# TAKING OAT ONE STEP FURTHER: PRESENTATION OF A FENTANYL PROTOCOLS USED IN OPIOID AGONIST THERAPY

Christy Sutherland MD CCFP (AM) dABAM

Medical Director, PHS Community Services Society

Clinical Associate Professor, UBC Department of Family Medicine

# Presenter Disclosure

- Christy Sutherland
- Relationships with commercial interests:
  - Grants/Research Support – CHRISM – Site PI for OPTIMA and PRESTO
  - Speakers Bureau/Honoraria: AGM for Federation of Medical Women in Canada
  - Consulting fees: AVI, Ask Wellness
  - Other: Medical Director PHS Community Services Society

  - Managing bias – highlight that the novel fentanyl programs we are running are off label and unproven.  They are being evaluated.

# Context

- At the PHS we have been operating

  - iOAT inside housing since 2016 (hydromorphone)
  - iOAT inside an Overdose Prevention Site since 2018 (hydromorphone)
  - TiOAT since 2019  (dilaudid)
  - Fentanyl Patches since 2019
  - Fentora Tablets since April 2021
  - Sufentanil IV since Dec 2021

- There is NO EVIDENCE to support the prescription of many of these interventions for opioid use disorder:

  - Fentanyl Patches
  - Fentora Tablets
  - Sufentanil IV

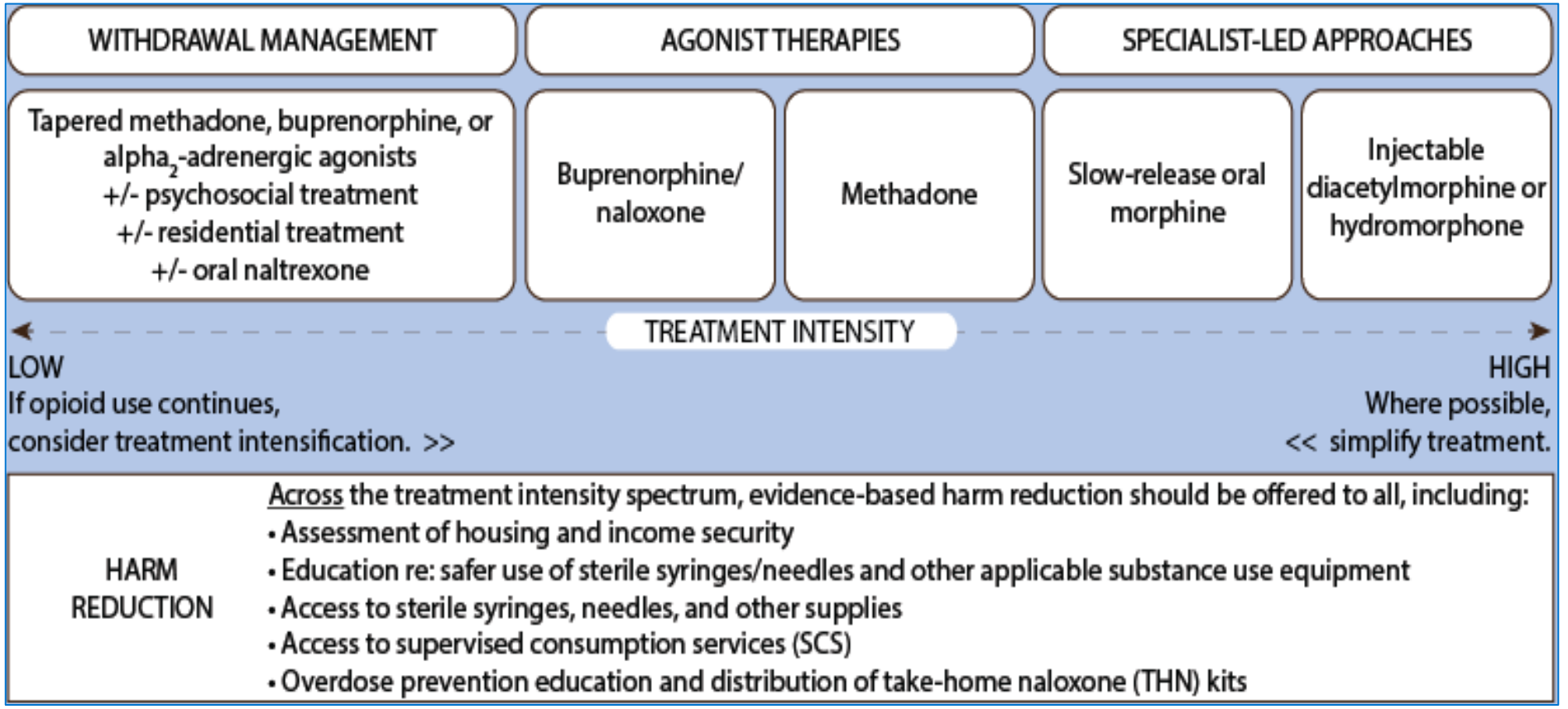
  There is one qualitative paper examining:
  - TiOAT

  - However, our programs are being studied
  - How we set up our programs is extrapolated from the iOAT literature

# Where is there evidence?

- There is a lot of evidence for OAT
- Lot of evidence for Heroin iOAT
- There is 1 paper that shows that hydromorphone iOAT is non-inferior to Heroin iOAT
- The challenge with Heroin is the supply chain for Canada

# iOAT in the Continuum of Care for OUD





1. Amato et al. 2013
2. Gowing et al. 2009
3. Gowing et al. 2014
4. Amato et al. 2011
5. Minozzi et al. 2011
6. Mattick et al. 2014
7. Mattick et al. 2009
8. Faggiano et al. 2003
9. Ferri et al. 2013

# Role of iOAT in the Continuum of Care

- Patients may not benefit from first-line medications (oral OAT) for a variety of reasons. Examples include:
  - Cravings despite optimal OAT dosing
  - Being unable to reach a therapeutic dose
  - Opting not to initiate oral OAT due to previous poor experience (e.g., side effects)
- Individuals who do not benefit from first-line medications are at increased risk for harm, including premature death, non-fatal overdose, blood-borne infectious diseases, violence, and arrest

# A bit of history

In the UK they have been prescribing heroin for opioid use disorder for more than a century as take home doses.

# Swiss National Clinical Study

- First trial started in Switzerland in 1994
- Has been standard treatment for opioid use disorder in Switzerland since 1998
- This is in the context of a very robust methadone system of care – very low barrier and available.

# Cochrane Review 2011

"Heroin maintenance for chronic heroin-dependent individuals"

Marica Ferri, Marina Davoli, Carlo A. Perucci

Objectives:

To compare heroin maintenance to methadone or other substitution treatments for opioid dependence regarding: efficacy and acceptability, retaining patients in treatment, reducing the use of illicit substances, and improving health and social functioning.

# Main Results

- Eight Randomized Control Studies involving 2007 patients met the inclusion criteria.
- Previous treatment failure for opioid use disorder
- Five studies compared supervised injected heroin plus flexible dosages of methadone treatment to oral methadone only and showed that heroin helps patients to remain in treatment
- Maintenance with supervised injected heroin has a not statistically significant protective effect on mortality
- There is a  greater risk of adverse events related to study medication
- Results on criminal activity and incarceration were not possible to be pooled

# Main Results

- Social functioning improved in all the intervention groups with heroin groups having slightly better results.
- If all the studies comparing heroin provision in any conditions vs any other treatment are pooled the direction of effect remain in favour of heroin.

# HAT (heroin assisted therapy)

- For people with severe opioid use disorder who have tried oral treatment and had ongoing drug use or negative consequences
- The patient attends clinic 2-3 times per day for a supervised injection of heroin
- They are given a dose of methadone at night in order to avoid withdrawal overnight between doses

- Average time in HAT is 3 years
- In general, patients stabilize on a dose and remain on that dose for the duration, or taper their dose
- On average, this maintenance dose is about half of the program maximum
- Patients usually transition to oral treatment, but many successfully taper to achieve no opioid use

# Public safety

- There have been no detrimental effects on public safety, or disorder from HAT

- People enrolled in HAT decrease criminal behaviour

# Why give people free heroin?

- This is just one end of the continuum of care for opioid use disorder
- The cost of not treating addiction is almost always **more** than the cost of treating it.
- Cost benefit analysis of HAT have shown it to be more economical than no treatment

# HAT

- Provides connection to primary care
- Multiple interactions with nurses each day
- Can be embedded in a interdisciplinary team with social work, pharmacist, nurse, and addiction specialist
- Decreases the illicit market of opioids

# Clinical Challenges

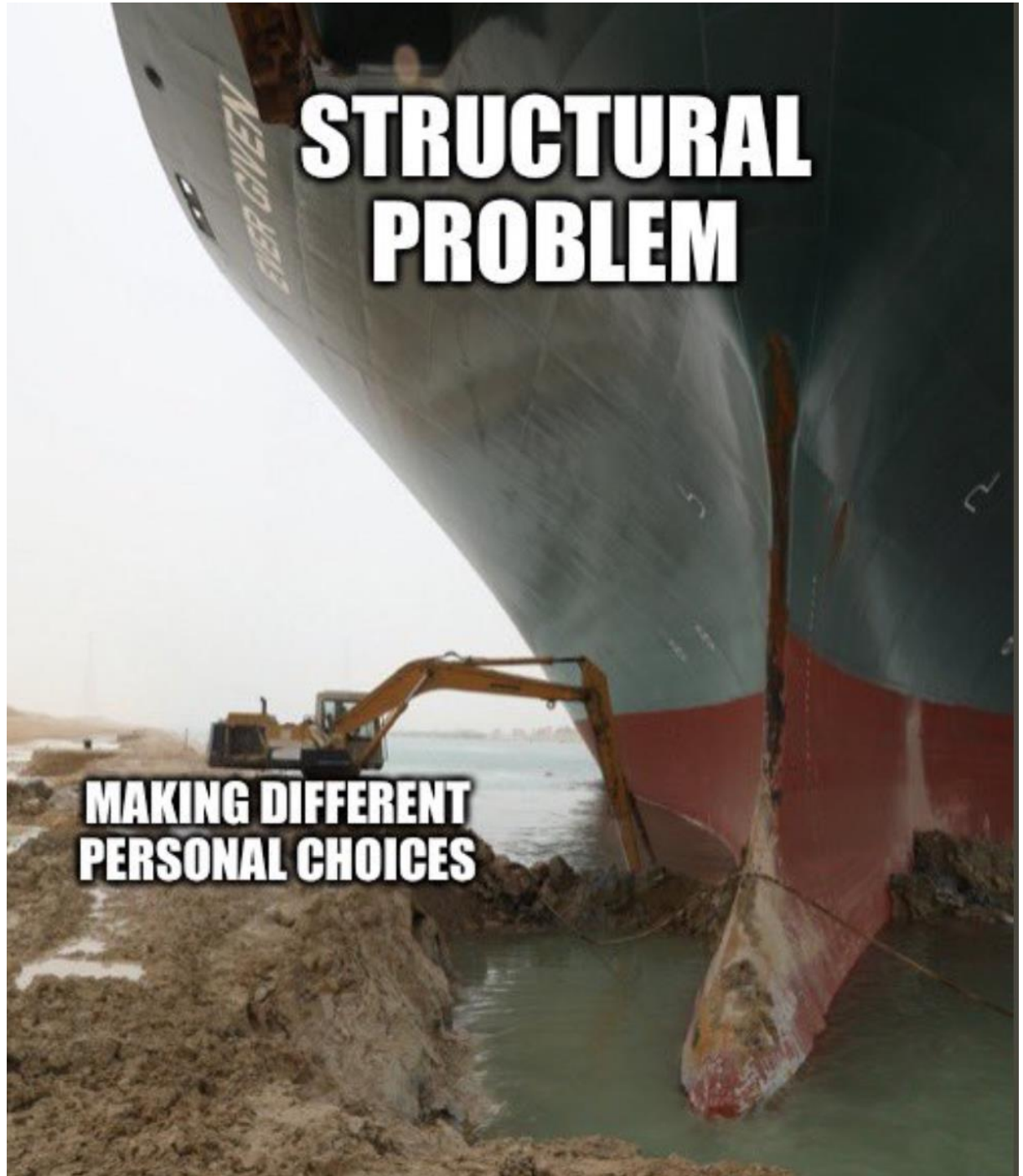
- We have found with the change of the street supply to fentanyl, that the regular dosing of medications (such as methadone) couldn’t meet the opioid need of our patients. They were still in withdrawal at high doses.
- Patients were requesting fentanyl
- Withdrawal was more complex than in the past due to benzodiazepine contamination in the supply

# Non toxic drug consumption in a safe space

Known substance, known dose, clean supplies

“For every complex problem there is an answer that is clear, simple, and wrong.”

H. L. Mencken


STRUCTURAL
PROBLEM
MAKING DIFFERENT
PERSONAL CHOICES

# Considerations for a Fentanyl program

- Fentanyl is a challenging molecule to use
  - The molecule itself is very large
  - It requires a large amount of liquid in solution
  - Available formulations of injectable fentanyl are for the operating room or inpatient pain and would require many ml to get to a dose appropriate for our patient population
  - The physical amount of granules per dose is incredible small

# The challenge

How to deliver fentanyl in community in a manner that is:

- Adequate dosing
- Reasonable delivery mechanism
- Safe for the patient
- Operationally feasible for nursing time and scope of practice

(we couldn’t hang mini-bags of fentanyl like they do in ICU!)

# Medication options we offer at PHS

- Fentanyl patch
  - Clinic
  - Overdose Prevention Site
  - Pharmacy
  - Housing
- Fentora titration and maintenance
- Fentora prn
- Sufentanil prn
- iOAT (hydromorphone)
- Prn iOAT (hydromorphone)
- TiOAT (dilaudid tablets)

# Creating Protocols

- Committee comprised of:
- People with lived experience
- Physicians
- Nurses
- Pharmacists
- External reviewers
  - I often ask a palliative care doctor to review our policies due to their experience with high and complex opioid regimens

# Creating Protocols

- Consider the scope of practice for each individual
  - LPN/RN
  - Physician
  - Pharmacist
  - Medical Office Assistant

  - We always review our policies with the College of nursing before launching a new program

# Fentanyl Patch

- We had been running a small fentanyl patch program in our clinic since 2019 (no funding for this, just off the side of our desks)
- We had 6 patients on this program and it was very successful
  - People stopped using non-prescribed fentanyl
  - They reported feeling comfortable and well
  - Many went to school, maintained housing, and connected with family
- People reported it was similar to “muscling” fentanyl
  - No peak and trough
  - Steady state

# Fentanyl Patch - starting

- People can convert over from Kadian
- Can do a cross-titration from methadone – less reliable for conversion from one opioid to another
- Accept patients who have been started in hospital – the titration is done

# Health Canada Funding

- We were able to scale up our fentanyl patch program and add on new medications through Health Canada funding.

# Fentanyl Patch Program

- As we have learned through delivering the program, we have made the titration faster and missed dose protocol lighter over the years
  - Challenging to try to extrapolate from methadone prescribing practice
  - No literature to guide this in our population
- No maximum dose
  - Some are limited by skin area
- Monday/Wednesday/Friday patch changes
  - Operationally works better
  - Easier for quality of life for a patient – a predictable schedule. With patch changes every 72 hours, the day of the week changes week to week.

# Fentanyl Patch Program Limitations

- Slow titration
- No euphoria
- Requires a lot of organization from the patient
  - Attending on a schedule
  - Not a low barrier program

# Fentora

- Sublingual fentanyl tablet

- A medication that was created for palliative care or cancer pain, so we thought it would be potent enough for our population

- PRN program
  - 400mcg BID prn – hasn't been very popular
  - It is hard to find a dose that is high enough to meet people's opioid need, but low enough to be safe for them to go and off the program in a flexible manner

- Titration
  - No maximum dose
  - Up by 200mcg per day
  - BID dosing

# Sufentanil

- We had been using in clinic for wound care, so had clinical experience
- High potency with low volume for injection
- Option for a sublingual route
- Up to 250mcg at a time, 1 hour apart, up to 5 doses per day
  - Often the maximum number of doses is determined by the operating hours of the project, not the half life of the medication
  - We do test doses for tolerance

# Considerations when creating a program

- Supply chain security
- Time to peak and half life of medication
- Ease of medication administration
  - Patient specific dosing versus fixed dosing
  - Nurse time to prepare the medication
  - How many doses in the day?
  - How far between doses – we base this on the half life
- Ease of narcotic counts for nurses and pharmacists
  - Pouch packs versus blister packs

# Considerations when creating a program

- Titration and maintenance versus prn
- When route of administration is not what is indicated for regular use
- Storage and shelf life
- Operational hours you are open
  - Leaving time for charting, admin work, and narcotic counting for the nursing team

# Adjusting the protocols as we learn

- Increasing the starting dose
- Decreasing the time between doses
- Extending the days before dose reduction
- Decrease the dose reduction with missed doses
- Increase the dose for the fixed dose prn program

# Opioid Agonist Treatment

- All of our programs are co-administered with OAT

- The fentanyl patch is sometimes the exception
  - it’s challenging to have people on 2 long acting opioids at the same time. Many patients stay on methadone, many consolidate to the patch alone.

# Primary Care

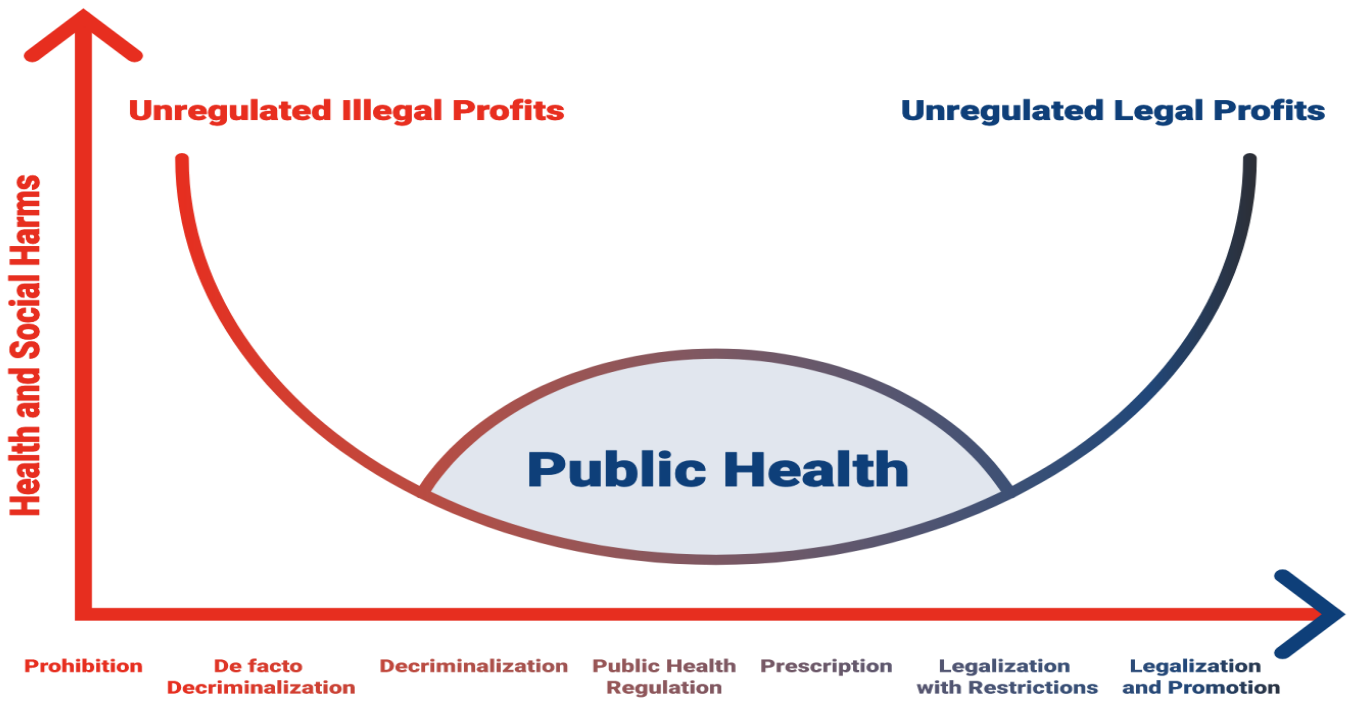
- Engagement in primary care
    - Contraception discussions
    - Pregnancy testing
    - Blood work
    - Vaccinations
    - Blood pressure monitoring
    - Chronic disease management
    - Wound care
- Co-administration of any other medications
    - Antiretrovirals
    - Hepatitis C treatment
    - Antibiotics
    - Regular ongoing medications for chronic disease

# Nursing lead titrations

- Nursing lead Methadone and Kadian titrations with support from a doctor of the day system
- Nursing lead titrations of fentanyl protocols for each medication option
- No need for physician visits for escalating doses

A program will never solve a problem that has been created by policy

**Figure 4.1 -** Continuum of Drug Policy Approaches




Source: Adapted from Marks J. 1990. The Paradox of Prohibition. In: *Controlled Availability: Wisdom or Disaster.*[69]

# Current Drug Policy - Multijurisdictional

- Justice
  - law making, and interpretation of law
  - Judicial decisions
  - Use of force
- Housing, shelter and social policy
- Resource allocation for services
- City planning
- Health
- School planning
- Work-safe and Employment

# Outcomes of Drug Policy

- If you use drugs, the outcome of your drug use is determined by:
  - Race
  - Gender
  - Wealth
  - Social capital
  - Health status
  - Purity and strength of the substance and if this is known
  - Context of where you use (in an alley versus at a fancy restaurant)

All drugs carry risk – those that are legal and illegal.

leftsplaining fentanyl to decent people.

4/4/21 · Twitter for iPhone

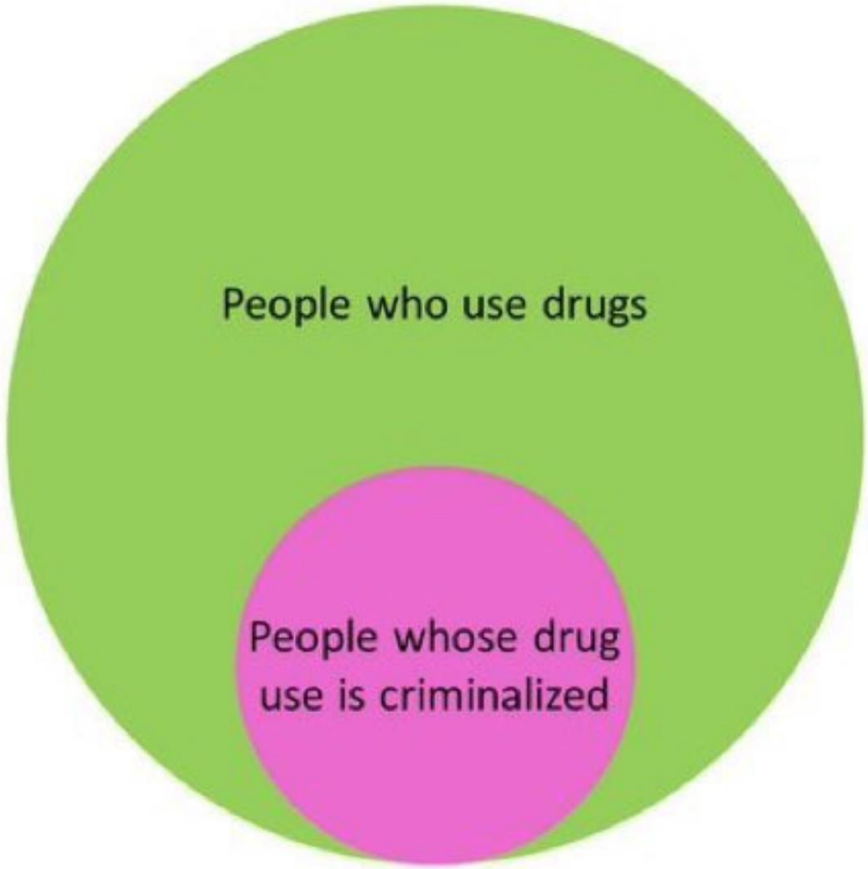
Following

**Ryan Marino**
@RyanMarino

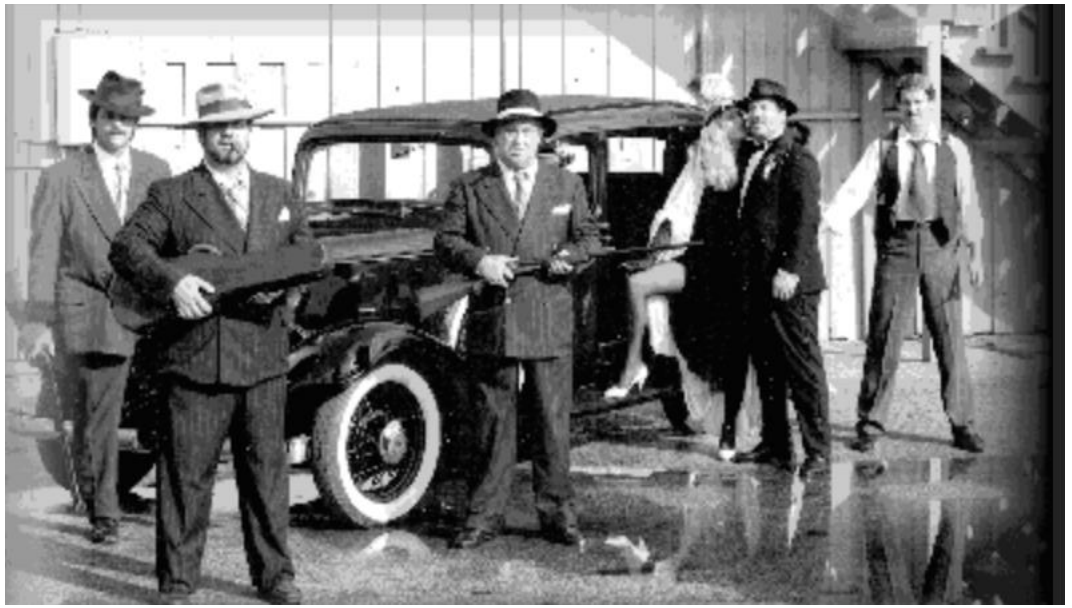
Human Doctor • Toxicology • Addiction • Emergency • #WTFentanyl & more often just WTF • drugs are misunderstood but people are misunderstood more • he/him

#LEGALIZE Joined March 2009

**2,550** Following **51.2K** Followers



# Alcohol Prohibition

# The war on drugs - Nixon

"You want to know what this was really all about? The Nixon campaign in 1968, and the Nixon White House after that, had two enemies: the antiwar left and black people. You understand what I'm saying? We knew we couldn't make it illegal to be either against the war or black, but by getting the public to associate the hippies with marijuana and blacks with heroin, and then criminalizing both heavily, we could disrupt those communities. We could arrest their leaders, raid their homes, break up their meetings, and vilify them night after night on the evening news. Did we know we were lying about the drugs? Of course we did."

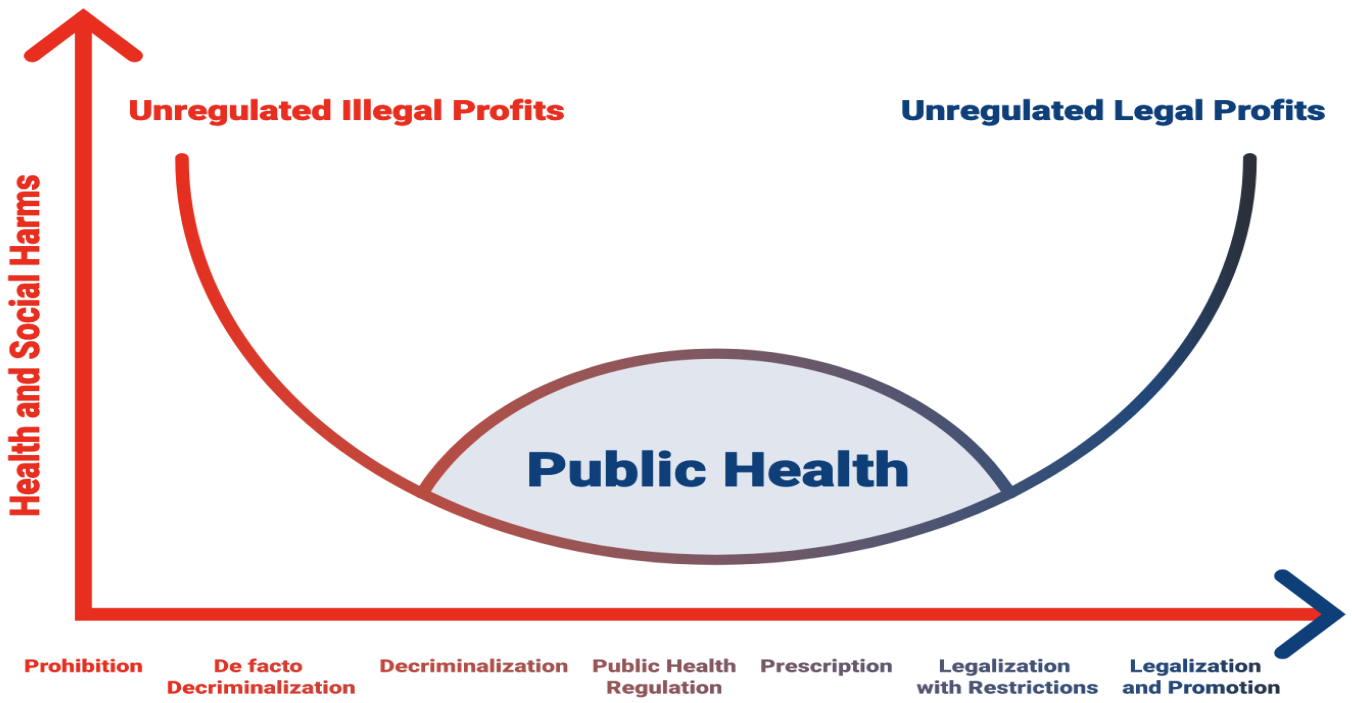
- John Ehrlichman

# Canada’s war on drugs

“Historians have demonstrated that drug law in Canada has not been a benign phenomenon aimed at safeguarding the health of Canadians, but a tool of social control directed unevenly at some groups of people”

Fischer et al 2003

**Figure 4.1 -** Continuum of Drug Policy Approaches




Source: Adapted from Marks J. 1990. The Paradox of Prohibition. In: *Controlled Availability: Wisdom or Disaster.*[69]

# Protocols?

Send me an email!

Christy.Sutherland@phs.ca


REVOLUTION
IS NOT
A ONE-TIME
EVENT
-AUDRE LORDE