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Research Paper

Challenges of implementing safer supply programs in Canada during the COVID-19 pandemic: A qualitative analysis

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ABSTRACT

Background: Canada is experiencing an unprecedented drug toxicity crisis driven by a highly toxic unregulated drug supply contaminated with fentanyl, benzodiazepine, and other drugs. Safer supply pilot programs provide prescribed doses of pharmaceutical alternatives to individuals accessing the unregulated drug supply and have been implemented to prevent overdose and reduce related harms. Given the recent emergence of these pilot programs and the paucity of data on implementation challenges, we sought to document challenges in their initial implementation phase.

Methods: We obtained organizational progress reports from Health Canada, submitted between 2020 and 2022 by 11 pilot programs located in British Columbia, Ontario, and New Brunswick. We analyzed the data using deductive and inductive approaches via thematic analysis. Analyses were informed by the consolidated framework for implementation research.

Results: We obtained 45 progress reports from 11 pilot programs. Six centres were based in British Columbia, four in Ontario, and one in New Brunswick. Four overarching themes were identified regarding the challenges faced during the establishment and implementation of pilot programs: i) Organizational features (e.g., physical space constraints, staff shortages); ii) Outer contexts (e.g., limited operational funds and resources, structural inequities to access, public perceptions); iii) Intervention characteristics (e.g., clients' unmet medication needs); and iv)

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Implementation process (e.g., pandemic-related challenges, overly medicalized and high-barrier safer supply models).

Conclusions: Safer supply pilot programs in Canada face multiple inner and outer implementation challenges. Given the potential role of safer supply programs in addressing the drug toxicity crisis in Canada and the possibility of future scale-up, services should be well-supported during their implementation phases. Refining service provision within safer supply programs based on the feedback and experiences of clients and program administrators is warranted, along with efforts to ensure that appropriate medications are available to meet the clients' needs.

Introduction

The ongoing drug toxicity crisis in Canada is driven primarily by unintentional opioid toxicity deaths resulting from the use of a highly adulterated unregulated drug market (Fischer et al., 2018; Kolla et al., 2022; Public Health Agency of Canada, 2022a), contaminated with fentanyl, fentanyl analogues, xylazine, benzodiazepines, and nitazene-class opioids (Russell et al., 2023). In particular, opioid toxicity deaths in Canada have surged rapidly since 2017, surpassing motor vehicle accidents, suicide, and homicide deaths combined (Donroe et al., 2018). Between January 2016 and March 2022, the crude rate of apparent opioid toxicity deaths increased from 7.8/100,000 to 20.5/100,000 population (Public Health Agency of Canada, 2022a). While Western Canada (e.g., British Columbia, Alberta) is the most impacted region in the country, rates of opioid toxicity deaths and hospitalizations have also surged in other provinces, including Ontario. Indeed, from January to March 2022, 90% of all opioid toxicity deaths and 89% of opioid-related hospitalizations across Canada occurred in British Columbia, Alberta, and Ontario (Public Health Agency of Canada, 2022a). Most opioid toxicity deaths and hospitalizations have occurred among males and those aged between 29 and 49 years old (Public Health Agency of Canada, 2022a). The drug toxicity crisis has contributed to reduced life expectancy in Western Canada and a flattening of life expectancy nationally (Xibiao et al., 2018; Young, 2019).

In response, an array of federal and provincial policies and programs have been implemented, including expanding access to harm reduction services and opioid agonist therapy (OAT) (Bonn et al., 2020; Busse et al., 2017; Fairbairn et al., 2019; Fischer et al., 2016). While OAT has demonstrated effectiveness in reducing opioid-related harms and deaths (Mattick et al., 2014), it may not adequately serve specific segments of the population and is underutilized due to various access barriers (McBournie et al., 2019; Volkow et al., 2014). These include, but are not limited to, the pervasive social and institutionalized stigma associated with opioid use disorder and accessing OAT (Earnshaw et al., 2013), inflexible structure and requirements of OAT programs, such as strict medication schedules and ongoing monitoring (Mark & Parish, 2019), and the side effects and tolerability of OAT medications (Klimas et al., 2021; Mancino et al., 2010). In light of these barriers, implementing safer supply programs is a complementary harm reduction strategy that can be scaled-up alongside the expansion of OAT access to address the drug toxicity crisis in Canada. Prescribed safer supply programs offer an alternative clinical pathway, providing a range of opioid medications beyond methadone and buprenorphine to reach individuals who face barriers in accessing and adhering to conventional OAT. These programs also recognize that not all individuals are able to engage in structured treatment at a given time. By effectively addressing the barriers faced within conventional OAT services, safer supply programs could contribute to a more comprehensive harm reduction strategy that caters to the diverse needs of individuals affected by opioid use disorders (Canadian Association of People Who Use Drugs, 2019).

Health Canada defines "safer supply" as "providing prescribed medications as a safer alternative to the toxic illegal drug supply to people who are at high risk of overdose" (Government of Canada, 2023), and others, such as the Canadian Association of People Who Use Drugs, define it as "a legal and regulated supply of drugs with mind/body altering properties that traditionally have been accessible only through the illicit drug market." This difference extends to the definition of discrete safer supply programs. Some have defined safer supply as including injectable opioid agonist therapy (iOAT) and supervised tablet-based injectable opioid agonist therapy (TiOAT) (Csete & Elliott, 2021; Ivsins et al., 2020); however, recent studies view iOAT and TiOAT as a form of treatment that involves supervised dosing of opioids, while conceptualizing safer supply as an "umbrella term for prescribing unsupervised doses of pharmaceutical alternatives to the unregulated drug supply" (Canadian Association of People Who Use Drugs, 2019; Glegg et al., 2022; Government of Canada, 2023).

One of the programs focusing on reducing harm and improving the health of people who use drugs has been the establishment of safer supply pilot programs (pilot programs, hereinafter) in 2020, which have been implemented across Canada via federal funding from Health Canada to help prevent drug-related overdoses and other harms by reducing the necessity to rely on the volatile, unregulated ("street") supply of drugs (Glegg et al., 2022; Health Canada, 2022; Klaire et al., 2022). Pilot programs provide pharmaceutical-grade medications with known potency and quantity, are designed to be low-barrier, and vary in terms of prescribed medications, delivery models, operating policies and procedures, and formulations and dosage options provided (Canadian Association of People Who Use Drugs, 2019; Glegg et al., 2022; Government of Canada, 2023). To date, prescribed medications have primarily been tablet hydromorphone (i.e., Dilaudid) and oxycodone in programs using take-home, unobserved dosing models, and have also included injectable hydromorphone, fentanyl patches, tablet fentanyl (i.e., Fentora), fentanyl powder, injectable fentanyl (i.e., Sufentanil) in observed dosing models, as well as stimulant replacements (e.g., methylphenidate, dextroamphetamine) (Canadian Association of People Who Use Drugs, 2019; Fleming et al., 2020; Glegg et al., 2022; Government of Canada, 2023; Klaire et al., 2022). Safer supply programs do not mandate that clients cease substance use; instead, they aim to separate individuals from the toxic and unregulated drug supply to mitigate the risk of drug overdose. In this endeavour, these programs strive to replace the unregulated and toxic drug supply through a harm reduction approach (e.g., different formulations of medication and take-home doses in some programs). Safer supply programs aim to improve retention in the program, provide access to harm reduction and overdose prevention supplies and education, and focus on the overall health and social well-being of people who use drugs (Canadian Association of People Who Use Drugs, 2019; Glegg et al., 2022; Government of Canada, 2023).

Given the recent implementation of safer supply programs across Canada and the ongoing process of evidence generation, there is a growing body of evidence supporting their effectiveness (Brothers et al., 2022; Gomes et al., 2022; Harris et al., 2021; Ivsins et al., 2021; Ivsins et al., 2022; Lew et al., 2022; McNeil et al., 2022; Selfridge et al., 2022; Young et al., 2022). However, few studies have examined the implementation challenges these novel services may be experiencing across Canada (Foreman-Mackey et al., 2022; McNeil et al., 2022). Further evidence is needed, given that policymakers have expressed an interest in expanding them across Canada (Health Canada, 2022). We sought to document the implementation challenges of pilot programs to identify potential areas for support and inform the future optimization and

possible expansion of safer supply programs.

Methods

Context

Health Canada's Substance Use and Addictions Program (funder, hereinafter) is a funding program established to support substance use-related prevention, harm reduction, and treatment initiatives in Canada. The funder provides project funding for many entities, such as non-profit health organizations (e.g., hospitals, community health centres), non-profit charity organizations, health authorities, Canadian educational centres (e.g., universities), and Indigenous-led organizations (Government of Canada, 2022). To date, the funder has supported 28 pilot programs across Canada (Public Health Agency of Canada, 2022b). This study is part of a more extensive implementation science study that encompasses qualitative research with clients and staff of pilot programs, as well as analysis of administrative data on client clinical outcomes and observational quantitative data.

Data sources

We obtained narrative data from performance and progress reports that 11 programs submitted to the funder as a requirement of their funding between February 2020 and March 2022. In our analysis, we viewed iOAT and TiOAT as a form of supervised treatment and conceptualized safer supply as a broad term encompassing the prescription of unsupervised pharmaceutical alternatives to the unregulated drug supply (Glegg et al., 2022). Reports from other Health Canada-funded programs were not available to us at the time of this analysis. Progress report templates were consistent across all programs. They were submitted on a biannual or triannual basis and covered topics, such as general information, performance measurement and evaluation updates, project partnerships, project efficiency, expenditure report, program outputs, knowledge translation, and communication of critical issues and implementation challenges. Programs are requested to "highlight specific challenges and needs and any action taken" under the "key issues and challenges" section of the report template. Issues could be related to various areas, such as project characteristics, financial, data collection, or partnership-related. Programs were not asked to report on successes, facilitators, or other positive aspects of their implementation experience. In the present analysis, reports were included from pilot programs located in British Columbia, Ontario and New Brunswick that provide safer supply integrated with an array of other services (e.g., harm reduction and outreach services, patient advocacy, housing and legal support, referrals to other supportive services).

Data analysis

Once reports submitted by pilot programs to the funder were retrieved, they were reviewed by two team members (MK and BR) and imported into a Microsoft Excel document. Program implementers, national research team members, and individuals with lived/living experience were invited to participate in the data analysis to incorporate their perspectives and expertise throughout the process, ensuring inclusivity and accuracy in our interpretations of the progress reports. Direct quotes from the reports were extracted on the challenges raised by the programs and measures taken to address them. Data were analyzed employing thematic analysis (Fereday & Muir-Cochrane, 2006) to generate an initial set of codes which were further developed through a combination of deductive (i.e., codes extracted from the reports' text) and inductive (i.e., codes developed through team discussions) approaches (Bradley et al., 2007). Discrepancies in coding and interpretations of the data were resolved in team meetings following a consensus-based approach. As themes and sub-themes about the barriers to implementing the programs emerged during our thematic analysis, we drew on the Consolidated Framework For Implementation Research constructs (Damschroder et al., 2009) to situate our findings in relevant domains (Louie et al., 2021). This multi-level framework aids in organizing the systematic investigation of the contextual aspects linked to a successful implementation of an intervention (e.g., pilot programs). The Consolidated Framework For Implementation Research, which has been increasingly used in substance use research (Louie et al., 2021; Sorensen & Kosten, 2011), provides a pragmatic approach to analyzing the inner (e.g., organizational) and outer (e.g., socio-economic) contexts, as well as the individuals involved (e.g., clients), the intervention (e.g., design characteristics), and the implementation process (e.g., impacts of COVID-19 restrictions on service delivery) (Damschroder et al., 2009).

Results

Overall, we analyzed data from 45 progress reports submitted to the funder by 11 safer supply pilot programs (average of four reports per program) that had provided services to 1712 clients (average of 156 clients per program; 1117 actively enrolled) up to March 2022. Six pilot programs were located in British Columbia, four in Ontario, and one in New Brunswick. Based on Statistics Canada's definition of urbanicity (Statistics Canada, 2016), one pilot program was located in a small (population of 1000 to 29,999), two were in medium (population of 30,000 to 99,999), and the remaining eight were in large urban settings (population of 100,000+). A detailed description of the programs and their services is presented in Table 1. Except for one program in British Columbia, which provided a safer supply of hydromorphone via a biometric dispensing machine available 24/7, other programs' service provision was restricted to the working hours of the programs themselves or the associated pharmacies.

Thematic challenges faced while establishing and implementing pilot programs fell into four overarching categories: i) Organizational features; ii) Outer contexts; iii) Intervention characteristics; and iv) Implementation process. We also summarized actions that these centres took to help address these challenges.

Organizational features

Physical space constraints

Due to the rapid scale-up of pilot programs during the early portion of the COVID-19 pandemic, some pilot programs had insufficient physical space to provide clinical and social services. This presented a challenge to performing basic intake procedures and clinical assessments with clients onsite. As a result, pilot programs' staff were often required to become creative and supported clients' access through outreach and care to clients in outdoor settings, including encampments where clients were experiencing precarious living conditions, particularly during extreme cold weather events. One pilot program from British Columbia that provided both iOAT and safer opioid supply reported the following:

> "Not having a physical location to see project participants poses a challenge, as does homelessness. Most participant interactions and care occur outdoors at encampments where inclement weather and poor living conditions create harms for our participants. This means that collecting urine samples, performing wound care, and meeting with participants for appointments is challenging."

One pilot program sought to mitigate these space constraints by securing a temporary location at an existing overdose prevention site, while others repurposed parts of office, meeting, and storage spaces into client/program space to help increase capacity. Some pilot programs in British Columbia that tried to repurpose their existing spaces faced challenges due to delays in completing renovations. For example, one of the small centres in British Columbia that provided TiOAT services, noted that:

Table 1
Description of the services provided within the pilot programs included in the study.

Organization[1]	Province	Urbanicity[2]	Intervention[3] (iOAT/TiOAT/ SOS)	Observed/unobserved dosing, medications	Description of service provision
#1	British Columbia	Large Urban	iOAT/SOS	*Non-observed:*Hydromorphone (short acting, controlled release) and Oxycodone *Observed:* Fentanyl (patch), Fentanyl (tablet), and Sufentanil (injectable)	-Provides low-barrier access to opioids, opioid agonist treatment, and stimulants. -Offers outreach and medication delivery, and fixed site services, with an emphasis on current gaps in the service continuum. -Provides entry point to wrap-around health and social services, including primary and addiction care.
#2	Ontario	Large Urban	SOS	*Non-observed:* Hydromorphone tablets (short-acting)	-Provides assessment, monitoring, and prescriptions for daily-dispensed, take-home oral hydromorphone tablets, and slow-release oral morphine or other OAT medications, based on individual assessment of patients. - Provides comprehensive primary care, psychosocial support and a range of wrap-around health and social services.
#3	British Columbia	Large Urban	SOS	*Non-observed:* Hydromorphone (tablet)	-Provides registered clients with a safer supply of hydromorphone tablets using secure dispensing storage machines.
#4	Ontario	Large Urban	SOS	*Non-observed:* Hydromorphone (short-acting)	- Provides access to short-acting opioids (hydromorphone), long-acting "backbone" medications (e.g., Kadian), with assessment and monitoring, to clients who report daily or near-daily illicit unregulated opioid use at intake. - Offers primary care, supervised consumption services, counselling, case management, housing support, and safer use education and equipment.
#5	Ontario	Medium Urban	SOS	*Non-observed:* Hydromorphone (short acting) and Oxycodone	-Offers a safer supply program aimed at reducing drug toxicity deaths and providing low-barrier access to a safe alternative for people through relationship-based health care. -Offers long-term primary care and wrap-around health and social support for participants who want those services.
#6	British Columbia	Large Urban	iOAT/SOS	*Observed:* Hydromorphone (short acting, controlled release, and injectable), Oxycodone, Fentanyl (patch), Diacetylmorphine (injectable), and Sufentanil (injectable)	-Offers a personalized, low-barrier approach, with a variety of opioid medications available including iOAT, hydromorphone, diacetylmorphine and fentanyl patches.
#7	New Brunswick	Medium Urban	iOAT/SOS	*Non-observed:* Hydromorphone (short acting); for holidays/closure days *Observed:* Hydromorphone (injectable)	-Offers individualized care pathways, flexible medical appointments, group therapy sessions, peer support, social support services, oral opioid agonist therapy, supervised injectable hydromorphone and stimulant replacement therapy (dextroamphetamine, risperidone, aripiprazole and/or bupropion).
#8	Ontario	Large Urban	iOAT	*Observed:* Hydromorphone (injectable) Fentanyl patch Sufentanil (injectable)	-Provides access to injectable hydromorphone for people whose needs are not currently being met by existing OAT services, supervised consumption services, and/or other safer supply interventions. -Helps clients access and remain connected with health, housing, income and community programs.
#9	British Columbia	Large Urban	iOAT/TiOAT/SOS	*Observed & non-observed:* Hydromorphone (tablet and injectable), Fentanyl (patch, injectable, inhalation, sublingual)	-Provides services in a decolonizing model of care including primary care OAT, Indigenous Elder-led cultural healing programs, and alcohol use disorder programs. -Offers supervised iOAT, counselling, social navigation, food security, and chronic pain management.
#10	British Columbia	Large Urban	iOAT/SOS	*Observed:* Fentanyl (patch, powder and tablet), Sufentanil, and Hydromorphone (injectable) *Non-observed:* Hydromorphone (tablet), Dextroamphetamine and Methylphenidate	-Provides access to a range of pharmaceutical-grade substances including fentanyl, hydromorphone and psychostimulants using a low-barrier approach. -Various formulations of medications are available, including injectable, oral, sublingual and transdermal. -Provides safer drug use education and supplies and connects participants with other treatments, care and services.
#11	British Columbia	Small Urban	TiOAT	*Observed:* Hydromorphone (tablet for intranasal and oral administration as well as injection), Fentanyl patch	-Provides access in a low-barrier setting to TiOAT in the form of hydromorphone tablets that can be injected under the observation of program's staff. Oral and intranasal hydromorphone are also offered under the same setting. -Offers wrap-around services such as peer support, linkage with primary care, mental health support and case management.

[1] The exact names of the organizations are anonymized.

[2] Urbanicty is based on the definitions proposed by Statistics Canada; Small urban (population of 1000 to 29,999), medium urban (population of 30,000 to 99,999) and large urban (population of >100,000). It is important to note that definitions of urbanicity can vary across provinces. In some provinces, urbanicity is determined by considering both population size and proximity to large urban centers. Therefore, when interpreting the level of urbanicity for each site, it is crucial to consider these nuanced variations.

[3] iOAT: Injectable Opioid Agonist Therapy; SOS: Safer Opioid Supply; TiOAT: Tablet Injectable Opioid Agonist Therapy.

> "Renovations at [the] service site will not be completed in June 2021 as planned. [The] planned opening date for service is in [late] fall. This has implications for the number of participants that can receive services due to size constraints in the temporary site."

Generally, pilot programs reported that innovative solutions to space constraints were somewhat helpful, though often inadequate, given the precarity of clients' housing situations. Ultimately, this reportedly led to reduced service provision capacity in some pilot programs.

Staff shortages

Pilot programs aimed to address clients' health and social needs through a high staff-to-client ratio; however, similar to other healthcare settings, most faced significant staff-related challenges. The intersecting COVID-19 and drug toxicity crises led to reduced service provision capacity due to the limited availability of staff and clinical care providers. For example, a pilot program in a large urban setting in Ontario that provided safer opioid supply, noted:

> "It has been challenging to hire staff for this project, in part due to the current high demand for harm reduction workers arising from [the] expansion of harm reduction services in response to COVID-19 (e.g., for physical distancing hotels). It has also been challenging to hire clinical team members […] who have the experience of working with our client population and who work from a harm reduction perspective."

These challenges were exacerbated when COVID-19 outbreaks occurred among clients or staff. As a result, several pilot programs increased screening protocols and restricted access to limit the number of staff and clients within the facility. While the staff developed resiliency in adapting to difficult and stressful situations throughout the pandemic, the COVID-19 waves during the 2020/2021 winter and the emergence of the highly contagious SARS-CoV-2 variants directly reduced the capacity of pilot programs to enroll clients. For example, a pilot program in a large urban setting in Ontario that provided safer opioid supply, posited:

> "The winter COVID waves and impacts of the Omicron variant have continued to negatively impact operations, particularly due to the impacts of COVID isolation and recovery time on staff members […] We have limited new client intakes into the [safer supply] program in order to ensure that we can provide a high quality of care to existing clients, and to ensure that staff do not burn out from the continuous burden of COVID-related illness."

Similar to other healthcare settings during the COVID-19 pandemic, several pilot programs also faced challenges due to staff shortages and turnover, given the taxing and challenging nature of their work, which often contributed to burnout. Some rectified the staff shortages by contracting nursing agencies, actively recruiting on employment platforms, and borrowing staff from other health centres to cover shifts. The high turnover was particularly taxing on the smaller programs with limited resources, given the extensive efforts required to hire and train new staff. For example, a small program in British Columbia that provided TiOAT services, noted:

> "Nursing staffing levels have been maintained through the fall and winter this year to maintain program delivery; however, there has been considerable staff turnover at all levels (front line and leadership) requiring constant recruitment and orientation. The program currently needs additional casual nurses to provide backup to regular staff."

Similar to other healthcare sectors, gaps in leadership and staffing were reported by multiple pilot programs. These issues, however, were partly resolved by the programs' commitment to hiring additional nurses and clinical staff to provide increased ongoing capacity and support for the level of nursing hours required by the programs.

Pilot programs' outer contexts

Limited operational funds and resources

Most pilot programs reported concerns about the limited and short-term nature of their funds and its impact on their staff and clients. For example, a pilot program in a large urban setting in Ontario that provided safer opioid supply, noted:

> "[S]hort-term funding creates precarity for staff that exacerbates the high-stress work conditions. Staff are anxious - not only about what will happen to their job come April 1st, but also regarding continuity of care for [safer supply] clients. Other providers operating through short-term funding have contacted our program with the hopes that we would take their safer supply clients, only to hear that [we] may not be operating if sustained funding is not secured before April 1, 2021."

The short-term funding mechanisms that significantly threaten the programs' sustainability were also highlighted as a barrier to building meaningful relationships and collective governance, particularly with Indigenous collaborators. A pilot program located in a large urban setting in British Columbia that provided iOAT, TiOAT, and safer opioid supply services, posited:

> "Shared informed decision-making between mainstream healthcare providers, Indigenous medicine providers and Indigenous leadership is time-consuming and often complex. The team continues to recognize the importance of Indigenous Elder involvement from the cultural wellness program in developing processes, key objectives, and tools. This impacted timelines and timing for both the prospective cohort study and evaluation activities."

These concerns were partly addressed, albeit in the short-term, when funding was temporarily renewed for only one additional year for some pilot programs. Although this temporary funding renewal was helpful in the short-term, pilot programs remained concerned about their staff's job security and their clients' continuum of care.

Structural inequities to access

Some pilot programs highlighted the structural barriers clients faced with accessing program services. Given the limited or lack of transportation services for some clients, particularly those living in poverty, access to pilot programs was often interrupted, leading to adverse health outcomes. Some programs explicitly identified a link between reduced transportation options and poor health outcomes among resource-limited people who use drugs, and advocated for additional transit services for vulnerable people who use drugs. For example, a centre located in a medium urban setting in New Brunswick that provided both iOAT and safer opioid supply services, posited that:

> "Due to city cuts on services, such as transportation during the pandemic, we are extremely saddened to report that three program participants passed away due to substance use-related complications. It is our strong belief that their passing was in great part due to lack of transportation to access the centre's services."

Client struggles with housing were also observed and intersected with the COVID-19 pandemic across multiple settings. The lack of appropriate and affordable housing and shelter spaces influenced the provision of services by pilot programs, with one pilot program located in a large urban setting in Ontario, that provided safer opioid supply services, reported:

> "It is very difficult to describe the absolute crisis being caused by the lack of shelter beds, and the lack of low-barrier, affordable housing options in [Ontario]. This is currently being exacerbated by the closing of hotels that were being used during the COVID-19 pandemic to provide emergency sheltering options for clients who were experiencing homelessness and could not find space in the

shelter system ... This has caused an incredible destabilization of people experiencing homelessness in [an Ontario city], as they were forced out of hotel rooms to live on the streets and in tents again. It has become impossible to find a shelter bed or housing for even the most vulnerable and medically unwell clients."

While programs continued to work with local partners to identify potential solutions, lack of affordable and non-temporary housing was a chronic issue that severely impacted the health of the majority of clients, particularly during the winter months. It critically attenuated the impact of safer supply on clients' risk of morbidity and mortality.

Public perceptions

A few pilot programs encountered challenges due to public resistance and concerns surrounding their services, with smaller urban settings experiencing greater opposition. This opposition was characterized by vocal resistance and apprehensions expressed by specific members of the public, primarily regarding the location of these services. The concerns raised revolved around the potential implications of introducing new safer supply services for preexisting social adversities within the community. For example, a program located in a small urban setting noted that some community members were unsupportive of the establishment of safer supply services in their neighbourhood:

"[There is] vocal opposition by some community members around location of services. Community concerns centre on existing challenges in the neighbourhood related to substance use, homelessness, poverty, shelter and question the additional impacts [on these social adversities] with [the establishment of these] new [safer supply] services."

In a medium urban setting, another program encountered difficulties in maintaining the operation of their drop-in centre, which was not funded by Health Canada. The establishment of this centre was a response to the closure of downtown public spaces due to COVID-19. This facility served as the sole daytime resource, offering access to washrooms and a temperature-controlled space for the homeless population. Additionally, the centre hosted workshops focused on wellness and empowerment, while also addressing substance use-related needs through providing support, treatment information, and access to harm reduction supplies. Unfortunately, the program experienced opposition from the community, adding to their challenges.

"It [drop-in centre] faced resistance from the neighbourhood it backed onto and the challenge of needing a zoning amendment to use the property as a drop-in centre and eventually to add supportive housing."

Some programs sought to address these concerns by hiring a third-party communication and engagement contractor to engage with stakeholders and the community and to lead knowledge dissemination activities to increase public awareness about the ongoing drug toxicity crisis and the significant role of pilot programs. For example, the program with the drop-in centre noted:

"Staff worked hard to address neighbourhood concerns by installing fencing, portable toilets, and smoking shelters; more closely monitoring outdoor behaviour during operational hours and hiring security guards; cleaning up the property; and installing lockers for personal belongings to keep the property looking nice and reduce conflict. They also spent a lot of time on public relations, joining the neighbourhood Facebook group to engage in discussion with concerned neighbours, educating the public about the need for the centre and efforts being made to lessen its impact on the neighbourhood; and soliciting support from across the city in the form of a letter-writing campaign. [Our physician] also gave presentations to the city's Planning Advisory Committee and City Council."

Despite following these proactive and practical steps, such as implementing physical improvements and engaging in public relations efforts to address community concerns, the amendment was eventually denied, forcing the closure of the drop-in centre at the end of April 2021.

Intervention characteristics

Clients' unmet medication needs

Most pilot programs expressed concerns that safer supply medications and dosages provided were inadequate in meeting their clients' needs, and some clients continued to experience withdrawal symptoms after safer supply enrollment. This was partly due to the high potency of opioids circulating in the unregulated drug supply (e.g., fentanyl and fentanyl analogues) and increased opioid tolerance from exposure to unregulated opioids. An additional factor was limited opioid availability on provincial formularies, with some medications (particularly high-dose injectable opioids) completely unavailable for prescription in some provinces. Moreover, some programs' dispensation practices limited the availability of take-home doses, 24-hour access, and unwitnessed dosing. These challenges contributed to the continued use of substances from the unregulated drug market among clients. For example, a program located in a large urban setting in British Columbia that provided both iOAT and safer opioid supply services, noted:

"Changing patterns of drug use amongst people who use drugs in a British Columbia's [neighborhood] has led us to consider additional fentanyl-related options as lower-potency opioids, such as hydromorphone and morphine are proving inadequate to separate people from the toxic illicit supply. People who use drugs in [this neighbourhood] have long been calling for access to [higher-potency opioids], but there are considerable supply chain issues even with the domestic supply."

In Ontario, clients were also interested in alternative medications currently unavailable to them (e.g., high-dose injectable hydromorphone, diacetylmorphine and fentanyl). Additionally, the need for smokable prescribed opioid medications (e.g., powdered diacetylmorphine or fentanyl) was highlighted, given the increasing transition from injecting to smoking among people who use drugs. For example, one pilot program located in a large urban setting in Ontario that provided safer opioid supply services, reported:

"There continues to be a very strong need for new medication options (both injectable and take-home formulations of hydromorphone, diacetylmorphine, and fentanyl). Additionally, as more clients transition to wishing to smoke/inhale opioids to preserve vein health and as an [overdose] prevention measure, there is a strong need for a prescribed opioid medication that is smokeable (and powdered diacetylmorphine would potentially address this need)."

Despite repeated requests by pilot programs for the expansion of access to alternative medications, they reported limited success due to existing regulations, insurance coverage, and supply interruptions (e.g., shortages of hydromorphone, morphine sulfate, and buprenorphine/naloxone).

Implementation process

Pandemic-related challenges

All pilot programs reported facing challenges in service provision during the COVID-19 pandemic, and more than half reported COVID-19-related challenges during our analytic timeframe (February 2020 to March 2022). For instance, the implementation of pilot programs faced significant challenges due to COVID-19 regulations that imposed restrictions on in-person meetings during the early phases of implementation. The capacity for care delivery was hampered, and some services had to be suspended to prevent the rapid transmission of SARS-CoV-2 among both staff and participants. As a result, the provision of care within these programs became difficult. For example, a pilot

program located in a medium urban setting in New Brunswick that provided both iOAT and safer opioid supply services, noted:

> "We have had several positive [COVID-19] cases this period amongst participants living in shelters or tent cities. There was the potential for cases to spread rapidly…Three times, positive cases among iOAT participants (including one positive staff member) caused us to close to all but iOAT. This meant group appointments, peer worker training, wellness & empowerment workshops, and in-person meetings with remote staff were all canceled for two weeks at a time. Nursing students were also not allowed in the clinic during these times."

Additionally, one program located in a medium urban setting in Ontario that provided safer opioid supply services had to halt their planned visits to the other safer supply programs due to COVID-19. Fortunately, they were able to adjust their plans swiftly and effectively. They noted:

> "[Our] plans to visit existing safer supply programs was put on pause due to COVID-19/evolving restrictions and public health protocols. [In response] all interactions with existing safer supply programs were done via Zoom/Microsoft Teams, which proved to be sufficient for understanding the structure, organization, planning, and lessons learned from each of the programs. The program manager was able to reach out to multiple members of the safer supply teams, including coordinators, registered nurses, ordering providers, harm reduction workers, and peer workers, in order to get a well-rounded view of the programs."

Following the initial COVID-19-related restrictions, service providers had to change their team meetings, recruitment, and interviews to virtual settings to ensure physical distancing. In some centres in Ontario and British Columbia, this led to the development of novel and decentralized programs. In a large urban setting in Ontario, this included a mobile outreach program established in February 2021 to provide pilot program services in partnership with four major program partners and 16 site partners. The key recipients were people marginalized by social conditions and at risk of poor health outcomes, severe harm, and death due to the intersection of the COVID-19 pandemic, drug toxicity crisis, and homelessness.

As a result of physical distancing restrictions, pilot programs also faced challenges in providing access to case management, mental health support, trauma counselling, housing services, options for social programming, volunteer or employment opportunities, and places for clients to spend time in the community. This was particularly concerning for the mental health of pilot programs' clients, given that most clients were struggling with grief, survivor guilt, trauma, and loss related to the drug toxicity crisis, while having limited interactions with their peers and supportive services. One pilot program in a large urban setting in Ontario that provided safer opioid supply, posited that:

> "COVID-19 has greatly exacerbated the lack of adequate programs and services for highly marginalized people who are experiencing homelessness, mental and physical health issues, social isolation, and structural violence. Prior to COVID-19, such services were already operating beyond capacity. An anticipated positive outcome for clients on safer opioid supply is that they have increased time and stability to engage in programming and services that address the social determinants of health, such as working on housing or doing volunteer work. However, COVID-19 has eliminated social programming and work and volunteer opportunities, and left people with very few places to 'pass time' during the day. As such, this 'added time' without activities and social interaction present challenges for people's mental health."

Pilot programs sought to address these challenges by seeking collaboration opportunities with their internal teams and external community partners (e.g., outreach and supervised consumption sites) to leverage resources to support their clients. Providing communication devices (e.g., cell phones, tablets, and SIM cards with data) was particularly helpful in hosting 'communications training' for clients not accustomed to virtual care. Pilot programs were able to speed up their recruitment by establishing outreach teams to actively engage with potential candidates for the service. Despite these initiatives, physical distancing challenges contributed to a slower-than-expected recruitment schedule and challenges in retaining clients in care.

Medication-related challenges

Most pilot programs reported facing significant challenges regarding the availability of opioid medications beginning in late 2020 up to mid-2021. These shortages often led to staff and client stress, as well as disruption in the clients' care and broader pilot program operations, which were exacerbated given a lack of coverage of alternative medications. For example, one pilot program in a large urban setting in Ontario that provided safer opioid supply, noted:

> "Between November and February, then again in March, and now April 14th – May 28th, there have been Dilaudid 8 mg shortages. Some of our clients were able to use the generic (Apotex – until it started experiencing a shortage) but others would not or could not use the generics [due to] rashes, and difficulty in injecting. In March, the other pharmaceutical most commonly prescribed (i.e., Kadian) also went on back order, with an anticipated end date of September (200 mg) and October (100 mg). The problem of drug shortages – particularly for Dilaudid 8 mg – is linked to the narrow range of pharmaceuticals that our clients can access due to lack of coverage for alternatives (diacetylmorphine, injectable hydromorphone, buccal fentanyl)."

Overly medicalized and high-barrier safer supply models

Most pilot programs noted that despite their efforts to make their services as accessible and low-barrier as possible, the current models of safer supply service provision were excessively medicalized and insufficiently client-centred. For example, one pilot program located in a large urban setting in British Columbia that provided both iOAT and safer opioid supply services noted that the existing structures (i.e., being offered within an addiction service) reduced their capacity to maximize service provision and noted that a public health approach that considers various determinants of substance use by placing emphasis on upstream factors influencing overdose and related social consequences was needed:

> "We are setting up our own electronic medical system to support safe supply provision through prescription- this takes time, training and administrative support. Time-consuming collection of urine drug screens required by addiction medicine surveillance means that our outreach staff are not able to focus on other priorities. Should a public health approach to safe supply be enabled by provincial and federal policy change, our ability to reach a much greater number of people would be significantly increased. Safe supply programs could then operate as such, rather than having to meet extraneous requirements."

Given the medicalized nature of safer supply service delivery, pilot programs encountered significant challenges in recruiting healthcare providers willing to participate. Clinicians expressed concerns regarding potential penalties and the burdensome nature of repeated audits issued by regulatory colleges for prescribing safer supply medications. The risk of being audited by regulatory colleges discouraged clinicians from prescribing safer supply. Such concerns have specifically affected pilot programs designed to have minimal contact with care providers (e.g., an intervention which dispenses hydromorphone tablets out of an automated biometric dispensing machine). For example, one pilot program located in a large urban setting in British Columbia that provided safer opioid supply services, reported:

> "The capacity to provide safe supply prescriptions by physicians remains limited primarily due to physicians' personal concerns with [the consequences] offering a non-witnessed safe supply. This has a direct impact on [our] project as prescribers are needed to operationalize the programs in each location and reach the goal of full enrollment for each machine."

These concerns were particularly prominent in the initial phases of pilot programs' implementation. They were later partially addressed through direct advocacy with prescribing physicians, expanding prescribing permissions to non-physicians (e.g., nurse practitioners), and growing confidence amongst prescribers that regulatory bodies would not punish safer supply prescribers. A few pilot programs also expressed concerns regarding the lack of safer supply continuity for institutionalized clients. For example, one pilot program located in a large urban setting in Ontario that provided safer opioid supply services, noted:

> "Hospitals and prisons have not yet begun prescribing [safer supply] for clients who are admitted as inpatients for medical treatment or who are incarcerated in prison. This leads to issues with continuity of care. For hospitalized clients this frequently results in shortened hospital stays, as patients leaving early due to withdrawal symptoms. For people who are incarcerated, they are offered sub-optimal or no treatment while imprisoned, which results in rapid loss of opioid tolerance and increased risk of overdose on release."

Programs' staff reported attempting to advocate for clients when hospitalized or incarcerated to address this issue; however, they were often unable to secure continued care due to abstinence-focused institutional policies.

Discussion

We examined 45 progress reports from 11 pilot programs in three provinces in Canada and identified various shared challenges faced by the programs since their implementation. In some cases, the organization of services (e.g., physical space restraints, staff shortages), the outer context affecting pilot programs (e.g., inadequate operational resources, structural barriers to access, public perceptions), the characteristics of the interventions (e.g., inadequacy in meeting the clients' medication needs), and implementation procedure (e.g., COVID-19-related challenges, and high-barrier safer supply models) undermined the capacity of these services to operate at their maximum potential in reducing harms among their clients.

A growing body of evidence suggests the positive impacts of using safer supply services among people who use drugs and highlights the benefits of safer supply interventions across Canada. For example, people who have accessed safer supply services have experienced significantly improved clinical health outcomes, such as reduced rates of emergency department visits, hospitalizations, incident infections, and substance use-related deaths when compared to those not receiving these services (Brothers et al., 2022; Gomes et al., 2022; Lew et al., 2022; McNeil et al., 2022; Young et al., 2022). Moreover, in the context of existing medicalized constraints, safer supply programs appear acceptable to people who use drugs who have faced challenges in accessing and being retained on first-line OAT modalities (Ivsins et al., 2020; Pauly et al., 2022), and emerging qualitative evidence suggests that they can also improve their quality of life (Ivsins et al., 2021). Despite these significant benefits, positive attitudes towards the intervention by clients (Foreman-Mackey et al., 2022; Ivsins et al., 2021; McNeil et al., 2022) and the relative flexibility of pilot programs' staff in terms of service provision (Foreman-Mackey et al., 2022; Ivsins, Boyd, Mayer, et al., 2020), our analysis identifies serious external challenges faced by the pilot programs included in our analysis due to staff shortages, physical space constraints, and lack of long-term consistent funding sources. Many of these challenges were exacerbated by the implementation of pilot programs during the initial stages of the COVID-19 pandemic and were seen across the broader health system. Given the significant and continuing financial and social burden of the drug toxicity crisis in Canada—particularly in terms of lives lost to drug toxicity deaths—and the potential role of pilot programs in helping address the issue, they must be adequately resourced to reach their full potential in service delivery and care provision for people at high risk of drug toxicity death.

Several pilot programs reported that not all client needs were met through these programs. For example, some pilot programs reported that clients continued to experience opioid withdrawal symptoms, could not be effectively titrated with available medications, and supplemented their safer supply prescriptions with drugs from the unregulated market. This is consistent with previous studies (Foreman-Mackey et al., 2022; McNeil et al., 2022) and is likely to attenuate the preventive impact of pilot programs on program retention and effectiveness. Pilot programs reported that these challenges, primarily stemming from the restricted range of available medications (e.g., unavailability of fentanyl-based drugs and smokable prescribed opioid medications) and dispensing protocols (e.g., lack of take-home doses and round-the-clock accessibility), were particularly acute among people who developed a high tolerance due to their known or unknown exposure to fentanyl. However, pilot programs faced considerable barriers in acquiring alternative drugs better able to meet the clinical needs of clients. Notably, in the province of British Columbia, particularly in the Downtown Eastside neighbourhood, a small program provides compounded powdered fentanyl for consumption through smoking, snorting, and injection. However, provincial PharmaCare does not currently cover this specific form of powdered fentanyl, and the above-mentioned program bears the financial burden of providing this medication, which is substantial and could amount to more than $30,000 per participant annually. More recently, in April 2022, a client-pay model called the "enhanced access" program was implemented in Vancouver, British Columbia. Currently under evaluation for effectiveness and scalability, this small program allows clients who have undergone precise dose titration to obtain prescriptions for fentanyl powder. Subsequently, they can purchase the medication from a designated partner pharmacy, following a process similar to obtaining other medications through a regulated model (Larsen, 2022). Moreover, the lack of uptake in safer supply prescribing in hospitals led to pilot programs' clients being forced to leave the hospital prior to completing treatment, due to their untreated opioid withdrawal. In some cases, the attenuated effectiveness of pilot programs may have also been related to untreated benzodiazepine withdrawal among pilot programs' clients, as this class of drugs is prevalent in unregulated drug markets in Canada though generally not co-prescribed with opioids by clinicians, including those at pilot programs (Bonn, 2022; Boone, 2022; Hutchison et al., 2022; Scarfone et al., 2022; Ti & Tobias, 2021; Russell et al., 2023).

The disconnect between the rapid evolution of the unregulated drug supply and the controlled prescribing models employed by pilot programs presents ongoing challenges to service provision. Pilot programs attempted to mitigate many of the service and treatment barriers posed by the external context for their clients. However, the increasing potency of unregulated synthetic opioids (e.g., fentanyl, carfentanil, isotonitazene, and other nitazene-class opioids) and co-adulteration with drugs which are absent from pilot program prescription models—owing to the absence of fentanyl and other high-dose options on many provinces' formularies and the reluctance to prescribe benzodiazepines—present serious challenges for pilot program prescribers. These hurdles arise due to regulatory constraints that curtail the spectrum of medications they can provide (Kolla et al., 2022; Krausz et al., 2022). Compounding this tension is the fact that pilot program services remain medicalized (e.g., have limited medication options, restrictions on take-home doses, a requirement for daily visits to a pharmacy, strict regulatory environments for certain substances), and a small pool of clinicians are currently willing and equipped to act as safer supply prescribers (Foreman-Mackey et al., 2022; Glegg et al., 2022; Ivsins

et al., 2020; McNeil et al., 2022), further attenuating their potential impact on reducing client consumption of unregulated substances. Concerns with highly medicalized models of care have also been previously expressed by people who use drugs enrolled in safer supply programs (Foreman-Mackey et al., 2022; Ivsins et al., 2020; McNeil et al., 2022). In these cases, people who use drugs have also noted that their substance use is motivated in part by a desire to achieve euphoric and pleasurable experiences during substance use, and medicalized models of care designed strictly to avoid withdrawal may have limited uptake (McNeil et al., 2022).

It is vital to recognize the heterogeneities among people who use drugs and reflect their varying needs in how pilot programs are designed and implemented (Pauly et al., 2022). A 'one-size-fits-all' medicalized approach can recreate the well-established challenges associated with conventional OAT services (Foreman-Mackey et al., 2022; Jin et al., 2020), which often fail to meet the needs of people who use drugs at higher risk of overdose mortality. This may also discourage people who use drugs from engaging with a broader continuum of care to address substance use-related harms and improve their well-being. As data are still required to identify the most practical models for providing safer supply services (e.g., wrap-around services vs. integration with primary care vs. low-barrier standalone services) and across a broad range of contexts (e.g., in urban areas vs. rural and remote settings), future implementation science studies are required to compare the health, social, and economic outcomes of each model of care, in specific settings, and for distinct client subpopulations. Regardless of the model of service provision, any model of care for providing safer supply needs to be conceptualized, designed, and must function using a harm reduction, trauma-informed, and culturally-sensitive lens (Brown, 2021; Canadian Association of People Who Use Drugs, 2019; Pauly et al., 2022). Moreover, while we did not have data to examine clients' perspectives towards such challenges, it is of utmost importance that people who use drugs and those impacted by the drug toxicity crisis are directly involved in the conceptualization, design, implementation, operation, and evaluation of safer supply programs (Foreman-Mackey et al., 2022; Ivsins et al., 2020; Wallace et al., 2019; Pauly et al., 2022).

There is an emerging scientific and policy consensus that efforts to prevent overdose through prohibition, drug law enforcement, and heightened restrictions on prescribing have failed (Fischer et al., 2017; Karamouzian et al., 2022). To that end, emerging evidence as well as the data presented herein, suggest that pilot programs meaningfully meet the needs of subgroups of people who use drugs and reduce their exposure to a toxic unregulated supply. However, the multiple barriers faced by pilot program models in Canada may position them poorly for scale-up. As noted above, this stems mainly from limitations in the broader environment in which programs are operating, ongoing socio-structurally rooted access barriers faced by clients, and the lack of non-prescriber-based models that can be scaled up quickly to match the dynamism of unpredictable unregulated drug markets. This suggests that, beyond the scale-up of medicalized pilot programs to meet the needs of people at higher risk of overdose mortality, a range of flexible and low-threshold regulatory options (e.g., compassion club models, client-pay models, legislative changes to the Controlled Drugs and Substances Act (British Columbia Centre on Substance Use, 2019) must be considered to address the drug toxicity crisis in Canada (Foreman-Mackey et al., 2022).

Limitations

We acknowledge the limitations of this study. First, we chose to utilize progress reports submitted by pilot programs for this analysis to access a parsimonious data source and maximize efficiency and economy. As these reports provide a detailed account of implementation progress, challenges, and strategies pilot programs employ, they offer a unique and informative perspective on their real-world experiences. Moreover, being readily available and prepared by the pilot programs themselves, they allow comprehensive access to diverse challenges without requiring extensive additional resources or burdening the pilot programs. However, it is possible that because reports were provided by grantees to funders, they might have been potentially influenced by their relationships with their funder. Indeed, potential reporting bias might have led to a selective emphasis on specific challenges or downplaying others in their progress reports. Second, reports may not capture all the nuances and contextual factors surrounding the reported challenges. Notably, they did not capture individual staff or client perceptions on the implementation challenges of pilot programs. Future longitudinal evaluations engaging with programs' clients and implementers through in-depth and group interviews are ongoing, and will likely provide a more comprehensive overview of implementation challenges and facilitators of pilot programs across various contexts. Third, reports were only available to us from 11 Health Canada-funded pilot programs primarily based in British Columbia and Ontario, and our findings might differ from the experiences of other pilot programs in Canada. In particular, these programs are distinct from prescribing under British Columbia's province-wide clinical guidance for pharmaceutical alternatives to the toxic drug supply (i.e., Risk Mitigation Guidance), which is being evaluated separately (Nosyk et al., 2021). Regardless, the evaluated programs provide a reasonable representation of the existing models of safer supply service delivery across Canada. Fourth, data for this analysis was extracted from sections within the progress reports that requested details on limitations experienced by program operators, and the reports lacked sections to capture the facilitators and "success stories" of implementing pilot programs. This limited the ability of our analysis to capture a complete picture of program operations. Fifth, most programs included in our analysis were located in medium to large urban settings in Canada, preventing detailed comparison of implementation challenges based on urban versus rural categorizations. This is an important limitation because context plays a crucial role in the implementation experiences of harm reduction interventions (Sarang et al., 2007; Bardwell et al., 2019; Lopez et al., 2022). Additionally, there are well-documented disparities in accessing substance use treatment and harm reduction services between rural and urban areas, due to factors, such as limited healthcare infrastructure, sparse distribution of healthcare facilities, geographical vastness, low population density, longer travel distances, increased transportation costs, limited public transportation options, more pronounced substance use-related stigma, and a shortage of addiction medicine care providers in rural settings (Baker et al., 2020; Ostrach et al., 2021; Rains et al., 2022; Thakarar et al., 2022; Rijnink et al., 2022; Bardwell et al., 2023). Sixth, because the study period occurred during the COVID-19 pandemic, it is likely that some challenges—even those seemingly not directly related to pandemic-related restrictions—would not be relevant to the implementation of pilot programs in periods when such restrictions are absent, and these services are more established. Lastly, although we found COVID-19 to have adversely influenced the implementation of pilot programs, the context of the pandemic may have provided a policy window to implement safer supply programs. Before the pandemic onset, there were significant challenges in persuading prescribers in British Columbia to authorize hydromorphone tablets as take-home supplies (Tyndall, 2018). However, the Risk Mitigation Guidance in this province (Nosyk et al., 2021), which was released in response to the dual public health emergencies of drug toxicity deaths and COVID-19, explicitly allowed individuals to receive a 7-14 day supply of hydromorphone tablets for personal use at home.

Conclusion

In summary, our findings document the implementation challenges faced by pilot programs across three provinces in Canada. Given the important role of safer supply programs in addressing the drug toxicity crisis in Canada and the potential for scale-up in the near future, there is a need to ensure that these programs are well-supported during their

implementation phases. It is equally important to ensure a thorough understanding of any limitations associated with these programs, in order to maximize their potential effects on client health and social well-being. It is also imperative to refine service provision approaches within safer supply programs based on the feedback and experience of clients and program administrators, and to consider how these programs may contribute to emerging strategies to curb the toxicity crisis in Canada.

Ethics approvals

This study was approved by the Unity Health Toronto Research Ethics Board (REB code: 21-273).

CRediT authorship contribution statement

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Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: KA and NH are employed by one of the pilot programs under evaluation. MB reports personal fees from AbbVie and grants and personal fees from Gilead Sciences, outside of the submitted work. MB and NT have also worked for the Canadian Association of People Who Use Drugs which receives funds from Health Canada. Other authors declare no have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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