Optimizing patient centered-care for prescription opioid misuse:

CRISM-ICRAS

THE OPTIMA RESEARCH TRIAL SUMMARY OF FINDINGS

INTRODUCTION TO THE OPTIMA TRIAL

Over the last two decades, North America has seen a rise in deaths due to drug overdose and an increase in substance use disorder related to prescription-type opioid medications. Such problems related to opioids (e.g., morphine, oxycodone, heroin, hydromorphone (dilaudid), fentanyl, and percocet), also called Opioid Use Disorder (OUD), means that a person is taking opioid drugs regularly, and is experiencing some kind of distress and/or negative health or social consequences because of their continued use.

OPIOID AGONIST TREATMENT

OPIOID AGONIST TREATMENTS (OAT):

Medications that work to notably alleviate withdrawal (feeling dope sick) and reduce cravings of opioid drugs.

Two of the most common medications offered for OUD are **Methadone** and a mix of two medications called **Buprenorphine and Naloxone** (BUP/NAL, also known as Suboxone). Currently, methadone is more commonly prescribed for OUD in Canada.

In 2017, the Canadian Research Initiative on Substance Misuse (CRISM) wanted to know if the flexible approach of treatment offered by BUP/NAL (I.e., being able to take doses home sooner) works as well for people with prescription type opioid use disorder (POUD) as methadone. To find out, they launched a national research trial called OPTIMA (Optimizing Patient Centered-Care: A Pragmatic Randomized Control Trial Comparing Models of Care In The Management Of Prescription Opioid Misuse).

PRESCRIPTION-TYPE OPIOID USE DISORDER (POUD)

People that fall under this category mostly use prescription type opioids including hydromorphone, oxycodone, fentanyl and/or morphine.

Basically, NOT heroin. The trial excluded people who used mostly heroin.

METHADONE VS. BUP/NAL

	METHADONE	BUP/NAL
	Reduces cravings and withdrawal symptoms (dope sickness).	Reduces cravings and withdrawal symptoms (dope sickness). For some people with high tolerances, it may not fully alleviate those symptoms.
	Overdose is possible if too much is taken or if it is mixed with other drugs. Potential risks and side-effects are greater.	It usually prevents getting the euphoria and expected effects of other opioids. Lower risk of overdose than methadone.
	You don't have to stop using opioids before starting treatment.	A person usually must be in withdrawal when starting BUP/NAL.
	Patients can get to their optimal dose (dose that makes you feel stable and craving-free) in several weeks or months.	Patients can get to their optimal dose (the dose that makes you feel stable and craving-free) in 2-3 days, sometimes a little longer.
	Patients must take their daily doses at a clinic or pharmacy under supervision. They may only be eligible for **take-home doses** after **several months.** This requirement can make work, travel, and social life difficult.	Patients can be eligible for **take-home doses after 2 weeks** since there is a lower risk of overdose. This means patients would not have to go to a clinic or pharmacy every day to take their medication.

THE OPTIMA RESEARCH TRIAL
SUMMARY OF FINDINGS

WHAT THEY DID

WHERE The clinical trial took place in 7 sites across Canada (BC, Alberta, Ontario, and Quebec)

WHEN October 2, 2017 to March 23, 2020

WHO PARTICIPATED 272 people with prescription-type opioid use disorder, between the ages of 18-64, for 24 weeks (about 6 months).

HOW IT WORKED Participants were randomly assigned to one of the groups**:** **Methadone or BUP/NAL.**

METHADONE

Starting dose:
30 mg MAX per day

Dose increase:
60-120mg/day or more

Length of time before receiving take home doses: if patient was clinically stable, take-homes were given after 2-3 months

BUP/NAL

Starting dose:
4mg BUP/1mg NAL MAX per day

Dose increase:
24 mg BUP/6 mg NAL

Length of time before take home doses: If patient was clinically stable, a 1-week supply of take-homes were given after 2 weeks. After 4 weeks, they could receive a two week supply

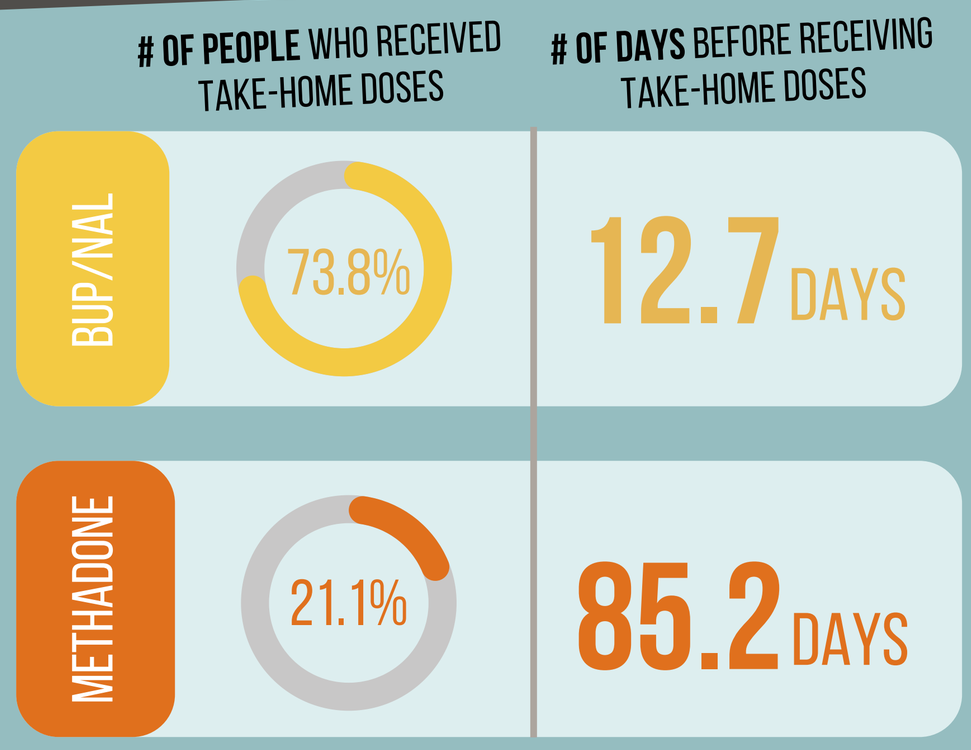
Both groups went to follow up visits every 2 weeks for 24 weeks to assess: Opioid use, medical history/experience (e.g., safety, side effects, negative events), and other health related outcomes (e.g., mental health, quality of life, employment etc.)

A COUPLE OTHER THINGS THEY FOUND:

Both groups reported an increase in quality of life, with very similar scores after the 24 weeks. The main difference was that the improvement in quality of life was reported sooner in BUP/NAL patients.

- People who are on methadone are more likely to stay on it longer but it is easier to switch or stop treatment on BUP/NAL.
- Drug-related negative events such as withdrawal, overdose, and low sex drive were similar in both groups.
- Other outcomes such as how well patients stuck to the treatment, satisfaction, mental health, risk behaviours and social outcomes were also studied in the trial. The team of researchers are working on publishing these other findings.

WHAT THEY FOUND



One of the key questions that the OPTIMA team wanted to know: **How do the treatments impact people's use of other opioids?** To answer this question they collected urine samples to see if they found any opioids in it. The two groups had similar outcomes:

AVERAGE PROPORTION OF OPIOID-FREE URINE:

24% IN BUP/NAL

18.5% IN METHADONE

So, both types of treatments had similar results. But what does that mean? It tells us that flexible models of care, where patients can take home their medication, work just as well as supervised methods in reducing a person's opioid use.

THE RESEARCH IS DONE... NOW WHAT?

The OPTIMA research indicates and provides confirmation to clinicians, scientists, and the community that the flexible model of care offered by BUP/NAL, is **just as safe and effective to decrease opioid use as methadone, without the need for close supervision**.

We need to consider how we can provide Canadians with more flexible treatment options for OUD, beyond BUP/NAL. This means not solely relying on the traditional more rigid methods of delivering OUD treatments, but creating models of care that better suit people's needs and situations, and autonomy.