OUR LIFE DEPENDS ON THIS DRUG

Competence and Voluntary Consent in Clinical Trials on Supervised Injectable Opioid Assisted Treatment

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Our Life Depends on This Drug: Competence, Inequity, and Voluntary Consent in Clinical Trials on Supervised Injectable Opioid Assisted Treatment

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Supervised injectable opioid assisted treatment (siOAT) prescribes injectable opioids to individuals for whom other forms of addiction treatment have been ineffective. In this article, we examine arguments that opioid-dependent people should be assumed incompetent to voluntarily consent to clinical research on siOAT unless proven otherwise. We agree that concerns about competence and voluntary consent deserve careful attention in this context. But we oppose framing the issue solely as a
Figure 1: Continuum of Care

- **WITHDRAWAL MANAGEMENT**
  - Tapered methadone, buprenorphine, or alpha₂-adrenergic agonists
  - +/- psychosocial treatment
  - +/- residential treatment
  - +/- oral naltrexone

- **AGONIST THERAPIES**
  - Buprenorphine/naloxone
  - Methadone

- **EXPERT-LED APPROACHES**
  - Slow-release oral morphine
  - Diacetylmorphine
  - Hydromorphone

**TREATMENT INTENSITY**

- **LOW**
  - If opioid use continues, consider treatment intensification.

- **HIGH**
  - Where possible, simplify treatment.

**HARM REDUCTION**

Across the treatment intensity spectrum, evidence-based harm reduction should be offered to all, including:

- Education re: safer use of sterile syringes/needles and other applicable substance use equipment
- Access to sterile syringes, needles, and other supplies
- Access to Supervised Injection Sites (SIS)
- Take-Home-Naloxone (THN) kits

Supervised Injectable Opioid Assisted Treatment (siOAT)

- Prescribes injectable opioids to treatment refractory opioid dependent people.
- Clinical trials have shown the safety and effectiveness of siOAT (Ferri et al. 2011).
- siOAT is available in several European countries.
- But (mostly) not in Canada and not in the United States.
Clinical Trials

- North American Opiate Medical Initiative (NAOMI): siOAT with diacetylmorphine (DM) compared to methadone.
- Study to Assess Longer-term Opioid Medication Effectiveness (SALOME): siOAT with DM compared to siOAT with hydromorphone.
Opioid Dependence and Voluntary Consent

• “Our life depends on this drug and here we’re offered this drug. . . . I always said, well, I would sign anything at that point. … I would probably say which finger do you want, you know, or which arm do you want” (Boyd & NPA 2013, p. 11).
Assumed Incompetence

- Charland: “we should assume they [opioid dependent people] are incompetent to consent unless proven otherwise” (Charland 2002, 45-46).

- Henden: “the safest assumption is that they [opioid dependent people] lack the competence to consent until proven otherwise” (Henden 2013, 401).
Addictive Compulsions

• For a heroin dependent person, “decisions that relate directly to heroin use are susceptible to powerful physiological and psychological compulsions that usually nullify any semblance of voluntary choice” (Charland 2002, p. 41).

• Critics object that this exaggerates the compulsive nature of opioid dependence (Carter & Hall 2008).

• But there’s a deeper, logical problem.
siOAT as Treatment

• BCCSA’s Guidance for Injectable Agonist Treatment for Opioid Use Disorder includes siOAT in the treatment spectrum.

• “Treatment of heroin addiction … is better conceptualized as the management of a chronic condition” (Bell 2014, 254).

• siOAT is useful for managing longer term opioid use disorder in patients refractory to other treatments.

• This view of siOAT contrasts with labeling siOAT “free heroin” (Henden 2013, 395).
Imagine...

• siOAT is available to those who need it. Now consider this choice:
  1. siOAT for sure now (i.e., as treatment), or
  2. 50% chance of siOAT at some future date (i.e., participation in clinical research).

• A person who chooses 2 over 1 has acted against addictive compulsions.

• So, Charland’s argument assumes that siOAT is unavailable as treatment.
No Acceptable Alternative

• According to Henden’s argument, “a person’s choice is voluntary if [and only if] it is not made because no other acceptable alternative options are available” (Henden 2013, p. 396).

• Henden takes this principle to apply even if the person *mistakenly believes* they have no alternative options.

• This is intended to avoid exaggerated claims that opioid dependent people are totally incapable of refraining from heroin use.
Henden’s Reasoning

• Henden says a person considering whether to consent to research on siOAT has 3 choices:
  • “(a1) Consent to take part in trials and obtain free heroin; (a2) Decline and obtain heroin from the street; (a3) Abstain from heroin” (Henden 2013, p. 395).
  • If the person thinks a3 is not possible and a2 is intolerable, then a1 would be chosen because there are no other options.
  • So, the person’s consent would not be voluntary.
Same Problem

- Henden’s list of options do not include:
  - (a4) Access siOAT as treatment from an addiction clinic.
- And if it did, his conclusion would not follow.
- That is, if the person chose a1 over a4, then a1 would not have been chosen because there was no alternative.
- So, like Charland’s argument, Henden’s presumes that siOAT is inaccessible.
A Question

If both arguments must assume that siOAT is unavailable as treatment, why focus on individual incompetence as the root of the problem?
Another Perspective

- siOAT is a medical therapy:
  1. Whose effectiveness has been shown by clinical research, but...
  2. Which is available in some places, not others.
- Like HIV anti-retroviral medications.
- But inaccessibility of needed medical care is a health inequity, not individual incompetence!
In SALOME...

- Foster care histories (23% of sample),
- Unstable housing (70% of sample),
- Sex work (41% of sample),
- Incarceration (an average of 37 months in lifetime), and
- 30% of participants self-identified with Indigenous ancestry.
Potential Harmful Effects

• Claims that opioid dependent people should be assumed incompetent to consent are likely to:

1. Encourage stigmatization,
2. Prevent opioid dependent people from exercising their autonomy even when they are capable of doing so, and
3. Suggest ineffective solutions that fail to address the underlying problem of inaccessibility of needed treatment.
Inequity not Incompetence

• There’s a genuine ethical concern related to voluntary consent here.
• But it’s not (primarily) about opioid dependent people’s individual competence (or lack thereof) to give voluntary consent.
• Instead, it mainly stems from inaccessibility, in Canada and the United States, of siOAT as a treatment for long-term opioid dependence.
• So, let’s take a closer look at this ethical issue.
Exploitation

• Exploitation: Taking unfair advantage of another’s vulnerability (Wertheimer 1996).

• Clinical research in developing countries that offers access to otherwise inaccessible treatments is sometimes argued to be exploitation.

• And it is also debated whether a person who is being exploited can truly give voluntary consent.
Principle 1 of the Nuremberg Code

- The voluntary consent of the human subject is absolutely essential.
- This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision.
Exploitation = Coercion?

• “Clinical trials are open to the charge of exploiting the vulnerable by taking advantage of their lack of options, so that they agree to risks to which better off individuals would not agree. Depending on how bad the agent’s circumstances are, the clinical trial (the “offer”) may be her only option, raising then the specter of coercion.” (McGregor 2005, 25)

• Critics charge that such views would create unreasonable barriers to beneficial research (Hawkins 2008, 24–26).
No Threats = Voluntary?

• “We generally say that consent is voluntary when it is not coerced. But what does that mean? In general, A coerces B to do X only if A proposes (threatens) to make B worse off with reference to some baseline condition if B chooses not to do X” (Wertheimer 2008, 75).

• So, consent is voluntary if the participant is not threatened by the researcher.

• But this defines “ulterior forms of constraint” out of the picture.
Post-Trial Access?

• “a good ethical working rule is that researchers should presume that valid consent cannot be obtained from impoverished populations in the absence of a realistic plan to deliver the intervention to the population” (Annas and Grodin 1998, 562).

• A similar idea is expressed in the Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (article 20).

• How “realistic” does the plan have to be?
Three Options

• Framed in terms of Principle 1 of the Nuremberg Code:

1. Accept Principle 1 and claim that clinical research is unethical when it is the only access to needed medical treatment.

2. Modify Principle 1 by defining “voluntary consent” to mean consent secured without threats.

3. Modify Principle 1 to permit research in such cases as long as further requirements are met, such as a plan to provide post-trial access to medications found effective in the trial.
The Parallel

- siOAT research in Canada offers needed treatment to patients who cannot otherwise access it.
- Researchers may also benefit professionally via grants and publications related to this research.
- So, the Three Options listed above are pertinent to this case.
- **Note:** None of these options frame the issue of voluntary consent as primarily a concern about individual incompetence.
Summing Up

- Ethical discussions about consent can be distorted by prevalent stereotypes and biases that place blame on individual others.
- That can result in measures that are stigmatizing or which fail to address central ethical challenges to consent (or both).
- In such cases, analogies with other examples where different stereotypes/biases tend to be in play can be useful for reframing.
- Thank you for your attention!
References