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Introduction

It is well documented that medication adherence is of great concern in many patients including those taking opioid pain medication. Taking medications outside of the prescribed regimen can lead to adverse events and can lead to improper adjustments to medication regimens. Additionally, diversion issues continue to be a problem with opioid pain medications, and the hospice setting is not devoid of these issues in palliation of symptoms including pain. A novel device, TAD, has been developed to aid adherence to prescribed regimens and may have a roll in hospice pain management. The TAD device collects dose timing information that can help clinicians assess patient compliance and can be programmed to dispense a dose in a specific time frame. This device can operate with and without the assistance of a mobile device application. However, concerns about the ability of the hospice patient population to use the technology exist.

This study aims to assess medication adherence relating to missed doses or improperly timed doses with and without the aid of a mobile device as a primary endpoint. Secondary endpoints will be patient, nursing, and provider satisfaction.

Inclusion/Exclusion Criteria

Inclusion criteria for the study are any Haven patient taking morphine ER or Oxycontin on one of three hospice home teams, Lake City, Palatka, or Gainesville. There will be no gender or racial bias in consideration for inclusion. Vulnerable patients will be included in this study as many of our patients suffer from dementia and are cognitively impaired. Inclusion in the study of a cognitively impaired patient will require the presence of a caregiver that is a legally authorized representative (LAR) of the patient. Exclusion criteria are age less than 18 and patient or caregiver inability to demonstrate competent use of the TAD device. Also, no pregnant women are under hospice care at Haven as they would not be appropriate for hospice. Patients that will be studied will primarily be in their own homes but may transition through Haven hospice care centers periodically. A patient's capacity to consent will be determined from the patient's medical assessment by the patient's hospice provider. Reassessment of the patient's understanding and willingness will occur with each phone call survey by asking the patient if they wish to continue the study. If the patient has been enrolled in the study without the capability to consent, the caregiver will be asked at every visit if they wish to continue the study.

The study will aim to accumulate approximately 1600 patient days with 20 patients enrolled each for 12 weeks. Three sites will be used, and each should have 6 to 7 patients enrolled.

Methods

Potential subjects will be identified by observing Morphine ER and Oxycontin utilization reports at Haven. Once a patient is identified as taking one of these medications, they will be contacted by telephone by a study investigator to set up a visit time to discuss the study in the patient's home or in a Haven inpatient care center if the patient is agreeable. All care centers have private rooms and provide a confidential environment for discussion. Upon, visiting the patient in person, written informed consent will be obtained and the patient will keep a copy for their records. Physicians, ARNPs, and nurses at the study sites will receive consent documentation via secure encrypted email but will not be required to sign the consent.

Patients will be randomized in a cross-over design to either use the TAD device with a mobile device or without a mobile device for 2 weeks, and then, alternate to the opposite group, respectively, for an additional 2 weeks. After the initial 4 weeks, patients will be allowed to choose whether or not to use the TAD device with or without a mobile device for the remaining 2 months of the study. An investigator will then provide patient education on the TAD device using a demonstration device and document the patient's ability to demonstrate proper use of the device. If a patient owns a mobile smart phone, the TAD application will run on the patient's phone. If a patient does not own a mobile device, Intent Solutions will provide a mobile device to the patient for use with the TAD device. If the patient or caregiver are unable to operate the mobile device application properly after instruction by an investigator, the patient will be categorized as "failed" for the mobile device phase of the cross over period. Primary outcome data will be collected by Intent solutions from the TAD device. No PHI will be obtained by Intent solutions in the data collected. Patient, nursing, and prescriber satisfaction surveys will be filled out weekly for each patient for the first 4 weeks and then every 2 weeks thereafter. In the event that the patient has a LAR acting on their behalf, the LAR will answer the survey questions.

The attending provider for the patient will send a prescription via fax to the mail order pharmacy for a 14-day supply. The mail order pharmacy staff will be adequately trained to place tablets inside simple gelatin capsules of appropriate size for the purpose of consistent dose delivery size pertaining to the TAD device. Also, the pharmacy staff will be trained on all functions of the TAD device including data collection. The TAD device filled with the patient's medication will be mailed to the patient 3 days before the last dose of the medication with a return label and packaging for the TAD device via second-day delivery so that there is no delay in drug therapy. If the patient has partial fills left on the prescription 3 days before the last dose of the medication, the registered nurse will call the mail order pharmacy to send another supply of the medication to the patient. When the patient has taken the last dose of medication, the patient or caregiver will send the TAD device to the principle investigator who will then ship the device back to Intent Solution upon verification that no patient information is labeled on the device. If there are no partial fills left, the registered nurse will notify the provider to send a new prescription to the mail order pharmacy. Should the device fail for any reason or the patient is unable to access the medication using the device, the patient will be categorized as "failed" for duration of the study, the registered nurse will contact the provider, and the provider will fax a prescription immediately to a local pharmacy for the patient. In this scenario, the registered nurse would remove the medication from the TAD device using a proper tool and dispose of the medication stored in the device in the Rx Destroyer product. The patient and/or caregiver will witness the disposal as part of normal clinical practice when a nurse disposes of medication. The patient would then send the TAD device to the principle investigator who will then ship the device back to Intent Solution upon verification that no patient information is labeled on the device. If the patient passes away while the TAD device still contains medication, the registered nurse will empty the device of medication and send the device to the principle investigator who will then ship the device back to Intent Solution upon verification that no patient information is labeled on the device. The medication will be disposed of by the registered nurse if the nurse attends time of death or if asked by the caregiver. Otherwise, the caregiver will be responsible for disposal of the medication as the caregiver becomes the party responsible for the medication at the time of death. At the completion of the study or at any point during the study the patient chooses to withdraw from participation in the study, the nurse will dispose of the medication and send the TAD device to the principle investigator who will then ship the device back to Intent Solution upon verification that no patient information is labeled on the device. The patient will then have a prescription filled at a local pharmacy for the medication.

Any patient safety issues reported to the investigators as concerns about the study protocol will be assessed monthly at the Haven patient safety committee meeting.

Analysis of Results

Demographic information such as birth date, race, sex, and hospice diagnosis will be collected as descriptive characteristics of each group. The primary endpoint will be measured as time of the dose taken compared to time when the dose was scheduled and whether the dose was completely missed or not. A missed dose will be greater than 1 hour before or after the scheduled dosing time. Secondary endpoints will evaluate patient, nursing, and physician satisfaction from the weekly survey for trends.

Storage of Data

Data collected by Intent Solutions on the primary outcomes will be sent to the primary investigator via encrypted email with document password protection. No PHI will be in this data and all data will be referenced to the patient's study identification number. All data will be recorded and stored on a secure network drive with limited user access. Additionally, the files containing research data will be password protected. All paper surveys which only contain the patient's assigned study number and PHI will be kept in a locked cabinet in a locked office until completion of the study at which point the paper surveys will be destroyed in confidential trash.

Risks and Benefits

The only minimal risk to the patient is that the device could malfunction or the patient may not be able to properly operate the device. The process for acquiring the medication is noted above and would ultimately not prevent the patient from receiving their medication should the device fail.

The potential benefit to the patient is that the device may aid the patient in taking the medication as intended by the provider and prevent missed doses.

Informed Consent

Informed consent will be required for every patient to be enrolled. In the case that the patient suffers from dementia and/or is otherwise deemed incapable of consenting by review of the medical records, the LAR will provide consent.

Cost/Compensation

There is no cost to the patient, and no patient will receive compensation for participation in the study.