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NEGOTIATING STRUCTURAL VULNERABILITY FOLLOWING REGULATORY CHANGES TO A PROVINCIAL METHADONE PROGRAM IN VANCOUVER, CANADA: A QUALITATIVE STUDY

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Abstract

While regulatory frameworks governing methadone maintenance therapy (MMT) require highly regimented treatment programs that shape treatment outcomes, little research has examined the effects of regulatory changes to these programs on those receiving treatment, and located their experiences within the wider context of socialstructural inequities. In British Columbia (BC), Canada, provincial regulations governing MMT have recently been modified, including: replacing the existing methadone formulation with Methadose® (pre-mixed and 10 times more concentrated); prohibiting pharmacy delivery of methadone; and, prohibiting pharmacies incentives for methadone dispensation. We undertook this study to examine the impacts of these changes on a structurally vulnerable population enrolled in MMT in Vancouver, BC. Qualitative interviews were conducted with 34 people enrolled in MMT and recruited from two ongoing observational prospective cohort studies comprised of drug-using individuals in the six-month period in 2014 following these regulatory changes. Interview transcripts were analyzed thematically, and by drawing on the concept of 'structural vulnerability'. Findings underscore how these regulatory changes disrupted treatment engagement, producing considerable health and social harms. The introduction of Methadose® precipitated increased withdrawal symptoms. The discontinuation of pharmacy delivery services led to interruptions in MMT and codispensed HIV medications due to constraints stemming from their structural vulnerability (e.g., poverty, homelessness). Meanwhile, the loss of pharmacy incentives limited access to material supports utilized by participants to overcome barriers to MMT, while diminishing their capacity to assert

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some degree of agency in negotiating dispensation arrangements with pharmacies. Collectively, these changes functioned to compromise MMT engagement and increased structural vulnerability to harm, including re-initiation of injection drug use and participation in high-risk incomegenerating strategies. Greater attention to the impacts of social-structural inequities on MMT engagement is needed when modifying MMT programs, especially as other jurisdictions are adopting similar changes. Comprehensive environmental supports should be provided to minimize adverse outcomes during transitional periods.

Keywords

Canada; Methadone maintenance treatment; Methadose®; drug treatment; drug policy; health policy; structural vulnerability; incentives

INTRODUCTION

North America is experiencing an opiate use epidemic (Tempalski et al., 2013), fuelled by dramatic increases in the availability of prescription opioids (Jones, 2013; Nosyk et al., 2012) and the resurgence of heroin markets (Rosenblum et al., 2014; Unick et al., 2014). Meanwhile, prescription opioid has also increased in Australia, and high rates of opiate use continue to be documented in Southwest Asia and Europe (United Nations Office of Drug Control, 2014). Injection opiate use is a major driver of overdose mortality and morbidities (Degenhardt et al., 2014), including HIV (Mathers et al., 2008) and hepatitis C virus (HCV) infections (Nelson et al., 2011), and represents an urgent public health priority. Methadone, an effective and highly cost-effective long acting opioid agonist used as a substitution drug for opioid dependence, has become a central component of the public health response to injection opiate use globally (Mathers, et al., 2010; Nosyk et al., 2013). Accordingly, while, at best, only approximately 8% of people who inject opiates globally are enrolled in methadone maintenance treatment (MMT) (Mathers et al., 2010), global coverage of MMT is increasing and many countries have recently initiated or expanded methadone programs (Degenhardt et al., 2014).

This global expansion of methadone programs has been propelled by epidemiological evidence demonstrating the role of MMT in decreasing injection opiate use (Corsi, Lehman, & Booth, 2009), and thereby accompanying harms. Among people who inject opiates, enrollment in MMT is positively associated with reduced HIV and HCV risks as well as lower transmission rates (Gibson, Flynn, & McCarthy, 1999; Nolan et al., 2014; White et al., 2014). There is growing evidence that MMT promotes HIV treatment initiation and adherence among injection drug-using populations (Roux et al., 2009; Uhlmann et al., 2010). In addition, previous studies have found evidence of reductions in drug-related criminal activity upon enrollment in MMT (Oliver et al., 2010).

In contrast to the documented public health benefits, qualitative and ethnographic research has illustrated how regulatory frameworks governing MMT shape the experiences of people on methadone, and, in some cases, produce adverse treatment outcomes (Anstice, Strike, & Brands, 2009; Bourgois, 2000; Fischer, 2000; Harris & McElrath, 2012; Holt, 2007; Ning, 2005; Strike, Millson, Hopkins, & Smith, 2013). Safety concerns regarding methadone,

along with policy objectives oriented toward reforming 'irresponsible drug users' (Bourgois, 2000), have led to regulatory frameworks that function to 'discipline' people on methadone by requiring compliance with strict MMT regimens (Bourgois, 2000; Fischer, 2000). Bourgois (2000) has documented how the requirements of these treatment regimens, which often include daily methadone dispensation and directly witnessed ingestion and urine drug testing, operate as a form of biopower regulating the bodies and lives of people on methadone. Perhaps unsurprisingly, strict MMT regimens have been found to contribute to treatment dissatisfaction, interruptions, and discontinuations (Radcliffe & Stevens, 2008; Reisinger et al., 2009), and reinforce stigma among people on methadone (Anstice et al., 2009; Harris & McElrath, 2012).

Meanwhile, previous research documenting how people on methadone seek to negotiate some degree of agency within the context of treatment has underscored how constraints stemming from regulatory frameworks often prevent them from asserting complete control over treatment (Harris & Rhodes, 2013; Holt, 2007; Ning, 2005). For example, Ning (2005) illustrated how, while people on methadone 'test the limits' of treatment requirements to assert agency and achieve some personal benefits (e.g., 'treatment rewards'), they must nonetheless exhibit 'complicity' to MMT requirements to avoid penalties (e.g., cancellation of 'treatment rewards') (Ning, 2005). Meanwhile, Harris and Rhodes (2013) found that, while the 'generous constraints' of take-home methadone doses and diverted methadone increased the capacity for agency among people on methadone by allowing them to self-regulate, these were also necessary to safeguard against constraints imposed by treatment protocols (e.g., restrictive pharmacy hours).

Whereas these studies have underscored the importance of considering how regulatory regimes influence MMT, little is known regarding how *regulatory changes* shape MMT-related experiences and outcomes. This is particularly noteworthy given widespread recognition of the primary role of policy frameworks in structuring drug-related outcomes (Rhodes et al., 2005). Periods immediately following regulatory changes represent critical transitional periods that present novel opportunities to document how *evolving* socialstructural contexts shape outcomes within the broader risk environment (Rhodes et al., 2005), and yet research examining the immediate impacts of such 'natural experiments' remains limited. This research gap is particularly striking in the context of MMT given the considerable influence of regulatory frameworks on the daily lives of people on methadone, and potential impacts of regulatory changes.

Moreover, closer attention to the differential impacts of regulatory changes on people on methadone is likely to illuminate how structural vulnerability influences the capacity to negotiate these changes. Although the concept of structural violence has advanced understanding of how political and economic arrangements function to produce social suffering among disadvantaged groups, Quesada, Hart and Bourgois (2011) have more recently advanced the concept of 'structural vulnerability' to extend the politicaleconomic dimensions of structural violence to include a wider range of socio-cultural determinants of social suffering. For Quesada, Hart and Bourgois (2011), structural vulnerability is viewed as a positionality – that is, the position that particular groups occupy within social hierarchies as a function of the social (e.g., racism, sexism, classism) and structural

inequities (e.g., poverty, drug criminalization) shapes their vulnerability to suffering (Quesada, Hart, & Bourgois, 2011). A structural vulnerability lens has informed studies exploring injection drug use practices (McNeil et al., 2014), sex work involvement (Syvertsen et al., 2013), and migrant labour (Holmes, 2011; Quesada, Hart & Bourgois, 2011), and has proven particularly useful in focusing attention on how intersecting social and structural factors constrain the agency of particular groups and render them vulnerable to risk and harm. Against this backdrop, research examining the impacts of regulatory changes to MMT programs within the context of structural vulnerability has the potential to inform efforts to modify regulatory frameworks to better provide treatment in a manner that accounts for social and structural inequities.

One such ‘natural experiment’ has recently occurred in the context of British Columbia, Canada’s provincial methadone program. In Canada, MMT programs are under provincial jurisdiction and administered in association with regulatory colleges of physicians and pharmacists (Luce & Strike, 2011). Colleges of physicians are generally responsible for MMT programs (e.g., prescribing and dosing guidelines, monitoring practices), while colleges of pharmacists are responsible for setting regulations regarding methadone dispensation and pharmacy practices monitoring (Luce & Strike, 2011). Physician visits required for enrolment in methadone and routine follow-up are covered under Canada’s universal health care system. However, although MMT is often covered for specific populations (e.g., low-income populations) by provincial drug programs, individuals not eligible for these benefits are responsible for payment (Luce & Strike, 2011). Consistent with MMT practices in other jurisdictions (Luce & Strike, 2011), regulations and guidelines established by the College of Physicians and Surgeons of British Columbia (CPSBC) and College of Pharmacists of British Columbia (CPBC) mandate highlystructured MMT regimens involving: dose monitoring and titration (40 mg at initiation with 10 mg weekly increases until stabilization); monthly physician appointments for new methadone prescriptions; daily dispensation and directly witnessed ingestion by pharmacists; and, routine and random urine drug testing (CPBC, 2014). Physicians may authorize take home doses of methadone; however, to limit diversion, these concessions require evidence of social stability and client stabilization including twelve consecutive weeks of negative urine drug tests (CPSBC, 2014). In turn, institutional practices surrounding take home doses of methadone function to largely exclude those who are structurally vulnerable (e.g., vulnerably housed, unemployed) from receiving these treatment concessions.

Despite this degree of regulation, individual pharmacies have for many years provided supports to attract and retain clients, including methadone delivery services (including daily witnessed ingestion) to offsite locations and pharmacy incentives (small amounts of money, food, bus tickets). Although never explicitly condoned by the CPSBC and CPBC, these practices stemmed from a fee-for-service system introduced in the mid- 1990s to encourage pharmacies to dispense methadone as part of the response to an epidemic of opiate injecting. Under this system, pharmacies could bill the provincial drug coverage program more than $6,000 annually per client (if eligible for drug benefits) for daily methadone dispensation and directly witnessed ingestion. Unsurprisingly, this payment system led many pharmacies, particularly those within or in close proximity to the province’s largest street-based drug scenes (i.e., Vancouver’s Downtown Eastside and Surrey’s Whalley neighbourhood), to

provide additional supports to ‘compete’ for clients. For example, some pharmacies began providing financial incentives (typically in the amount of $5 to $10 per week) to clients dispensed methadone at their pharmacy. Others began to deliver methadone directly to clients at their place of residence. These pharmacy supports became the subject of negative academic and media portrayals associating them with client coercion, pharmacy fraud, and methadone diversion (Howlett & Andreatta, 2013; Nosyk & Anis, 2009; Sinoski & Fowlie, 2008). For example, investigative reports into the payment of financial incentives to people on methadone sparked community concerns regarding their potential role in ‘triggering’ further drug use (Sinoski & Fowlie, 2008). Media reports also circulated associating methadone delivery services with pharmacy fraud and methadone diversion (Lazaruck, 2008). Most egregiously, one pharmacy had its license revoked after it was discovered that the owners had overbilled the provincial drug coverage program, provided financial incentives, and required tenants of a single room occupancy hotel that they owned to enrol in MMT at their pharmacy as a condition of receiving housing (Harbottle, 2011).

Several changes were recently introduced to the provincial methadone program with the stated goals of improving client safety and treatment standardization, while preventing methadone diversion and the perceived exploitation of people on methadone. Beginning February 1st 2014, the existing methadone formulation, an anhydrous formulation (1 mg/ml) mixed with juice, was replaced with Methadose®, a pre-mixed formula that is more concentrated (10 mg/ml), thereby lessening the potential for diversion or compounding errors (CPSBC, 2014b). All people on methadone in British Columbia were transitioned to Methadose® by March 1st (CPBC, 2014c). Simultaneously, the CPSBC and CPBC prohibited methadone delivery services to promote compliance with narcotics control measures in the Controlled Drugs & Substances Act (1996), which they interpreted to prohibit the delivery of narcotics (CPBC, 2014d). Under this policy, methadone delivery services can only be authorized for individuals with ‘severe mobility restrictions’ (temporary or permanent mobility impairments) (CPBC, 2014d). Finally, in December 2013, the CPBC prohibited pharmacies from providing monetary and non-monetary incentives to their clients in response to negative media portrayals and a formal complaint by a Downtown Eastside physician linking incentives to increased drug use (CPBC, 2014a). While these regulatory changes represented significant changes to the provincial methadone program, these top-down regulatory changes were implemented with little to no input from people on methadone.

These regulatory changes resulted in widespread community concern, particularly among drug user and methadone consumer advocacy groups in the Downtown Eastside, regarding their potential impacts on MMT treatment access and engagement and drugrelated risks (Robinson, 2014; Stuek, 2014). We undertook this qualitative study to explore experiences among structurally vulnerable people on methadone following the implementation of these regulatory changes. We sought to understand how their structural vulnerability interacted with the evolving regulatory context to frame their treatment experiences and outcomes prior to and following these regulatory changes, as well as to inform recommendations to promote equity within MMT programs during transitional periods.

METHODS

We draw upon semi-structured qualitative interviews conducted with people on methadone as part of the qualitative component of an ongoing ethno-epidemiological study initiated in February 2014 to explore experiences with drug treatment programs in the Vancouver area in British Columbia, Canada. Ethno-epidemiology merges longitudinal epidemiological and ethnographic approaches to explore how social meanings and socialstructural contexts shape health risks and harms over time (Lopez et al., 2013) – in this case, evolving experiences with MMT following regulatory changes. Participants in the larger study were recruited from two ongoing prospective cohort studies that include more than 2000 people who use drugs: the Vancouver Injection Drug Users Study (HIV-negative cohort) and AIDS Care Cohort to Evaluate Exposure to Survival Services (HIV-positive cohort). Cohort participants are recruited from a storefront research office located in the Downtown Eastside neighbourhood and through community outreach, and complete structured questionnaires and clinical assessments every six months (Strathdee et al., 1998; Wood et al., 2003).

Individuals were eligible to participate in the qualitative component of the larger ethno-epidemiological study if they answered “yes” to the following question during baseline or biannual follow-up cohort interviews completed during active recruitment periods after February 2014: “In the last six months, have you been in any kind of alcohol or drug treatment (including methadone)?” Study personnel explained the study to eligible participants (based on interviewer availability) and scheduled interviews with those wishing to participate. Study personnel were requested to prioritize the recruitment of individuals enrolled in MMT during the initial six months of this study to enable us to explore the impacts of this ‘naturally occurring’ event. While there were no refusals to participate, several individuals did not show up for scheduled interviews.

We draw upon a subsample of 34 of the 45 participants in this ongoing study who were interviewed in the six-month period immediately following the changes to the provincial methadone program (February 2014 to July 2014). All of these participants reported that they had been enrolled in MMT when these regulatory changes were introduced. Three trained interviewers conducted the interviews at the research study office. The interviewers explained the study procedures and obtained informed consent prior to the interviews. Participants were remunerated with a $30 honorarium following the completion of their interview. An interview guide was used to facilitate discussion regarding experiences with the methadone program and the impacts of the regulatory changes on MMT, drug use, and income-generating strategies, among other topics. Interviews were audio-recorded and averaged 45 minutes in length. Interviews were transcribed verbatim and checked for accuracy by one of the interviewers. Ethical approval for the study was obtained from the University of British Columbia/Providence Healthcare.

Analysis began during data collection and emerging themes informed subsequent interviews. We sought to characterize experiences with the provincial methadone program, and how the newly introduced regulatory changes shaped treatment experiences and outcomes. Interview transcripts were imported into NVivo qualitative analysis software to facilitate coding. We coded transcripts using an inductive and iterative process (Corbin & Strauss, 2008), and

research team members met regularly to discuss emerging themes. The lead author re-coded sections of the data following establishment of the final themes to enhance their reliability and validity (Corbin & Strauss, 2008). We then used a 'structural vulnerability' lens (Quesada et al., 2011) when interpreting these themes. Specifically, we sought to illuminate how the structural vulnerability of people on methadone shaped how they negotiated the parameters of MMT following these regulatory changes and their exposure to risk and harm.

In addition, we partnered with a local methadone consumers group, the British Columbia Association for People on Methadone (BCAPOM), over the course of this study in reflection of the importance of engaging people who use drugs in the research process (Fry, Treloar & Maher, 2005), and to enhance the interpretive validity of our findings (Creswell & Miller, 2000). The lead author consulted with BCAPOM members prior to the launch of this study and drew upon their input to inform the study design. We also presented our findings to BCAPOM members in the preliminary stages of analysis and following the completion of this manuscript as a member-checking exercise (Creswell & Miller, 2000). They provided substantive feedback during the initial presentation and confirmed that our themes reflected their experiences during the follow-up presentation.

RESULTS

Sample Characteristics

Thirty-four individuals participated in this study, including 20 men and 14 women. Participants averaged 46 years of age (range 26–59 years). Participants identified as white (n=24, 71%), Aboriginal (n=9, 26%), and African-Canadian (n=1, 3%). Approximately half (n=18) were living with HIV. Twenty-nine participants (85%) reported using drugs in the 30 days prior to interview and 23 (68%) reported injecting drugs. Heroin (n=23, 68%), crack cocaine (n=16, 47%), and cocaine (n=11, 32%) were the most commonly used drugs. Nearly all participants (n=31, 91%) had been transitioned to Methadose® by the time of their interview.

Adaptations to regimented MMT regimens prior to regulatory changes

The regulatory context of MMT prior to the changes to the provincial methadone program imposed highly regimented treatment that had required considerable adaptation among participants due to factors related to their structural vulnerability. The constraints imposed upon participants by their structural vulnerability, such as insufficient resources (e.g., lack of transportation) or disruptions due to drug criminalization (e.g., arrest, detention) or housing instability (e.g., homelessness, eviction), posed barriers to compliance with MMT program requirements and led to periodic treatment interruptions in the years preceding the regulatory changes. The subsequent withdrawal symptoms that participants experienced due to missed methadone doses or treatment interruptions were characterized as "*like heroin withdrawal times ten*". This suffering motivated participants to adapt their lives in response to the demands of MMT program requirements. This meant devoting their time and limited resources to overcoming barriers stemming from their structural vulnerability, as well as utilizing pharmacy supports (outlined below) that lowered the threshold of MMT.

The majority of participants described how their lives revolved around MMT program requirements, particularly regular medical appointments and daily witnessed ingestion. While several participants reported that these requirements lent needed structure to their lives and, in combination with reduced drug cravings, limited the need for drug scene engagement (e.g., drug dealing, sex work), most emphasized how MMT was a mechanism of social regulation that constrained their agency and reinforced their marginal position within social hierarchies. Multiple participants described how pharmacy attendance for directly witnessed ingestion constrained their capacity to determine their own schedule and restricted opportunities, such as engaging in formal employment. For example:

> *I didn't think I could get a job because there was no* [pharmacy] *open early enough to get your methadone, go to work and feel comfortable. Then, you tell your boss that you're on methadone – what's he going to think? You give up on a rational, normal life. You figure, the ball and chain* [methadone]*, it's better than nothing.* [Participant #28, White Male, 55 years old]

However, despite dissatisfaction with MMT program requirements, participants acknowledged that adapting to the rigours of treatment compliance was necessary because they lacked alternate means to reliably manage withdrawal.

"Doesn't hold you 'til your next dose" – Methadone formulation changes & increased suffering

Participant accounts underscored how the introduction of the new methadone formulation precipitated increased withdrawal symptoms (e.g., pain, nausea) that fostered severe suffering. Approximately three quarters of our participants reported experiencing increased withdrawal symptoms after switching to Methadose® despite remaining on equivalent methadone doses. Several participants cautioned that their withdrawal symptoms might be "*in their head*" (i.e. psychological) due to the smaller volume of methadone consumed, or possibly the result of pharmacist dispensation errors. As one participant explained:

> *As soon as I went on Methadose®, I don't really think they measure it properly…I was sweating hard…tossing and turning at nighttime. Methadose® is crap.* [Participant #25, Aboriginal Female, 35 years old]

However, the vast majority of participants attributed their withdrawal symptoms to the properties of the new methadone formulation itself. Many participants emphasized that Methadose® "*seems weaker*" than the previous formulation, and "*doesn't hold you 'til your next dose*". In turn, participants reported that, while Methadose® should manage withdrawal symptoms for a minimum of twenty-four hours, these symptoms began to appear within twelve to sixteen hours of ingesting the new formulation. Participant accounts expressed how the severe suffering experienced as a result of increased withdrawal symptoms contributed to decreased treatment satisfaction. For example:

> *It's not agreeing with my body. I can feel a little bit of the effects of it* [alleviation of withdrawal symptoms]. *Other than that…the pain seems to be a lot more than it was when I was taking the regular methadone. I still don't understand this fucking bullshit, but I don't think I really wanna be on it* [Methadose®]. *In the middle of the night, I feel nauseated, whereas before I was always fine…I get my methadone*

at 6:30 [am] *and by about eight or nine o'clock at night, my body aches a lot more.* [Participant #19, White Male, 51 years old]

Additionally, some participants had negotiated split methadone dosages with their physicians (i.e., twice versus once daily treatment) prior to the introduction of Methadose® to better manage medication side effects and withdrawal symptoms, but were returned to once daily treatment following the change due to the smaller volume of methadone consumed. These participants emphasized how these changes further restricted their agency by disrupting their individualized treatment regimens, thereby increasing their difficulty in managing withdrawal symptoms. As one participant explained:

I used to have a split dose…I'd take half of my dose in the morning and the other half usually around three, four o'clock in the afternoon…I've just been drinking it all at once [since February]. *I'd like a split dose again because then I wouldn't be feeling icky* [withdrawal symptoms] *about now* [10 hours after last dose]. [Participant #14, White Female, 50 years old]

Finally, despite increases in withdrawal symptoms following the methadone formulation and dosing changes, only a few participants reported that their dosages had been titrated to larger volumes by their physician to account for these adverse outcomes.

Structural vulnerability as a 'severe mobility restriction'

Most participants emphasized how pharmacy methadone delivery services had previously facilitated treatment adherence by reducing the burdens associated with daily directly witnessed ingestion (e.g., transportation costs, time commitment) and better accommodated competing demands (e.g., income generation, medical appointments). However, participant narratives underscored how the poverty and geographic isolation stemming from their structural vulnerability functioned as a 'severe mobility restriction' that constrained their access to MMT following the discontinuation of pharmacy methadone delivery services. Many participants, particularly those living outside of the Downtown Eastside neighbourhood, expressed that extreme poverty often limited their capacity to travel to pharmacies, with one participant noting, "[people on methadone] *can't get on the bus because they don't have bus fare*". Meanwhile, among participants with competing demands, such as medical appointments or court appearances, the loss of pharmacy methadone delivery services led to missed methadone doses, as well as interruptions in co-dispensed medications such as antiretroviral therapies. As one participant explained:

I was staying at different shelters [prior to the changes]. *They were delivering* [methadone] *right there every morning…If I got court dates, I'm not going to go and drink my methadone and risk going to jail* [for late court appearances]…*On days like that, they'd deliver at 6:30 in the morning…I've missed a lot of doses because of* [the cancellation of deliveries], *same with my* [HIV] *meds because I got them at the same time…Instead of being able to know that I'm going to get my meds 6:30 in the morning…* [If] *I have* [something] *important to do, I end up missing my* [HIV] *meds* [and] *my methadone* [due to difficulty traveling to the pharmacy]. [Participant #29, White Male, 25 years old]

Several participants reported that some smaller pharmacies had adapted to this regulatory change by implementing shuttle services, which transported multiple pharmacy clients to and from pharmacies by van at a time. However, while these participants reported that this intervention reduced barriers to complying with daily pharmacy attendance, most participants emphasized that shuttle services were less convenient due to the travel time (up to two hours) and, in turn, interfered with other activities (e.g., service referrals, income generation) critical to negotiating survival within the context of their structural vulnerability. Accordingly, these participants commonly reported missing methadone doses when unable to take the shuttle due to conflicting appointments or opportunities. For example:

> *I've had a movie thing* [film production security guard work]…*When he* [shuttle driver] *shows up at eight* [am], *it's like, "I'll make it there later…I'll go on my own." And, I'll flake* [i.e., forget to leave for pharmacy] *and, if I can't get there by three* [pm], *I'm shit outta luck…Every time I don't make it with this guy* [shuttle driver], *I've missed* [methadone doses]. [Participant #7, White Male, 43 years old]

Negotiating incentives, structural vulnerability, & agency in the context of regulatory change

Many participants reported receiving monetary or non-monetary incentives prior to the policy changes from pharmacies in the Downtown Eastside and Whalley, typically in the amount of $10 to $20 per week. Participant accounts underscored how these incentives functioned to reduce hardships and risks stemming from their structural vulnerability. Among participants reporting polysubstance use, monetary incentives were primarily used to purchase drugs, and sometimes reduced their need to engage in informal or illegal income generating activities associated with increased risks of violence and HIV transmission (e.g., drug dealing, sex work). Meanwhile, other participants emphasized how incentives aided them in meeting everyday survival needs (e.g., food) and defraying the costs (e.g., bus tickets) associated with daily pharmacy attendance.

Some participants reported having *negotiated* more favourable treatment conditions than those prescribed by their physician by "*shopping their 'script'*" – that is, taking their prescription to multiple pharmacies to find methadone dispensation arrangements that reduced the constraints that they experienced due to their structural vulnerability. In these instances, participants had negotiated take home doses (known as "*carries*") in addition to financial incentives, which were viewed as more convenient and thus helpful in facilitating MMT adherence, as a condition of providing smaller pharmacies with their business, and, hence, lucrative dispensing fees. Although not permitted under the provincial methadone guidelines, some participants nonetheless reported success in negotiating these arrangements. In doing so, these participants were able to assert a greater degree of agency of their treatment than permitted within the parameters of the provincial methadone program. As one participant explained:

> *They'll give me whatever I want within reason* [i.e., take home doses]…*Just for me to bring my prescription there all the time. That's what I told them. I said, "You know, you'll rub my back and I'll rub yours."* […] *All these little hole-in-the-wall*

> [pharmacies] *and that's all they do is put out methadone.* [Participant #9, White Male, 59 years old]

Although several participants reported that several pharmacies continued to provide nonmonetary incentives to avoid losing clients, most reported no longer receiving incentives of any kind. In turn, many participants emphasized how this regulatory change further reduced the resources available to them, thereby functioning to exacerbate their structural vulnerability. Meanwhile, participant narratives further underscore how this change infringed upon their agency by reducing their capacity to assert control over their interactions with pharmacies, and thus their treatment regimens (e.g., obtaining nonmonetary incentives, negotiating carries). Taken together, these changes served to increase the difficulty in complying with treatment parameters prescribed by their physicians and imposed by the regulatory context of the provincial methadone program. As a consequence, many participants decried policies prohibiting pharmacy incentives as "*unfair*". For example:

> *They are trying to get it so that you will go to those drug stores* [larger pharmacy chain stores] *as opposed to the ones that are smaller 'cause they're the ones that are giving incentives. Why shouldn't drug stores be able to offer whatever to get more customers? I think that only benefits people such as ourselves…an extra 10 bucks here and there…when you're living below the poverty* [line], *you're absolutely going to take it.* [Participant #2, White Female, 52 years old]

The risks and harms of managing treatment disruptions

Our analysis of participant accounts underscores how the collective disruptions in MMT experienced as a consequence of these regulatory changes functioned to increase structural vulnerability to harm among those seeking to alleviate the suffering associated with increased withdrawal symptoms. Whereas some participants "*toughed out*" withdrawal symptoms until their next dose, approximately two thirds of our participants reported consuming heroin or illicit opioids to alleviate withdrawal symptoms stemming from the regulatory changes. In turn, some participants re-initiated injection drug use (e.g., heroin, prescription opioids), sometimes following extended periods of injection drug use cessation. Meanwhile, other participants reported purchasing diverted methadone (previous formulation) and Methadose® within the street-based drug scene. While participants were able to minimize drug-related risks due to the availability of harm reduction services locally, most expressed that the changes to the methadone program were "*more trouble than they were worth*" because the treatment disruptions produced severe social harms. Specifically, poverty and limited employment opportunities led many participants to re-initiate or intensify informal and illegal income-generating activities (e.g., drug dealing, sex work) to generate income to purchase drugs to cope with their increased withdrawal symptoms. Some participants had previously taken great efforts to limit their street involvement and these changes reduced their capacity to assert control over their lives. For example:

> *I wasn't working* [selling sex] *for 'bout a month, like all of January and February 'cause I was still getting my methadone. I've been having to work everyday* [since switching to Methadose®]…*I was just starting to feel normal – change my life –*

> *but now I'm having to hustle* [sell sex] *to feel better* [purchase heroin to manage withdrawal]. [Participant #16, Aboriginal Female, 31 years old]

These participants also described how the urgent need to alleviate withdrawal symptoms associated with regulatory change led them to take risks when working that increased their vulnerability to violence and exploitation, including accepting sex work clients they would normally refuse or accumulating drug debts by injecting drugs that they were supposed to be selling. For example:

> *You'll go into a cheap date… When you're sick, you don't give a damn…A fivedollar date means five milliliters of methadone…Girls aren't supposed to be doing that shit. It makes it worse for other girls…I mean, I don't do five-dollar dates but that's the extremeness of it* [withdrawal]. [Participant #27, Aboriginal Female, 52 years old]

> *I was still selling drugs* [following the regulatory changes], *so I could supplement. I could take a little money out and buy one or two papers* [of heroin] *and supplement that* [Methadose®] *to make it balance out. Got me in a lot of trouble because then I was short on my money to the dealer. I'm still working off drug debts. That's a pretty big thing when you owe somebody money.* [Participant #28, White Male, 55 years old]

DISCUSSION

Our findings demonstrate how regulatory changes to the provincial methadone program produced adverse health and social outcomes among participants by disrupting strategies that enabled them to comply with MMT regimens within the context of their structural vulnerability. While changes to the methadone formulation produced increased withdrawal symptoms, our findings also demonstrate how the elimination of delivery services and pharmacy incentives disrupted strategies that had enabled people on methadone to comply with or assert greater control over treatment regimes. These regulatory changes led to missed doses and withdrawal symptoms that, in turn, led to increased injection opiate use, as well as the consumption of diverted methadone. The urgent need to mitigate withdrawal symptoms within the context of limited opportunities for income generation led to involvement in sex work and drug dealing and facilitated risks (e.g., accepting low-paying clients, accumulating drug debts), thereby underscoring how regulatory changes can serve to exacerbate structural vulnerability. Collectively, our findings demonstrate how these regulatory changes served to undermine the health and social benefits associated with MMT among structurally vulnerable persons.

Importantly, our findings illustrate how the introduction of Methadose® precipitated real or perceived increased withdrawal symptoms. While this may in part be a psychological phenomenon, possibly due to the reduced medication volume dispensed with the newer formulation, dispensation challenges and pharmacological or pharmacokinetic effects might also explain these dynamics. Meanwhile, previous studies of methadone formulation changes (tablets to liquid formulations) have documented high rates of 'change intolerance' resulting in adverse outcomes (e.g., withdrawal symptoms, injection opiate use) (Silver &

Shaffer, 1996; Steels, Hamilton, & McLean, 1992), underscoring the need for pharmacokinetic studies undertaken real world conditions. This is of particular importance as populations enrolled in MMT increasingly report polysubstance use and require a variety of daily medications to manage complex comorbidities (Sharif et al., 2013), which potentially impact treatment effectiveness (McCance-Katz, Sullivan, & Nallani, 2010). However, evidence demonstrating the effectiveness of Methadose® in comparison to other formulations appears limited. While finding no differences in pharmacodynamic or clinical measures, the only study comparing methadone formulations (including Methadose®) was limited to 18 people on methadone who were drug abstinent and HIV-negative (Gourevitch et al., 1999).

Strategies that account for change intolerance and dispensation challenges are needed following the introduction of methadone formulation changes, particularly in light of the cascading harms associated with MMT disruptions. One potential strategy would be to continue to offer existing methadone formulations alongside newer formulations to people on methadone demonstrating intolerance to formulation changes pending further study, while simultaneously undertaking evidence-informed public education and outreach activities to limit the potential for harms stemming the diversion of methadone to illicit drug markets with varying levels of concentration. For example, it would be important to undertake pharmacokinetic studies to determine whether experiences of change intolerance are attributable to pharmacokinetic issues and, if so, allow those intolerant to this change to remain on existing formulations. Furthermore, those switched to new methadone formulations should be closely monitored and have their dosages titrated to minimize withdrawal symptoms. Additional consultations undertaken with people on methadone immediately following formulation changes might further expedite the identification of any problems. In Canada, this is particularly important as provincial methadone programs increase standardization, with Ontario recently following British Columbia in introducing Methadose® (Ontario Ministry of Health and Longterm Care, 2014). Meanwhile, treatment standardization efforts involving methadone formulation changes are likely in other settings and those involved would be wise to similarly examine factors that might impact treatment effectiveness during transitional periods.

Building upon research into the role of low threshold MMT programs in promoting treatment access and retention (Strike et al., 2013), our findings underscore the tensions between low threshold supports, such as methadone delivery services, and regulatory regimes primarily concerned with reducing methadone diversion. In addition to positioning harm reduction rather than drug abstinence as the goal of treatment, low threshold methadone programs involve flexibility and supports oriented toward promoting treatment retention (Strike et al., 2013). However, while we found that methadone delivery services served as a low threshold support with significant potential to improve treatment retention, these supports were nonetheless prohibited to ensure compliance with narcotics control measures contained in federal legislation, as well as address concerns regarding coercive uses of delivery services by profit-motivated pharmacies. Although pharmacy shuttle services mitigated treatment disruptions to some degree, these regulatory changes nonetheless raised the threshold of MMT and compromised access to treatment as well as adherence to co-dispensed medications among some participants. Given the important role

of MMT programs in supporting related public health priorities (e.g., HIV Treatment as Prevention programs), and ways in which highly-structured program requirements can limit employment opportunities (Richardson, Wood, Montaner, & Kerr, 2012), our findings highlight the need to pursue innovative strategies to improve MMT access, including methadone delivery services, as well as policy frameworks that permit such low-threshold approaches. In light of previous concerns regarding methadone delivery services, formally integrating this approach into methadone programs and orienting it toward enhancing treatment safety and retention would likely allow for sufficient oversight to prevent abuses.

Building upon previous studies demonstrating their role in improving drug treatment retention (DeFulio & Silverman, 2012), we found that incentives mediated access to supports that facilitated treatment retention and reduced the need to engage in informal and illegal income-generating strategies associated with higher risks of harm. Accordingly, concerns regarding the potential for coercion and exploitation of people on methadone by pharmacies offering incentives may be more complex than previously described (Strike et al., 2013). In addition, criticism focusing on the role of incentives in 'triggering' drug use are likely rooted in popular understandings that define drug abstinence as the only acceptable 'end goal' of drug treatment. The fact that some participants relied on incentives to meet everyday survival needs and access treatment suggests that formal incentive programs may serve to offset barriers to MMT stemming from structural vulnerability. Moreover, among those using financial incentives to purchase drugs (primarily stimulants), incentives allowed them to moderate their involvement in informal and illegal income generating activities that increased their vulnerability to violence and HIV transmission, a laudable goal aligned with self-identified goals (e.g., reducing sex work involvement) and broader public priorities (e.g., reducing street-based drug dealing).

Unique to this study is the finding that the lucrative dispensation fees received by pharmacies had an indirect effect of allowing some people on methadone to exert greater control over their treatment regimens. While methadone programs conventionally enact treatment requirements that deny so-called 'irresponsible drug users' agency within treatment regimens (Bourgois, 2000), some of our participants reclaimed agency to some extent by negotiating with pharmacies to achieve more favorable treatment arrangements than those prescribed by their physicians. Previous studies have outlined how 'tactics' employed in resistance to MMT program requirements often outwardly signal complicity toward disciplinary power (Holt, 2007; Ning, 2005), in that they represent adaptations to the rigors of MMT program compliance. However, our findings suggest that subverting the power dynamics of methadone dispensation to determine the parameters of treatment programs (*negotiating with pharmacies*), and thus assert agency within the context of MMT (*more favorable treatment conditions*), did not appear to compromise participants' treatment. Our findings thus further underscore the need to explore low-threshold approaches that allow for agency among people on methadone by giving them greater voice in determining treatment regimens.

Finally, our study underscores the need for greater attention to structural vulnerability when introducing changes to policies or programs affecting populations disproportionately impacted by social and structural inequities, such as people on methadone. In contrast to

epidemiological studies that have longitudinally examined impacts of regulatory changes on MMT enrollment and adherence to dosing guidelines (Nosyk et al., 2010; Strike et al., 2005), our findings demonstrate how social and structural inequities interacted with regulatory changes to shape treatment access and engagement. Notably, the adaptation required of participants to comply with MMT regimens within the context of their structural vulnerability led to strategies that were disrupted following the regulatory reforms and, in turn, led to risks and harms (e.g., engagement in high-risk income generation) that still further marginalized them. Previous studies have examined how policy and regulatory frameworks render people who use drugs vulnerable to harm due to their position within social hierarchies (McNeil et al., 2014; Rhodes et al., 2012). However, our findings further illustrate how regulatory reforms may function to alter the positionality of drug-using populations by changing their social and material circumstances. Importantly, this underscores how the social positions occupied by structurally vulnerable populations are fluid, and can change (for better or worse) as a consequence of social-structural reforms. Furthermore, the greater degree of structural vulnerability experienced by socially and materially disadvantaged populations (in this case, people on methadone) can pose challenges to efforts to renegotiate the parameters of their daily lives (e.g., MMT regimens) and, in turn, exacerbate social suffering. These dynamics highlight the urgent need to consider the potential impact of regulatory reforms on structurally vulnerable populations. For example, community consultations that involve affected populations (in this case, people on methadone) should be undertaken during planning phases to elucidate the potential impacts of regulatory changes and orient reforms towards the promotion of health and social equity.

This study has several limitations that should be taken into consideration. First, our participants were recruited in the Downtown Eastside from among structurally vulnerable people on methadone, and their experiences are likely to differ from those of individuals in other contexts and from other social positions with greater access to resources (e.g., housing, income, transportation). Second, studies undertaken in settings where MMT programs operate within dramatically different regulatory frameworks might identify different health impacts. Further studies into the impacts of regulatory changes in these settings are likely to yield additional insights. Finally, nearly all participants (97%) had the cost of their methadone prescription covered by Pharmacare, and individuals elsewhere might face financial barriers to MMT that pose additional challenges following regulatory changes.

In conclusion, this study illustrated how the introduction of Methadose® and accompanying regulatory changes produced unexpected adverse treatment outcomes for many people on methadone. This study highlights the need to consider strategies to mitigate client concerns with methadone formulation changes, as well as low-threshold approaches that promote MMT engagement within the broader context of structural vulnerability.

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Highlights

1. Explores regulatory changes to British Columbia, Canada's methadone program
2. The methadone formulation change precipitated increased withdrawal symptoms
3. Additional regulatory changes served to disrupt routine treatment strategies.
4. Findings outline how these regulatory changes functioned to foster risk and harm
5. Regulatory changes increased the structural vulnerability of people on methadone