FACTSHEET

PUBLICATION TITLE:	**The OPTIMA study, buprenorphine/naloxone and methadone models of care for the treatment of prescription opioid use disorder: Study design and rationale**
REFERENCE:	Socias, M. E., Ahamad, K., Le Foll, B., Lim, R., Bruneau, J., Fischer, B., Wild, T. C., Wood, E., & Jutras-Aswad, D. (2018). The OPTIMA study, buprenorphine/naloxone and methadone models of care for the treatment of prescription opioid use disorder: Study design and rationale. Contemporary clinical trials, 69, 21–27. https://doi.org/10.1016/j.cct.2018.04.001
QUICK FACTS:	• This article describes the methodology that will be used for the OPTIMA study. • The study is designed to assess the relative effectiveness of buprenorphine/naloxone- and methadone-based models of opioid agonist therapy (OAT) for the treatment of prescription opioid use disorder (POUD) in routine clinical care. • Participants will be recruited in 7 sites across Canada and will be randomly assigned to BUP/NX or Methadone treatment groups. • The primary outcome of the study will measure the suppression of illicit opioid use in both treatment groups, with a number of additional secondary and ancillary findings. • The results will give clinical significance on the effectiveness of both types of models of care which can inform health services and clinical practice.
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WHAT THE RESEARCHERS WILL DO

The researchers will conduct a pragmatic randomized controlled trial that will be 24 weeks long comparing the effectiveness and safety of methadone versus BUP/NX models of care for the treatment of Prescription-Type Opioid Use Disorder. This pragmatic trial model incorporates the diversity of patient characteristics and service deliveries into the study design. Participants will be recruited from existing patient populations in research locations across 7 sites in Canada, by voluntarily signing up for the study. They will undergo a pre-screening to assess eligibility and will be randomly assigned to either BUP-NX treatment with flexible dosing or methadone with initial daily witnessed doses. Once the OAT begins, participants will be followed for 24 weeks with visits every 2 weeks.

WHAT IS BEING MEASURED?

- The primary outcome measure of the research study will be suppression of illicit opioid use, as proven by the percent of urine drug screens (UDS) that are negative for opioids.
- The secondary outcomes that the research will determine are:
  - retention on assigned OAT (how long clients stay on the assigned treatment)
  - medication adherence
  - safety
  - participant satisfaction
  - participant engagement.
- Other exploratory outcomes that will be measured include:
  - cost-effectiveness
  - quality of life
  - pain
  - use of other substances
  - changes in drug related problems
  - psychological functioning
  - drug and sex-related HIV and viral hepatitis risks
  - proportion of participants who initiate taper
  - opioid craving
  - opioid withdrawal

In addition, several ancillary studies will take place alongside the main trial.

WHY IT MATTERS

The OPTIMA trial is CRISM's first national study and was conceived in response to the escalating public health opioid crisis in Canada. In this context, comparing the effectiveness of the flexible BUP-NX and Methadone models of care, two widely available medications in Canada, is particularly timely and relevant. Due to their different safety profiles, methadone usually requires daily witnessed ingestion in a pharmacy, while BUP-NX allows for early take-home doses upon achieving clinical stability. The flexibility of take-home doses has the potential to reduce access barriers, which is critical given the state of the crisis. Existing clinical trials comparing BUP-NX and methadone have usually assessed similar daily witnessed ingestion dosing on strict dosing schedules, and therefore the evidence base on the relative effectiveness, safety and acceptability of the two different models of

care is limited. Also, very few studies have compared these two medications among the growing population of individuals with OUD primarily using prescription opioids.

WHAT'S NEXT?

- [ ] This trial will provide an assessment of the effectiveness of existing model of care and is clinically meaningful for both clinicians and patients.
- [ ] The additional outcomes of the study will also contribute to our understanding of the effectiveness and accessibility of both treatments which is valuable information for health systems, and social services.
- [ ] Lastly, the evidence will help inform the evidence base for clinical practice and systems of care. The findings can create and generate meaningful discussions and reflections on how to continue expanding flexibility in the clinical management of OUD.