2019 ACMT Annual Scientific Meeting
MedTox Shark Tank Research Forum

Primary Investigator: Amelia Curtis, Stephanie Carreiro
Department of Emergency Medicine
University of Massachusetts Medical School, Worcester, MA

Title: Smart Pill Bottles to Measure Medication Usage and Fidgeting Behaviors in Short Term Opioid Prescriptions

Background:
Medication non-adherence, such as underuse or overuse, is a significant contributor to preventable hospital admissions and associated morbidity and mortality. Biosensor systems, including ingestible and wearable sensors and smart pill bottles that detect participant interactions with medication containers, are of increasing interest as a means of decreasing non-adherence. In the midst of the ongoing opioid epidemic, accurate measures of how patients are taking their medications are essential for clinicians prescribing opioid analgesics.

We are interested in understanding how patients interact with pill bottles containing opioid medications, as compared to non opioid analgesics and non analgesic medications (e.g. antibiotics). In prior research, individuals with prescription opioid dependence reported increased craving, anger, and anxiety, and demonstrated increased heart rate after exposure to opioid related cues including pill bottles. In this manner, pill bottles appear to function as "cues" in cue reactivity, a phenomenon wherein an individual learns to associate the positive effects of a substance with certain previously neutral environmental cues associated with its use. In prescription drug use and other substance use disorders, cue reactivity has been associated with craving and relapse. Also established is that restlessness and fidgeting behaviors are inherent in the opioid withdrawal syndrome as well opioid craving. We hypothesize that the smart pill bottles may serve as both a cue, or trigger, in cue reactivity, as well as a method of measuring craving or withdrawal through measurement of fidgeting behavior.

Aims:
The overarching goal of our work is to understand factors that contribute to the development of opioid use disorder following therapeutic opioid use. In this study, we intend to deploy a novel smart pill bottle system with the intent of understanding whether interactions with medication containers can accurately detect opioid-craving behaviors. To accomplish our goals, we will:

1. Evaluate efficacy of our smart pill bottle at measuring pill dispensing events. *We hypothesize that the smart pill bottle will provide us with accurate data of medication use when compared to patient generated logs and final pill counts.*
2. Evaluate acceptance of smart pill bottle technology by participants. *We hypothesize that participants will be accepting of the smart pill bottle and find the technology unobtrusive.*
3. Measure frequency of patient interactions with the pill bottles that are not associated with pill dispensing. *We hypothesize that patients will have a greater frequency of interactions ("fidgeting") with smart pill bottles containing opioid medications than non-opioid medications.*

Methods:

1. Smart Pill Bottle. The metawear smart pill containers used in this study have been designed and tested by engineers at the University of Massachusetts at Amherst. The smart pill container utilizes a single sensor in the base of the pill bottle that collects accelerometer and gyroscope data. The outer surface of the bottle is covered with a capacitative touch surface that detects participant touch and subsequently activates the motion sensor and data streaming function of the bottle, limiting the amount of noise collected from spurious bottle movements and allowing us to see how frequently the participants interact with the pill bottles.
2. **Setting/Adequacy of Study Population**: Given the preliminary nature of our study, we have elected to enroll from the emergency department (ED) during hours of study staff availability. We will recruit study participants from individuals receiving care in the UMass Memorial Medical Center Emergency Departments. This medical center is divided into two campuses, together treating approximately 135,000 patients annually. Given the large number of patients evaluated in the Emergency Department for acute conditions, we think that this will serve as an adequate setting to approach patients who will be started on a new prescription medication for a short duration. In future studies, we will plan to enroll patients from other settings (e.g. outpatient clinics) and include patients on longer-term medication regimens.
3. **Inclusion Criteria**. We will include patients who are:
- Age ≥ 18 years old;
- Presenting to the Emergency Department (ED);
- Planned discharge from the ED with a new prescription for an opioid analgesic, non opioid analgesic, or an antibiotic for a <7 day course;
- Able to dispense their own medications directly from the bottle;
- Not already using other smart pill containers or medication organization systems (e.g. weekly pill boxes);
- Able to provide informed consent;
- Able to communicate in English.

4. **Exclusion Criteria**. Patients will be excluded if she or he is:
- Age < 18 years old;
- Unable or unwilling to dispense their own medications directly from the bottle;
- A prisoner or in police custody

5. **Specific Aim 1**: Evaluate the efficacy of our pill bottle at detecting pill removal events as compared to prior standards of in-person pill counts and patient self-report. Pill dispensing events captured by the smart pill bottle gyroscope and accelerometer will be streamed by a Bluetooth beacon and reviewed by study staff. These event logs will be compared to patient generated logs of medication use as well as in-person pill counts at a follow-up visit.
6. **Specific Aim 2**: Evaluate the acceptability of our smart pill bottle with participants. At the follow up visit, we will determine if the participants found the technology acceptable in day to day use. We will communicate any participant concerns back to the engineering team for iterative design improvements.
7. **Specific Aim 3**: Determine frequency of fidgeting behavior of participants with the opioid containing bottle as compared to non opioid containing bottles.
The touch capacitance bottle coating permits collection of data on interactions with the smart pill bottles even when a pill is not dispensed. We will compare the frequency and timing of such non-goal-directed interactions ("fidgeting") between the different classes of medications prescribed. We will determine if any differences exist between classes of medications, as well as if there are any patterns regarding when these fidgeting behaviors occur (e.g. time of day, proximity to next dose, day of therapy).

Major Limitations/Questions:
This is a preliminary study set in a single academic health center ED. Future studies in other health systems and health care settings (e.g. outpatient offices) will provide more robust data regarding accuracy and acceptability of our smart pill bottle to participants. We also anticipate that different trends in fidgeting behavior would be observed in patients on long term opioid therapy as compared to those started on short courses in the ED.