Trial Description Document

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Content Area:
Some key investigations include: (1) Screening preoperative patients to mitigate perioperative adverse outcomes, (2) Enhancing perioperative pain control protocols, and (3) Evaluating perioperative safety and satisfaction.

Trainee goal:
On a provincial level, I am collaborating with CEOs of 15 hospitals across Southwestern Ontario, spearheading a ground-breaking first time large-scale pragmatic trial protocol—a significant cluster randomized control trial (RCT). This trial aims to implement a multi-faceted opioid-use reduction strategy to manage opioid exposure to the broader community by controlling prescription protocols.

Trial Description:
This large-scale pragmatic stepped-wedge cluster randomized trial aims to assess the effectiveness of a multi-faceted opioid reduction strategy in adult surgical patients, addressing the pressing issue of opioid overuse in the perioperative setting. The intervention, implemented across twelve Southwestern Ontario Academic Hospital Network (SWAHN) hospitals, incorporates opioid prescription caps, patient and provider education tools, and prescriber feedback. Through comprehensive data collection utilizing the ICES database, we aim to determine whether this approach reduces total community opioid exposure and mitigates adverse events.

Hypothetical Research Question:
We aim to conduct a large-scale pragmatic stepped-wedge cluster randomized trial to assess the effectiveness of a multi-faceted opioid reduction strategy for adult surgical patients in reducing total community opioid exposure and associated adverse events.

Intervention (to be randomized):
The intervention comprises a three-pronged approach, involving 1) opioid prescription caps (imposing a default maximum number of tablets for discharge prescriptions), 2) patient education tools, 3) provider education tools, and 4) bi-weekly cumulative prescriber feedback on opioid prescribing patterns post-intervention until the end of the study.

Methodology:
We aim to conduct a large-scale pragmatic stepped-wedge cluster randomized trial to assess the effectiveness of a multi-faceted opioid reduction strategy for adult surgical patients in reducing total community opioid exposure and associated adverse events.

Setting:
Twelve Southwestern Ontario Academic Hospital Network (SWAHN) hospitals have been invited to participate, with London Health Sciences Centre and St. Joseph's Healthcare London serving as lead sites. The study focuses on the perioperative setting, where opioid analgesia prescribing is common during hospital discharge.

Participants/Population: will include patients receiving postoperative analgesia at the participating study sites following elective surgical procedures. As the intervention will be implemented institution-wide through changes in hospital order sets and protocols, randomization of individual patients will not be necessary.

Outcomes:
The primary outcome is the total morphine milliequivalents (MME) prescribed at discharge and cumulatively up to 30 days postoperatively. Secondary outcomes encompass serious opioid-related events (overdose-related death, cardiac arrest, respiratory depression, naloxone use, or opioid-related ED visit), readmissions (hospital or ED) within 30- and 90-days post-discharge, total family physician visits at 30 and 90 days, conversion from opioid-naïve to chronic user (continued opioid use at 90 days), and total opioid community exposure (morphine equivalents discharged to the community via postoperative prescriptions). Additionally, we will report the composite outcome of "days alive, out-of-hospital, and opioid-free" at 90 days.

Routinely Collected Data Source(s):
This prospective stepped-wedge allocation study relies on ICES database-dependent outcomes to streamline data collection. Deidentified data will be collected from ICES, including baseline characteristics and outcome information. Utilizing ICES
databases enables comprehensive data collection related to opioid prescriptions, hospital readmissions, emergency department visits, and hospital deaths for both pre-randomization and post-randomization periods at each hospital.