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## Study Personnel

- Sarah Osmundson MD, MS (Maternal-Fetal Medicine)
- Michael Richardson MD (Anesthesiology)
- Fellows TBA (Anesthesiology)
- Medical Student TBA
- Resident TBA (Ob/Gyn)
- LeAnn Lam (University of Utah undergraduate, UCHIP program)

**Background**: The number of opioid overdose deaths in the United States has quadrupled in 15 years, a dramatic manifestation of the current opioid abuse epidemic.[1] This rise parallels a sharp increase in the amount of legal prescription opioids dispensed[2]. The abundance of prescription opioids available is a primary pathway for opioid abuse and diversion. Adjusting post-cesarean delivery opioid prescribing practices to better match actual patient need has the potential to reduce unused opioids available for diversion, nonmedical use, and development of chronic dependence, as well as reduce wasted resources.

**Preliminary Data**: Phase 1 of this project concluded:

1. Overall, most women are prescribed opioids after discharge in excess of the actual opioids used.
2. There is a subset of women (~25%) who use all opioids and complain that they were not prescribed enough.
3. Inpatient opioid use is strongly associated with outpatient opioid use.
4. Data from inpatient use was used to develop a formula for estimating outpatient use based on inpatient use (personalized use)

**Objective:** To compare a personalized prescribing algorithm based off of inpatient opioid use to standard discharge opioid prescribing

## Eligibility

- Inclusion Criteria
  - Women 18-45 years old
  - Women undergoing cesarean delivery at VUMC
  - English or Spanish Speaking
- Exclusion Criteria
  1. Major post-surgical complications:
     - cesarean hysterectomy, bowl or bladder injury, reoperation, ICU admission, wound infection or separation
  2. Chronic opioid use: Taking buprenorphine during pregnancy or taking an opioid daily for > 14 days during pregnancy.

## Recruitment

- Recruitment will on postpartum day 1 in the patient's postpartum room.

**Screening:**
- StarPanel will be used to identify women meeting inclusion criteria
- Anyone meeting inclusion criteria who we will approach for the study will be entered into the Screening Page in RedCap.

**Enrollment**
- Informed written consent will be obtained by a trained research assistant (i.e. medical student) or by the study researchers (Attendings, fellows)
- The short form consent will be available in Spanish
- After enrollment, complete the Enrollment page in Redcap and ask the patient to complete Survey 1 either in person or by giving sending participants the web link
- Be sure to obtain contact information: Ask for two ways to contact participants.
- Once enrolled place the laminated Study Banner on the patient's door, a note in StarPanel, and update the patient summary in order to notify providers and nurses of the patient's participation.

**Randomization**
- Participants will be randomized just prior to writing the discharge prescription.
- Enrolled patients will be randomized in a 1:1 ratio using permuted blocks of 4-8
- Randomization sequence will be developed through sealedenvelope.com
- Randomization and allocation will be done through RedCap

**Blinding**
- Blinding will not be used

**Intervention**
1. Control = Discharge prescription for 30 tablets of oxycodone 5 mg
2. Intervention
    - Number of tablets determined by (48.8 + (1.77 x IP2447))/7.5
    - Where IP2447 is Inpatient MME = total MME between hours 24:00 to 47:59
    - This data will have to be manually extracted from EMR into RedCap
    - Minimum threshold of 5 tablets of oxycodone 5 mg

**Follow up**
- All participants will be contacted starting on postoperative day 14
- Attempts to contact each participant will be done **3 times** before they are designated as "lost to follow up"
- If a participant is still using opioids on postoperative day 14, they should be contacted weekly until they are no longer taking opioids
- The Controlled Substance Monitoring Database will be accessed for each participant to confirm what prescriptions were filled.

**Primary Outcome:**
Median morphine milligram equivalents (MME) unused after hospital discharge
= MME filled – (MME used + MME disposed)

**Secondary Outcomes:**

- VAS pain score (median)
- Percentage of patients reporting pain since discharge as worse than expected
- Percentage of patients obtaining additional prescriptions for pain
- Percentage of patients with unscheduled visits for pain
- Mean ibuprofen milligrams used hours 24-47 after cesarean
- Mean acetaminophen milligrams used hours 24-47 after cesarean
- Total MME used per hour of inpatient stay

**Sample Size and Feasibility**

Based on our pilot data, the average unused opioid MME per person was 130 MME (SD 90) in the “average use” group. With an alpha of 5% and a beta of 80%, we estimate that 160 total participants are required to show a 30% reduction in unused opioid. Assuming a lost to follow up rate of 20%, we plan to enroll 200 women. On average 100 cesareans are performed per month. With a 50% enrollment rate, we anticipate this study will take 4 months to complete