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# Feasibility and Acceptability of a Mobile Application to Monitor Opioid Use and Promote Behavior Modification Following Cesarean Section

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## Abstract

Opioid misuse and associated negative sequelae, including opioid use disorder and overdose, continue to comprise a public health crisis of epidemic proportions. One opportunity for upstream primary prevention of opioid misuse is the management of opioid use during the postoperative period, including following cesarean section. Research shows that most patients who have a cesarean delivery receive a prescription for opioids on discharge, though limited data exist on postoperative opioid use and misuse. Continuous Precision Medicine (CPM) has developed a mobile application that allows patients to track their pain and usage of both opiates and non-steroidal anti-inflammatory (NSAID) medications and includes elements intended to promote behavior modification through psychoeducation and gamification. The aims of this study were to determine logistical and technological feasibility and acceptability of the mobile application by patients and clinicians and to assess preliminary postoperative opioid use and misuse patterns to inform future directions. Participants ($N = 9$) were women between the ages of 23 and 41 years old who underwent a repeat cesarean section at an inner-city academic hospital and were without a history of self-reported opioid use. Participants received a tablet loaded with the mobile application and electronic pill packs with the standard postoperative prescription of 14 Roxicodone tablets. On review, 53% of opioids were unused. Four patients took four or fewer Roxicodone pills, with three patients taking none. Additionally, three were noted to have aberrant behavior that was inconsistent with prescribed instructions

provided to the patient by the provider. Results of this feasibility study suggest that the CPM mobile application is feasible and acceptable for both patients and practitioners and provides traceability for clinicians to make better-informed decisions regarding patient care. Preliminary data suggest an excess of prescribed narcotics as well as a potential concern for utilization of medication not as prescribed.

## Keywords

Opioids, Misuse, Pain Management, Obstetrics, Cesarean Section, Mobile Application, Maternal Health, Prescribing Practices, Primary Prevention

## 1. Introduction

Opioid misuse and associated negative sequelae, including opioid use disorder and overdose, continue to comprise a public health crisis of epidemic proportions, and opioid-related harms have continued to increase over the past two decades (Upp & Waljee, 2020). Among civilian, noninstitutionalized adults living in the United States, more than 9.7 million people (3.5%) misused prescription opioids (Substance Abuse and Mental Health Services Administration, 2020), and drug overdose deaths in the United States rose 29.4% in 2020 to an estimated 93,331, including 69,710 involving opioids (Ahmad et al., 2021; Centers for Disease Control and Prevention, 2020). The cost of opioid overdose, abuse, and dependence in the U.S. has been estimated at $78.5 billion annually, which includes health care costs, productivity loss, the cost of addiction treatment and criminal justice involvement (National Institute on Drug Abuse, 2021). Including reduced quality of life from opioid use disorder and the value of life lost due to fatal opioid overdose increases that estimate to be more than $1 trillion (Florence et al., 2021).

### 1.1. Prescription Opioids

Among opioid overdose deaths in 2017, 35% are credited to prescription opioids (Upp & Waljee, 2020). One risk factor related to opioid misuse and abuse is prescription following minor and major surgical procedures (Brummett et al., 2017). Many people receive their first exposure to opioids after surgery. Despite this concern, postoperative opioid prescription patterns are commonly variable for the same surgery and often with excess opioids dispensed (Hill et al., 2017; Hill et al., 2018a, 2018b). According to a large cohort study, 6% of these patients had new persistent opioid use, defined as use 90 days after surgery (Brummett et al., 2017). Furthermore, many surgeries have been associated with increased risk of chronic opioid use, which was defined as filling 10 or more prescriptions or more than 120 days' supply in a 1-year period (Sun et al., 2016). In a retrospective analysis of a variety of surgeries and risks of chronic opioid use in previously opioid naïve patients, those who underwent cesarean delivery had a 28% increased

risk of chronic opioids use compared to nonsurgical patients (Sun et al., 2016). More recently, a large US national cohort study of 308,226 deliveries found rates of new persistent opioid use to be 2.2% for cesarean delivery (Peahl et al., 2019).

### 1.2. Opioids Following Cesarean Section

This is of particular importance for women for whom opioid-related death has been associated with an initial exposure during routine medical care. For many women, this exposure is during their postpartum care. Approximately one-third of women will undergo cesarean section and it is currently common practice to prescribe opioids for postoperative pain (Bateman et al., 2016). Furthermore, one in seventy-five women in the United States who have filled an opioid prescription in the peripartum period will continue to fill prescription one-year postpartum (Peahl et al., 2020). The high prevalence of cesarean section along with opioid prescription pattern in the postpartum period makes this a clear place for intervening in the opioid crisis (Washio et al., 2020).

A recent retrospective review highlights a wide range of morphine milligram equivalents (MME) prescribed at hospital discharge following delivery (Badreldin et al., 2018). Specifically, 86.7% of women who were post-cesarean delivery received a prescription at discharge, with a median MME of 300, or 15 tablets of oxycodone, but a wide variation in opioid prescription patterns was identified (Badreldin et al., 2018). Of these patients, 18.5% used 0 MME during the final hospital day. A separate multi-site prospective study was completed to address the lack of evidence on optimal amount of prescription opioids after cesarean delivery. In this study, women were enrolled 24 hours after delivery of an elective or unplanned cesarean delivery and were called 2 weeks after hospital discharge to review opioid use and satisfaction with pain management postpartum (Bateman et al., 2017). Results revealed that the median number of dispensed opioid tablets was 40, the median number consumed was 20, and the median number leftover was 15 (Bateman et al., 2017). Of those with leftover opioids, 95.3% had not disposed of the excess medication at the time of the interview (Bateman et al., 2017). There was an association between a larger number of tablets dispensed and the number consumed, independent of patient characteristics, and the amount of opioids dispensed did not correlate with patient satisfaction, pain control, or the need to refill the opioid prescription (Bateman et al., 2017). This study identified the lack of standardization of opioid dispensing along with the significant excess of opioid prescription but was limited by a reliance on patient recall and lack of data on specific time of opioid use (Bateman et al., 2017).

### 1.3. Technology-Based Health Interventions

Over 97% of Americans own cellphones, 85% of which are smartphones; this is even more pronounced in younger adults, as 96% of people between 18 and 29

years old, and 95% of people between 30 and 49 years old, own smartphones (Pew Research Center, 2021). As a result, technology-based health interventions are becoming increasingly common. Smart applications specifically have been used to augment treatment for substance use disorders, promote self-management of chronic conditions, engage patients with health research, assess or measure symptoms, and assist with adherence to both treatments and appointments (Frank et al., 2018; Ploug & Holm, 2017; Santo et al., 2017; Scott et al., 2017). Research has reported a number of ways in which these technologies may be used for substance use disorders, including text messages, web-based software, and mobile applications (Tofighi et al., 2018). In patients with chronic pain, a pilot study found that 78% of patients who downloaded an app to track their pain used the daily report feature and in the first month of use, patients submitted 16.4 daily assessments. Patients found the application easy to use and reported willingness to use the application even after the study was complete (Jamison et al., 2017). Additionally, evidence suggests that symptom reporting with smart applications is well tolerated by patients and has better validity and reliability than hard copies, which often rely on recall (Jamison et al., 2017). Previous studies have shown the feasibility and acceptability of several methods of electronic monitoring of medication to promote adherence (Aguilar-Rivera et al., 2020; Robiner et al., 2015).

### 1.4. The Present Study

Currently, there are no studies using a smart application for evaluation of opioid consumption in the postpartum period. The present study uses a combined effort of a "smart pill pack" and a smart application (CPMRx) to capture accurate pain medication consumption, including opiates, nonsteroidal anti-inflammatories (NSAIDs) and acetaminophen, and the corresponding pain scores at the time of consumption. This application has been designed to promote behavior modification through psychoeducation and gamification and is currently being piloted at several large health systems. The aims of this study were to determine logistical and technological feasibility and acceptability of the mobile application by patients and clinicians, and to assess preliminary postoperative opioid use and misuse patterns to inform future directions.

## 2. Methods

### 2.1. Participants

Patients between the ages of 18 and 50 years who were undergoing a scheduled repeat cesarean section at an inner-city academic hospital were recruited between February 2020 and March 2021. Patients were offered the option to use the Continuous Precision Medicine mobile application (CPMRx) in conjunction with their current standard of care post-delivery. Exclusion criteria for participation included patients with contraindications to opioids, NSAIDs or acetaminophen (including but not limited to allergy, intolerance, history of prior misuse,

inability to tolerate pills), a diagnosis of acute or chronic pain disorder, use of an opioid within the past 12 months, non-English speaking, unable to provide consent and if the patient was currently incarcerated. A total of ten participants were recruited and one was lost to follow-up. The study was approved by the institutional review board of Temple University Hospital prior to recruitment of participants. All participants provided voluntary written informed consent.

### 2.2. Data Sources

To assess acceptability and feasibility outcomes, we utilized two sources of data: patient assessments and the mobile application. The patient assessments assessed acceptability and were completed by patients at the end of their post-operative period. The assessment took approximately 3 minutes to complete and included questions on acceptability, usability, and perceived usefulness. The patient provided information via the mobile application on their current level of pain, usage of NSAIDs, and dosage and timing of opioid use. Subject usage data were de-identified and stored locally on the device prior to being uploaded for monitoring and analysis. To assess opioid use and identify potential patterns in usage after discharge, an electronic monitoring pill pack was also dispensed that would time-stamp medications as they were used at home.

### 2.3. Study Design and Conduct

Patients were recruited for study participation during their prenatal visits. After their procedure, a member of the team met with each subject to review the study, obtain consent to participate, and demonstrate the usage of the tablet and the CPMRx app, which was issued on third-party hardware and the electronic pill pack.

At the time of discharge, patients have been prescribed pain medications according to usual practice at Temple University Hospital. The current postoperative standard of care advises a stepwise approach. Patients were instructed to take scheduled ibuprofen (dispense 28 tablets) and acetaminophen (dispense 28 tablets). Opioids (14 tablets of Roxicodone) were reserved for breakthrough pain control. The patient was directed to take this medication post-operatively as an outpatient. The medications' (ibuprofen, oxycodone and acetaminophen) anticipated use is approximately 1 to 2 weeks postoperatively. The ibuprofen, acetaminophen and Roxicodone were pre-loaded into the smart pill packs and provided to the patients at the time of discharge.

Upon discharge, the patient self-manages their pain using the pain medications prescribed to them in the electronic pill packs. When the subject required pain medication, they were instructed to use the CPMRx application. The first screen of the application allowed subjects to report a pain score prior to taking medication. The patient was instructed to journal pain whenever pain is greater than 0 and before taking any form of pain medication, both opioid and nonopioid. When a patient indicated that they were going to take a dose of medication, the

subject was prompted for their pain level on a standard 0 - 10 pain scale. For low levels of pain (0 - 2), the subject was directed to a new screen asking if an opiate dose is needed. If yes, the subject was then asked if they had recently taken ibuprofen or acetaminophen to manage pain. The subject was then offered an option to postpone the dose and then directed back to the home screen. For moderate levels of pain (3 - 8), the subject was asked if they had recently taken ibuprofen or acetaminophen to manage pain. The subject was then offered an option to postpone the dose and then directed back to the home screen. For severe levels of pain (9 - 10), the subject was prompted to call 911 if they considered the pain a medical emergency.

Within seven days after discharge, a member of the research team called the patient to remind her to return the tablet with the downloaded electronic application and the smart pill-packs to the research site when they came to the office for a postoperative check at 1 to 2 weeks postpartum. When the subject returned to deliver the pill packs, the research coordinator downloaded the compliance data. The subject then completed a satisfaction questionnaire.

### 2.4. Statistical Analysis

All analyses were run using SAS version 9.4 software (SAS Institute Inc, Cary, NC). We used univariate analyses on data from patient assessments to examine the distribution of responses related to acceptability. To assess feasibility of the mobile application in managing pain and reducing opioid use, we examined group-level rates of opioid use and potential misuse.

## 3. Results

### 3.1. Sample Characteristics

Participant characteristics mirrored those of the hospital's obstetrics department in general and are listed in Table 1. Participants ($n$ = 9) ranged in age from 23 to 41 years old with an average age of approximately 29 years old. The average BMI at time of delivery was consistent with obesity with a BMI of 34. While only patients undergoing a scheduled repeat cesarean section were eligible, 88% of participants ($n$ = 8) had a history of one prior cesarean section. Fifty-five percent of participants ($n$ = 5) identified as African American or Black and 22% ($n$ = 2) as Hispanic. One participant reported her race as White.

### 3.2. Descriptive Statistics

***Acceptability of mobile application***. Of the nine participants, six participants completed the questionnaire provided to them. This is because three participants did not return for postpartum visit and required several phone calls in order to return issued tablet and pill-packs. Results from the six participants after completion of questionnaire revealed that the use of a mobile application was feasible. Four of six participants found the applications "very easy" to use and two participants reported it was 'easy' to use. Five participants found the study

Table 1. Participant characteristics.

| | Number (SD) |
|---|---|
| Total Participants | 9 |
| Age In Years | 29.8 (6.1) |
| BMI | 34 (8.6) |
| Race | |
| White | 1 |
| Black | 5 |
| Other | 3 |
| Ethnicity | |
| Hispanic | 4 |
| Non-Hispanic | 4 |
| Unknown | 1 |
| Smoking | |
| Current | 1 |
| Former | 2 |
| Gravity | |
| G2 | 7 |
| G3 | 1 |
| G4 | 1 |
| Parity Hx | |
| Preterm | 3 |
| Term | 7 |
| Abortion | 3 |
| Gestational Age at Time of C-Section | 38w1 (2 Days) |
| Anxiety | 1 |
| Depression | 1 |
| Breastfeeding | 8 |
| Readmission | 1 |

to take "very little" time and one participant found it to be 'reasonable.'

***Patterns of opioid use and pain.*** Overall patient medication use, application use, and pain scores are reported in Table 2. Data from the 9 participants showed that 33% of participants ($n$ = 3) used 0 Roxicodone after discharge and 11% ($n$ = 1) used only 4 Roxicodone pills. The mean number of opioids used was 6.55 ($SD$ = 5.83).

As all patients were prescribed ibuprofen (28 tablets), acetaminophen (28 tablets), and oxycodone (14 tablets), the total number of oxycodone (Roxicodone) prescribed in the study was 126 tablets. Results indicated excess opioid dispersal,

Table 2. Overall patient medication and application use.

| Patient ID | Number of opioids used | Number of NSAIDs used | Number of acetaminophen used | Number of App entries | Average time (hr) between doses | Average pain score |
|---|---|---|---|---|---|---|
| 001 | 4 | 0 | 20 | 4 | 16.8 | 8.8 |
| 002 | 0 | 0 | 11 | 11 | - | 3.5 |
| 003 | 0 | 0 | 28 | 18 | 9.4 | 5.7 |
| 004 | 0 | 5 | 14 | 11 | 11.5 | 4.5 |
| 005 | 14 | 28 | 28 | 15 | 216 | 6.6 |
| 006 | 9 | 20 | 23 | 22 | 18.9 | 6.9 |
| 007 | 14 | 6 | 14 | 10 | 12.5 | 7.3 |
| 008 | 11 | 7 | 10 | 11 | 14.9 | 1.7 |
| 009 | 8 | 14 | 14 | 27 | 7.2 | 3.4 |

with 53% of these tablets recorded as unused. This leaves 67 unused tablets that are available for potential diversion into the community.

On review of pill pack data, 3 participants were flagged for aberrant behavior, and were the three patients who took the most opioids. Review of pill dosage and timing among Participant 005, Participant 007, and Participant 008 revealed irregularities in the way they took the medications, which did not correspond with the way the medications were prescribed. For instance, on discharge, patients are advised to alternate taking ibuprofen and acetaminophen at lower pain scores ranging from 1 - 7. They are advised to take these tablets prior to taking oxycodone, which is to be used for breakthrough pain. Participant 005 was noted to use all prescribed tablets of ibuprofen, acetaminophen and Roxicodone. On review of the timing of usage, Participant 005 was using all three medications at the same time for a pain score of 5. The patient also took more than was prescribed (975 mg of acetaminophen vs 650 mg of acetaminophen prescribed, 1200 mg of ibuprofen vs 600 mg ibuprofen prescribed) and was also noted to take all medications at the same time (i.e., 975 mg acetaminophen, 1200 mg ibuprofen and 10 mg of Roxicodone) and then again improperly took 600 mg of ibuprofen approximately 2 hours later. See the corresponding Table 3.

Unusual use of prescribed prescription was also noted with Participant 008. On several occasions, the patient was noted to take all three or two of the medications, with one being Roxicodone, for what is considered low pain scores (0 - 3). Medications were not only incorrectly taken but also were noted to sometimes exceed the maximum single dose that was prescribed (i.e., 1200 mg of ibuprofen at one time). See Table 4 below for medication usage information.

## 4. Discussion

Results of this feasibility study suggest that the CPMRx mobile application is feasible and acceptable for both patients and practitioners and provides traceability for

Table 3. Example of medication misuse by participant 005.

| Participant 005 | | |
|---|---|---|
| **Medication** | **Times Dispensed** | **Pain Score** |
| Opioid | 7/26/2020, 5:58:45 AM | 5 |
| Ibuprofen | 7/26/2020, 5:59:05 AM | 5 |
| Ibuprofen | 7/26/2020, 5:59:05 AM | 5 |
| Acetaminophen | 7/26/2020, 5:59:14 AM | 5 |
| Acetaminophen | 7/26/2020, 5:59:14 AM | 5 |
| Acetaminophen | 7/26/2020, 5:59:14 AM | 5 |
| Opioid | 7/26/2020, 5:59:45 AM | 5 |
| Ibuprofen | 7/26/2020, 8:05:05 AM | 5 |

| Participant 005 | | |
|---|---|---|
| **Medication** | **Times Dispensed** | **Pain Score** |
| Opioid | 7/27/2020, 8:53:44 PM | 5 |
| Opioid | 7/27/2020, 8:53:44 PM | 5 |
| Acetaminophen | 7/27/2020, 8:54:00 PM | 5 |
| Ibuprofen | 7/27/2020, 8:54:16 PM | 5 |

Table 4. Example of medication misuse by participant 008.

| Participant 008 | | |
|---|---|---|
| **Medication** | **Times Dispensed** | **Pain Score** |
| Acetaminophen | 3/22/2021 10:26:46 PM | 2 |
| Acetaminophen | 3/22/2021 10:26:46 PM | 2 |
| Opioid | 3/22/2021 10:27:14 PM | 2 |
| Opioid | 3/22/2021 12:00:15 AM | 1 |

| Participant 008 | | |
|---|---|---|
| **Medication** | **Times Dispensed** | **Pain Score** |
| Acetaminophen | 3/22/2021 9:46:46 AM | 1 |
| Acetaminophen | 3/22/2021 9:46:46 AM | 1 |
| Opioid | 3/22/2021 9:47:15 AM | 1 |

| Participant 008 | | |
|---|---|---|
| **Medication** | **Times Dispensed** | **Pain Score** |
| Acetaminophen | 3/23/2021 9:25:12 PM | 3 |
| Acetaminophen | 3/23/2021 9:25:45 PM | 3 |
| Ibuprofen | 3/23/2021 9:25:45 PM | 3 |
| Opioid | 3/23/2021 9:26:28 PM | 3 |

| Participant 008 | | |
|---|---|---|
| **Medication** | **Times Dispensed** | **Pain Score** |
| Opioid | 3/25/2021 10:15:08 PM | 1 |
| Ibuprofen | 3/25/2021 10:16:26 PM | 1 |
| Ibuprofen | 3/25/2021 10:36:26 PM | 1 |

| Participant 008 | | |
|---|---|---|
| **Medication** | **Times Dispensed** | **Pain Score** |
| Opioid | 3/25/2021 12:33:10 AM | 1 |
| Opioid | 3/25/2021 12:33:10 AM | 1 |

| Participant 008 | | |
|---|---|---|
| **Medication** | **Times Dispensed** | **Pain Score** |
| Opioid | 3/27/2021 10:32:04 PM | 1 |
| Ibuprofen | 3/27/2021 10:33:23 PM | 1 |

clinicians to make better-informed decisions regarding patient care. All participants found the application easy to use. Participants also found that the time it took to be "very little" or "reasonable" indicated that the device did not add additional burden to the participants. This indicates that scaling up implementation to a larger patient population would be feasible.

The results from this study also suggest that there is diversity in the use of opioids after cesarean section but that a majority of patients do not use the entire opioid prescription. Results of this study show that 53% of opioids were unused and 44% of patients took 4 or fewer Roxicodone pills. This parallels previous studies that show concern for excess opioid prescriptions allowing for more opioids that could be diverted out into the community. It is reasonable to consider prescribing fewer narcotics at the time of discharge and re-evaluating postoperative pain at their one-week incision check. Currently, a one-week incision check is standard practice at Temple Hospital for all c-sections and thus would not add any additional burden to the patient or clinician.

Furthermore, on review of patient pill-pack data, there was significant evidence of opioid misuse. It should be noted that opioid misuse is defined as: taking the medicine in a way or dose other than prescribed, taking someone else's prescription medicine, or taking the medicine for the effect it causes to get high. This means that opioid misuse can be unintentional, but that it still presents possible dangers or harm to the patient. Notably, results revealed that three patients were not using prescriptions as prescribed by the providers. It is standard practice to not only verbally review instructions with patients on day of discharge but also to include written discharge instructions. Additionally, the physical prescriptions include the instruction for the medication as prescribed by the provider. However, a review of individual data showed patients taking more pain

medications than what was prescribed and also taking all medications at the same time. This represents a potential area of harm for patients as they are taking more than the maximum dose of medications and not following directions to take ibuprofen and acetaminophen prior to oxycodone use. Another potential concern given the excess use is that the medications are being dispensed to others. This is harmful because it shows a potential avenue for accidental overdose, and also identifies a patient that may be at risk for habit-forming behavior and finally a concern of diversion into the community. It has been noted that among people who misused prescription pain relievers, more than half (50.8%) obtained them by being given them, buying them, or taking them from a friend or relative (Substance Abuse and Mental Health Services Administration, 2020).

Pain scores recorded by the patients with inappropriate use of medications were also notable. Both Participant 005 and Participant 008 were noted to have a pain score less than 6 (5 and 1, respectively) when they were taking all three medications at the same time. This identifies a possible area of concern. Some possible reasons for this are that patients did not understand the instructions that were provided to them at discharge or patients have varying perceptions of pain and treatment.

When reviewing the results and application of this initial study, it is important to identify limitations of the study. The results are based on 9 participants and are particularly homogenous with regards to race and thus have limited generalizability. Furthermore, compliance with follow-up appointments was difficult despite counseling. Many patients missed their postpartum incision check appointment even when reminded and were unable to reschedule. Recollecting the electronic tablet and pill pack was difficult when participants did not present to their office visit. However, given the clear identification of variable prescription opioid use amount these participants and the identification of incorrect usage of prescribed mediation, there is a clear need for further investigation. The CPMRx mobile application does provide additional information that was previously limited on exact usage on discharge and relies less on recall bias by patients and retrospective review as data are collected real-time.

Future studies should include a larger randomized control trial looking at the effectiveness of CPMRx's mobile application in modifying behavior and increasing medication adherence compared to basic monitoring with the pill pack. Additionally, in future studies, it will be important to continue gathering additional data on the acceptability of patient engagement techniques. Finally, further identifying opioid use and opioid misuse patterns in a larger study population will be necessary to move toward precision medicine in prescribing practices that will prevent overprescription and possible diversion into the community.

## Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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