reasoned Action (TRA) informs conceptually how the proposed intervention components will affect the desired outcome of opioid disposal. Targeting behavioral beliefs and normative beliefs about opioids will affect the outcome behavior of opioid disposal. This study will assume that all participants have control over opioid disposal as they are all consenting adults, therefore the intervention will solely target behavioral beliefs and normative beliefs. For example, a potential behavioral belief participants’ may hold is “keeping my pills has nothing to do with the opioid crisis”. The intervention will seek to change attitudes with positive motivation and information about disposal of unused opioid pills in the home. In fact, 80% of heroin users state that they first became addicted to prescription pain medications that they received from family or friends (M. V. Hill et al., 2017). One normative belief that participants may hold is “my family and friends want me to be safe and keep them safe”. The intervention will seek to target this belief and reinforce the fact that disposing of unused opioids is one way to keep yourself and your family and friends safe. Please see the conceptual model below in Figure 1 that is adapted from the Theory of Reasoned Action.
The reasoned action approach uses a number of concepts. The definitions of the concepts are summarized in Table 1 below (I Ajzen & Fishbein, 2010):
Table 1. DEFINITIONS OF TERMS DESCRIBED IN THE THEORY OF REASONED ACTION

<table>
<thead>
<tr>
<th>Concepts</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral Beliefs</td>
<td>Belief that behavioral performance is associated with certain positive or negative feelings or certain attributes or outcomes</td>
</tr>
<tr>
<td>Normative Beliefs</td>
<td>Belief about whether important people such as family or friends approve or disapprove of the behavior and motivation to do what those important people want.</td>
</tr>
<tr>
<td>Control Beliefs</td>
<td>The overall measure of the perceived control over the behavior and the likelihood of overcoming a constraining condition to that behavior</td>
</tr>
<tr>
<td>Attitude</td>
<td>Tendency to respond with some degree of favorableness or unfavorableness to a psychological object</td>
</tr>
<tr>
<td>Perceived norm</td>
<td>Perceived social pressure to perform or not perform a given behavior. Two types include: Injunctive norm is the perceptions concerning what should or ought to be done and descriptive norms are perceptions that others are or not performing the behavior in question</td>
</tr>
<tr>
<td>Perceived behavioral control</td>
<td>People’s perceptions of the degree to which they are capable of, or have control over, performing a given behavior</td>
</tr>
<tr>
<td>Intentions</td>
<td>Person’s estimate of the likelihood or perceived probability of performing a given behavior</td>
</tr>
<tr>
<td>Behaviors</td>
<td>Observable events composed of four elements: the action performed, the target at which the action is directed, the context in which it is performed, and the time at which it is performed</td>
</tr>
<tr>
<td>Actual Control</td>
<td>Relevant skills and abilities, as well as, barriers to and facilitators of behavioral performance</td>
</tr>
</tbody>
</table>
Application of the Theory of Reasoned Action to this Study

The Theory of Reasoned Action (TRA) has been used successfully to guide behavioral intervention studies. The TRA, which focuses on the constructs of attitude, subjective norm, and perceived control, explain a large proportion of the variance in behavioral intention and predict a number of different behaviors, including health behaviors. Evidence comes from hundreds of studies that have been summarized in several meta-analyses and reviews (Albarracin, Johnson, Fishbein, & Muellerleile, 2001; Albarracín, Kumkale, & Johnson, 2004; Armitage & Conner, 2001; Downs & Hausenblas, 2005; Durantini, Albarracin, Mitchell, Earl, & Gillette, 2006; Hausenblas, Carron, & Mack, 1997; McEachan et al., 2016; Webb & Sheeran, 2006). Many published intervention studies report that changing the constructs within the TRA lead to subsequent change behaviors (Albarracin et al., 2001; De Leeuw, Valois, Ajzen, & Schmidt, 2015; Hackman & Knowlden, 2014; Hausenblas et al., 1997; Jemmott 3rd, Jemmott, & Fong, 1992). TRA has been used successfully to predict and explained a wide range of health behaviors and intentions, including smoking, drinking, health services utilization, exercise, breast-feeding, substance use, HIV/STD prevention behaviors, mammography, safety helmets and seatbelts (Albarracin et al., 2001; Albarracín et al., 2004; Albarracín et al., 2003; Armitage & Conner, 2001; Jemmott 3rd et al., 1992). TRA provides a framework to identify key behavioral, normative, and control beliefs affecting behaviors. Interventions can be designed to target and change these beliefs, thereby affecting attitude, subjective norm, or perceived control and leads to changes in intention and behavior. Numerous studies have supported perceived control as a direct predictor of both intentions and behavior (Icek Ajzen, 1991; Albarracin et al., 2001; Hausenblas et al., 1997; Montano & Kasprzyk, 2015). Therefore, this study will be sure to target the intervention on the perceived control of safe and timely disposal of opioid pills. Findings
have been used to develop many effective behavior change interventions (Albarracín et al., 2003; Downs & Hausenblas, 2005; Tuokko, McGee, Gabriel, & Rhodes, 2007; Webb & Sheeran, 2006).

According to the theory, a particular behavior is most likely to occur if a person has a strong intention to perform it, the knowledge and skill to do so, and there is no serious environmental constraint preventing the behavior. These components and their interactions are important to consider when designing interventions to promote health behaviors. For example, if a person has a strong intention to dispose of their opioid pills, it is important to ensure that they have sufficient knowledge of their resources to act on this intention, such as knowledge of a disposal site or how to safely dispose of their pills at home; and that there are no serious environmental constraints such as lack of transportation to a disposal site. The theory asserts that there are three constructs that can affect intention and behavior. These three constructs are attitude toward behavior (behavioral beliefs), subjective norm (normative beliefs), and perceived behavioral control (control beliefs). Definitions of these three constructs shown in Table 2 below.

Table 2. CONSTRUCT DEFINITIONS IN THE THEORY OF REASONED ACTION

<table>
<thead>
<tr>
<th>Construct</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral Belief/Attitude toward behavior</td>
<td>Belief that behavioral performance is associated with certain positive or negative feelings, or certain attributes or outcomes.</td>
</tr>
<tr>
<td>Normative Belief/ Subjective or Perceived Norm</td>
<td>Belief about whether most people approve or disapprove of the behavior. A belief about whether most people perform the behavior. And motivation to do what others want you to do.</td>
</tr>
<tr>
<td>Control Beliefs/ Perceived Behavioral Control</td>
<td>Overall measure of the perceived control over the behavior. Overall measure of the ability to perform the behavior. Or the perceived ability to overcome a constraining condition of the behavior.</td>
</tr>
</tbody>
</table>
The intervention in this study will seek to address two of the three constructs in hopes of affecting intention and behavior- behavioral beliefs and normative beliefs. As the participants in this study are all adults with the capacity to make decisions for themselves, it will be assumed that each participant has behavioral control over the decision to keep or dispose of excess opioid pills. Table 3 outlines the components of the video intervention as it relates to the constructs in the TRA.

Table 3. COMPONENTS OF THE VIDEO INTERVENTION AS IT RELATES TO THE THEORY OF REASONED ACTION

<table>
<thead>
<tr>
<th>Construct in the TRA</th>
<th>Key Component in the Intervention Video</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral Beliefs- attitude toward behavior</td>
<td>Explain why disposal is necessary to decrease epidemic</td>
</tr>
<tr>
<td></td>
<td>Explain why keeping pills is dangerous</td>
</tr>
<tr>
<td></td>
<td>We want to keep our family and friends as safe as possible and this is one way to do so</td>
</tr>
<tr>
<td></td>
<td>Explain why sharing medication is dangerous</td>
</tr>
<tr>
<td></td>
<td>Explain why/how keeping medications unsecure can lead to misuse</td>
</tr>
<tr>
<td></td>
<td>Explain harm reduction of disposing at least some of the pills if you do not intend to dispose of all of the pills.</td>
</tr>
<tr>
<td>Normative Beliefs- subjective or perceived norm</td>
<td>Explain our friends and family want us to be safe</td>
</tr>
<tr>
<td></td>
<td>Explain many people in our community are choosing to dispose of their medications and why</td>
</tr>
<tr>
<td></td>
<td>Explain that our healthcare community and government are in favor of medication disposal for individual and community health.</td>
</tr>
<tr>
<td>Control Beliefs- perceived behavioral control</td>
<td>Participants in this study are assumed to have behavioral control over the decision to dispose, as all participants are consenting adults.</td>
</tr>
</tbody>
</table>
Participants in the study will be taught a specific knowledge set of how to safely store and dispose of leftover opioids as described in Table 4.

Table 4. KNOWLEDGE PROVIDED IN THE VIDEO INTERVENTION

<table>
<thead>
<tr>
<th>Knowledge</th>
<th>Key component in the Intervention Video</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Show how to safely store pills in a secure/locked place</td>
</tr>
<tr>
<td></td>
<td>Show how to dispose of the pills</td>
</tr>
<tr>
<td></td>
<td>Show where to dispose of pills</td>
</tr>
</tbody>
</table>

Methods

Overview

This feasibility study will use a randomized controlled trial design to examine the efficacy of an online intervention video with postoperative adult general surgery patients to dispose of their unused opioid medications in a safe and timely manner. Potential participants (preoperatively) will be identified by the PI via the electronic operating room schedule. Participants will be screened using inclusion and exclusion criteria and those who are eligible will be approached to be part of the study. Participants will be called by the PI via telephone, information regarding the study will be given, and participants will be asked to participate in the study. Consent will take place during this telephone encounter. A consent form and fact sheet will be mailed to the participant along with a self-addressed stamped envelope for the participant to sign and return allowing access to their electronic health record for data collection. All participants who agreed to participate will be sent an initial survey via their email to obtain baseline data. Participants will then be randomized to either the control group or the intervention group.
Both the intervention and the control groups will follow the usual care. Usual care is defined as information patients routinely receive from their surgeon or healthcare provider team regarding opioid disposal. Currently at the facility where this study will take place, there is no formal routine teaching regarding medication storage or disposal given to this patient population. The information provided is individualized based on the patient and the provider. Some providers at the institution provide a fact sheet about postoperative pain management with non-opioid medications such as Tylenol or ibuprofen. None of the current surgeons or nurse practitioners in this practice provide routine information regarding storage and disposal of opioid medications. Patients are also seen by the anesthesia department, both anesthesiologists and nurse practitioners, prior to surgery to receive pre-operative instructions. However, there is no current protocol within these instructions to teach about opioid storage and disposal. The nurses in the post anesthesia care unit at one of the campuses at the medical center are trained to provide information to patients after surgery about opioid medications including storage and disposal, however, the nurses on the campus where the participants in this study are having surgery have not been educated to provide this information. The nurses do not cross cover the campuses’ post anesthesia units. The medical center where this study seeks to take place is an academic institution and residents are involved with general surgery patients and potential participants in this study. Residents have been educated on opioid prescriptive practices and reducing the number of pills prescribed at one time, but they have not had formal education on opioid storage and disposal teaching for patients.

The intervention group will be given an educational video on opioid disposal during the first postoperative week. Both the control group and the intervention group will receive the final survey after postoperative day 14. The two groups will then be compared for the desired outcome.
of opioid disposal. Upon completion of the study, participants in the control group will also receive the educational video on opioid disposal. See figure 2 for the study map.

Figure 2. STUDY MAP

Sample

A convenience sample of 40 (20 per treatment group) adult general surgery patients at a tertiary medical center in the Northeast United States will be invited to participate. All eligible participants who meet the inclusion criteria will be invited to participate in the study. See Table 5
for inclusion and exclusion criteria. The sample size for this feasibility study is based on 90% confidence interval if the true retention rate is 70% and 40 total participants (56.0%, 81.7%).

Table 5. INCLUSION AND EXCLUSION CRITERIA

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 years of age or older</td>
<td>Less than 18 years of age</td>
</tr>
<tr>
<td>Undergoing a general surgery: laparoscopic and open cholecystectomy,</td>
<td>Currently on or routinely taking opioids before surgery</td>
</tr>
<tr>
<td>laparoscopic and open hernia repair, excisional biopsies, Nissen Fundoplication +/-</td>
<td></td>
</tr>
<tr>
<td>gastropexy, splenectomy (non-traumatic), bowel resection (non-cancer),</td>
<td></td>
</tr>
<tr>
<td>laparoscopic/open appendectomy, adrenalectomy, ostomy reversal</td>
<td></td>
</tr>
<tr>
<td>English speaking- the intervention is only available in English at this</td>
<td>Participant is unable to take opioid medications i.e. allergy or another</td>
</tr>
<tr>
<td>time</td>
<td>contraindication</td>
</tr>
<tr>
<td>Able to provide informed consent</td>
<td>Cognitive impairment</td>
</tr>
<tr>
<td>Has access to phone and email</td>
<td>Prisoners</td>
</tr>
<tr>
<td></td>
<td>Currently enrolled in other opioid research studies</td>
</tr>
<tr>
<td></td>
<td>Participant has no intention of filling the opioid prescription</td>
</tr>
</tbody>
</table>

The intervention and data collection procedures will be administered online via email using REDCap. Participants who do not have access to email will be excluded from this study.

Limiting participation in this way will decrease the generalizability of the results, however, the benefits of decreased cost using an online modality is necessary for this project. The number of patients excluded based on computer or email access will be collected and described.

**Setting**

The practice from which participants will be recruited from resides at a tertiary medical center in the Northeast United States. The Medical Center has 779 beds, employs 1,242 medical providers
and 2,498 nurses, and sees over 1.1 million outpatient visits per year. The general surgery practice performed 2901 inpatient and outpatient surgeries from October 2017 to September 2018. There were 572 cholecystectomies, 538 hernia repairs, 233 appendectomies, 88 Nissen Fundoplications, 11 adrenalectomies, 174 excisional biopsies, 1 non-traumatic splenectomy, and 112 bowel surgeries. Eight general surgeons’ practice at this facility, and surgeries are performed at three campuses within the city. The outpatient surgeries take place at 2 of the campuses and recruitment will take place from those 2 campuses alone.

**Procedures**

IRB approval will be sought at the recruitment site.

**Recruitment**

Approximately 10 participants per week will be recruited at the study site. The PI will identify possible candidates for the study via the operating room schedule. The electronic health records for the identified participants will be reviewed to determine eligibility based on the inclusion and exclusion criteria of the study. I will apply for a HIPPA waiver from the IRB in order to access the information to identify and screen potential participants from the electronic health record. So as to not approach potential participants that would be ineligible to participate in the study, I will need access to their medical record to screen for current opioid use, allergies or inability to tolerate opioids, and language spoken. Those who are eligible for the study will be approached by the PI and consented if they agree to participate. Recruitment and informed consent will occur prior to the planned surgery. Participants will be called and asked to participate and verbally consented over the telephone. A waiver of written documentation of consent will be sought from the IRB. De-identified data regarding reasons why individuals choose not to participate in the study will be collected.
I am a nurse practitioner in the general surgery practice for which potential participants may be recruited. In order to ensure there is no potential conflict, coercion or confusion between my researcher role and clinical role, my direct patients will not be approached to participate in the study.

**Retention**

In order to increase retention rates for the study, study participants will be offered an incentive for participation and completion of the study. Gift cards in the amount of $25 to Amazon will be given to participants via their email who complete the study. Participants in the study will also have access to the PI via email and phone if they have any questions about the study or difficulty with any of the technology or links. Participants will also be provided with follow-up reminders to view the video and complete the survey. These follow-up reminders will be in the form of emails and phone calls. A second invitation and a reminder email will be sent out 7 to 10 days following the first email. If there is no response, a phone call and third email will be sent out 7 to 10 days following the second email attempt. After the third attempt, no further contact will take place. These emails will contain the link to the video and questionnaire for the intervention group and a link to the questionnaire for the control group.

**Randomization**

Prior to randomization, both the control group and the intervention group will receive a survey that serves to assess baseline knowledge and demographics. This survey will be distributed via email using RedCap preoperatively.

Participants will then be randomized to either the control group or the intervention group. The randomization will take place after the participant completes the initial survey. A statistician will prepare the randomization schedule via opaque sealed envelopes and it will be provided to
the PI. These opaque sealed envelopes will contain the treatment allocation, and as participants are enrolled, they will either be randomized to the control group or the intervention group. The PI will record the participant’s name, the ID number and the assigned group which will be kept in a secure research drive that is only accessible to the PI.

**Control Group Protocol**

The control group will receive a survey to assess baseline knowledge and demographics preoperatively, please see FORM- A. The control group will receive usual care, comprising of any information they are given regarding opioid disposal by their surgeon or other members of their surgical team such as nurses. On postoperative day 14 (+/- 1 day), another survey will be sent via email to collect data about opioid disposal (see Form-B).

Since the control group will not have access to the education that is provided in the video intervention tool, a link to the video will be provided for all participants in the control group at the completion of the study.

**Intervention Group Protocol**

The intervention group will take the baseline survey via email preoperatively, please see FORM-A. Within the first week postoperatively, they will be provided an educational video via a link in their email that will address opioid disposal. They will then receive the final survey via email at postoperative day 14 (+/- 1 day), please see FORM- C.

**Intervention**

The intervention is a brief, 5-minute video designed to elicit a behavior change and provide patient education regarding the hazards of prescription opioid misuse, and ways to safely use, store and dispose of prescription opioids. The video will deliver critical information recommended by the Food and Drug Administration (FDA) and the Centers for Disease Control
(CDC) regarding reducing risks associated with opioid medications. The intervention video consists of the following components and is broken down as related to the Theory of Reasoned Action:

Theory: Intervention to address Behavioral Beliefs

- Explain why disposal is necessary to decrease epidemic
- Explain why keeping pills is dangerous
- We want to keep our family and friends as safe as possible and this is one way to do so
- Explain why sharing medication is dangerous
- Explain why/how keeping medications unsecure can lead to misuse
- Explain harm reduction of disposing at least some of the pills if you do not intend to dispose of all of the pills.

Theory: Intervention on Normative Beliefs

- Explain our friends and family want us to be safe
- Explain many people in our community are choosing to dispose of their medications
- Explain that our healthcare community and government are in favor of medication disposal for individual and community health.
- Explain the environmental impact of unsafe vs safe opioid disposal

Knowledge will also be imparted in the intervention video. The key points of knowledge to be addressed are:

- Show how to safely store pills in a secure/locked place
- Show how to dispose of the pills: mix with kitty litter, coffee grounds, or inedible substances prior to disposal in trash can. Also, black out personal information on the prescription bottle and dispose in trash.
- Show where to dispose of pills: disposal boxes, pharmacies, police stations, trash, toilet

**Measures**

A baseline survey will consist of:

- Age (continuous/ratio), sex (categorical/nominal), ethnicity (categorical/nominal), education (categorical/nominal), employment status (categorical/nominal), surgery type (categorical/nominal)- collected from participant report on the survey
• Name of opioid prescribed (categorical/nominal) and dose of opioid prescribed (continuous/ratio), number of pills prescribed (continuous/ratio)- collected from participant medical record
• Previous education received on opioid storage and disposal- collected from participant report on the survey

The following will be collected to measure normative and behavioral beliefs with the response option being a 7-point Likert scale (interval level of measurement) ranging from 1= strongly disagree to 7= strongly agree, with higher scores indicating higher intent and likelihood of the target behavior- opioid disposal.

<table>
<thead>
<tr>
<th>Application to Theory of Reasoned Action</th>
<th>Survey Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral Beliefs</td>
<td>I intend to dispose of my pain pills as soon as I am no longer taking them for pain after my surgery.</td>
</tr>
<tr>
<td></td>
<td>I keep my pain pills in a secure, locked place.</td>
</tr>
<tr>
<td></td>
<td>Disposing of unused pain pills can help combat the opioid epidemic.</td>
</tr>
<tr>
<td></td>
<td>I am capable of disposing my unused opioid medications.</td>
</tr>
<tr>
<td></td>
<td>I know how to safely dispose of my unused pain medications.</td>
</tr>
<tr>
<td></td>
<td>Sharing my pain medications with family and friends is dangerous.</td>
</tr>
<tr>
<td></td>
<td>I have shared pain medication with family or friends in the past.</td>
</tr>
<tr>
<td></td>
<td>I know of a medication disposal center where I can drop off my unused medications</td>
</tr>
<tr>
<td>Normative Beliefs</td>
<td>Most people around me keep their unused pain medications</td>
</tr>
<tr>
<td></td>
<td>People in my community are choosing to dispose of their pain medications</td>
</tr>
<tr>
<td></td>
<td>My healthcare team wants me to dispose of my unused pain medications</td>
</tr>
</tbody>
</table>
Using safe disposal methods can help keep the environment safe.

To measure participant intervention receipt as part of the intervention fidelity plan, the following questionnaire will be given to the intervention group. There are 3 response options, 0=not covered, 1= covered somewhat, but would have liked more information about this and 2= covered completely.

<table>
<thead>
<tr>
<th>Knowledge Points</th>
<th>Response Options</th>
<th>Level of Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statistics about the opioid crisis</td>
<td>0=not covered, 1=covered somewhat, 2=completely covered</td>
<td>Nominal</td>
</tr>
<tr>
<td>Causes of the opioid crisis</td>
<td>same</td>
<td></td>
</tr>
<tr>
<td>Ways to safely store opioids/pain medication</td>
<td>same</td>
<td></td>
</tr>
<tr>
<td>Dangers of keeping unused opioids/pain medication</td>
<td>same</td>
<td></td>
</tr>
<tr>
<td>Importance of opioid/pain medication disposal</td>
<td>same</td>
<td></td>
</tr>
<tr>
<td>Ways to dispose of opioids/pain medication</td>
<td>same</td>
<td></td>
</tr>
<tr>
<td>Environmental impact of safe opioid/pain medication disposal</td>
<td>same</td>
<td></td>
</tr>
<tr>
<td>Where to dispose of opioids/pain medication at the medical center</td>
<td>same</td>
<td></td>
</tr>
</tbody>
</table>

The following measures will also be collected as part of the intervention fidelity plan to measure receipt of the intervention:

<table>
<thead>
<tr>
<th>Survey Question</th>
<th>Response Options</th>
<th>Level of Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>At any point, have you received education about disposing of your pain medications after you no</td>
<td>Yes/No</td>
<td>Dichotomous/nominal</td>
</tr>
</tbody>
</table>
longer need them for pain after surgery? (This will also be collected from the control group.)

Did you watch the educational video about opioid/pain medication disposal? Yes, all of it Yes, some of it No

The following measures will be collected to address the Dependent Variable for all participants:

<table>
<thead>
<tr>
<th>Survey Question</th>
<th>Response Options</th>
<th>Level of Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did you fill your opioid/pain medication prescription?</td>
<td>Yes/No</td>
<td>Dichotomous/nominal</td>
</tr>
<tr>
<td>Did you elect for partial fill of the pain medication prescription at the pharmacy?</td>
<td>Yes/No</td>
<td>Dichotomous/nominal</td>
</tr>
<tr>
<td>Do/did you have any unused pain medication after your surgery?</td>
<td>Yes/No</td>
<td>Dichotomous/nominal</td>
</tr>
<tr>
<td>Did you dispose of unused pain medication?</td>
<td>Yes/No</td>
<td>Dichotomous/nominal</td>
</tr>
<tr>
<td>If yes, how did you dispose of your unused pain medication?</td>
<td>Threw them in the trash, Flushed them in the toilet, Took back to pharmacy, Took to disposal box at the medical center, Other (please specify)</td>
<td>Categorical/Nominal</td>
</tr>
<tr>
<td>I plan on sharing the information I learned from the video with family and/or friends.</td>
<td>7 item Likert scale</td>
<td>Interval/continuous</td>
</tr>
<tr>
<td>Did you store your pain medications in a secure, locked place?</td>
<td>Yes/No</td>
<td>Dichotomous/nominal</td>
</tr>
<tr>
<td>Question</td>
<td>Answer Options</td>
<td>Data Type</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>Did you call your doctor for additional pain medication after surgery?</td>
<td>Yes/No</td>
<td>Dichotomous/nominal</td>
</tr>
<tr>
<td>Do you feel you were given enough pain pills to treat your post-operative pain?</td>
<td>Yes/No</td>
<td>Dichotomous/nominal</td>
</tr>
<tr>
<td>Were you given additional prescription pain medications from any provider after you completed the initial prescription?</td>
<td>Yes/No</td>
<td>Dichotomous/nominal</td>
</tr>
<tr>
<td>Some people choose to keep unused pain medications. If you chose to keep your unused pain medications, please explain why.</td>
<td>Open box to write in response</td>
<td>Qualitative content analysis</td>
</tr>
</tbody>
</table>

In order to assess for social desirability bias, Marlowe Crowne Short Form (2)- (MC-2) (10) social desirability scale will be administered to all participants (Strahan & Gerbasi, 1972). This is a 10 item short form version of the original 33 item scale measuring the respondent social desirability bias using a true-false format (Strahan & Gerbasi, 1972). It has demonstrated an acceptable level of psychometric properties with internal consistency is ranging from 0.62 to 0.76 (Reynolds, 1982). Please see FORM-D.

**Intervention Fidelity**

To ensure that the intervention is delivered as planned, data will be collected as to how many participants watched the video intervention, if the video intervention played in its entirety, if the video was only partially viewed before being stopped, and if it was viewed multiple times. I will also make sure that the video link is functioning correctly so participants can see the video in its entirety throughout the time course of the study.
To measure the receipt of the information, participants will be administered a post intervention questionnaire related specifically to the content of the informational video. A knowledge test will be administered as well as a questionnaire specifically addressing the participant receipt of the video content. Only the intervention group will receive the intervention video, therefore only this group will receive this questionnaire. Both the control and the intervention groups will receive the knowledge test about safe storage and disposal practices. This information will be used to compare the groups and to adjust for prior knowledge. Please see Form-E in the appendix.

Enactment of safe storage and disposal of opioid medications by participants will also act as a measure of intervention fidelity. Increased rates of safe storage and disposal suggest the video intervention was successfully delivered.

There are five domains of a treatment fidelity plan described by the NIH Behavior Change Consortium and all five will be addressed in this study (Bellg et al., 2004). Please see Table 6 to highlight treatment fidelity strategies.

**TABLE 6. TREATMENT FIDELITY STRATEGIES**

<table>
<thead>
<tr>
<th>Treatment Fidelity</th>
<th>Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Design</td>
<td>Theoretical model to guide intervention</td>
</tr>
<tr>
<td>Training Providers</td>
<td>The intervention is a video so all intervention group participants will receive the same information</td>
</tr>
<tr>
<td>Delivery of Treatment</td>
<td>Redcap computer program will be used to deliver the intervention. Treatment manual and complete records will be kept to ensure all participants in the intervention group receive the video at the intended time</td>
</tr>
<tr>
<td>Receipt of Treatment</td>
<td>Survey will be given to measure treatment receipt</td>
</tr>
</tbody>
</table>
Disposal rates of unused opioids will be calculated for both intervention and control groups.

Data Management

Study data will be collected and managed using REDCap electronic data capture tools hosted at the University of Massachusetts Medical School (Harris et al., 2009). REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

All data will be maintained on a secure password protected research drive. Only the PI will have access to the data with identifying information. This list with identifying information will be kept in paper form only in a locked file cabinet in a locked office. Only the PI will have access to this file cabinet. This paper with the identifying information will be destroyed as soon as participant enrollment is complete. The database which will be accessible to the dissertation committee containing the data points will contain no identifying information and will be stored on a secure research drive acquired through the Graduate School of Nursing.

Data Analysis

Study variables will be examined for skewness, outliers, and systematic missing data. Descriptive statistics will be computed for all demographic, intervention fidelity and clinical variables. Qualitative content analysis will be done to describe participant responses to the two open-ended questions about the reason for retaining some opioids and feedback about the
intervention video. Descriptive statistics will be used to summarize how many study participants viewed the video, for how long, how many times it was viewed and responses to the treatment receipt questionnaire.

**Analysis by Specific Aim**

Aim #1. Explore the feasibility of recruiting, enrolling, randomizing and retaining participants who recently had a general surgery into the study.

Descriptive statistics will be used to describe:

a. the number of participants recruited.

b. the number of participants actually enrolled.

c. The recruitment timeline, retention, reasons for study drop out and issues with randomization process.

d. Descriptive statistics (gender, age, diagnosis, type of surgery) will be used to describe the number who chose not to participate in the study and the reasons for non-participation.

Aim #2. Describe the differences in opioid disposal by age, sex, education, and type of surgery for the entire sample and by treatment assignment.

a. T-test will be used to examine differences in disposal by age. Chi square will be used to examine differences in disposal by sex, education, and type of surgery.

Aim #3: Describe the preliminary change in knowledge, behavioral beliefs, normative beliefs and disposal of opioids from baseline to post intervention by group.

a. T-test will be used to examine difference in knowledge, behavioral beliefs, normative beliefs and opioid disposal from baseline to post intervention by group.
Aim #4 Describe the relationship between social desirability and intentions to dispose of opioids for the entire sample.

a. Spearman correlation will be conducted to examine the relationship between the Marlow Crowne total score and scores on the intention to dispose and disposal.

**Potential Challenges and Difficulties**

One potential challenge of the study is ineffective recruitment and retention. This study is a pilot study so fewer participants are required. The general surgery service is a relatively high-volume service with quick turnaround of patients. There were over 2000 surgeries the previous fiscal year there is a high likelihood of being able to recruit approximately 40 participants for the study over a six to eight-week timeframe. One of the exclusion criteria is of the study is not being able to speak English. We are a diverse Medical Center with approximately 20% of our population speaking languages other than English. Even taking this into consideration it is still likely to be able to recruit 40 participants who meet the English-speaking inclusion criteria. Adequate and timely communication with participants as well as offering an incentive for completion of the study seeks to increase retention. The intervention will also be kept at a minimum time commitment so as to increase the likelihood of participant completion of the video. Also, the number of questions asked to each participant on the questionnaires will be kept to a minimum as to decrease participant burden.

When working with technology, there is always the potential challenge of technical glitches with the Internet links or uploading the data into a data management software. All links will be tested in the platforms will be compatible prior to participant recruitment. I will test the process on a peer test participant prior to recruitment and data collection from actual participants.
As with any intervention study, there is always a concern that there will be no difference between the control or intervention groups. An open-ended question will also be included regarding reasons for deciding to either keep or dispose of their excess opioid medications. This open-ended question may be useful for providing insight if the intervention needs to be modified.

**Conclusion**

The opioid epidemic continues to ravage this country. Despite regulatory efforts in education for prescribers, people continue to have unused opioids left over after surgeries. This feasibility study seeks to determine if a video intervention educating patients on safe storage and disposal practices for unused opioids will be an effective means for decreasing the number of unused opioid pills kept in homes. Decreasing the number of available opioid pills for unintended users is an important aspect of combating this crisis.
References


Executive Summary

The following changes were made in the execution of the study:

1. The video was unable to be delivered through YouTube, therefore the video was delivered through Kaltura. Limited data was able to be captured through this platform. I was unable to capture individual view times, but instead overall view times.
A VIDEO INTERVENTION TARGETING OPIOID DISPOSAL AFTER GENERAL SURGERY: A FEASIBILITY STUDY

Joanne Lewis MS, RN, ACNP-BC
University of Massachusetts, Graduate School of Nursing

To explore the use of an online video intervention to prepare surgical patients to properly dispose of unused opioids

PURPOSE
• Rapid increase in opioid prescriptions from 1990’s-present

• More Americans died from drug overdoses (70,237) in 2017 than the number of American lives lost in the entirety of the Vietnam War (58,200)

• Sixty percent of people who use prescription opioids without being under the care of a provider received these pills for free from family and friends

• Initiatives: PMP, provider education, and addiction treatment

• No guidelines or standard of care for prescribers to educate patients on safe storage and disposal of opioids

---

• Recent studies regarding opioid prescriptions after general surgery have concluded that many patients do not take all of the opioid pills that are prescribed, resulting in excess opioids available in the community

• The majority of patients with excess opioids store them in the home unlocked risking potential misuse

---

Background and Significance

Background and Significance cont.
Lacking is research on prevention of opioid misuse by encouraging safe storage and timely disposal

WHERE’S THE GAP?

Opioid Disposal Model Adapted from the Theory of Reasoned Action

Interventions change attitudes with positive marketing, information on importance of disposal for saving lives

Interventions show social pressure to help with opioid crisis: “you can help too” “your family/friends want you to protect them”

Assumed this population has control over behavior so intervention needed

Behavioral Beliefs → Attitude toward Disposal

Normative Beliefs → Perceived norm social pressure to dispose

Perceived Behavioral Control: perception of control to dispose

Intention to dispose → Outcome Behavior (optimal disposal)

Actual Control: Ability to dispose and environmental opportunity to dispose

Intervention: provides an accessible medication disposal box at facility that patients can freely access
To Describe:

1. Feasibility of recruiting, enrolling, randomizing and retaining participants who recently had a general surgery into the study.
2. Differences in opioid disposal by age, gender, education and type of surgery.
3. Preliminary change in knowledge, behavioral beliefs, normative beliefs and disposal of opioids from baseline to post intervention.
4. Relationship between social desirability and intention to dispose of opioids.

Specific Aims

Methods

- Feasibility study
- Randomized Controlled Trial design
- Recruitment
- Timeline
- Inclusion/exclusion criteria
- Retention
- Time 1 surveys sent via REDCap
- Randomized: control vs intervention group
- Both groups followed usual care
- Intervention group received video intervention post op week
- Both groups sent 2nd survey on POSTOP day 14
• A brief (6 minutes 36 seconds) educational video delivered by Kaltura
• Developed based on the Theory of Reasoned Action
• Addressed both Normative and Behavioral Beliefs
• Provided knowledge on safe storage and disposal practices of left over opioids
• Included key information on the opioid crisis and step by step instructions on safe storage and disposal of unused opioids
• Link to video: https://umassmed.mediaspace.kaltura.com/media/Opioid+Disposal+Video/1_2j1nmiao

---

• Baseline survey measured:
  • Demographic data
  • Normative (4 items) and behavioral beliefs (8 items)
  • 5 point Likert scale- higher scores indicated higher intent for opioid disposal
  • Social Desirability bias measured with Marlow Crowne (10) short form (α = 0.62-0.76)
• Time 2 Survey (2 weeks post-op)
  • Same norm and beh belief questions as well as MC
  • measured information about opioid prescription use, storage, and disposal
  • Intervention group who received the educational video also received a survey to measure intervention receipt as part of the intervention fidelity plan
<table>
<thead>
<tr>
<th>Treatment Fidelity</th>
<th>Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Design</td>
<td>Theoretical model used to guide intervention</td>
</tr>
<tr>
<td>Training Providers</td>
<td>The intervention was a video, so all intervention group participants received the same information</td>
</tr>
<tr>
<td>Delivery of Treatment</td>
<td>Kaltura computer program was used to deliver the intervention. Treatment manual and complete records were kept to ensure all participants in the intervention group received the video at the intended time</td>
</tr>
<tr>
<td>Receipt of Treatment</td>
<td>Survey was given to measure treatment receipt</td>
</tr>
<tr>
<td>Enactment of Treatment Skills</td>
<td>Disposal rates of unused opioids were calculated for both intervention and control groups</td>
</tr>
</tbody>
</table>

**INTERVENTION FIDELITY**

---

**Specific Aim 1:**

**Consort Flow Diagram**
Demographic Data

<table>
<thead>
<tr>
<th>Variables</th>
<th>Control (n=20) n (%)</th>
<th>Intervention (n=20) n (%)</th>
<th>Total n (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) ^1</td>
<td>46.2 (13.6)</td>
<td>45.0 (10.0)</td>
<td>44.7 (14.0)</td>
<td>0.878</td>
</tr>
<tr>
<td>Gender</td>
<td>male 9 (45.0)</td>
<td>6 (30.0)</td>
<td>15 (40.0)</td>
<td>0.508</td>
</tr>
<tr>
<td></td>
<td>female 11 (55.0)</td>
<td>14 (70.0)</td>
<td>25 (60.0)</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td>High school or less</td>
<td>4 (20.0)</td>
<td>0 (0.0)</td>
<td>0.451</td>
</tr>
<tr>
<td></td>
<td>College or higher</td>
<td>16 (80.0)</td>
<td>20 (100.0)</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td>White 16 (80.0)</td>
<td>17 (85.0)</td>
<td>33 (82.5)</td>
<td>0.367</td>
</tr>
<tr>
<td></td>
<td>Other 4 (20.0)</td>
<td>3 (15.0)</td>
<td>7 (17.5)</td>
<td></td>
</tr>
<tr>
<td>Employment</td>
<td>Employed 15 (75.0)</td>
<td>15 (75.0)</td>
<td>30 (75.0)</td>
<td>0.295</td>
</tr>
<tr>
<td></td>
<td>Unemployed 5 (25.0)</td>
<td>5 (25.0)</td>
<td>10 (25.0)</td>
<td></td>
</tr>
<tr>
<td>Type of surgery</td>
<td>Hernia 5 (25.0)</td>
<td>5 (25.0)</td>
<td>10 (25.0)</td>
<td>0.409</td>
</tr>
<tr>
<td></td>
<td>Endovac 5 (25.0)</td>
<td>7 (35.0)</td>
<td>12 (30.0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lap-chow 2 (10.0)</td>
<td>8 (40.0)</td>
<td>10 (25.0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Extraluminal 4 (20.0)</td>
<td>6 (30.0)</td>
<td>10 (25.0)</td>
<td></td>
</tr>
<tr>
<td>Baseline intention to discontinue (energy program)</td>
<td>56 (55.2)</td>
<td>19 (44.0)</td>
<td>0.480</td>
<td></td>
</tr>
<tr>
<td>Number of opioid pills prescribed ^2</td>
<td>53 (94.5)</td>
<td>12 (90.9)</td>
<td>0.500</td>
<td></td>
</tr>
<tr>
<td>Participants with left over pills</td>
<td>4 (7.5)</td>
<td>8 (40.0)</td>
<td>0.599</td>
<td></td>
</tr>
</tbody>
</table>

Outcome Flow Diagram
### Specific Aim 2: Differences in Opioid Disposal by Age, Gender, Education, and Treatment Assignment

<table>
<thead>
<tr>
<th>Variable</th>
<th>Chose Opioid Disposal in (%)</th>
<th>Chose to Keep Opioids in (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)*</td>
<td>50.1</td>
<td>68.8</td>
<td>0.003</td>
</tr>
<tr>
<td>Gender</td>
<td>Male 4 (80)</td>
<td>3 (42.5)</td>
<td>0.408</td>
</tr>
<tr>
<td></td>
<td>Female 4 (57.1)</td>
<td>3 (42.5)</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td>High School or less</td>
<td>1 (100)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>College or higher</td>
<td>8 (66.7)</td>
<td>0 (33.3)</td>
</tr>
<tr>
<td>Treatment assignment</td>
<td>Control 4 (57.1)</td>
<td>3 (42.5)</td>
<td>0.408</td>
</tr>
<tr>
<td></td>
<td>Intervention 5 (83.3)</td>
<td>1 (16.7)</td>
<td></td>
</tr>
</tbody>
</table>

### Specific Aim 3: Baseline beliefs and changes in knowledge, behavioral beliefs, normative beliefs and intention for opioid disposal by group

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Change: Time 2-Time 1</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control, mean [SE], N=20</td>
<td>Intervention, mean [SE], N=20</td>
<td>p</td>
</tr>
<tr>
<td>Knowledge</td>
<td>0.70 (0.11)</td>
<td>0.60 (0.112)</td>
<td>0.520</td>
</tr>
<tr>
<td>Behavioral beliefs</td>
<td>25.1 (0.59)</td>
<td>26.2 (0.82)</td>
<td>0.387</td>
</tr>
<tr>
<td>Normative Beliefs</td>
<td>13.5 (0.55)</td>
<td>13.8 (0.59)</td>
<td>0.712</td>
</tr>
<tr>
<td>Intention for Opioid Disposal</td>
<td>4.23 (0.25)</td>
<td>4.10 (0.25)</td>
<td>0.721</td>
</tr>
</tbody>
</table>
Specific Aim 4:
Relationship between social desirability and intention to dispose of opioids.

There was no significant relationship found between scores on the MC(10) and scores on intention to dispose at baseline (Spearman rho = .15, p = .36) or actual disposal and the MC (10) at time 2 (Spearman rho = -.35, p = .24) suggesting no evidence of social desirability bias.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Agree or Strongly Agree n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventional video adequately covered the causes of the opioid crisis</td>
<td>15 (83.3%)</td>
</tr>
<tr>
<td>Ways to safely store prescription pain medication</td>
<td>16 (88.9%)</td>
</tr>
<tr>
<td>The importance of prescription pain medication</td>
<td>18 (88.9%)</td>
</tr>
<tr>
<td>Ways to dispose of leftover pills</td>
<td>18 (100%)</td>
</tr>
<tr>
<td>The environmental impact of safe disposal</td>
<td>14 (77.8%)</td>
</tr>
<tr>
<td>Planned to share the video information with family and friends</td>
<td>14 (77.8%)</td>
</tr>
</tbody>
</table>

- The majority of participants watched the video in its entirety (75%)
- 12.5% watched some of it, 12.5% reported not watching the video
- 56.3% of participants watched it on a tablet or smartphone and 31.3% watched on a computer
- The majority of participants (68.4%) felt receiving the video after surgery was a good time.
- Video was played 29 times over 37 visits to the site and the average view time was 4 min and 16 seconds.
• 20 (80%) kept the opioids unsecured in a cabinet in the kitchen, bedroom or bathroom

• 9 (45%) participants stated they felt their pills were stored in a secure location despite not being kept locked

• only 3 (12%) participants stored them in a secure location

• 3 out of 4 (75%) participants stated reason for choosing to keep their unused medication was: “just in case” they need them in the future.

• Participants stated they kept the pills “in the event myself or my husband need relief for intense pain” and “I’ve held on to them in case any pain comes back.”

———

• Limited in terms of race, ethnicity and educational background

• Non-English speaking was a major reason for ineligibility for the study

• Intention to dispose of left-over opioids at baseline was high in this sample which had the potential to reduce the effect of the intervention due to a ceiling effect

• Purposefully excluded persons currently on opioids or with addiction for this feasibility study so we have no information about how a video intervention would work in this population

———
Conclusions

• The study design is feasible.
• The video was well received. (maybe a little long)
• More participants felt they securely stored their pills than actually did. (more education is needed)
• Nurses are involved in the care of surgical patients from their initial visits in clinic to the surgical stay to the postoperative visits. Education provided by nurses at multiple steps in the surgical timeline could be effective.

Next Steps

• The next step is to conduct a full randomized controlled trial examining the use of the opioid disposal video with a broader subject group.
• Qualitative research to reach a deeper understanding of the “just in case” reasoning to keep opioids can help drive future interventions.
A BIG thank you to my dissertation committee
Carol Bova PhD, RN
Sybil Crawford PhD
Susan Sullivan-Boylai DNSc, MN, RN, CNS, FAAN

ACKNOWLEDGEMENTS

Thank you’s

- Ricardo Poza- for your tireless efforts in perfecting the video
- Diane Quinn- for helping me distribute the funds to the participants
- Sue Young- for always making sure I was registered :)
- All the GSN faculty- for a world class education and helping me grow as a person with social justice always in mind
- My cohort who have become amazing friends
- My friends and family for your unwavering support through the ups and down
- AND to Grace- my fierce, strong, kind and smart girl- I hope to one day grow my heart as big as yours 😊
Acknowledgments

I would like to thank my dissertation committee Sybil Crawford, Susan Sullivan-Bolyai and especially my committee chair Carol Bova. It was an absolute pleasure working with and learning from the best. I am grateful for your support and mentorship, and I am proud to have been your student.

I would like to thank Ricardo Poza for his dedication and support with producing the intervention video. You are not only fun to work with but provided great ideas on how to present the educational material.

A big thanks to Diane Quinn for distributing the incentive money to participants in the study as well as keeping me on track and organized.

I could not have made it through this journey without the support of my family and friends. I am particularly grateful to and proud of my daughter, Grace, who sat through many dissertation seminars after a long day of school.
Dissemination Plan

The primary description of this dissertation work was submitted as a manuscript on May 13, 2020 the Journal of Surgical Research for review and consideration for publication.
Appendices

FORM-A

Initial survey (ALL participants)

What is your gender?
  o Female
  o Male
  o Other (please specify) _______________________

What is your age in years? ______________

What is the highest level of school you have completed or the highest degree you have received?
  o Less than high school degree
  o High school degree or equivalent (i.e. GED)
  o Some college but no degree
  o Associate degree
  o Bachelor degree
  o Graduate degree

Which of the following categories best describes your employment status?
  o Employed, working 40 or more hours per week
  o Employed, working 1-39 hours per week
  o Not employed, looking for work
  o Not employed, not looking for work
  o Retired
  o Disabled, not able to work

Are you white, black or African-American, American Indian or Alaska native, Asian, native Hawaiian or other Pacific Islander, or some other race?
- White
- Black or African-American
- American Indian or Alaskan Native
- Asian
- Native Hawaiian or other Pacific Islander
- From multiple races
- Some other race (please specify)___________

Are you Mexican, Mexican-American, Chicano, Puerto Rican, Cuban, Cuban-American, or some other Spanish, Hispanic, or Latino group?
- I am not Spanish, Hispanic, or Latino
- Mexican
- Mexican-American
- Chicano
- Puerto Rican
- Cuban
- Cuban-American
- Some other Hispanic, Spanish, or Latino group
- From multiple Spanish, Hispanic or Latino groups

Baseline knowledge

At any point, have you received education about disposing of your prescription pain medications after you no longer need them?
- Yes
- No

If yes, please explain (for example, from your surgeon or other doctor, nurse, nurse practitioner, from the media, family or friends)
Please circle the number that most reflects your point of view. There is no right or wrong answers, we are just interested in your personal point of view.

**How strongly do you agree with the statements below?**

I intend to dispose of my prescription pain pills as soon as I am no longer taking them for pain after my surgery.

Strongly Disagree: __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree

It is safest to keep my prescription pain pills in a secure, locked place.

Strongly Disagree: __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree

I intend to keep any extra prescription pain pills I might have after my surgery.

Strongly Disagree: __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree

I have prescription pain pills at home already.

Strongly Disagree: __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree

Most people around me keep their unused prescription pain medications.

Strongly Disagree: __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree

Disposing of unused prescription pain pills can help combat the opioid addiction epidemic.

Strongly Disagree: __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree

I feel capable of disposing my unused prescription pain medications.

Strongly Disagree: __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree

I know how to safely dispose of my unused prescription pain medications.

Strongly Disagree: __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree
Sharing my medications with family and friends is dangerous.
Strongly Disagree: __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree

I have shared medication with family or friends in the past.
Strongly Disagree: __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree

I know of a medication disposal center where I can drop off my unused medications.
Strongly Disagree: __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree

People in my community are choosing to dispose of their prescription pain medications
Strongly Disagree: __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree

My healthcare team wants me to dispose of my unused prescription pain medications.
Strongly Disagree: __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree

Using recommended disposal methods for medications can help keep the environment safe.
Strongly Disagree: __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree

FORM-B
Second Survey- control group

At any point (either before or after surgery), have you received education about disposing of your pain medications after you no longer need them for pain after surgery?

- Yes
- No

If yes, please explain (for example, from your surgeon or other doctor, nurse, nurse practitioner, from the media, family or friends)

____________________________________________________________________________________

Please circle the number that most reflects your point of view. There is no right or wrong answers, we are just interested in your personal point of view.

How strongly do you agree with the statements below?

I intend to dispose of my pain pills as soon as I am no longer taking them for pain after my surgery.

Strongly Disagree: 1, 2, 3, 4, 5, 6, 7: Strongly Agree

It is safest to keep my pain pills in a secure, locked place.

Strongly Disagree: 1, 2, 3, 4, 5, 6, 7: Strongly Agree

I intend to keep any extra pain pills I might have after my surgery.

Strongly Disagree: 1, 2, 3, 4, 5, 6, 7: Strongly Agree

I have pain pills at home already.

Strongly Disagree: 1, 2, 3, 4, 5, 6, 7: Strongly Agree

Most people around me keep their unused pain medications.

Strongly Disagree: 1, 2, 3, 4, 5, 6, 7: Strongly Agree
Disposing of unused pain pills can help combat the opioid addiction epidemic.
Strongly Disagree:  _1_, _2_, _3_, _4_, _5_, _6_, _7_: Strongly Agree

I feel capable of disposing my unused pain medications.
Strongly Disagree:  _1_, _2_, _3_, _4_, _5_, _6_, _7_: Strongly Agree

I know how to safely dispose of my unused pain medications.
Strongly Disagree:  _1_, _2_, _3_, _4_, _5_, _6_, _7_: Strongly Agree

Sharing my medications with family and friends is dangerous.
Strongly Disagree:  _1_, _2_, _3_, _4_, _5_, _6_, _7_: Strongly Agree

I have shared medication with family or friends in the past.
Strongly Disagree:  _1_, _2_, _3_, _4_, _5_, _6_, _7_: Strongly Agree

I know of a medication disposal center where I can drop off my unused medications.
Strongly Disagree:  _1_, _2_, _3_, _4_, _5_, _6_, _7_: Strongly Agree

People in my community are choosing to dispose of their unused pain medications
Strongly Disagree:  _1_, _2_, _3_, _4_, _5_, _6_, _7_: Strongly Agree

My healthcare team wants me to dispose of my unused pain medications.
Strongly Disagree:  _1_, _2_, _3_, _4_, _5_, _6_, _7_: Strongly Agree

Using recommended disposal methods for medications can help keep the environment safe.
Strongly Disagree:  _1_, _2_, _3_, _4_, _5_, _6_, _7_: Strongly Agree

Dependent Variable (target outcome)
Did you fill your pain medication prescription?
  
  o  Yes
Did you elect for partial fill of the pain medication prescription at the pharmacy?
- Yes
- No

Do you feel you were given enough prescription pain pills after your surgery?
- Yes
- No

Did you contact a healthcare provider for additional prescription pain medication after the initial prescription was finished?
- Yes
- No

Do/did you have any unused prescription pain pills after your surgery?
- Yes
- No

If Yes, how many pills did you have left over ______________

If you had any unused prescription pain pills after surgery, did you dispose of them?
- I disposed ALL of the unused prescription pain pills.
- I disposed SOME of the unused prescription pain pills.
- I chose to keep the unused prescription pain pills.
- I did not have any unused pills- I took them all.

If you chose to dispose some or all of the pills, how did you dispose of them?
- Threw them away in the trash
- Flushed them down the toilet
- Brought them back to a pharmacy
Disposing of them in a medication disposal box at the medical center

Other (please specify) __________________________

If you chose to keep some of your prescription pain pills, how many did you keep?_________________________

Did you store your prescription pain medications in a secure, locked place?

  o  Yes
  
  o  No

If no, please explain why________________________________________________________

Some people decide to keep their unused prescription pain medications. If you chose to keep your unused prescription pain medications, please explain why.
FORM-C
Second Survey- Intervention Group

At any point (either before or after surgery), have you received education about disposing of your pain medications after you no longer need them for pain after surgery?

- Yes
- No

If yes, please explain (for example, from your surgeon or other doctor, nurse, nurse practitioner, from the media, family or friends)

_____________________________________________________________________________________

Did you watch the educational video about prescription pain medication disposal?

- Yes, all of it
- Yes, some of it
- No

Please circle the number that most reflects your point of view. There is no right or wrong answers, we are just interested in your personal point of view.

How strongly do you agree with the statements below?

I intend to dispose of my pain pills as soon as I am no longer taking them for pain after my surgery.

Strongly Disagree:  __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree

It is safest to keep my pain pills in a secure, locked place.

Strongly Disagree:  __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree

I intend to keep any extra pain pills I might have after my surgery.

Strongly Disagree:  __1__, __2__, __3__, __4__, __5__, __6__, __7__: Strongly Agree
I have pain pills at home already.  
Strongly Disagree: ___1__, ___2__, ___3__, ___4__, ___5__, ___6__, ___7__: Strongly Agree

Most people around me keep their unused pain medications.  
Strongly Disagree: ___1__, ___2__, ___3__, ___4__, ___5__, ___6__, ___7__: Strongly Agree

Disposing of unused pain pills can help combat the opioid addiction epidemic.  
Strongly Disagree: ___1__, ___2__, ___3__, ___4__, ___5__, ___6__, ___7__: Strongly Agree

I feel capable of disposing my unused pain medications.  
Strongly Disagree: ___1__, ___2__, ___3__, ___4__, ___5__, ___6__, ___7__: Strongly Agree

I know how to safely dispose of my unused pain medications.  
Strongly Disagree: ___1__, ___2__, ___3__, ___4__, ___5__, ___6__, ___7__: Strongly Agree

Sharing my medications with family and friends is dangerous.  
Strongly Disagree: ___1__, ___2__, ___3__, ___4__, ___5__, ___6__, ___7__: Strongly Agree

I have shared medication with family or friends in the past.  
Strongly Disagree: ___1__, ___2__, ___3__, ___4__, ___5__, ___6__, ___7__: Strongly Agree

I know of a medication disposal center where I can drop off my unused medications.  
Strongly Disagree: ___1__, ___2__, ___3__, ___4__, ___5__, ___6__, ___7__: Strongly Agree

People in my community are choosing to dispose of their unused pain medications  
Strongly Disagree: ___1__, ___2__, ___3__, ___4__, ___5__, ___6__, ___7__: Strongly Agree

My healthcare team wants me to dispose of my unused pain medications.
Strongly Disagree: 1, 2, 3, 4, 5, 6, 7: Strongly Agree

Using recommended disposal methods for medications can help keep the environment safe.
Strongly Disagree: 1, 2, 3, 4, 5, 6, 7: Strongly Agree

Dependent Variable (target outcome)
Did you fill your pain medication prescription?
  o Yes
  o No

Did you elect for partial fill of the pain medication prescription at the pharmacy?
  o Yes
  o No

Do you feel you were given enough prescription pain pills after your surgery?
  o Yes
  o No

Did you contact a healthcare provider for additional prescription pain medication after the initial prescription was finished?
  o Yes
  o No

Do/did you have any unused prescription pain pills after your surgery?
  o Yes
  o No

If yes, how many? ________________

If you had any unused prescription pain pills after surgery, did you dispose of them?
- I disposed ALL of the unused prescription pain pills.
- I disposed SOME of the unused prescription pain pills.
- I chose to keep the unused prescription pain pills.
- I did not have any unused pills - I took them all.

If you chose to dispose some or all of the pills, how did you dispose of them?
- Threw them away in the trash
- Flushed them down the toilet
- Brought them back to a pharmacy
- Disposed of them in a medication disposal box at the medical center
- Other (please specify) __________________________

If you chose to keep some of your prescription pain pills, how many did you keep?________________________

I plan on sharing the information I learned from the video with family and/or friends.

Strongly Disagree:   __1__, ___2___, ___3___, ___4___, ___5___, ___6___, ___7___: Strongly Agree

Did you store your prescription pain medications in a secure, locked place?
- Yes
- No

If no, please explain why______________________________________________________________
Some people decide to keep their unused prescription pain medications. If you chose to keep your unused prescription pain medications, please explain why.
FORM-D
Marlowe-Crowne SF2-10 Scale

Listed below are a number of statements concerning personal attitudes and traits. Read each item and decide whether the statement is true or false as it pertains to you.

<table>
<thead>
<tr>
<th>T</th>
<th>F</th>
<th>1. I never hesitate to go out of my way to help someone in trouble.</th>
</tr>
</thead>
<tbody>
<tr>
<td>T</td>
<td>F</td>
<td>2. I have never intensely disliked anyone</td>
</tr>
<tr>
<td>T</td>
<td>F</td>
<td>3. I sometimes feel resentful when I don’t get my way.</td>
</tr>
<tr>
<td>T</td>
<td>F</td>
<td>4. There have even been times when I felt like rebelling against people in authority even though I knew they were right</td>
</tr>
<tr>
<td>T</td>
<td>F</td>
<td>5. I can remember “playing sick” to get out of something.</td>
</tr>
<tr>
<td>T</td>
<td>F</td>
<td>6. When I don’t know something, I don’t at all mind admitting it</td>
</tr>
<tr>
<td>T</td>
<td>F</td>
<td>7. I am always courteous, even to people who are disagreeable.</td>
</tr>
<tr>
<td>T</td>
<td>F</td>
<td>8. I would never think of letting someone else be punished for my wrong doings.</td>
</tr>
<tr>
<td>T</td>
<td>F</td>
<td>9. There have been times when I was quite jealous of the good fortune of others.</td>
</tr>
<tr>
<td>T</td>
<td>F</td>
<td>10. I am sometimes irritated by people who ask favors of me.</td>
</tr>
</tbody>
</table>
FORM-E
Subject Receipt of Opioid Disposal Content

Directions: the following areas may have been covered to different degrees during the opioid disposal education video you received. Please indicate, using the response options below, to what degree each of the following areas were covered during the opioid disposal educational video. Thank you.

Response Options: 0= Not covered
1= Covered Somewhat- but would have liked more information about this
2= Covered completely

1. The magnitude of the opioid/pain medication crisis: ________
2. Causes of the opioid crisis: ________
3. Ways to safely store prescription pain medication: ________
4. Dangers of keeping unused prescription pain medications: ________
5. Importance of prescription pain medication disposal: ________
6. Ways to dispose of prescription pain pills: ________
7. Environmental impact of safe medication disposal: ________
8. Where to dispose of prescription medications at UMASS Memorial Medical Center: ________

Please let me know what you thought about the educational video. Any feedback both positive and negative is welcome.