TITLE: Determining optimal pain medication prescription for postoperative outpatient surgical pain using an innovative oral patient controlled analgesia (PCA) device

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BACKGROUND: Despite guidelines to help educate physicians on appropriate use of opioids, several studies have shown that physicians over prescribe opioid medications for patients of which a vast majority are unused and thus a potential target for theft, abuse, and drug diversion. 67%, 86%, and 93% of patients who underwent outpatient urological surgery, dermatological procedure, and upper extremity surgeries, respectively, had more than 50% of their prescription opioids left unused. With over 19.9 million surgeries in hospitals and 14.9 million surgeries in freestanding ambulatory surgery centers performed each year in the United States alone, there exists a huge potential surplus of unused opioids due to overprescription that can be diverted to non-medical users of prescription opioids. We hypothesize that surgeons who receive objective feedback on a patient's postoperative pain using opioid dispensation data as a surrogate marker, will give them confidence to prescribing fewer quantity of short acting opioids for future patients undergoing similar surgical procedures.

For the past 6 months, our engineering team is producing a proof of concept internet connected oral PCA dispenser that is portable, holds 60 tablets of short-acting opioid, performs unit dose dispensing, recognizes patient's thumbprint for activation, is able to be programmed on the device itself, records and transmits unit dispensation device to a HIPAA-compliant server, and functions when there is no WiFi connection. A barrel with 6 chambers will hold 60 oxycodone tables. A spring will apply constant downward force on each column. A patient will press the side button with embedded thumbprint reader. The dispenser will check whether the thumbprint is valid and whether the patient is due for their medication. If both are true, then the actuator will move to the off position allowing the button to fully depress, causing the chamber to rotate once, and aligning one silo in the round chamber with the single pill holder. The patient withdraws the button with the pill in the chamber and the actuator turns back on preventing another dispensation. If the prescription calls for two pills, the actuator remains in off position and patient can press the button a second time to retrieve the mediation.

RESEARCH PLAN: Evaluation and validation of efficacy of the device in allowing for delivery of the lowest effective dose in the quantity needed and in improving medication adherence.
Subaim 2.1. To conduct focus groups and surveys with patients and physicians at regular intervals during the design process for the cartridge, device, and software. We will conduct a survey of prescribers to collect data on preference of prescription opioids for post-operative pain management (to be used for design of pill dispenser/cartridge).
Subaim 2.2. To review the prescription patterns and patient characteristics from outpatient surgeons to collect baseline prescription data for post-operative pain management, and to identify a study population for the early feasibility study.
Subaim 2.3. To simulate use of PICARD and measure adherence in an outpatient setting, we will identify 5 participants who will receive opioids upon discharge for a surgical procedure. Patients will be given a log to write down any issues with the device. We will provide 24/7 troubleshooting, technical support and monitor data that is returned from the device through the web portal.

EXTRAMURAL FUNDING PLANS: At the end of the funding period, we will data showing proof of concept of our device and data to improve on the design and functionality. We will then write grants for funding opportunities from the National Institute of Drug Abuse, National Institute of Aging, and University of California Center for Accelerated Innovation to help fund our clinical trial on use of the oral PCA in improving ability of the physician to prescribe the lowest effective dose of short acting opioids in the quantity needed for the expected duration of postoperative pain, thereby reducing unused prescription opioids.