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Study: Excess Opioid Disposal Following Orthopedic Foot and Ankle Surgery
NCT03285061

Detailed Protocol

I. Background and Significance

Prescription drug use, particularly opioid analgesics, has become an increasingly prevalent issue in the United States. (1-4) After orthopedic surgery, opioids are most often the drug of choice for post-operative pain management, and orthopedic surgeons are the third highest prescribers of opioid prescriptions among physicians in the United States. (5) With the growing concerns of addiction and abuse, there has been a drive to reduce the prevalence of excess opioid medication in local communities.

In orthopedic surgery, there is variability and unpredictability in provider preference for prescription length and dosage. This further varies by patient and procedure. These factors can result in excess, unused medication, which can be deleterious and even dangerous. For instance, in one study of opioid naïve patients, the probability of long-term use correlated with the opioid dosage during the first post-operative month (6). This suggests that the amount of opioids initially available to a patient may affect the likelihood of long-term use. Additionally, left-over post-operative opioids may fall into the possession of an individual other than the patient to whom the opioid was prescribed.

Developing a system for proper opioid disposal has the potential to decrease misuse. When given a prescription here in the BWH Foot and Ankle clinic, patients are instructed to dispose of left-over medication in the drop box at the main BWH campus or at a similar drop box at a local police or fire department. A recent review of 6 studies with 810 patients found that 67%-92% of patients reported having unused opioids and that 42% to 71% of the pills in the original prescription went unused. However, no more than 9% of patients in any study reported bringing medication to drop off locations to be disposed of properly. (7)

Deterra Drug Deactivation System offers a series of pouches and containers that contain carbon MAT12 that renders opioids non-retrievable and 99% deactivated. Deterra has been proven to work with narcotics, antibiotics and transdermal patches. (8) By deactivating the compounds, they are rendered unusable, and made safe for landfill disposal, meeting both FDA and DEA standards. (8) This product also falls within the guidelines of the Office of National Drug Control policy supporting at home drug deactivation systems for the removal of unwanted medication from the home. (9)

Drug deactivation pouches offer a safe and effective method for opioid disposal. However; it is unknown to what degree patients will use this system compared to the standard protocol that utilizes a community drop box. The current investigation will address this by means of a prospective, randomized control trial in which test subjects be instructed to dispose of unused opioid medications using either a deactivation pouch or a state approved medication drop box.

II. Specific Aims

The primary objective of the study will be to compare patient compliance with two different methods for disposing of left-over opioids following foot and ankle surgery. Specifically, the study will compare disposal using an FDA approved deactivation bag to disposal using a drop-off box.

III. Subject Selection

This study will include foot and ankle orthopedic patients at Brigham and Women's Hospital undergoing a surgical procedure. These patients will stand to benefit from the increased information about opioid use in this population. Those under age 18 will be excluded from this study, as their variation in care could affect the data. Those over the age of 65 will be included and, due to their possible variation in care, we will perform a subgroup analysis of these geriatric patients. We will also exclude adults with impaired decision-making capacity and adults who take methadone or have a history of prior opioid dependence.

IV. Subject Enrollment

Subjects will be identified in the outpatient orthopedic foot and ankle clinic of Brigham and Women's hospital. Patients can be identified at any of the Brigham orthopedic locations: main campus, 850 Boylston, Faulkner Hospital, or Foxborough. Orthopedic foot and ankle outpatients that fit our criteria will be approached during their pre-operative visit by a study staff member. Patients who arrive for a preoperative visit at Brigham and Women's Hospital Orthopedic Foot and Ankle Center will be assigned to either the experimental or control group after consenting. The study staff will then proceed as described in the below procedure.

V. Study procedures

After obtaining approval from the hospital's Institutional Review Board, Brigham and Women's foot and ankle orthopedic surgical patients will be eligible to participate in this study. We will monitor opiate disposal after all foot and ankle orthopedic procedures over the course of four months. We expect to enroll 100 subjects based upon a power analysis. We will exclude patients under the age of 18. We will also exclude adults with impaired decision-making capacity. Finally, we will exclude patients who take methadone or have a history of prior opioid dependence.

Patients will be informed of the nature of the study and, if willing to participate, be verbally consented by someone on the study staff at the patient's pre-operative clinical visit. They will be asked if they would be interested in hearing more about the study. If they respond yes, the person consenting the patient will read through the fact sheet with them and ask if they would like to participate in the study. A record of consent will be

maintained on a Microsoft Excel spreadsheet with the patient's name, date of birth and date of consent. Participants will be informed that their survey responses will be anonymous and remain separate from any documents containing personal information. Subjects will be randomized into 2 categories prior to being given their prescription and instructions for disposal post operatively. 50 patients will be given disposal bags with their prescription medication, and compared to 50 control patients.

Our study will take place at the Brigham and Women's Hospital and its distributed campuses, including the Brigham and Women's Faulkner Hospital, 850 Boylston, and Foxborough. All eligible subjects visiting for a preoperative orthopedic appointment will be recruited. A member of the study staff will explain the study to the patient, including the scope of the questions asked and how the information will be used. A study staff member will also provide the patient with an information form for the patient to read and learn about the research. This will be performed during their clinic visit, after surgery has been decided upon.

Patients enrolled in the experimental group will be given a disposal bag either when they are given their prescription postoperatively or at their initial post-operative visit. A member of the study staff will carefully explain how to use the bag by placing medication inside, pouring in warm water and letting it sit for at least 30 seconds. The bags can then be sealed and thrown out. If a patient forgets, directions for proper use are conveniently printed on the side of the package.

Patients in the control group will not be given a disposal bag. Instead, they will be instructed to dispose of any excess medication at a community drop off site at their local police station or fire department, or at the main BWH campus, as is normal standard care.

All enrolled patients, experimental and control, will be given a survey on an iPad at their 6-week post-operative follow-up appointment. The survey will be anonymously completed on REDCap a Partners approved website. An Excel spreadsheet will be generated with de-identified data responses only. All responses will be stored on Partners secure computers using Partners approved applications.

If a patient does not attend their 6 week follow up appointment, they will be contacted by phone and asked if they would like to complete the survey electronically. If they chose to complete the surveys online, the following statement will be read over the phone to patients:

"The Partners HealthCare standard is to send email securely. This requires you to initially set up and activate an account with a password. You can then use the password to access secure emails
sent to you from Partners HealthCare. If you prefer, we can send you "unencrypted" email that is not secure and could result in the unauthorized use or disclosure of your information. If you want to receive communications by unencrypted email despite these risks, Partners HealthCare will not be held responsible. Your preference to receive unencrypted email will apply to emails sent to you from research staff in this study. If

you wish to communicate with other research staff at Partners regarding additional studies, your preference will have to be documented with each research group."

Depending on the response of the patient, the REDCap link to administer the survey will be sent via the patient's choice of secure or unsecure email. Documentation of the patient's communication preference will be made in the research record.

VI. Biostatistical Analysis

The endpoint for the study will be after all available patients have completed the brief survey.

VII. Risks and Discomforts

The subjects in this study will already be at BWH for an orthopedic foot and ankle procedure. This standard of care will not change. The only difference is the additional survey and provision of the pill disposal bag. Although the Deterra system is not routinely used at BWH, it has been widely used in other healthcare settings and is an approved technology for safe drug disposal. If subjects decline to participate in the study, they will not be offered a Deterra system as it is not routinely administered.

There will be no follow-up or note in the medical record concerning participation in the survey or answers recorded by the subject. No information will go into the patient's medical record regarding their participation in the study.

The subjects' responses to our survey will remain confidential. Subjects will not be forced to fill out the questionnaire and, if they choose, may decline to answer any of the questions. It is anticipated that the questionnaires have no affiliated risk of physical or emotional harm.

This study carries no associated risk of physical or emotional harm to the subjects. If the subject feels uncomfortable participating in the study or answering any of the questions, he/she may decline to participate. The questionnaire responses will remain anonymous.

VIII. Potential Benefits

The study may benefit patients by removing potentially harmful medication from their homes, reducing the risk of abuse and overdose. It will also help determine if this is an effective means of excess drug disposal for future patients and the community at large.

IX. Monitoring and Quality

Study staff listed in IRB is responsible for monitoring validity and integrity of all data. All data will be collected, viewed, recorded, and analyzed only by members of the study staff. Principal investigators will oversee all monitoring and quality assurance.

X. References

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