Foundation *for* Opioid Response Efforts

Program Advisory Meeting: Imagining a More Patient-Centered Approach to Methadone Treatment

Executive Summary

Note: This summary captures the breadth of discussion and guidance provided to the Foundation for Opioid Response Efforts (FORE) during the meeting but is not intended to be a consensus document. The use of the term "participants" does not imply majority agreement.

On September 7, 2023, FORE convened an advisory meeting in New York City to understand the current landscape of methadone treatment for people with opioid use disorder (OUD), including the challenges faced by opioid treatment programs (OTPs) in providing patient-centered care as well as the differences among them in terms of for-profit vs. nonprofit status, range of services offered, and the extent to which they've adopted new regulatory flexibilities (e.g., provision of take-home doses). Participants also explored how the experiences of patients taking methadone differ by geography, race/ethnicity, and criminal justice involvement; discussed ways that methadone might be offered more routinely outside of traditional, standalone OTPs; and considered wraparound or co-located health care services that patients taking methadone might be offered. The meeting objectives were:

- to enhance FORE's understanding of the barriers that prevent OTPs from providing patient-centered care;
- to consider changes to practice, state and federal policy and regulations, and payment that could promote patient-centered methadone treatment; and
- to identify opportunities for FORE to promote a patient-centered approach through grantmaking, convenings, and information dissemination.

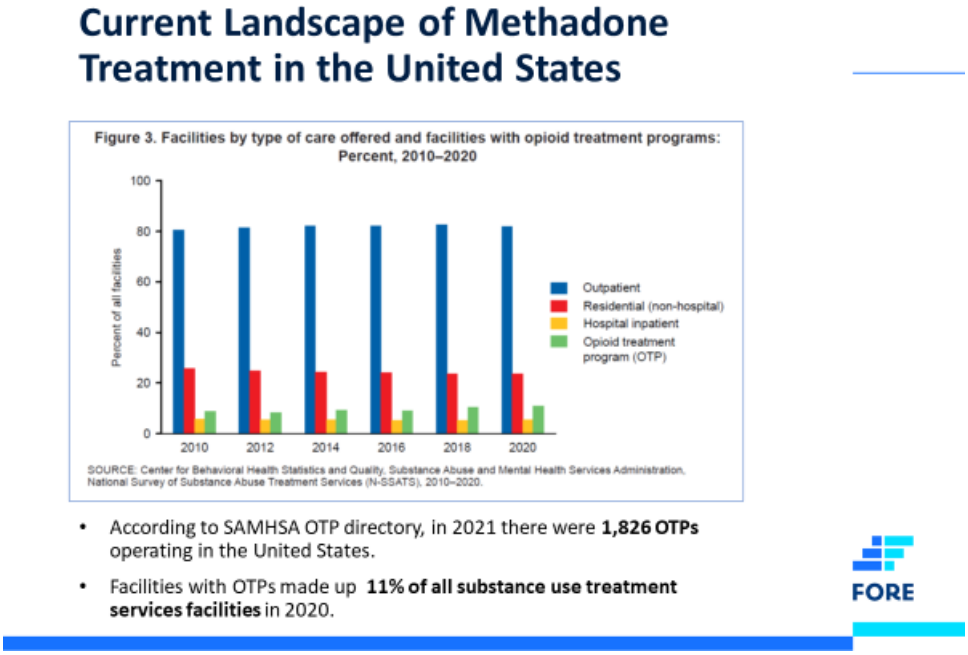
This report summarizes the discussion.

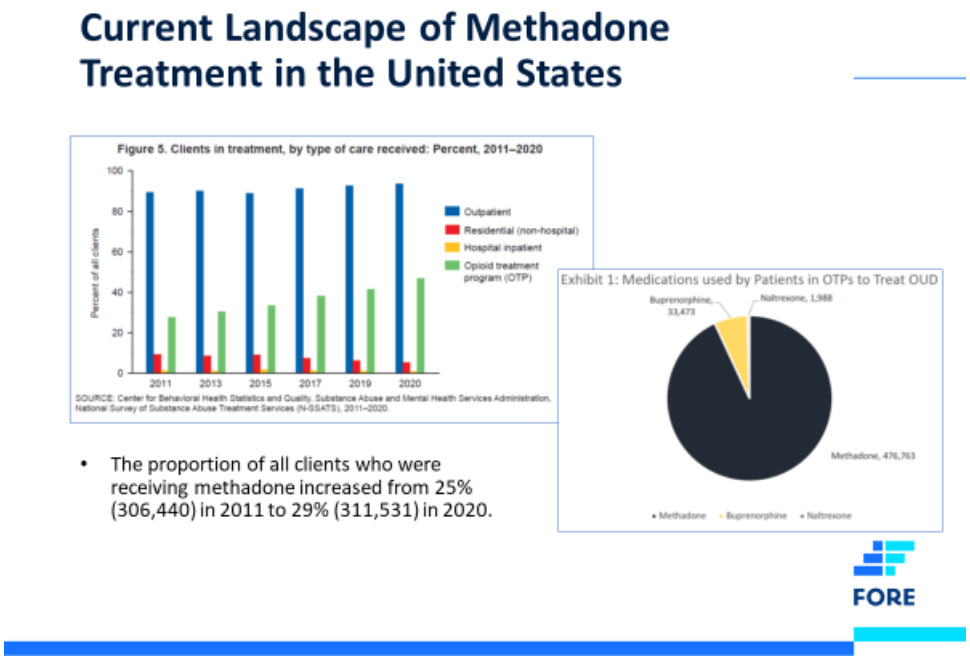
BACKGROUND AND RESEARCH FINDINGS

Methadone, an opioid agonist medication that reduces cravings and withdrawal and blocks the effects of opioids, was shown to be effective in treating OUD in the mid-1960s and was approved by the FDA for this use in 1972. Since then, research has shown that methadone treatment can reduce opioid use as well as opioid-associated transmission of infectious diseases. One recent study found that, compared to people not receiving any medications for opioid use disorder (MOUD), opioid overdose deaths decreased by 59 percent among those receiving methadone.

In the United States, methadone must be prescribed in OTPs, clinics that are certified by the federal Substance Abuse and Mental Health Services Administration (SAMHSA) to provide MOUD. OTPs must also be licensed in their states and must register with the Drug Enforcement Agency. In addition to methadone treatment, OTPs provide counseling and other behavioral health therapies as well as education on how to prevent the spread of HIV/AIDS. SAMHSA also recommends that OTPs screen for and provide education on preventing other infectious diseases.

To launch the discussion, FORE staff shared data on the current landscape of methadone treatment in the United States. In 2021, there were 1,826 OTPs across the country. At the OTPs, methadone is the most common medication prescribed, far surpassing prescribing of buprenorphine and naltrexone.





To sustain access to OUD treatment during the COVID-19 pandemic, federal policymakers loosened some of the regulations governing the prescribing and use of methadone and other MOUD — the first substantial changes in decades. In particular:

- Providers were allowed to give up to 28 days of take-home doses of methadone for patients deemed stable and up to 14 days to patients deemed less stable. Typically, patients taking methadone visit OTPs for daily dosing, though federal guidelines in place before the pandemic allowed minimal numbers of take-home doses.
- Providers were also allowed to use telehealth to initiate buprenorphine but were still required to have in-person exams for methadone induction.
- Providers were allowed to hold telehealth visits for medication management and counseling.

The changes helped keep patients connected to treatment and did not result in substantial unintended consequences such as drug diversion or overdoses. Still, the changes were voluntary and not all providers adopted them nor did all patients benefit. One participant shared research showing that Black and other patients of color in New York State were less likely to be offered take-home doses than white patients, for example.

BARRIERS TO PATIENT-CENTERED METHADONE TREATMENT

Next, participants discussed the barriers that impede efforts to center methadone treatment on the needs and priorities of patients.

Tight Regulation

Participants noted that regulations that dictate initial doses, numbers of visits, toxicology screens, and other rules for OTPs inhibit methadone providers' ability to customize treatment for patients. In addition, the regulations are promulgated at the federal and state levels, so that a change may be made by SAMHSA but not approved in a particular state, fueling variation across programs.

Separation from the Rest of Health Care

OTPs are unicorns among health care facilities: they have their own regulations, treatment protocols, and even their own electronic health record system.

Participants pointed to the separation of OTPs from the rest of the health care system as a central challenge. It has perpetuated stigma and ignorance of OUD and of methadone treatment and made it harder for OTP providers to coordinate patients' care. Managing treatment for a patient taking methadone who develops cancer, for example, requires close coordination that's not typical between OTPs and other providers. Non-OTP clinicians are generally unfamiliar with methadone dosing, drug–drug interactions, and other issues that may be important when they're treating patients taking methadone.

It's also hard for providers to integrate additional health care services within OTP clinics. Because the clinics focus on one treatment, providers are generally unable to address patients' other health and social needs. The few non-methadone services typically provided at OTPs, such as screening for Hepatitis C, are reimbursed at lower rates than they are when provided outside of OTPs.

Need for Alternate or Co-Located Treatment Settings

Participants agreed on the need to develop alternatives to traditional, standalone OTPs to expand access and to integrate methadone treatment with other types of health care. These alternate settings could be set up alongside federally qualified health centers (FQHCs) and other primary care clinics. One participant noted that many people, particularly rural residents, don't have any OTPs in their regions and often have poor access to primary care. In these areas, local departments of health might be able to provide methadone treatment.

A few participants described their experiences working in OTPs that are co-located with other health care facilities. For example, one OTP offers methadone and other addiction treatment alongside an FQHC providing behavioral and physical health care services. Patients can come to one place to receive their methadone then receive preventive services or help managing their other medical conditions. Leaders decided to co-locate services after learning that 70 percent of patients receiving methadone had not accessed primary care, outside of an emergency department, in years. In this model, the two systems work in tandem to build a therapeutic relationship with patients.

Some Indian Health Services and Veterans Health Administration (VHA) clinics offer methadone alongside other types of services. One participant said that, as a result of her VHA clinic's comprehensive model and ease of access, more than 90 percent of patients taking methadone stay in treatment.

Participants noted that other countries take different approaches to methadone treatment. In Australia, for example, methadone can be prescribed by a general practitioner and picked up in a community pharmacy. Canada has rapid-access clinics that offer either methadone or buprenorphine with the goal of giving patients and providers a choice of evidence-based treatment options.

Participants noted that setting up OTPs alongside other health care settings requires additional funding, outside of current sources of revenue. It also requires expertise in navigating federal and state regulations. For example, an FQHC and an OTP must be set up as separate organizations and must use different ordering and billing systems.

Workforce

Participants agreed there are not enough trained and willing clinicians and other staff members to work at OTPs. It's hard to recruit physicians, nurses, counselors, and others to the field, given the low earning potential and lack of opportunities for advancement. One participant said her OTP had a job opening that had gone unfilled for three years. And many OTP providers — like many health care providers generally — are aging and may soon retire, worsening workforce shortages.

Early-career methadone providers may lack sufficient training and may not stay in their jobs long enough to develop expertise. One participant noted that while most clinical scenarios related to methadone treatment aren't complex, patients' social circumstances often are. Another noted that

non-clinical staff, including front-desk staff, would benefit from training related to substance use disorders and trauma-informed care.

Workforce shortages hinder innovation at OTPs. One participant said it was typical for an OTP medical director to be responsible for hundreds of patients. A few participants shared that when their clinics opted to give patients more take-home doses during the pandemic, they faced new challenges, such as having long lines of people waiting to pick up their doses. Another noted that it's hard for OTPs that have used the same billing and ordering systems for decades to adopt new approaches, such as the bundled payments proposed in New York State. Another participant noted that her OTP had planned to deploy mobile vans to expand access to treatment, but staffing the vans has proven challenging.

Need for Clinical Guidance in Evolving Drug Environment

Participants pointed to a need for clinical guidance to respond to fentanyl and other highly potent synthetic opioids. An experienced clinician said he no longer felt confident in titrating methadone for some patients. Others said there aren't clear guidelines for determining whether a patient is stable or unstable in methadone treatment and noted that regulators, providers, payers, and patients may have varying definitions.

Reimbursement

Participants noted that most OTPs are for-profit enterprises; a SAMHSA survey found that, in 2020, 62 percent of OTPs were private, for-profit organizations. Their leaders may be invested in maintaining their business model and thus resistant to change.

On the other hand, methadone providers who are interested in trying new models may be impeded by current reimbursement models. While some have leveraged grants to do things such as convening patient advisory boards or deploying mobile clinics, the time-limited nature of grants makes these efforts hard to sustain.

Medicaid is the largest payer for methadone treatment and Medicare began covering methadone treatment for OUD in 2020. Despite this, one participant observed that the federal Center for Medicare and Medicaid Innovation — tasked with developing new approaches to improve the quality and reduce the costs of care in these programs — has not focused on substance use disorder. Leaders have an opportunity to review the benefits covered, reimbursement rates, and quality measures for methadone treatment in these programs.

Participants also noted that some patients lose access to affordable methadone treatment when they change coverage, for example from Medicaid to commercial insurance.

Aging Population

Participants noted that many people taking methadone are older adults, and that diseases and frailty that often accompany aging may complicate their treatment. For example, several people noted that most subacute rehabilitation or skilled nursing facilities (SNFs) are not willing to accept patients taking methadone. Some participants said that, because of the difficulty of collaborating with SNF staff, their OTPs send staff members to hand-deliver methadone and check on patients.

SOLUTIONS: CHANGES TO METHADONE TREATMENT

Next, participants discussed ways to lower these barriers and move toward a patient-centered approach to methadone treatment. The discussion centered on the need to help OTPs become patient-centered and to make methadone more accessible in other clinical settings.

Promoting Harm Reduction

Participants emphasized that a patient-centered approach to methadone treatment should be grounded in harm reduction, given the toxicity of the illicit drug supply and the high numbers of people who continue to die from overdoses. Providers, payers, and regulators should lower barriers that keep patients from accessing and staying in treatment. For example, some participants called for reducing the frequency or doing away altogether with toxicology screenings, while others said they should be used for therapeutic, rather than punitive, purposes.

To promote harm reduction, participants called for training to counter some clinicians' view of methadone as a highly dangerous medication — rooted in its flawed use decades ago to treat pain patients, some of whom died from overdoses. As discussed below, clinicians need greater understanding and firsthand experiences of the safety and efficacy of methadone for patients with OUD, particularly in the current environment of fentanyl and other synthetic opioids.

Creating Accessible Sites of Care

Participants agreed on the need to make methadone treatment much more accessible. The discussion ranged from completely dissolving the OTP system to a broad range of reforms that could increase accessibility and promote patient-centered care.

All agreed that methadone should be provided much more routinely in many more places. While a handful of OTPs are co-located alongside FQHCs and other primary care clinics, these

arrangements are rare, given the regulatory, financial, and logistical burdens. If the Drug Enforcement Agency were to reduce the regulatory burdens, more providers might decide to offer methadone treatment. Should regulations change, participants also suggested that pharmacies might dispense methadone for patients with OUD; currently, they are only allowed to dispense methadone for pain. Participants also noted that having more methadone facilities co-located with other health care facilities could promote collaboration among methadone prescribers and other clinicians.

One participant cautioned that some patients taking methadone including unhoused individuals may struggle to come into clinics, no matter how accessible. For them, street-medicine approaches (e.g., mobile clinics) may be needed. Given that younger patients may find the daily-dosing model particularly burdensome, efforts may be needed to engage them through greater reliance on telehealth and other approaches. And because many patients at OTPs drop out of treatment during the induction stage, one participant suggested some patients would benefit from having short hospitalizations while they are beginning treatment.

Educating Clinicians

Training and education for methadone providers are needed. For example, gathering and disseminating information on safe and effective dosing for people who've taken synthetic opioids could make providers feel more confident prescribing methadone. One participant suggested that the electronic medical records used by OTPs could be leveraged to answer questions about effective dosing, geographic reach, and racial and ethnic disparities, among others.

Providers who do not prescribe methadone would also benefit from clinical education about the safety and efficacy of methadone treatment. To build clinicians' comfort in treating patients who take methadone, systems such as e-consults or telephone hotlines could be used to connect them with addiction medicine specialists.

Recruiting More Clinicians to Provide Methadone Treatment

Given the high level of need, participants argued that many more providers apart from addiction medicine specialists should be encouraged to offer methadone treatment, just as primary care providers, emergency medicine providers, and others have begun to prescribe buprenorphine. This would require changes to the rules governing methadone prescribing or efforts to encourage more types of providers to work in OTPs.

In addition, participants suggested that OTP staff members, including nurses and peer counselors, should be allowed to take on more responsibilities as a way of offloading some duties from prescribers. This would require training and regulatory changes.

Involving Patients

Participants agreed on the need to redress the long history of paternalism in methadone treatment and to listen to and learn from patients. To do so, participants called for the use of surveys, focus groups, and advisory boards to understand patients' experiences and to partner with them to design new approaches. In particular, patients should have a greater say in defining metrics of success and determining what health and social supports they need.

One participant noted that the recently formed National Coalition to Liberate Methadone, an alliance between people with lived experience of methadone treatment, advocates, addiction medicine clinicians, and substance use researchers, provides a forum in which to conduct participatory research.

SOLUTIONS: POLICY AND PAYMENT CHANGES

Next, participants discussed state or federal policy changes as well as new payment models that could promote a patient-centered approach to methadone treatment.

Federal Policy Changes

Participants called for a transition away from tight regulation of methadone toward more flexible clinical guidance.

SAMHSA is currently reviewing OUD treatment standards as well as the accreditation and certification of OTPs. In December 2022, the agency released proposed rules with the stated intention to: "promote practitioner autonomy; remove stigmatizing or outdated language; support a patient-centered approach; and reduce barriers to receiving care." Among proposed changes, the rules would make permanent the COVID-era changes related to use of take-home methadone doses and telehealth for medication management and counseling. The agency said the proposed rules are intended to promote harm reduction and shared decision making among patients and providers.

Participants welcomed the agency's proposed rules, noting that the ending of the public health emergency has created uncertainty. In particular, they appreciated the proposal enabling OTP providers to continue to offer take-home methadone doses, though they noted that this policy change, on its own, would not ensure equitable access.

In addition to changes in regulation, participants called for the Centers for Medicare and Medicaid Services to be much more involved in improving methadone treatment. This could be done through several avenues, including: Medicaid guidance and waivers, review of quality measures and reporting, and promotion of value-based payment models and demonstration programs, as discussed below.

The Joint Commission could also be more involved in reviewing OTPs through its accreditation standards. For example, one participant suggested the Joint Commission could ensure patients are given equitable access to take-home doses and other services.

Medicaid Waivers to Reach People in Jails and Prisons

Participants noted the opportunity to connect people with OUD treatment afforded by California's section 1115 waiver, which allows the state Medicaid program to pay for methadone and other MOUD as well as case management services for people leaving jails, prisons, and youth correctional facilities. Several other states have submitted similar waiver applications and in 2019 Maryland passed a law requiring all jails and correctional institutions to provide MOUD. Participants also noted that Chicago's Cook County jails and a county jail in New Jersey already have programs in place that offer methadone to people who are incarcerated.

Participants agreed on the need to build on these approaches to extend methadone, along with other MOUD, to more people who are incarcerated. They noted the efficacy of "hearts and minds" campaigns aimed at jail wardens and corrections officers, many of whom have come to appreciate that things go better when prisoners aren't actively withdrawing in their facilities. Evidence is also needed to show the impacts of MOUD on recidivism rates and other factors.

Value-Based Payment

As noted above, participants called for the Centers for Medicare and Medicaid Services, through its Center for Medicare and Medicaid Innovation, to develop value-based payment approaches for methadone treatment. Across the health care industry, Medicaid and Medicare set the tone for reimbursement; if those programs make changes, commercial insurers may follow. One person noted that, already, some commercial insurers have launched demonstration programs or hired vendors to better manage care and reduce costs for patients with substance use disorders.

Value-based payment approaches could spur treatment innovation. For example, participants suggested that payers could reward methadone providers that excel at retaining patients in treatment or managing their co-occurring conditions. If methadone providers were included in

accountable care organizations, they would have greater opportunity to collaborate with other providers.

One participant suggested that methadone providers could be paid more to care for complex patients as a way of rewarding the extra work involved, while non-specialists take on more stable patients. But another participant noted that her institution has struggled to create such step-therapy approaches. She noted several reasons why: patients are reluctant to change clinicians; addiction medicine providers don't want to treat only the most complex patients; and primary care providers aren't stepping up to care for these patients.

PRIORITIES FOR FORE

Next, participants discussed how FORE could promote changes to practice, policy, and payment to advance a patient-centered approach to methadone treatment. Drawing on the daylong conversation, participants suggested the following priorities:

- Research on what it would take to deliver methadone treatment in settings other than traditional, standalone OTPs. Studies could shed light on the practice supports and regulatory and policy changes that would be needed to engage primary care providers, pharmacists, health departments, mobile clinics, and others. White papers, webinars, and case studies could spotlight challenges in spreading access to methadone treatment and what's working to overcome them.

- Research on methadone treatment rates, experiences, and outcomes of different patient groups, including people of different races/ethnicities, ages, geographies, and those incarcerated in jails and prisons.

- Support to convene patient advisory boards to help redesign care delivery as well as conduct participatory research. In particular, research is needed to elicit patients' ideas and involvement in making methadone treatment more accessible and responsive to patients' priorities.

- Demonstration programs or pilots to help pharmacies, primary care clinics, health departments, and other providers begin offering methadone treatment and to help OTPs provide more services. Such programs should also include funds to convene patient and community advisory boards. These efforts would depend on regulatory changes.

- Workforce development opportunities, which could include:

    - Training and toolkits to prepare clinicians to deliver methadone treatment.
    - Training staff at SNFs and other providers who may need help understanding OUD treatment protocols and collaborating with methadone providers.
    - Training for non-clinical staff who work at methadone treatment facilities. This should include training on substance use disorders and how to respond to and help people who've experienced trauma.
    - Training for health care professional students (e.g., medical students, nursing students, and social work students) to encourage more of them to work in substance use disorder treatment and to reduce stigma against OUD patients.

- Efforts to encourage federal policymakers including from the Center for Medicare and Medicaid Innovation to develop value-based payment models and other supportive policies to promote patient-centered approaches to methadone treatment. Such payment models and policies should be developed by convening diverse stakeholders to hear about practical approaches and outcomes that matter to them.

PARTICIPANTS

The following individuals attended the advisory board meeting. Their participation does not constitute their endorsement of this document.

Facilitator: Charles J. Neighbors, MBA, PhD, Associate Professor, Department of Population Health, New York University Grossman School of Medicine

Attendees:

- Michael C. Barnes, Esq., Principal Attorney, Sequel Legal; Chairman, Center for U.S. Policy
- Andrea Barthwell, MD, DFASAM, Medical Director, Encounter Medical Group; Founder and CEO, Two Dreams Chicago; Chair, FORE Board of Directors
- Angela Bonaguidi, LCSW, LAC, Director, Adult Outpatient, Addiction Research and Treatment Services
- Lawrence S. Brown, Jr., MD, MPH, FASAM, Former CEO, START Treatment & Recovery Centers
- Malik Burnett, MD, MBA, MPH, Medical Director, Center for Harm Reduction Services, Maryland Department of Health
- Jane Calabrese, LPC, LCADC, Executive Director, Outpatient Services, John Brooks Recovery Center

- David A. Fiellin, MD, Professor of Medicine, Emergency Medicine, and Public Health; Vice Chief for Faculty Affairs, General Internal Medicine; Director, Program in Addiction Medicine, Yale School of Medicine
- Nicole Gastala, MD, Clinical Physician and Researcher, Mile Square Health Center; Assistant Professor, Department of Family Medicine, University of Illinois
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