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Treatment provider perceptions of take-home methadone regulation before and during COVID-19

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ABSTRACT

Background: The loosening of U.S. methadone regulations during the COVID-19 pandemic expanded calls for methadone reform. This study examines professional perceptions of methadone take-home dose regulation before and during the COVID-19 pandemic to understand responses to varied methadone distribution policies.

Methods: Fifty-nine substance use disorder treatment professionals were interviewed between 2017 and 2020 in-person or over video call. An inductive iterative coding process was used to analyze the data. Constructivist grounded theory guided the collection and analysis of in-depth interviews.

Results: Treatment professionals expressed mixed views toward methadone take-home regulations. Participants justified regulation using several arguments: 1) patient care benefitting from supervision, 2) attributing improved patient safety to take-home regulation, 3) fearing liability for methadone-related harms, and 4) relying on buprenorphine as an “escape hatch” for patients who cannot manage MMT policies. Other professionals suggested partial deregulation, while others strongly opposed pre-pandemic take-home regulation, explaining such regulations impede medication access and hinder patient-centered care. Some professionals supported the COVID-19 policy changes and saw these as a test run for broader deregulation, while others framed the changes as temporary and cautiously applied deregulation to their services, at times revoking looser rules for patients they perceived as nonadherent.

Conclusion: Treatment professionals working in a range of modalities, including opioid treatment programs, expressed hesitation toward expanded take-home methadone access. While some participants also supported forms of deregulation, post-pandemic efforts to extend looser methadone distribution policies will have to address apprehensive professionals if such policy changes are to be meaningfully adopted in community services.

1. Introduction

Methadone Maintenance Treatment (MMT) improves treatment retention (Bao et al., 2009; Mattick et al., 2009) and reduces risky opioid use (Mattick et al., 2009) and overdose (Kimber et al., 2015; Larochelle et al., 2018; Sordo et al., 2017). In the U.S., MMT is regulated by state and local authorities, as well as multiple federal bodies, including the Drug Enforcement Agency (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA), which require MMT to be prescribed and dispensed in licensed opioid treatment programs (OTPs).

OTP licensing requires program adherence to federal standards regulating unsupervised “take-home” methadone doses, counseling services, and patient monitoring (Center for Substance Abuse Treatment, 2005; Federal Guidelines for Opioid Treatment Programs, 2002). Given limited scalability of the U.S. OTP model (McBourmie et al., 2019), several studies have demonstrated the feasibility of changing policies to allow office-based prescribing (Harris et al., 2006; Merrill et al., 2005; McNeely et al., 2000) and pharmacy dispensing (Hohmeier et al., 2021), which are already used in other countries (Cochran et al., 2020).

Critics have raised concerns for decades about how MMT regulations

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contribute to stigma (Madden, 2019; Wakeman and Rich, 2018; Harris et al., 2006; National Institutes of Health, 1997) and logistical hurdles for patients (Calcaterra et al., 2019; Joudrey et al., 2020), especially in light of increased overdose deaths from illicit opioids. However, it is unclear the extent to which providers working in community-based substance use treatment favor MMT regulations.

Regulation of MMT remained stagnant until the COVID-19 pandemic prompted a substantial relaxation of key areas of U.S. pharmacotherapy regulation on March 16, 2021, including take-home dose policies for methadone. Before the COVID-19 pandemic, OTPs were required by federal regulations to offer take-home doses gradually in a “stepped” process that only after two years allowed patients the maximum 28-day supply of take-home medication (Federal Guidelines for Opioid Treatment Programs, 2002). Among the MMT changes allowed by SAMHSA during the COVID-19 pandemic is expanded access to take-home doses that do not rely on explicitly scheduled stepped timelines (Table 1). OTPs are allowed to give 14 days of take-home doses for “less stable” patients and “stable” patients are allowed up to 28 days. Stability assessment includes similar factors as those OTPs were directed to consider prior to the pandemic (e.g., program attendance, social functioning, etc.). Federal regulations before and during COVID-19 continue to require monitoring “theft or diversion of take-home medications” (Federal Guidelines for Opioid Treatment Programs, 2002), creating a surveillance role for OTP staff.

The swift and significant changes to take-home dose regulation during the COVID-19 pandemic have renewed calls for U.S. MMT policy reform. Some have framed the COVID-19 changes as both evidence of the speed at which reform may be enacted and an opportunity to test the feasibility of longer term deregulation (Green et al., 2020; Vecchio et al., 2020). This study draws on qualitative research to explore how professionals working in community-based substance use treatment perceive MMT regulations, specifically take-home policies, and deregulation. The data provide context to better understand how providers are responding to calls to extend COVID-19 MMT policies and to identify considerations for meaningful adoption of longer-term policy changes in community methadone services.

2. Methods

2.1. Data collection

Constructivist grounded theory guided the collection and analysis of in-depth, semi-structured interviews. This methodology uses a systematic inductive approach to building abstract understandings of qualitative data (Charmaz, 2014). Recruitment in Texas and New Mexico used flyers, emails, and phone calls to directors of treatment sites, as well as direct email recruitment of substance use professionals with contact information on facility websites. Convenience sampling initially guided participant selection, and individuals were included if they had any past

Table 1

Comparison of pre-COVID-19 take-home methadone dose regulations and reforms allowed by SAMHSA during the COVID-19 pandemic.

Step levels for take-home methadone doses	Pre-COVID-19 schedule to attain step level		COVID-19 rules for step level
1 take-home dose/week	0–90 days	Patient stability assessment throughout	No explicit rule
Up to 2 take-home doses/week	91–180 days		No explicit rule
Up to 3 take-home doses/week	181–270 days		No explicit rule
Up to 6 take-home doses/week	271–365 days		No explicit rule
Up to 14 take-home doses (2 weeks)	1 year-2 years		“Less stable” patients
Up to 28 take-home doses (1 month)	>2 years		“Stable” patients

or present substance use treatment experience and affirmed they had knowledge of medications for opioid use disorders, including MMT. Participants included peer support workers, licensed counselors, program administrators, and physicians. Later recruitment was guided by theoretical sampling that specifically sought participants with knowledge of methadone take-home regulation. Interviews ($n = 59$) were primarily conducted by the first author with student assistance both in-person and via video calls between 2/17/2017–8/31/2020. Of the 11 interviews conducted in 2020, eight of these were collected during the COVID-19 pandemic. Each digitally recorded and transcribed interview lasted 45–120 min and participants were assigned pseudonyms by the study team.

2.2. Data Analysis

Data collection and analysis occurred simultaneously, with analyses influencing interview guides to more specifically focus on questions related to methadone regulation. Data collection ceased when interviews did not yield additional insights into themes identified in the analysis process. The first two authors analyzed the data using an inductive iterative coding process. Early analyses used “open coding” in which segments of data were categorized with a brief summarizing label (Charmaz, 2014). The authors then selected the most significant early codes and created an organized list of “focused codes.” Focused codes were applied to the data using Dedoose© and the authors jointly reviewed coding to identify areas of disagreement and achieve consensus on interpretation of key themes. Analytic memos explored connections between codes and identified themes that are presented in the results below.

3. Results

We first explore why professionals embraced restrictive take-home dose policies, followed by accounts from participants calling for more radical forms of deregulation and participants suggesting a middle ground of reformed regulation. Finally, perceptions of COVID-19 take-home dose reforms are presented, including participant views on maintaining reforms in the future.

3.1. Arguments for regulation

Four themes emerged for supporting MMT take-home regulation: 1) patient care benefitting from the “structure” of supervised methadone dosing, 2) attributing improved patient safety to regulations, 3) providers fearing liability for methadone-related harms, and 4) relying on buprenorphine as an “escape hatch” for patients who cannot manage MMT policies. “Structure” was a common participant term used to refer to a variety of policies and expectations of patient adherence.

“Recovery from any substance dependence requires structure... they can’t just give out a month’s worth [of methadone] at a time. getting a week’s worth at a time creates a large temptation to sell it to somebody who got kicked out of the clinic and go get a shot of heroin.” (Lorenzo, counselor and administrator at a treatment facility that does not provide MMT)

This provider describes the structure of daily dosing and limiting access to additional take-home doses as a mechanism for reducing diversion, which was a central concern of many participants. Other benefits of “structure” included social support, promoting patient adherence, and providing mechanisms for monitoring patients more closely.

“A pregnant mother that I can recall, she just needed the contact that came with daily dosing. She needed the support that we were giving her, and the love and attention we were giving her that she wasn’t getting at home to help her get through her pregnancy... I like that

accountability piece of coming in every day, so we have eyes on them. That's why I prefer methadone over Suboxone." (Vincent, OTP director)

The benefits of MMT structure are also often tied to a second theme around patient safety. Some providers were less worried about diversion and counselor check-ins, and more worried about how take-home doses could increase methadone overdose risk, even if daily dosing requirements also required significant patient time and energy,

"How methadone clinics are regulated [is] for accountability... it's a terrible burden for patients to have to get there every day, but it's also because it truly is a dangerous medication. One does have to be really careful with it... As physicians we're all taught to be scared of methadone, hardly anybody will prescribe methadone even for pain unless it's hospice because the risk of overdose, but it's so low with Suboxone. That's one of my biggest reasons why I like Suboxone better." (Dr. Harrison, former OTP physician)

Safety concerns were also connected to a third theme among regulation supporters: legal and emotional liability for prescribers,

"If you give everyone buprenorphine or methadone with no strings attached, you probably are going to reduce the harm, the number of bad outcomes. However, you're accountable for those few bad outcomes... You may face litigation. More likely, you'd be potentially defending your license in front of the state regulatory agency and licensing bodies... We also have to live with the medications that we have given—and I had firsthand experience with this—resulted in a patient death. Someone may say 'That patient may have died anyway from taking heroin.' But that still is something that resides in the mind of the prescriber." (Dr. Snyder, OTP physician)

Many treatment providers described a fourth theme: buprenorphine as a solution to the regulatory barriers to methadone. Dr. Harrison touched on the issue of relative safety differences between the two medications previously when she mentioned lower overdose risk for buprenorphine products like Suboxone. Buprenorphine's relatively lighter regulation served as an "escape hatch" that vindicated methadone regulation because buprenorphine is framed as a viable alternative for patients who cannot manage MMT regulation,

"I totally get that argument that coming in every day [for MMT] is a burden and I hear it from patients a lot like, 'I'm not coming in.' And I think that's why I always liked to try Suboxone first because it is a burden." (Dr. Reid, OTP physician)

Take-home restrictions improved perception of MMT safety for some providers, however the safety concerns voiced are largely framed around the overdose risk from methadone rather than how barriers might lead to riskier illicit use that could also result in overdose. Dr. Snyder described a tension between this harm reduction principle and fear of significant professional and emotional repercussions for adverse events. However, Dr. Reid echoes sentiments from Dr. Harrison, acknowledging that daily dosing can be a challenge for patients, and thus considers this when making medication recommendations with patients, preferring buprenorphine in part because of looser regulation.

3.2. Arguments against regulation

A smaller number of participants objected to restrictions on MMT take-home doses, and these critiques focused two themes: 1) undermining patient-centered care, and 2) impeding MMT access. Several participants discussed how regulations reflect implicit distrust of patients from the onset of treatment initiation. Prescriptions were contingent upon urinalyses and observed dosing, demonstrating an assumption that patients were otherwise susceptible to misuse of the medication.

"...methadone is so enslaving because usually you have to go five days a week, and then can only take it home on weekends. This really made it difficult for employed people. And they're treated like inmates. They're coming in and receiving it and it's directly observed therapy and they have to swallow [methadone] in front of the people. It's like people taking TB medication who failed to complete their treatment and now they're on directly observed therapy. It's the assumption that they won't take the drug, then sell the drug. They're not going to play by the rules. That's why they have to be observed... Whereas Suboxone, it just seems more humane and treats addiction like a true disease... [Suboxone] can be provided monthly by a primary care physician." (Justine, retired OTP administrator)

This critique stands in stark contrast to those framing regulations as beneficial for professional practice and even therapeutic for patients. MMT patients are compared to the treatment of both highly infectious patients and to incarcerated people; framed as a threat to public safety and deserving of punishment,

"They're too strict...It seems like we came up with a model that was punitive, and it's never veered from that model... [Patients] have to come, produce their urine, and they get to take [doses] home for the weekend, but then if they have 'dirty' urine, they won't get to take it home again. They'll be punished." (Justine, retired OTP administrator)

Providers also suggest the multiple agencies regulating this area of healthcare contribute to punitive care practices in OTPs,

"A lot of OTPs have the approach, 'You follow the rules, or you get out.' I don't have that same mentality... It's not encouraging. But the regulations from the state and the DEA, and SAMHSA, and CARF, and all of those things are so stringent. I think sometimes that overshadows the patient care. They get so wrapped up in the rights and the wrongs, the rules..." (Maria, OTP director)

These structural critiques highlight the role of government agencies in facilitating OTP conditions that undermine patient-centered care. OTPs may demonstrate a preoccupation with assuring adherence to regulations that overshadows patient care and leads to discharge from programs. Consistent with the attitudes above, a second theme described how take-home regulation creates logistical barriers to MMT,

"[MMT] patient struggles are common...when they bring their kids [to the hospital], they're afraid that if they disclose [MMT use] they're going to call CPS [child protective services] on them... The kid has to stay in there, a kid broke an arm, a leg, so they can't leave... It's hard for them to say to the provider, 'I got to go get my dose, and come back,' so they'll skip a day or two and go through withdrawal." (Hector, OTP counselor)

MMT patients with limited take-home doses experience difficulties with competing commitments. The case of medical emergencies with children of MMT patients highlights an example of potential threats to child custody if MMT use is revealed by the parent, but forgoing methadone doses in an attempt to avoid stigma and legal problems can result in withdrawal and increased overdose risk.

3.3. A middle ground: advocacy of partial deregulation

A small number of participants suggested modest reforms to MMT regulations that allow a slightly faster stepped timeline.,

"Safety-wise, I think it's good at first to have more regulation with methadone than Suboxone... I think that there could certainly be a shift in the amount of time it takes—It takes two years to get to a month of [methadone] take-homes, which is very limiting for people who are working or have families. If everything goes as planned.

That's a hard time in treatment rule. It takes 90 days to get just one take home." (Dr. Reid, OTP physician)

"...to get a month of take-home, I would want it to be a little closer to a year, somewhere maybe a year or to a year and a half. But I don't think it should be less than a year to earn a month of take-home with methadone considering how dangerous methadone is." (Dr. Snyder, OTP physician)

Both providers expressed concern with patient safety, and named this as a factor limiting their support for greater deregulation.

Some providers explain that if deregulation was more than they felt comfortable with, they would implement stricter policies requiring more supervision of patients.

"I agree with [the harm reduction] philosophy. However, when it comes to medications, I lean a little bit more the other way. I am responsible for making sure medications are given safely... I see the state or federal regulations that limit the amount [of take-homes] we can give to patients; I don't think that those regulations limit me much more than I would already be limiting myself because of cautious prescribing practices." (Dr. Snyder OTP physician)

While Dr. Snyder supported modified regulation, he also emphasized safety arguments explored previously, and used these to explain why he would continue to limit take-home doses even if future deregulation were to drastically reduce such requirements.

3.4. COVID-19 as a test run for deregulation

A small number of participants cautiously expressed optimism regarding COVID-19 MMT take-home changes, expecting such deregulation to expand access to care during and post-pandemic.

"There's one patient who has a lot of trouble with transportation, so her not having to deal with that and doing visits by video is really convenient and she's very excited about that... On the downside, some people feel a little more isolated with fewer check-ins." (Dr. Kamra, primary care doctor and former OTP physician)

Comments about the benefits of COVID-19 take-home changes were rarer than concerns about risks,

"On paper it sounds good because it increases access. I've estimated that about 65% of people I see in the hospital have insecure housing or are homeless. And getting to a methadone clinic regularly is a problem... However, one of the reasons why methadone has a different success rate than buprenorphine is the mandated structure... without that structure, I see them overtaking their methadone because they—for good reasons—didn't have take-home doses before and now they're getting two weeks at a time." (Dr. Arnold, physician at a hospital addiction program)

Most participants voiced uneasiness regarding COVID-19 policy changes around deregulation. While some agreed that dosing changes were needed to prevent spread of COVID-19, the idea of maintaining these policy changes was not broadly embraced. Concerns mirrored those presented earlier, namely lessened ability to assess and respond to patient risks and fear of professional repercussions.

"We did an exercise giving a full month out. Which I think was totally crazy. You don't give someone brand new in treatment 28 bottles of methadone. And methadone is such a high commodity because it goes for a dollar a milligram on the street. We were really cautious about the way we did it; they either got six days or 13 days' worth of take-homes, but once they gave a dirty [urinalysis] for fentanyl or benzodiazepines, we would have them come in every other day." (Vincent, OTP director)

This OTP tried to expand access to take-home doses up to one month,

as allowed by COVID-19 policies, but ultimately rolled this back to 13-days or 6-days for people who would not otherwise have reached these step levels before the pandemic. Expanded take-home doses were also revoked in cases where patients exhibited evidence of poly-substance use. Others also disagreed that COVID-19 provided an opportunity for testing out lower threshold MMT models and felt pandemic-related changes harmed care quality,

"...Due to COVID-19 we cut back on so many things, but usually people have to do at least two groups a month and do a behavioral health one-on-one. That's harm reduction though... I would not just [only give medication] to someone. I would be doing them a disservice if I did that. I would be hurting them more than helping them." (Roberto, OTP peer support worker)

The reduction in face-to-face contact allowed under COVID-19 reduced provision of in-person supportive services that professionals value.

A small number of participants advocated for increasing MMT regulation beyond pre-COVID-19 levels. These participants had a negative perception of MMT altogether and worked in abstinent treatment sites that did not offer opioid agonist treatment,

"There's a lot of drug and alcohol abuse around [MMT]... because a lot of the clinics aren't strict about it, like, 'We might threaten to cut back your methadone if you don't stop drinking.' But there isn't any real great boundaries... The expectations are low... I wish they had strict rules for Suboxone too, come in five or seven days. Because I don't want them to divert it to make money... Where's the control around this?" (Gerald, abstinent treatment facility administrator)

Reasons for supporting stricter regulation included the belief that policies expanding control of opioid agonist treatment may reduce diversion and provide greater incentives for people treated with methadone to cease polysubstance use.

4. Discussion

This study demonstrates that professionals working in community-based substance use treatment hold mixed attitudes regarding regulations around MMT. Regulation support and opposition did not fall along treatment ideology lines, with both people who self-described as "pro-harm reduction" and those adamantly opposed to opioid agonist treatment and harm reduction expressing varied views and experiences. Daily dosing was perceived by some professionals as unnecessary burden, and for others as a way to maintain provider contact with patients as part of the therapeutic benefits and social wellbeing that comes with adherence. The emergence of COVID-19 resulted in reduced MMT take-home regulations, yet providers described reluctance toward implementing such changes, with some adding barriers and revoking expanded privileges for patients unable to demonstrate ongoing adherence. These findings highlight a potential challenge for MMT deregulation because it may be idiosyncratically applied and create uneven access.

Recent research demonstrates increased mortality during the COVID-19 pandemic due to fentanyl-related overdose (Appa et al., 2021; Currie et al., 2021), suggesting access to evidence-based treatment like MMT is greatly needed. The emerging body of research on MMT during the pandemic shows promising results regarding risk for methadone-related overdose and relaxed SAMHSA regulation of MMT take-home doses. Brothers et al. (2021) found that increased take-home access among Connecticut OTP patients did not result in increases in methadone-related fatalities. Nevertheless, provider fear of overdose persists in the context of MMT during COVID-19. Hunter et al. (2021) documented U.S. provider perceptions of COVID-19 MMT policy changes in 13 states, finding concern with reduced patient monitoring (e.g., urine toxicology frequency) and concerns of "medication abuse,"

seemingly referring to diversion and non-prescribed use of methadone.

Providers in this study described perceived benefits of MMT take-home regulation stemming from the ability to monitor patients more frequently. Other participants opposed to MMT take-home regulation reframe “monitoring” in a more critical light, using the term “punitive” to highlight a paternalistic approach to surveillance of MMT patients. Medical paternalism is often criticized and rejected in many areas of healthcare in favor of approaches to care that respect patient autonomy (Kilbride and Joffe, 2018). However, in the case of MMT, the tension between professional control and patient choices are wrapped up in complex social forces tied to stigma, moralism, and a persistent cultural and regulatory orientation toward criminalization and the war on drugs. Regulations exist in all areas of medicine, and patients are subject to them, but in most other areas, patients are not actively screened for criminal activity in order to continue care and receive increased autonomy in medication management. The orientation toward criminalization in treatment for opioid use disorders is rooted in histories of racism and classism (Hansen and Roberts, 2012), and the drug war has generated controlling treatment environments (Frank, 2018; J. Harris and McElrath, 2012; McNeil et al., 2020) and contributed to fear of punishment among prescribers working in MMT. These fears held by prescribers create contradiction between strategies for population-level outcome improvement on the one hand, and concern with blame for individual patient outcomes on the other.

This study aligns with previous research suggesting a complex picture of the relationships between treatment provider ideology and clinical practice. For example, a systematic review by Barnett and Fry (2015) demonstrated that treatment provider support for the disease model of addiction may coexist with their support for other models, such as the moral model where addiction is seen as a character flaw. Different ideologies may be used to support varied interventions, such as providers deploying the disease model when it aligns with specific therapeutic approaches (e.g., pharmacotherapies for opioid use disorder) and a moral model when desiring patient acceptance of personal responsibility for substance use behaviors (Barnett and Fry, 2015). This study similarly suggests professionals may simultaneously hold ostensibly conflicting ideologies in the context of MMT; favoring higher MMT take-home regulation while also explicitly supporting other features of harm reduction and MMT access. Providers here too deploy ideologies strategically to explain support for more restrictive or liberal approaches to MMT care provision.

This study was limited by recruitment of professionals from only two southwestern states and the sole focus on provider populations. Regional differences in MMT regulation or availability may mean professional perspectives and experiences differ across U.S. regions in ways that affect the study results. This study did not collect data on MMT patient perspectives, but these should also be considered when assessing take-home regulations. Similar to provider perspectives illustrated here, past research exploring patient attitudes toward MMT take-home policies in the U.S. and England suggest mixed views. Many patients reported daily dosing imposes significant burdens that negatively affect family and employment responsibilities (Notley et al., 2014; Radcliffe and Stevens, 2008; Yarborough et al., 2016), while other patients described positive perceptions of restrictive take-home policies, attributing better treatment adherence to these regulations (Notley et al., 2014; Yarborough et al., 2016). Future research should systematically document patient perspectives during COVID-19 in order to further understand how reforms affect the population receiving MMT.

5. Conclusions

MMT policy reforms have been proposed throughout the last two decades, and a small number of studies demonstrate the feasibility of lowered take-home dose regulations (King et al., 2006; Merrill et al., 2005), even among patients experiencing high social marginalization (Harris et al., 2006). The experiences and attitudes of providers in this

research suggest that reforms to MMT take-home policies may nevertheless face professional hesitancy and opposition. More broadly, this study raises the specter of incomplete implementation if professionals have some discretion in how any future MMT take-home regulation changes are put into practice.

Experts working in overdose prevention with persons who use drugs have consistently highlighted the risks of an illicit drug supply that has been increasingly contaminated with more potent and lethal substances. In particular fentanyl, a synthetic opioid that is 50–100 times more potent than morphine, is present in more than 80% of U.S. opioid overdose deaths in 2020 (Ahmad et al., 2021). However, throughout the interviews with providers there is no mention of this. Instead, the overdose concern still stems from ideas around patient behaviors. Like many providers working to treat those with opioid use disorders, those in OTP settings need to recognize the harms associated with opioids in this illicit market when considering the risks of take-home MMT. Providers must receive clear messaging from regulators assuaging fears of liability for the relatively rare outcome of methadone-related overdose (5% of opioid overdose death in 2020 (Ahmad et al., 2021)). And future research may further elucidate effective interventions to improve provider willingness to implement changes in MMT take-home dose policies.

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CRedit authorship contribution statement

Erin Fanning Madden, PhD MPH: Led conceptualization, data collection, analysis, manuscript writing, Bryson Christian: Assisted with data analysis and manuscript writing, Pooja Lagisetty, M.D., M.Sc.: Assisted with conceptualization and manuscript writing, Bradley Ray, PhD: Assisted with conceptualization and manuscript writing, Sandra Sulzer, PhD: Assisted with conceptualization and manuscript writing.

Declaration of Competing Interest

No conflict declared.

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