

Methadone in Primary Care — One Small Step for Congress, One Giant Leap for Addiction Treatment

Jeffrey H. Samet, M.D., M.P.H., Michael Botticelli, M.Ed., and Monica Bharel, M.D., M.P.H.

The opioid-overdose epidemic has had a devastating impact throughout the United States and currently claims an average of 115 lives a day. Federal, state, and local public health officials, health care agencies, and community partners are working hard to stem the tide of deaths. Opioid use disorder, the major driver of overdose deaths, is a complex chronic medical condition that can be successfully treated — yet treatment is out of reach for many people.

Medications for opioid use disorder can facilitate recovery and prevent deaths.¹ One of the oldest and most effective of such medications, methadone, is available for prescription in primary care clinics in Great Britain, Canada, and Australia, but it is not approved for the treatment of opioid use disorder in primary care settings in the United States.

Unlike morphine and codeine, which are natural products of the poppy plant (*Papaver somniferum*), methadone is a synthetic opioid. Developed in 1937, it was originally studied as a treatment for opioid use disorder in people who used heroin in New York City in the 1960s.² By the 1970s, a system of methadone delivery had been developed in the United States that requires patients to visit a designated clinic site that is organizationally and often physically separate from the general medical care system. Such “methadone clinics” provide specialized, highly structured care. Medication is typically administered daily under observation, and patients periodically take urine drug tests, which can distinguish methadone from sub-

stances of abuse, and receive counseling.

The structured nature of these programs serves the needs of some patients well. But for others, the need to obtain medication daily at one fixed site can be too burdensome. The methadone-clinic structure was carved into law in the United States in 1974, when Congress passed the Narcotic Addict Treatment Act. The regulations associated with this law, which were rooted in widespread concern about accidental overdose and diversion, evolved in such a way that primary care physicians almost never delivered methadone treatment. Of the more than 1000 medical research articles describing the use of methadone for opioid use disorder, only a handful address its use in primary care in the United States. A 2001 study of 47 opioid-dependent patients showed that administration of methadone in primary care was feasible.³ A 2005 evaluation of the implementation of methadone treatment in a primary care setting enrolled 30 stable patients from a methadone treatment program; 28 stayed in the new program for 1 year, and only 2 had opioid-positive urine drug tests.⁴

Increasing the availability of medications that can effectively treat opioid use disorder will be essential in addressing the epidemic of overdose deaths. Only three medications are approved by the Food and Drug Administration for treating opioid use disorder: methadone, buprenorphine, and naltrexone. Roughly 20% of Americans who have an opioid use disorder are taking one of these.⁵

Restricting the availability of methadone to designated clinics has contributed to this treatment gap. This strategy has been locked in place because changing it requires an act of Congress. But the current public health emergency could serve as the catalyst for altering the law so that methadone could be delivered both within the current methadone treatment clinic model and in primary care settings. The Controlled Substances Act could be amended to allow clinicians who have the required training to prescribe buprenorphine for opioid use disorder to also engage patients in methadone treatment for this condition in office-based settings.

It is worth considering the international experience incorporating methadone prescribing into primary care. Methadone has been available by prescription in Australia since 1970, in Great Britain since 1968, and in Canada since 1963; in all these places, it is the most commonly prescribed treatment for opioid use disorder. Methadone prescribing in primary care is standard practice and not controversial in these places because it benefits the patient, the care team, and the community and is viewed as a way of expanding the delivery of an effective medication to an at-risk population. Safety concerns about the use of methadone in primary care for opioid use disorder can be assessed through the lens of overall mortality. A 2017 systematic review and meta-analysis showed a reduction in pooled all-cause mortality among people with opioid use disorder who were treat-

ed with methadone (from 36.1 per 1000 person-years among people not receiving methadone to 11.3 per 1000 person-years with methadone treatment); 3 of the 16 studies described care by general practitioners and showed similar safety profiles.¹

The ability to obtain a prescription for methadone in the course of routine primary care is especially valuable for people living in nonurban areas, in which the infrastructure required for a methadone clinic may be too expensive and disproportionate to the level of need. Regardless of cost, establishing a new methadone clinic can be challenging in any setting, given the common “not in my backyard” sentiment, which pits perceived local concerns against public health benefits. Allowing physicians to prescribe methadone in primary care settings obviates both of these challenges. What’s more, it could reduce the stigma associated with opioid use disorder and place its management more in line with that of other medical conditions that are treated seamlessly in primary care.

In the United States, methadone has been prescribed in primary care settings under rare circumstances in which extensive

efforts were made to meet all pertinent regulations. Our experience in Boston over a 10-year period with a very limited number of patients who were transitioned into a primary care–based methadone program after being stable on treatment at a methadone clinic was excellent. Medication prescriptions and clinical care were provided without adverse incident. Indeed, one patient in the program, in which she received a prescription for methadone treatment as well as general health care in a primary care setting, told us that the experience “is to me like winning the lottery — better actually.”

The last act of Congress that expanded access to effective medications for opioid use disorder in primary care, the Drug Addiction Treatment Act of 2000, enabled buprenorphine to become available to thousands of patients in the United States. Expanding access to methadone in primary care will require more than legislation. It will also be necessary to enhance training for physicians on opioid use disorder, consider incentives for prescribing medications to treat it, and integrate treatment into existing models of care. But the solution to a complex problem often begins with small,

pragmatic steps. We believe the time has come to update laws that regulate the prescription of methadone in primary care in order to reduce barriers to access and extend the benefits of a proven, effective medication to people throughout the country.

Disclosure forms provided by the authors are available at NEJM.org.

From the Boston University Schools of Medicine and Public Health and Boston Medical Center (J.H.S.), the Grayken Center for Addiction, Boston Medical Center (J.H.S., M. Botticelli), and the Massachusetts Department of Public Health (M. Bharel) — all in Boston.

1. Sordo L, Barrio G, Bravo MJ, et al. Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies. *BMJ* 2017;357:j1550.
2. Dole VP, Nyswander M. A medical treatment for diacetylmorphine (heroin) addiction: a clinical trial with methadone hydrochloride. *JAMA* 1965;193:646-50.
3. Fiellin DA, O'Connor PG, Chawarski M, Pakes JP, Pantalon MV, Schottenfeld RS. Methadone maintenance in primary care: a randomized controlled trial. *JAMA* 2001;286:1724-31.
4. Merrill JO, Jackson TR, Schulman BA, et al. Methadone medical maintenance in primary care: an implementation evaluation. *J Gen Intern Med* 2005;20:344-9.
5. Saloner B, Karthikeyan S. Changes in substance abuse treatment use among individuals with opioid use disorders in the United States, 2004-2013. *JAMA* 2015;314:1515-7.

DOI: 10.1056/NEJMp1803982

Copyright © 2018 Massachusetts Medical Society.

Will You Forgive Me for Saving You?

Torree McGowan, M.D.

I remember the day I first met you. It was a quiet Sunday, early in the morning. I heard a commotion out by the check-in desk, and your mom’s scream: “My baby’s not breathing!” The first time I saw you was in your mom’s arms. Heartbreakingly, you weren’t snuggled like a baby should be, or even limp. Your tiny body was

twitching, seizing. The cold clinical term “decorticate posturing” that flashed in the physician part of my brain seemed too rigid to be applied to your chubby toddler arms.

We rushed you to our trauma room, and the entire hospital came to help you. In moments, I had every hand available, every

heart pulling for your tiny body. All those hands let me do the hardest thing: step back and start making decisions that would alter your life forever.

Your tiny heart was so slow. Children’s hearts should be fast, like running feet and quick smiles. Yours beat at the slow stuttering pace of a heart about to surrender.