

BC's change in methadone formulation: A metanarrative review of the literature

Approval

Abstract

British Columbia's Opioid Substitution Treatment (formerly Methadone Maintenance Therapy¹) made a switch in formulation from generic methadone to a proprietary medication called Methadose™ (BC Ministry of Health, 2013) effective February 1 of 2014. The switch to Methadose™ in British Columbia (BC) offers an opportunity to examine the literature about methadone, MMT, and opioids and trace the evolution of policy and practice that inform this substitution therapy. A metanarrative review of the literature demonstrates the evolving perspective on MMT and offers insights to how a society views substance use, as well as future medication changes that affect a particular patient population, especially when that population is comprised of individuals who face structural inequities in mainstream Canadian society.

Keywords

methadone; Methadose™; change intolerance; British Columbia; opioid substitution therapy; drug policy; addictions

¹ “The Government of BC uses the term “opioid substitution treatment” (OST) to include the use of methadone and Suboxone® (buprenorphine and naloxone formulation) for maintenance treatment.”(Office of the Provincial Health Officer, 2014). For the purpose of this report I will be using the term Methadone Maintenance Treatment (MMT) as the population involved in the survey were only asked about MMT, and not prescribed Suboxone® for maintenance treatment.

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List of Acronyms

BC	British Columbia
BCAPOM	British Columbia Association of People on Methadone
BCCDC	British Columbia Centre for Disease Control
BCMHS	British Columbia Ministry of Health Services
CAPUD	Canadian Association of People who Use Drugs
CPBC	College of Pharmacists of British Columbia
CPSBC	College of Physicians and Surgeons of British Columbia
FNHA	First Nations Health Authority
HAT	Heroin Assisted Treatment
IDU	Injection Drug User
MMT	Methadone Maintenance Treatment
MSP	Medical Services Plan
OST	Opioid Substitution Treatment
PWUD	People Who Use Drugs
SALOME	Study to Assess Longer-term Opioid Medication Effectiveness
UHRI	Urban Health Research Initiative
VANDU	Vancouver Area Network of Drug Users
VCH	Vancouver Coastal Health

1. Introduction

This capstone paper will employ a metanarrative perspective in reviewing and synthesizing the literature about methadone, its use in treatment of opioid dependency, and the involvement of methadone-users in treatment policy and administration. I argue that the metanarrative perspective is useful in uncovering the ways in which research has inadvertently relied on and perpetuates a negative view of methadone-users, contributing to the on-going stigmatization of this patient group. The switch to Methadose™ in British Columbia (BC) offers an opportunity to critically reflect on the body of research about opiate dependency and the methadone-patient and evaluate how research has contributed to the current policies, practices, and viewpoints about opioids, opioid dependency, and patients who use opioids or are involved in treatment. Throughout this paper I reflect on how the literature impacts the policy and practices associated with People Who Use Drugs (PWUD).

Background

British Columbia's Opioid Substitution Treatment (OST) (formerly Methadone Maintenance Therapy-MMT) made a switch in medication from generic methadone to a proprietary medication called Methadose™ ("BC PharmaCare Newsletter," 2013) effective February 1 of 2014. The explanation given for the change is that the new highly concentrated medication, as it is pre-mixed, would reduce errors made through manual compounding ("BC PharmaCare Newsletter," 2013). Additionally, the product has a longer shelf life, is painful if injected, and has the ability to be stored unrefrigerated (if it is undiluted). Within Canada, BC is neither the first, nor the last of the provinces and territories, to make the switch in medication (J. Buxton, personal communication, November, 4, 2014) but what is significant is that BC, unlike other provinces such as Alberta or Ontario, was not able to use the dye-free/unflavoured version² of Methadose™, and dilute the medication with Tang™, an orange-flavoured drink, or other similar drinks as was usual practice, potentially creating an issue that may or may not affect the uptake of the medication with BC consumers. Both formulations, methadone and Methadose™, serve the purpose of substituting a patient's need to use an illicit or licit opioid to meet their substance-dependency needs with a prescribed medication, or is used in other arenas to address pain outside of opioid-dependency, such as an analgesia for cancer-related pains or neuropathic pain. Both medications serve the same purpose yet several differences exist between the products, namely concentration of the product. The preparation that was previously compounded

² The BC Ministry of Health decided that coverage would not be offered for the dye-free, sugar-free, unflavoured solution "as the amount of sugar in the regular liquid is minimal and unlikely to affect blood sugar" (BC PharmaCare Newsletter", 2013).

and diluted by pharmacists is replaced with undiluted cherry-flavoured syrup this is 10X the strength and a 10th of the volume. The decision for the medication change involved several stakeholders, including the BC Ministry of Health Services (BCMHS), the College of Pharmacists of BC (CPBC), and the College of Physicians and Surgeons of BC (CPSBC). Notable no PWUD advocacy groups were included in the decision-making.

Engagement with PWUD and implementing patient-based initiatives requires an examination regarding issues such as ‘public order’ and ‘public safety’ and deciding for whom do policies and practices benefit. In BC, several patient and peer-led groups have advocated for changes to be made to the MMT program historically, and specifically related to the formulation switch to Methadose™. The Vancouver Area Network of Drug Users (VANDU), and the BC Association of People on Methadone (BCAPOM) have been instrumental in pushing for the inclusion of users/patients in the decisions made about policies and practices that affect that drug users. VANDU is arguably Canada’s largest and most successful organization representing PWUD and former users in Canada. The group formed in 1997 in response to the public health crisis of rising new HIV infections and rising mortality rates from drug overdoses (Kerr, Small, Peeace, Douglas, Pierre, and Wood, 2006; Jürgens, 2008). VANDU is strictly member-driven and base membership on the criteria that one must be a current or former drug user. VANDU has involved itself in user-driven health and political initiatives such as needle exchanges, SIS, safe smoking sites, as well as other research and advocacy needs. The BCAPOM, like VANDU, were essential in bringing forth the need to identify users’ experience during the transition from methadone to Methadose™ and formulate the questions that would be included as part of the 2014 Harm Reduction Survey (BCCDC Provincial Harm Reduction Program, 2015). In addition

to their involvement in the Harm Reduction Survey, BCAPOM had direct consultations with the CPBC to discuss the impact of the formulation switch to Methadose™ (Mullins, 2014). At the meeting, advocate and journalist Garth Mullins reported that pharmacists partook of a taste-testing of an inert version of the formulation; and reported that the tasters said it reminded them of gasoline, something MMT-patients are too familiar with (Mullins, 2014). Advocates at both BCAPOM and VANDU note that the disconnect between MMT patients and service providers “could have been avoided if patients were part of the decision ... [and that] BCAPOM explicitly asked to be part of a [Methadose™] trial to make sure it was okay, and their request was turned down” (Mullins, 2014).

Critically reflecting on the switch in formulation using a metanarrative perspective affords an opportunity to discuss broader themes related to substance-use, substance-use treatment, as well as the people who consume substances and patient groups. A metanarrative employs a realist synthesis and is particularly useful in understanding the various outcomes for complex interventions (Wong, Greenlaugh, Westhorp, Buckingham, & Pawson, 2013). Synthesizing evidence to determine “issues and understand contextual influences on whether, why, and how interventions might work” (Pawson, 2006, Pearson & Coomber, 2010 in Wong et al., 2013, p. 1006) is of concern to both researchers and policymakers. A metanarrative is analogous to the concept of a story about a story; it takes a timeline of a body of research and uses this as a unit of analysis. The body of research is assessed to uncover the underlying philosophical positions that are represented in the literature (Greenhalgh, Wong, Westhorp, & Pawson, 2011). Development of the metanarrative arose as a way to “illuminate the different paradigmatic approaches to a complex topic area by considering how the ‘same’ topic had been

differently conceptualised, theorised and empirically studied by different groups of researchers” (Greenhalgh et al., 2011, p. 116).

A metanarrative perspective is particularly suited to the topic of methadone, treatment of opioid dependency, and the target patient group. The metanarrative approach can uncover the implicit assumptions made by researchers and provides a strategy for understanding conflicting research and policy outcomes. What is not readily and explicitly acknowledged in much research about methadone is the assumptions that: opioid dependency is inherently problematic; patients who are prescribed methadone are inherently undisciplined and need stricter controls for their own safety; that patients are not the experts in knowing what course of treatment is best for them; and that methadone is a logical, less harmful drug than other opioids, among others.

2. Methods

Literature Review

A metanarrative approach was used to focus the literature reviewed and to provide a basis for abstraction of the literature in order to gain better understanding of the patterns that emerged. Simply looking at the history of methadone in substance-dependency treatment overlooks the generative explanation for causation in its effectiveness or ineffectiveness in a treatment context. Further, it overlooks the arc of philosophical and value-driven beliefs that guide research and policy in this topic arena.

To begin the literature review I chose to examine research that described the history of opioid use and substitution treatment. Focussing from this initial set of parameters required an iterative process of forward and backward snowballing based on research relevance (as opposed

to research type, such as only examining case-control research), as well as employing my pre-existing knowledge and experience in working with populations who use substances and/or are involved in substance-use treatment.

A limitation of the parameters used to conduct this literature review is that articles discussing neoliberal discourse and how this specifically impacts populations involved in harm reduction or drug use were not captured. Inclusion of these types of articles will be useful for a more in-depth discussion of the issues presented in this paper.[1]

I accessed several databases through the online SFU library including PubMed, CINAHL, Web of Science, Medline, the Canadian Health Research Connection, Biomed Central, along with grey literature in the fields of health, human behaviour, social sciences, as well as drug use and treatment. Example Boolean terms and keywords used to conduct the search included: addiction; drug treatment; harm reduction; Methadone Maintenance Therapy; and opioid substitution treatment. Grey literature was searched using the search engine Google and included government sites and publications from professional colleges. To illustrate the flow of the literature review process I have included a diagram below (see Table 1).

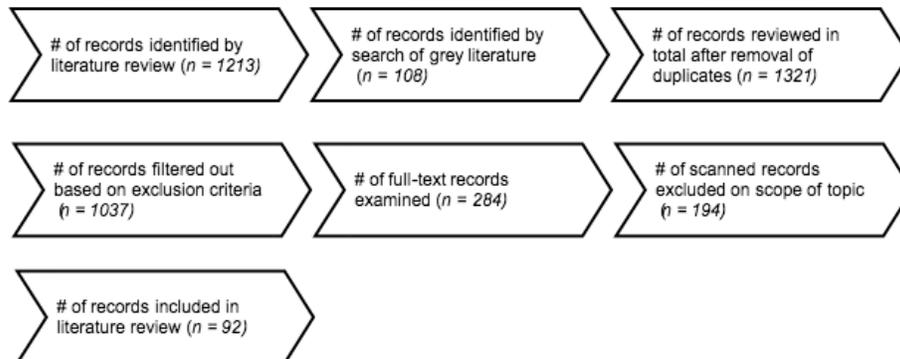
From this initial search articles were excluded if they did not meet the following criteria: uni-substance or polysubstance that included heroin and/or opioids; related to Canada; scholarly and peer-reviewed publications; grey literature attached to a recognized organization such as university-affiliated research groups or governmental publications; and adult-related. Articles focusing on youth or alcohol or gambling were also excluded. Methadone in palliative care use or treatment for cancer pain were also excluded. Further focusing of the literature arose from my knowledge of vocabulary and descriptors used by PWUD as well as terminology from the multi-

disciplined health and support services that seek to engage PWUD. Knowledge of the multiple systematic barriers that many substance-users face also led to the inclusion of research about poverty, violence, and interconnected risk; articles that would not necessarily be included if search terms were constricted to straightforward research on methadone treatment efficacy.

Remaining literature was scanned by examining titles, keywords, and abstracts. Articles that were retained were chosen if they fit the scope of the chosen topic. These articles were read and grouped into thematic categories. Further investigation searched for connections between thematic groupings and with the paper's topic.

Table 1

Flow diagram for literature review (2000-2015)



Findings

From the records reviewed (92), I determined 6 thematic groupings: History of treating opioid misuse in Canada/BC; MMT involvement; change intolerance with MMT; barriers to service; engagement & perspectives of patients; and summaries of treatment alternatives.

History of treatment of opioid misuse in Canada/BC.

Methadone's chemical make-up and mode of action upon neural processes and biological function is well documented throughout the literature (Cadario, Wlock, & Li, 2005; Gerra, Maremmani, Capovani, Somaini, Berterame, Tomas-Rossello, Saenz, Busse, & Kleber, 2009; Kreek, 2000). Methadone is a synthetic morphine-like drug originally developed in Germany in response to an opium shortage during the 1930s.

Methadone binds to opioid receptors in the brain to block the euphoric effects of opioids (Cadario et al., 2005). Guidelines in Canada for the use of methadone in treating opioid dependence were initially prepared in 1971 (Minister of National Health and Welfare, 1994). While reducing the effects of withdrawal, methadone also prohibits the user from experiencing the rush or euphoria that is delivered by consumption of another opioid. This lack of euphoria is a sensitive topic and one that cannot be unaddressed. Lack of the euphoria, along with other problems associated with treatment such as the multiyear or lifelong dosing regime, is likely responsible for MMT's extremely high relapse rate, over 90% (Collège des médecins du Québec, 2000), leading many to enter and then quit MMT several times over the course of their lives. This is the fundamental flaw of MMT; focusing treatment on pharmacology does not change any of the conditions that lead to one using illicit substances in the first place. Yet, MMT, as it is currently implemented in BC, does not address what the motivators are, other than avoiding withdrawal, of opioid-seeking behaviour.

Methadone does possess risks and complications, as all medicines do. Mitigating these risks falls to prescribing physicians, dispensing pharmacists, overseers of regulations, manufacturers, researchers, and treatment guidelines. Concerning methadone, the greatest risk to

the patient may be its undetermined toxicity level; that is tolerance is subjective to one's susceptibility. These high-priority individual-based risks are not addressed through the switch to the new formulation Methadose™.

Goals of treatment and drug acceptability.

Extensive research (Amato, Davoli, Aperiucci, Ferri, Faggiano, & Mattick, 2005; Collège des médecins du Québec, 2000; Farrell, Ward, Mattick, Hall, Stimson, Des Jarlais, Gossop, & Strang, 1994; Nosyk et al., 2013; Van der Brink, Haasen, 2006; Veilleux et al., 2010) spanning several decades has demonstrated, arguably, the successes of MMT. Why the need for treatment for opioid-dependency? Broadly, the need for treatment falls into two categories: protection of an individual's health and inclusion into mainstream society; and/or protection of public safety and welfare. Investigating the ideas behind the intended goals of treatment I uncover a reflection of our current society's expectations of its citizens through the governance and discipline of the body that consumes opioids. Using the metanarrative lens uncovers value-driven information that informs, reiterates, confirms, and perpetuates how drug dependency is characterized and what story is told about PWUD.

Opioids have a turbulent and changing history within Canada and especially within BC. A full exposure of the legal and legislative history of opioids in BC and in Canada is beyond the scope of this paper. However, it is sufficient to note that opioids and other narcotics were unregulated in Canada and governments earned revenue from taxing opium factories (Solomon & Green, 1988 as cited in Dias, 2003; McCormick, 1960 p. 9) until the Opium Act of 1908 and the Opium and Drugs Act in 1911 were passed (Fischer, 1999). These legal proceedings and following acts increasingly targeted those who used drugs and labelled these users as criminals,

punishing their drug use and/or involvement with penalties through fines and incarceration. The changing nature of a substance's legality has a corresponding effect on how that substance is viewed by society.

While goals of MMT initially relate to reducing individual high-risk behaviour they can also be viewed as a way of society protecting itself from the harms that an individual may inflict upon others: physically, socially, or financially. Indeed, most of the successes of MMT are defined in terms of costs, but also including health-care outcomes and involvement with the criminal justice system. Research points out that treatment “has also been deemed highly cost-effective, if not cost-saving” (Nosyk et al., 2013, p. 2) and focuses on figures such as the “overall social cost of one untreated opioid-dependent person in Toronto has been estimated to be \$45,000/year (2001 figure)” (Popova, Rehm, & Fischer, 2006, p. 2) or in terms of lifetime care for those with HIV and/or hepatitis C. Implications of defining one aspect of success for MMT in terms of monetary cost-benefits challenge the usual course that public health professionals take to implement research into action and policy.

Vancouver has the highest concentration of people using illicit opiates in BC (the Provincial Health Officer of BC estimated there were nearly 16,000 patients receiving OST in BC (PHOBC, 2014)) (MacPherson, Mulla, & Richardson, 2006; Nosyk, Marsh, Sun, Schechter, & Anis, 2010; Urban Health Research Initiative, 2009). In response, the City of Vancouver implemented a four pillar approach to managing drug-related harm and disorder in 2001 (MacPherson, 2001). MMT falls under the treatment category and its objective is to offer “a range of interventions and support programs that encourage people with addiction problems to make healthier decisions in their lives ...[and work to] improving social integration”

(MacPherson, 2007). Although each pillar is intended to hold equal weight, critics say far too much focus remains on enforcement (Fischer, Patra, Cruz, Gittins, & Rehm, 2008; McNeil, 2013, p. 49; Nosyk, Marshall, Fischer, Montaner, Wood, & Kerr, 2012; Thorneloe, 2013).

Harm reduction as a principle is not included in a national drug strategy, nor have regulations federally allowed for anything but a methadone-first approach to opioid addiction although other options exist (Thorneloe, 2013). Canada has experienced a disconnect between what best evidence demonstrates and what policies are enacted. Under the Conservative government of Stephen Harper (2006-2015), the Canadian government underwent a dramatic shift in view of drug dependency; one that moved away from a public health approach to an increasingly punitive anti-drug approach, similar to the United State's war on drugs (Hathaway & Tousaw, 2008). Harper's government policies included opposition to needle exchange programs, stiffer prison sentences and mandatory jail time for drug possession, a fight over supervised injection sites that went to Canada's highest courts, and a suppression of evidence that supports international standards on drug control (Hathaway & Tousaw, 2008; Small, 2006; Small, 2008; Webster, 2011). These policies reinforce negative viewpoints of PWUD as deviant (Pauly, 2008).

MMT Involvement.

Opioid Dependence: Definition and Scope.

Defining opioid use disorder is an imperfect and not uniformly agreed-upon diagnosis. Diagnosing relies on evolving screening tools and cultural shifts in understanding of what is and isn't an illicit substance and what does and does not determine a threshold for dependency or addiction. For some individuals and groups, drug dependency or addiction will remain a moral

issue, sinful and depraved, questioning an individual's fortitude when confronted with temptation. For others, dependence and addiction on any substance is criticized as dependent on what larger system benefits or profits from controlling that substance (Luce & Strike, 2011; Medical Beneficiary and Pharmaceutical Services Division, 2015; Mullins, 2015; Nosyk & Anis, 2009; Stueck, 2015). Western critical research has moved away from a behavioural disorder model, or social model of addiction, to the disease model (MacPherson, 2001; Small; 2008; Small, Drucker, & Editorial, 2006). Labelling opioid-dependency as a disease comes with both benefits and harms. The disease model of addiction encompasses varying assumptions and anticipated outcomes, which inform the direction of treatment and whom should bear the costs (MacPherson, 2001; Small; 2008; Small, Drucker, & Editorial, 2006). Positioning opioid dependency as a chronic condition is a hallmark of the disease model of addiction. This characteristic services a multitude of purposes, depending on one's viewpoint: a convenient excuse for one's drug-taking behaviour; an exoneration or confirmation of one's motivation for criminal behaviour; a validation for the need of long-term medication requirement; an explanation for one's unsuitability for certain prospects in work or education; an argument for one's involvement or not with a criminal justice system; a rationalization for denial of child custody; a vindication of the triumph of a faith-based or non-medical based therapy; or a justification for the continuous monitoring of certain groups of people. Conversely, a positive outcome of the disease model is that in some instances it can temper the judgment bestowed upon PWUD as addiction is viewed as a disorder of the brain and may alleviate feelings of guilt and shame; one is helpless against a disease and cannot simply get better on their own. The use

of the disease model is helpful for some agencies for justifying public health dollars being spent to improve the health of PWUD.

Individualizing the responsibility of drug dependency and the burden of treatment serves to distract from the larger social context in which drug use takes place. It is hard to imagine another disease that receives the same level of scrutiny as addiction does.

Determining opioid dependency is further complicated by the varying drug use patterns based on local availability, preferences, and responsive interventions that determine planning and delivery. MMT focuses on treating “a[n] (increasingly non-existent) target group of mono-heroin or opioid users,” (Popova et al., 2006, p. 7) yet getting an accurate picture of the scope of problematic use is complicated by facts including that “coroner’s data does not disaggregate between illegal, prescription or non-prescription opioids” (Thorneloe, 2013, p. 48), there is not a consistent and federal-wide tracking and reporting process, and overdoses may be difficult to determine in the presence of multiple of substances. Without knowing which opioids are contributing to morbidity and mortality, determining policy interventions remains a near impossible task (Popova et al., 2006).

Administration of MMT in BC.

In BC, the provincial health ministry entered agreements with various regulatory colleges to manage MMT after the federal government devolved responsibility for health care to the provinces in 1996. Provincial health ministries make the decision on which services connected to MMT are covered under provincial budgets, along with other areas of addiction funding, essentially creating two parallel systems: one of MMT services provided by fee-for-service in individual or group practices; the other through a provincially-funded clinics (Luce & Strike,

2011). MMT services, programs and supports however, operate over a variety of areas including other non-health areas such as the criminal justice system (although inmates in federally-run prisons can be initiated on MMT, BC is the only province where MMT can be initiated in provincially-run prisons (Luce & Strike, 2011, p. 2)), supportive housing, and family services. Coordinating across jurisdictional systems is a significant challenge to delivering effective MMT services. As it remains today, optimal involvement in MMT is restricted not only by cross-jurisdictional challenges, but also by lack of prescribers and dispensers in remote and rural environments as well as local bylaws, originating from negative perceptions about PWUD and/or MMT patients, which can prohibit where MMT services can be located and the hours they are allowed to operate (Thorneloe, 2013). Without a regulatory body with disciplinary power, integrating MMT in a consistent province-wide manner, remains elusive.

The CPBC licenses and regulates pharmacists and provides policy guidance and training for those who wish to dispense methadone (CPBC, 2013). Regulatory bodies exist for the prescribing (CPSBC) and dispensing (CPBC) components of MMT, there is no regulatory body to oversee the adjunct supports needed, mostly identified as psychosocial supports. Despite being identified as a critical component of effective MMT (Veilleux et al., 2010), no system currently exists to implement, train, and oversee its delivery nor to measure and evaluate its outcomes. Currently, psychosocial supports are offered in varying degrees in varying ways across each health authority and through privately funded systems. While payment for prescribing and dispensing are clearly outlined in the provincial health care system (more on this below), there is no framework related to the costs stemming from psychosocial supports. The assumption now is that individual health authorities will include psychosocial supports through the varying

programs targeting addiction and or mental health, and private agencies will include it as part of their programming, but without a consistent funding and regulatory mechanism in place, this area remains the critical component of MMT that is undelivered.

The lack of regulatory and disciplinary teeth means large gaps remain between best evidence-based practice and current delivery (BCMA, 2009; Luce & Strike, 2011; Parkes & Reist, 2010). Further, essentially having two parallel systems operate (private fee-for-service clinics and provincially-funded systems), means there is little opportunity, incentive, or knowledge-sharing happening between various stakeholders in each group and no mechanism to bring them together and create consistency, limiting reach and effectiveness.

Physician education & screening tools.

Diagnosing of an individual's addiction disease rests upon a clinician's assessment. The unique difficulty with opioid dependency is the subjective experience and explanation of one's pain of withdrawal. Beginning a patient on MMT is not a cursory task; the medication is highly potent and differentiating between opioid toxicity and opioid withdrawal is of the utmost consideration. Clinicians are required to use a "combination of observable behaviors (e.g. yawning, restlessness, rhinorrhea), physiological measure (e.g. pulse rate, blood pressure, or pupil size), and patient's' subjective rating of opioid withdrawal symptoms. Observable behaviors (more conventionally called "signs" in medical parlance) are generally considered more valid than addicts' self report of symptoms" (Wesson & Ling, 2011, p. 253).

The CPSBC is tasked with providing training to its members on MMT as well as liaising with the provincial Pharmaceutical Division to operate the Controlled Prescription Program (CPSBC, 2014; Thorneloe, 2013). There exist many limitations to increasing the number of

prescribers especially since training in prescribing opioids is not mandatory and remains a physician's choice on whether they will offer it to their patients. These limits, along with a physician's own values and judgments regarding the treatment of opioid-dependency, hinder the number of prescribers available.

Pharmacy regulations.

Regulation changes for dispensing practices coincided with the switch from methadone to Methadose™ in February 2014 (CPBC, 2013a, 2013b). Municipalities control bylaws regarding how many MMT patients a pharmacy may see during a day, how many pharmacies dispensing MMT can exist in a local area, and if a pharmacy is required to dispense the medication or not. The CPBC is required to provide regulation of how methadone is dispensed, including what particular tool is used to measure the medication, what procedures must be implemented for correct dispensation, and what type of prescriptions they can accept (CPBC, 2013a, 2013b). Pharmacists' role with patients, as with prescriber's, is also associated with a high-level of surveillance. The surveillance of MMT patients by pharmacists and the CPBC is to deter abuse and diversion.

Take-home doses.

Take-home doses are prescriptions that a prescriber decides that a patient may take-away a set amount of days worth of medication to self-dispense colloquially known as carries. This means that the patient is not required to have ingestion of the medication witnessed by a pharmacist. Carries are cited by both prescribers and patients as a tool of motivation and punishment (Adrian, 2002; Anstice, Strike, & Brands, 2009; Bell & Salmon, 2009; Fisher, Chin,

Kuo, Kirst, & Vlahov, 2002; Gerra et al., 2009; Gourlay, Ricciardelli, & Ridge, 2005; Hunt, Lipton, Goldsmith, Strug, & Spunt, 1985; McNeil, Kerr, Anderson, Maher, Keewatin, Milloy, Wood, & Small, 2015). Take-away doses are often referred to as a “privilege” (Newman, 2012; Smye, Browne, Varcoe, & Josewski, 2011; Strike & Rufo, 2010) that must be earned by good behaviour. The “privilege” of carries is skewed toward more privileged and mainstream individuals who are less constrained by social determinants of health including poverty, mental health issues, and homelessness. Patients who do not have access to these stable qualities are denied take-aways; creating scenarios that can perpetuate inequities by making it more difficult to seek employment, engage in personal relationships, attend to family duties, and travel outside of their immediate community among other competing priorities. Patients who do have carry privileges are routinely punished by having this privilege taken away when they fail to keep some commitment to their treatment plan such as: missing a doctor’s appointment; incarceration; or “failing” a urine screen (detecting the presence of consumed substances such as other opioids) (Newman, 2012; Smye et al., 2011; Strike & Rufo, 2010).

The regulations that guide take-away policies ostensibly are in place to avoid diversion of methadone to the street-based market (Baldwin & Duffy, 2013; Fischer & Argento, 2012; Larance, Degenhardt, Lintzeris, Winstock, & Mattick, 2011; Ritter & Di Natale, 2005). The public health implication is that opioid-naïve individuals and other consumers of products diverted to street-based markets will ingest diverted methadone leading to fatalities. Driving this policy is the belief that the patients who are the least stable (defined in terms of MMT history, adequate housing, involvement in the judicial system, child custody arrangements, employment, and general cooperativeness) are more likely to divert and be engaged in ongoing drug user and

illicit drug markets) (Ritter & Di Natale, 2005). As a consequence these individuals are subject to more restrictive take-home privileges. McNeil et al., suggest that take-away policies may not be the primary driver of methadone diversion, but other “system variables, includ[ing] drug preference, drug availability, treatment availability and degree of treatment penetration” (2015, p. 351) are factors that should be considered. Local opinion that informs policy place the diversion problem on areas like the DTES and on MMT-patients in urban centres, although research supports the hypothesis that if methadone, now Methadose™, is being diverted, it is likely from rural or remote regions, where patients need to travel farther to access a prescribing physician and a dispensing pharmacist, and therefore may be more likely to be given take-home doses (carries). Further, the Centre for Disease Control reported in 2012 that overdoses are more likely linked to patients who have been prescribed methadone for pain, rather than as maintenance for addiction (Nosyk et al., 2013), calling into question the underlying assumptions that inform current regulation and practice for prescribers, dispensers, and various policy informers.

Despite the considerable risks associated with mis-measurement or diversion of Methadose™, initial education about the product and the dangers, especially to the opioid-naïve, was not discussed with some patients with take-home privileges (Moreheart, 2014). Further, safe-storage instructions or materials such as locked medicine cabinets were not made available to patients by pharmacists until the transition month of February 1-28, 2014 (CPBC, 2013a; Moreheart, 2014). Informing the decision to exclude patients reflects a stigmatizing and condescending attitude on behalf of health professionals and policy makers. Knowledge about the switch in formulations was in discussion with pharmacists and physicians over a year before

the switch was made; allowing time for new policies to be developed. Patients were not involved in any of the planning or policy development.

Fees.

The fees associated with MMT can be broadly separated into system-borne fees and patient-borne fees. Fees associated with MMT can easily be confuscated to obscure who is vulnerable to fees and who benefits from this system.

BC, along with the other provinces and territories of Canada, has policies in place to cover health-related costs for its citizens commonly known as Universal Coverage. Universal coverage does not include coverage for prescription medication. In BC, PharmaCare is a program to assist certain groups of people to pay for their prescription fees such as those receiving income assistance or whom fall below minimum income benchmarks (BC Ministry of Health, 2014). Methadone and now Methadose™, unlike other daily dispensed medication, can be especially lucrative for pharmacies as it requires reimbursement, typically, for three costs: medication fee, dispensing fee; and a witnessing or interaction fee (BC Ministry of Health, 2015a,b; Nosyk & Anis, 2009; Reist, 2010). Although limited by new regulations in dispensing policies associated with the switch to Methadose™, a delivery fee may also be charged (BC Ministry of Health, 2015a). So lucrative is the dispensation of this medication that there are some pharmacies in BC that operate to solely dispense Methadose™ (City of Surrey, 2002; Matas, 2008; Stueck, 2015), and whom, in face of the changes to delivery options, will pick-up patients to come to the pharmacy (McNeil, 2013).

Parkes & Reist (2010) demonstrate that while physician fees, dispensation fees, and drug costs are covered under provincial plans, no allocation of funds are set aside for counselling

services, nor for the extra fees that pharmacies may charge patients as client or user fees, or other discretionary fees, up to \$80 per month. In BC the total cost paid by PharmaCare (for drug costs, dispensing fees, and interaction fees) totalled \$44 million in 2012/2013, the second highest payout for a medication in BC after a rheumatoid arthritis medication (BC Ministry of Health, 2015b). Total costs paid by MSP and PharmaCare averaged per patient in 2012/2013 was \$3268, and pharmacies netting up to \$6500 for methadone-only patients and over \$13000 if that patient is also receiving other medications (BC Ministry of Health, 2015b).

Governing the Patient.

The focus in research and media has portrayed the harms from MMT diversion as primarily originating from disobedient and untrustworthy patients. Only more recently, in the last few years, has there been a shift in negative coverage away from patients to prescribers and dispensers. The onus is upon these service providers to be more accountable for harms related to MMT diversion. More literature is pointing to the over-prescription of opioids, the lack of oversight and coordination for collaborative patient-centred care for the MMT patient; the lack of comprehensive and standardized institutional training for prescribers; the lack of awareness of opioid dependency in medical schools; as well as the financial abuse by service providers (Luce & Strike, 2011; Nosyk, Marsh, Sun, Schenchter, & Anis, 2010).

While there is little disciplinary power available to exert power over the CPSBC and the CPBC there is abundant disciplinary power exerted by this group over MMT patients. Surveillance for methadone patients is a complicated issue; safety issues are always a concern when it concerns opioid consumption and it is a physician's duty to ensure that the patient is not being over-prescribed; placing the prescriber in the position of constant doubter required to test

their patient. Alternate viewpoints show a system that is geared to profiteering; prescribers are rewarded for prescribing opioids and drug manufacturers can count on a long-term consumer; patients are told to reduce their dosage slowly, often just 5 mg at a time (typical maintenance dosage is between 60-120mg daily).

Change intolerance with MMT.

Changes in methadone formulation are appealing from the viewpoint of health care delivery and financing, as the changes attend to concerns related to diversion, improvement and accuracy of measurement and record keeping, as well as standardization.

In a randomized double-blind study findings demonstrate that intolerance to changes were not due to the pharmacodynamic nature of methadone formulations (Gourevitch, Hartel, Tenore, Freeman, Marion, Hecht, & Lowinson, 1999). In Silver & Shaffer's study, the intolerance was reported even 7 months after the change. Similar conclusions that change intolerance is a psychological rather than pharmacological were found in research conducted outside of North America (Steels, Hamilton, & McLean, 1992).

This finding is not surprising when viewed in the context of a patient's agency especially when forced to accept a change that is against their will, and one in which they were not consulted. The literature mentioned above supports an assumption, in simplistic terms, of patients needing to *trust* in the authority of their prescribers and other service-providers. This assumption lies in the belief that the physician, the professional, knows best in the treatment of opioid-dependency for their patients. A more nuanced interpretation of change intolerance includes recognizing the lack of agency patient's experience and that the response of non-acceptance and non-adaptation of formulation change is representative of the limited means of

expressing resistance. Group members who were involved in MMT in BC during the transition to Methadose™ *anticipated* a response demonstrating the new formulation would ‘not hold’ in comparison to the previous formulation, echoing the concerns patients discussed Gourevitch et al.’s, and in Silver & Shaffer’s research.

Barriers to service.

Stigma toward methadone and methadone patients originates from the moralistic perspectives regarding addiction, and that methadone therapy is simply replacing one drug with another. The entire structure of MMT creates a framework that makes it difficult for service providers to view methadone patients outside of a criminalized context; and indeed the stigma can apply to how methadone patients view themselves. In Bell & Shannon’s (2009) analysis they find that prescribing practices are often dictated not from the patient’s views on what their pain needs are, but rather who is deserving of pain relief with opioids and who is not. Further, despite opioids having a long-history in pain management, there can be confusion between these opioids and ones obtained in illegal street-markets. This confusion can influence the attitudes of prescribers, patients, employers, and policymakers.

The language used to define substance use disorders and dependency shape a negative concept of patients seeking methadone for opioid-dependency. How clinicians and others define dependence, abuse, misuse, and addiction largely rests on utilization of criteria found in the Diagnostic and Statistical Manual of Mental Disorders (DSM). The DSM is the accepted standard of classification of mental disorders used in clinical, research and policy areas and has a vast influence on how disorders are identified, classified, and treated. The most recent DSM (DSM-V), in response to the stigma associated with the term ‘addiction,’ made a special note

that for classification purposes ‘substance use disorder’ is the preferred term because of the “potentially negative connotation” of addiction (American Psychiatric Association, 2013). Prior to the 2013 change to the DMS dependence and addiction were differentiated along several lines, most notably that ‘abuse’ was connected to a lower threshold than ‘dependency’ and, in many cases ‘abuse’ was diagnosed with the presence of just one syndrome; hazardous use (Hasin, O’Brien, Auriacombe, Borges, Bucholz, Budney, ... & Grant, 2013). A further update removed the criteria of ‘legal problems’ (incarceration, arrest, litigation) as a criteria for the ‘abuse’ diagnosis, partially due to recognition that legal problems stemming from drug user vary in the individual’s socio-economic status.

Clinicians are also advised to mistrust patient’s self-reports of pain and withdrawal symptoms (Baldwin & Duffy, 2013; Bell & Salmon, 2009; CPSBC, 2015;) and that from an administrative view, ‘addicts’ require more surveillance “for their own good since they’re not using drugs for the right reason and their claims are illegitimate and require a punitive response” (Bell & Salmon, 2009, p. 175). MMT effectively perpetuates a system of injustice for those who are vulnerable to the negative impacts of association with opioid-dependency. MMT is active in regulating and monitoring the lives of vulnerable participants yet fails to address underlying social-structural causes of health inequalities and social injustice that may bring forth opioid-dependency in the first place.

Research that investigated MMT-patient perspectives routinely reported themes of social regulation (Anstice et al., 2009; Fischer et al., 2002; Hunt et al., 1985; Latowsky & Kallen, 1997; Smye et al., 2011; Stancliff, Myers, Steiner, & Drucker, 2002), constrained personal agency (Anstice et al., 2009; Fischer et al., 2002; Latowsky & Kallen, 1997; McNeil et al., 2015; Smye

et al. 2011; Stancliff et al., 2002), increased structural vulnerability (Fischer et al., 2002; McNeil et al., 2015; Galea & Vlahov, 2002; Smye et al., 2011), competing personal interests (Anstice, Strike, & Brands, 2009; Fischer et al., 2002; Gourlay et al., 2005; Smye et al., 2011; Zaller, Bazazi, Velazquez, & Rich, 2009), acquiescence of their own knowledge in order to receive services; (Fischer et al., 2002; Montagne, 2002; Reist, 2010) and lack of integration for multiple health concerns despite the reported higher rate of physician and emergency-room visits (Fischer et al., 2002; Jackson, McWilliam, Martin, Dingwell, Dykeman, Gahagan, & Karabanow, 2014; Reist, 2010; Smye et al., 2011; Zaller et al., 2009).

For many who have significant intersected structural barriers, resistance to the order of MMT may express itself as one last stab or innate defence to retain some sort of agency in their own lives. The tension for those involved or contemplating MMT is also reflected in service provider and policymaker attitudes about balancing public health issues with an individual's desire to "get high" or lead an "exciting and unpredictable lifestyle" (Adrian, 2002, p. 545) on the taxpayer's contribution.

Engagement with and perspectives of patients.

A shift to a public-health orientated approach to dependency recognizes that people have a right to exert influence on services that affect them and should be considered as knowledge-partners rather than passive knowledge-listeners. However, research investigating survey tools to evaluate users' satisfaction with services and programs have been criticized as serving the efforts of service providers; providing a measurable variable to justify the successes of the program (Trujols, Iraurgi, Oviedo-Joekes, & Guàrdia-Olmos, 2014). While similar movements to bring in population groups (women, immigrants, among others), the "Injection Drug Users (IDU)'s were

one of the last groups to respond to the community development model,” and this was “perhaps a reflection of the degree to which they had been disenfranchised by the prevailing ethos of demonizing of drug use” (Crofts et al., 1993 as quoted in Jürgens, 2008). This is not to say that organizations of PWUD have not existed before the community model (Jürgens, 2008); indeed many did and some have been co-opted by agencies that were previously involved in structurally oppressing them. Engagement with PWUD and implementation of patient-based initiatives requires an examination regarding issues such as ‘public order’ and ‘public safety’ and deciding for whom do policies and practices benefit.

Research supporting the need to involve MMT-patients.

Examining engagement of PWUD and methadone-patient groups as part of a metanarrative reveals a disconnect between the stated rhetoric and the actual practices. Also revealed is the way in which public health discourse and harm reduction principles can be viewed as simply replacing an overt blunt method of social control for a more surreptitious one that even the actors themselves might not be aware of propagating. This is operationalized in multiple ways including vocabulary and what is viewed as evidence-based best practices. The story of what addiction is has changed over time and place from a nuisance issue to moral issue to a criminal justice issue and now we are in an era of viewing addiction as a physiological issue; coming under the sphere of the biomedical model. Focusing on the *individualized* nature of addiction, on the pathways that dictate addictive behaviour in one’s own brain and body, shifts the aims of harm reduction away from critiques of the structural forces that perpetuate the social milieu in which addiction can take place.

Much as assumptions of the capabilities and intentions of patient descriptors in pharmacological interventions rest on the patient needing instruction and direction, the same assumption can be found in engagement exercises. Again, the people and organizations that represent PWUD or methadone-patients are assumed to *inherently* need organization, instruction, and guidance from an outside authority. Without an examination of the overall metanarrative that uncovers these policies and practices that perpetuate inequities, well-meaning service organizations on all levels are engaging in the very oppressive modes of action they seek to rectify.

Treatment alternatives.

Alternatives to MMT described in the literature are described as being alternatives not just to the pharmacological compound of the treatment; alternatives are linked to differences in the overall treatment-aspect of MMT such as challenging underlying assumptions of the addiction model as it relates to opiate-dependency and assumptions about the patient. I identify two thematic distinctions in the therapeutic alternatives to MMT; one based in the pharmacology of blocking withdrawal-symptoms; and one based in negotiating the desire to achieve a “high” while ameliorating the negative social, physical, psychological, and societal outcomes of using illicit opioids.

The two most prominent pharmacological alternatives presented in the literature include buprenorphine and Suboxone® (a combination of buprenorphine and naloxone) as well as the pharmaceutical heroin (diacetylmorphine) that is not contaminated by unknown additives or fillers. This latter option is the basis for what is called Heroin-Assisted Therapy (HAT). The

other alternative I identified is abstinence-based treatment where no pharmacological tools are used to detox or manage opioid withdrawal or opioid cravings.

Very recently, as of the the end of writing this paper, changes were made to BC's PharmaCare coverage scheme in October 2015 to include Suboxone® as a regular benefit, making this a financially-accessible option for BC's population of opiate-dependency treatment seekers who were previously excluded from this option unless they demonstrated an contradictory response or intolerance to methadone (BC PharmaCare Newsletter November 16, 2010 Edition 10-014; The Early Edition, 2015).

HAT is not currently a sanctioned approach to opioid dependency treatment although it has been researched and established in other countries over the last 15 years, including fully supervised self-administered injection heroin sites and treatment officially endorsed in the United Kingdom, Switzerland, Germany, Denmark, and the Netherlands (Ferri, Davoli, & Perucci, 2006). In Canada, despite strong opposition by a Conservative federal government, research into HAT is being investigated through 2 studies: the North American Opiate Medication Initiative (NAOMI) and the Study to Assess Longer-term Opioid Medication Effectiveness (SALOME) with initial results appearing in peer-reviewed publications in 2015.

Outside of pharmacological tools the other treatment methods include psychosocial approaches and behavioural modifications. Research on non-pharmacological approaches do not show\positive outcomes (Amato et al., 2005; BC Medical Association, 2009; Collège des médecins du Québec, 2000; Connock et al., 2007; Farrell et al., 1994; Gomart, 2002; Hathaway & Tousaw, 2008; Luce & Strike, 2011; Reist, 2010). Further, proponent individuals and groups

for abstinence-only treatment approaches ground arguments less in research trials and studies and rely more on moralistic and experiential views. Viewpoints that methadone is equivalent or ‘worse’ than heroin permeate many aspects of opioid-dependency; opinions of user-groups; policies of recovery centres; attitudes of prescribers, pharmacists, and service providers; and values promoted through community discussions by community leaders such as church leaders or those involved in business associations (Fischer et al., 2002; Greer et al., 2015; Montagne, 2002; Smye et al., 2011).

3. Discussion

Tracing methadone’s narrative across disciplines (biomedical research, social science research, social justice research, policymaking, physicians and pharmacists education and practice) as well as its narrative over time and geography, and lastly over its historical-political context in situating it amongst the field of addiction and dependency, uncovers a complex and tangled intersection of thoughts, ideas, and values. Methadone, perhaps along with antiretroviral pharmaceuticals, occupies one of the most politicized positions of a pharmaceutical in Western medicine. The polarity associated with methadone generates questions about the psychosocial, structurally-maintained, biomedical-focus of addiction itself. PWUD and methadone patients continue to struggle in a trench of mixed meanings and value-laden vocabulary which reflect our society’s changing perspective of what constitutes a ‘sick body,’ a ‘criminalized body,’ and what we mean when we say ‘cure’ or ‘recovery’ from dependence and even what ‘dependence’ means. The use of the term ‘substitution’ is one that bears scrutiny as well since formulations such as methadone/Methadose™ don’t truly substitute opioids such as heroin; they serve to simply mitigate the physiological effects of withdrawal symptoms and accompanied cravings as

well as the psychosocial-economical considerations one must engage in to maintain a state of non-withdrawal.

Larance et al., (2011) expand on the public health implications of using more exact terminology to better identify types of dependencies and therefore create a more uniform set of definitions that can be used across many disciplines. The need to quantify and classify is a hallmark of the biomedical model and serves to justify that the experts in this field are health care practitioners who will assist people on an individual level. However, systemizing terminology potentially masks the conditions and scenarios related to the production of the condition of “addiction”.

Using a metanarrative analysis of terminology demonstrates the way that language and descriptors can have powerful effects on how individuals are categorized, what their intentions are, and what controls will be needed to bring them into compliance. Underscoring these associations between intentions and definitions is the *necessary* role of the health care practitioner to identify what is the cause of non-compliance and *instruct, monitor, or suspend* the patient; the health care practitioner is the ultimate knowledge holder.

Assumptions regarding the capabilities and intentions conveyed by patient descriptors in pharmacological interventions rest on the patient needing instruction and direction, the same assumption can be found in engagement exercises. Again, the people and organizations that represent PWUD or methadone-patients are assumed to *inherently* need organization, instruction, and guidance from an outside authority. Countering this argument is the work done by VANDU and other user-run organizations. Indeed user-run groups have been instrumental in important studies and legal arguments such as the opening of North America’s first supervised injection

site in Vancouver's Downtown Eastside; Insite; along with other research concerning health services and programming. Without an examination of the overall metanarrative that uncovers these policies and practices that perpetuate inequities, well-meaning service organizations on all levels are engaging in the very oppressive modes of action they seek to rectify.

Scrutiny is also needed when considering methadone a "medication" and heroin an illegal substance. Drug classifications change over time and with research and it is important to consider the political, social, and historical context in which we view heroin and other opioids. Gomart (2002) expands on this topic in the article *Six Effects in Search of a Substance*. Drawing from various commentators and epistemological traditions, Gomart seeks to differentiate between methadone and heroin and questions if this difference is due to 'labelling' through social processes; that is, does the difference between substances exist with a fixed inherent action that is played out or does the very manner in which the comparison happens determine the action of the substance.

Gomart's research highlights an overlooked flaw in MMT; that is, that methadone is supposedly inherently a better substance than heroin. This assumption is not grounded in purely medical or empirical research; it is an *opinion* generated as a produce of wider social-structural forces such as drug prohibition and the criminalization of PWUD. The credibility of these opinions is reinforced over the course of time due to historical, political, and legal impacts. When considering where stigma for PWUD or MMT-patients arises, it is necessary to view the context in which one forms the basis to justify the stigma.

The 'necessity' to substitute heroin (and more recently prescription opioids) is for the broad aims of stabilization and integration into mainstream society. This assumption rests on

accepting that something intrinsic about heroin is ‘wrong’ and needs correcting. And, as the above quoted research demonstrates, it is difficult for those involved in MMT to truly integrate due to the requirement to participate in programs demanding compliance, surveillance, and loss of agency. Walmsley (2013) examines the connections between poison and bodies as it relates to agency and political control. Walmsley argues that the history of substitution originates from the medical viewpoint of the late 19th century that abrupt removal of the poison from a human may lead to fatal consequences. The overseeing of the process of poison removal was best left in the hands of the medical system, even though this may interfere with one’s autonomy (p. 401). Abrupt withdrawal and cessation was cause for concern so an extended medical regime was introduced (p. 403).

Using a metanarrative approach, I aimed to draw out the story about methadone and apply my findings in order to situate the fraught position PWUD and former PWUD occupy and attempts to rectify inequities may actually be perpetuating them. An examination brought upon the switch in formulation in BC demonstrates the ongoing tension about illicit substances and the people that use them. That is to say that while the intention to create social justice is present in today’s policies and guidelines, achieving transformative change requires a larger and more complex transformation of the systems in which these inequities exist; social justice may not be achievable as long as we continue to participate in the current story of methadone.

The transformative change needed for policies that affect PWUD and MMT-patients must be one that is the result of coalition building, lobbying, and mobilization to shift public opinion, and the acquisition of advocates and allies who hold greater power in the current structural systems. This transformative change, I argue, requires:

- conscientization of the patient group; specifically recognizing and nurturing the assets and skills already present within user-run groups and legitimizing group members insights when engaging with institutions;
- acquisition of strategic partnerships to lend voice, credibility, access to new knowledge and resources to conduct the training and capacity building needed to navigate complex systems;
- alliance with other groups with similar interests such as other patient-care groups; patient-watchdog groups, and civil liberty groups, especially those who have favourable public opinion;
- a transformation of the public face of PWUD and MMT patients; one that defies the usual story of a ‘sick body,’ a ‘criminalized body,’ a social welfare resource-drainer, and whom lacks responsibility, education and community-minded leadership capacity.

Such transformation may not be operationalized under the current social, legal, and medical milieu that MMT occupies. Methadone and MMT are currently in the realm of the patient-specific biomedical model; that is that the issues of dependency and addiction are acted out in biochemical and physiological processes that for the most part ignores the contextual and structural forces that drive addiction such as poverty or issues such as incarceration (Galea & Vlahov, 2002).

Challenging the neoliberal discourse of a punitive, moralistic, and diseased views of PWUD and MMT-patients will require critiquing the vocabulary to describe diagnoses, patients, users, and treatments. These terms are value-laden and perpetuate the stigma that is experienced, both acted out on through structural inequities and also embodied. Within certain macro, meso,

and micro-level institutions the push to challenge the stigmatizing views of patient/users is being led by public health organizations [such as the BC Centre for Disease Control (BCCDC) and health authorities such as Vancouver Coastal Health (VCH) and First Nations Health Authority (FNHA)], the research community [through various institutionally-supported groups such as Urban Research Health Initiative (URHI), Centre for Applied Research in Mental Health (CARMHA), Centre for Addictions Research of BC (CARBC)], and grassroots user-groups [VANDU, BCAPOM, Canadian Association of People Who Use Drugs (CAPUD)].

Increasingly there are steps and actions that bring PWUD and MMT patients to a more equitable position within the institutions and systems that they engage in. These steps are representative of much needed ameliorative change. For true transformative change to happen, we must examine the metanarrative of methadone and reject the current story's projection. We need to close this book and begin anew with a different one.

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