Optimized Opioid Management or Usual Treatment to Reduce Opioid Use Following Surgery (OPT-OUT): A Pragmatic, Patient-Centered Trial

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Disclosures

No conflict of interest

Supported by: AUA/IARS/SOCCA

Funding not related to this proposal

- NIH/NHLBI 1 R61 HL138650-1

- Industry funding
  -Covidien
  -Merck
  -Edwards

The Opioid Crisis

- 115 people die every day from opioid overdose
- The CDC reported a substantial increase in death related to prescription opioids and synthetic opioids
- The acute pain setting is often the initial exposure
- After surgery, 6-15% previously naive patients remain persistent opioid users

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Background

- A large proportion of prescription opioids are unused after several types of surgery
- Opioid treatment not superior to non-opioid medications for pain related function or pain scores
- Multi-modal analgesia is associated with reduced postoperative complications
- Engaging and educating patients improves opioid handling

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Study Rationale

- Limited research has evaluated the patient's pain experience with a tailored approach to post-operative opioid pain management
- Regulatory oversight has mostly focused on reducing the number of pills prescribed
- A multi-disciplinary team informed by anesthesiologists stands to address the perioperative prescription practice to reduce post-surgical pain, opioid consumption, and the amount of opioids available for public consumption or diversion

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Study Question

- Can a postoperative pain management plan effectively treat surgical pain while reducing the overall amount of opioid prescription after hospital discharge and improving patient satisfaction with pain management?

Hypotheses to be Tested

Compared with usual care based on fixed prescription practices, a postoperative pain management plan that uses a shared decision making model and a protocolized, patient-centered opioid prescription strategy will

1. Reduce the amount of opioid consumed (morphine milligram equivalents) at 30 and 90 days following hospital discharge
2. Improve pain related functioning and quality of life at 5, 30, and 90 days following hospital discharge
3. Reduce the amount of unused prescription opioids through appropriate prescribing and take-back program.

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Study Design

- Pragmatic, multi-center, randomized controlled trial
- Approximately 1,662 opioid naïve participants undergoing selected elective surgical procedures, with planned discharge to home
- Participants will be randomized 1:1 to pain managed according to the postoperative pain management plan or fixed prescription based on usual care for the surgical procedure

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Study Endpoints

Primary Endpoint

- Oral morphine mg equivalent (MME) prescribed and consumed at 30 days after hospital discharge

Secondary Endpoints

- Pain related functioning based on the Brief Pain Inventory scores
- Quality of Life (Short Form 36)
- Pain Catastrophizing Scale
- Sleep Quality (PROMIS)
- Anxiety (GAD)
- Oral morphine mg equivalent (MME) unused and unreturned
- Proportion of patients remaining on opioid prescription at 90 days

Primary and Secondary Endpoints will be collected at 5, 30, and 90 days after hospital discharge

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Study Procedures

At the time of enrollment, all participants will

- Receive a brochure on opioid safety
- Download and be trained in the use of a phone application to report their pain, function, and pain medication use
- Be randomized 1:1 to intervention or control group

At the time of discharge, all participants will

- Be followed to collect study endpoints
- Receive financial incentives each time they report or complete a required survey
- Be offered opioid disposal through a take-back program

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Randomization Assignment

Intervention Group

At the time of enrollment

- Receive opioid education and determine pain management expectations

At the time of discharge

- Pain will be managed by prescribing team using shared decision model and a multi-modal approach with opioid limited up to a 5-day supply

Control Group

At the time of enrollment

- No other intervention

At the time of discharge

- Pain will be managed by prescribing team using a fixed dosing schedule based on average prescription amounts for surgical procedure categories

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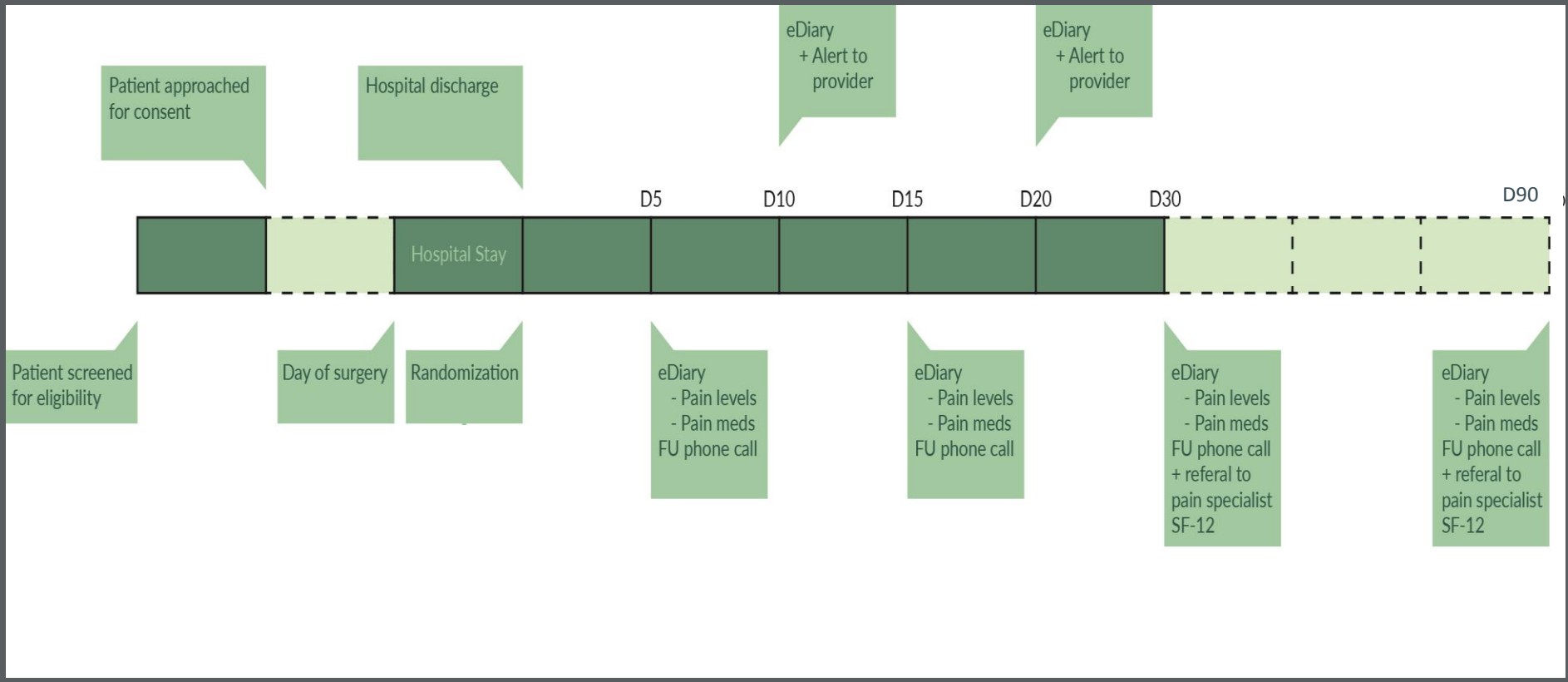
Study Schedule



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Tracking

- Mobile application reports of pain, opioid consumption, function, catastrophizing

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Innovation

- The patient is engaged in shared decision making regarding their pain management
- Reduced opioid prescribing has not been tested in a prospective randomized fashion
- Anesthesiology clinical trials network & MPOG
- Incorporation of modern patient tracking

Preliminary Data

- MPOG Enhanced observation study (PI Kuck) recruited 1,137 patients across 12 center in a 2 week period
- Pain and opioid use recorded at 30 and 60 days post-operatively
- Existing literature describes the problem, provides adequate estimates for sample size calculations, and targets for intervention

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Preliminary Data - Ongoing

- Host institution approved observational study of current prescription practices for the targeted surgical populations
- Broader query of a Kaiser pharmacy database to track initial and subsequent prescriptions up to 90 days postoperatively
- Pilot data collection to test the App
- Identifying funding opportunities (NIH HEAL)

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Environment

- Host institution has past and current government funding in clinical research including multi-center RCT's
- MPOG serves as the most robust data coordinating center in the United States
- Interested collaborators
  - Feasibility questionnaire to be distributed to interested investigators for site selection

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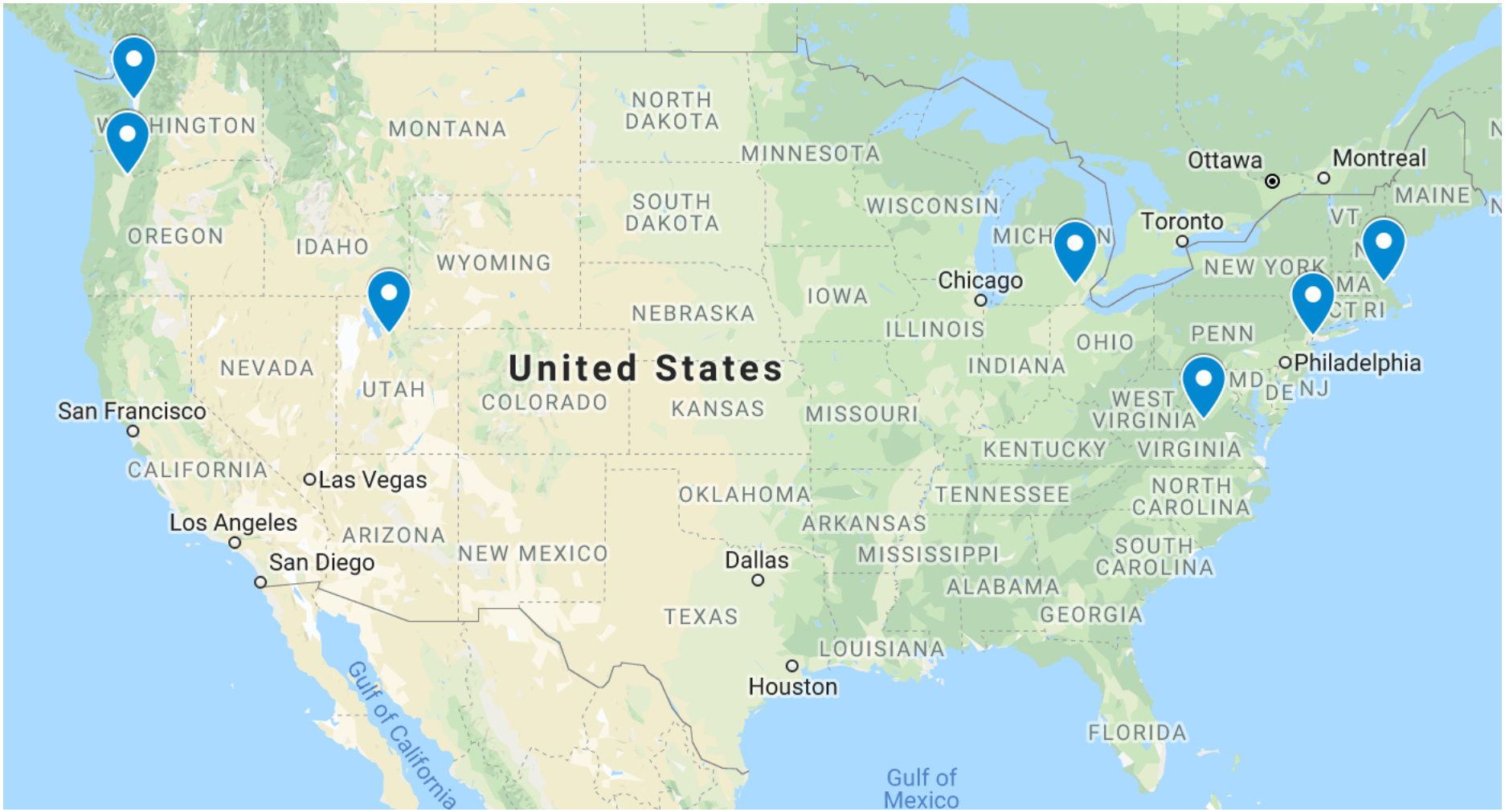
Potential Participating Sites

- OHSU
- Michigan
- Utah
- Virginia
- Washington
- Brigham and Women's
- NYU
- Yale
- MGH
- Others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Thank you

- Questions ?

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