Discharge opioid education to decrease opioid use after cesarean: a randomized controlled trial

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1.0 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. This rise parallels a sharp increase in the amount of legal prescription opioids dispensed. The abundance of prescription opioids available is a primary pathway for opioid abuse and diversion and higher opioid use after surgery has been associated with an increased risk of chronic opioid use. Reducing the amount of opioid used after cesarean delivery may decrease the risk of chronic opioid use and will help towards better estimating and reducing the amount of opioids prescribed at discharge.

2.0 Objective: To compare discharge opioid education to standard care to ascertain whether opioid education reduces opioid use after hospital discharge

3.0 Preliminary Data: Our previously published study (Osmundson, 2018) found that 30% of women used all their opioids after discharge for cesarean delivery because they "were following directions" and not because they had pain.

4.0 Eligibility

- Inclusion Criteria
  - Women 18-45 years old
  - Women undergoing cesarean delivery at VUMC

- 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, taking an opioid for > 7 days during pregnancy.
  3. Women who do not speak English

5.0 Enrollment & Randomization

Enrollment

- Participants will be approached after their cesarean delivery either in the recovery room or in their private postpartum room
- Informed written consent will be obtained by a trained research assistant (i.e. medical student) or by the study researchers (Attendings, fellows)
- After enrollment, participants will be asked to complete Survey 1 either in person or by giving sending them the web link with RedCap

Randomization

- Enrolled patients will be randomized in a 1:1 ratio using permuted blocks of 6
- Randomization sequence will be developed through sealedenvelope.com
- Randomization and allocation will be done through RedCap

6.0 Study Procedures

1. Enrollment
2. Postoperative Day 0-1: Survey 1 through RedCap (takes ~10 minutes)
3. Randomization education versus usual care
    a. Control = Standard discharge instructions, which list medications prescribed at discharge
    b. Intervention = a single page handout (see attachment) with information about how to use medications for pain after discharge. This handout contains the following instructions
        - Get baseline pain control with ibuprofen
        - Use your opioid prescription only if your pain is very bad
        - Taper your medications
        - Get rid of leftover opioid tablets
4. At discharge all patients will receive the follow medications using PillsyCaps. These are standard medications given at discharge at our institution
    - Ibuprofen 600mg: 30 tablets
    - Hydrocodone 5mg -acetaminophen 325mg: 30 tablets
5. Postoperative day 14: All participants will be contacted to complete Survey 2 (Takes ~ 15 minutes
    - 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

Primary Outcome
Median number of tablets of hydrocodone 5mg -acetaminophen 325mg used after hospital discharge

Secondary Outcomes:

- Frequency of disposing opioids correctly
- Median score on the analgesic assessment

7.0 Risks

- Breach of confidentiality of protected health information

8.0 Reporting Adverse Events

Any adverse events or unanticipated problems involving risk to participants or others will be reported to the IRB and the VUMC privacy office within 7 days of discovery.

9.0 Study Withdrawal/discontinuation

Participants may withdraw at any time by providing written intent to the Primary Investigator. Participants may be removed from the study if they develop a major surgical complication after their cesarean.

10.0 Statistical Considerations

Using prior data, the average opioid MME used 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 opioid used. Assuming a lost to follow up rate of 20%, we plan to enroll 200 women.

11.0 Follow-up and Record Retention

On average 100 cesareans are performed per month. With a 50% enrollment rate, we anticipate this study will take 4 months to complete

The patient list will be destroyed upon data analysis and publication. Redcap will be archived upon publication.