

Data Studio

1:30–2:50pm, Wednesday, September 25, 2019
Li Ka Shing Center 205/206

Investigator: **Pamela Flood** Professor of Anesthesiology, Perioperative and Pain Medicine (OB)

Presenter: **Haley Hedlin** Biostatistician, Quantitative Sciences Unit

Title: **Prevention of Persistent Opioid use in Mothers**

Abstract:

Opioid-sparing analgesic strategies are desperately needed for pregnant women at risk for prolonged pain and opioid use after surgical delivery. This is the largest iatrogenic exposure of young women to opioids in the United States. Each year, approximately 1.2 million American women undergo the most common surgical procedure. Up to 11% will persist with analgesic use, reporting prolonged pain and reduced function.

I propose a double-blind, randomized clinical trial of gabapentin which is titrated over 12 weeks compared to placebo. The primary outcome is time to opioid cessation. Secondary outcomes are pain resolution, return of physical function, and psychological wellbeing. I have enrolled over 30 subjects with 2 lost to follow-up before achieving the primary outcome variable of time to opioid cessation.

My need for statistical advice concerns the statistical analysis plan and the sample size calculation. The study is designed with a time to event outcome. In my current plan, event times are measured every 2 weeks. However, most of the events occur in the 26 week range. I also have count data measured at each of the 2-week measurements but need help to incorporate these into the study design. The patient population is relatively limited. Therefore, I need help finding an appropriate design that will be sufficiently powered.

For more information about Data Studio:

<http://med.stanford.edu/dbds/cool-tools/data-studio.html>