

Medication-Assisted Treatment for Opioid Use Disorder: The Gold Standard

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Introduction

Harm related to substance use disorder (SUD) is a large and growing problem in the United States. In 2014, an estimated 21.5 million Americans over the age of 12 experienced SUD. In 2016, close to 64,000 individuals died of overdose, which is now the leading cause of accidental death in persons under 50. The majority of those deaths – approximately 42,000, or one every 20 minutes – involve opioids.

Opioid use disorder (OUD) affects individuals and families from all educational and socioeconomic backgrounds.⁵ It is imperative that people with OUD have access to the most appropriate care available, which for many people is medication-assisted treatment (MAT). Too often, however, low-income and underserved individuals with OUD do not receive evidence-based care for their condition. According to the Surgeon General, only around 11 percent of people with SUD receive any type of specialty treatment.⁶ Less than half of private sector OUD treatment programs offer MAT and only a third of patients in those programs receive it.⁷

The vast majority of patients receiving MAT do so in the outpatient setting, but it is also important that it be available in residential treatment facilities. Several federal statutes create unnecessary barriers to MAT in both settings, including arbitrary patient caps, restrictive dispensing limitations, and funding limitations. Legislative action is urgently needed to remove these barriers and increase access to this gold-standard treatment for OUD.

Medication-Assisted Treatment

Background

Medication-assisted treatment is the term for the use of medication, often in in conjunction with behavioral therapy, to treat OUD.⁹ Currently, three FDA-approved MAT medications exist: methadone, buprenorphine, and naltrexone.¹⁰

Both methadone and buprenorphine work by activating opioid receptors in the brain. ¹¹ This keeps the person with OUD from experiencing the painful and sometimes debilitating withdrawal and craving that accompany opioid cessation. Methadone has been approved for MAT since 1972 and is typically taken once daily. ¹² Buprenorphine has been approved for use in MAT since 2002 and is often sold as a combination product with naloxone, an opioid antagonist, to prevent potential abuse. ¹³ Both buprenorphine and methadone are safe in pregnancy and while breastfeeding. ¹⁴

Naltrexone, a less common form of MAT that is also used to treat alcohol use disorder, is an opioid antagonist that blocks the effects of opioids. Because it causes withdrawal in a person who has opioids in their system, the patient must be completely withdrawn from opioids prior to beginning treatment. For OUD treatment, it is generally administered in the form of a oncemonthly injection.

MAT Is Highly Effective

MAT – particularly methadone and buprenorphine – is considered the "gold standard" of OUD treatment because of the overwhelming evidence of its effectiveness. ¹⁶ The American Society of Addiction Medicine (ASAM), the Centers for Disease Control and Prevention (CDC), the National Council for Behavioral Health (NCBH), the National Institute on Drug Abuse (NIDA), the World Health Organization (WHO), and patient advocate groups all strongly support increased access to MAT. ¹⁷ According to the Secretary of the Department of Health and Human Services, Alex Azar, treating OUD without MAT is "like trying to treat an infection without antibiotics." ¹⁸ MAT is primarily delivered on an outpatient basis, either through an opioid treatment program that a patient visits once a day (also known as a methadone clinic), or prescribed individually by a doctor for patients to self-administer (buprenorphine treatment).

Evidence convincingly demonstrates that MAT has numerous benefits, including:

- Reducing overdose death: MAT cuts the mortality rate from any cause by half or more for patients with SUD.¹⁹ A recent study of overdose prevention in Rhode Island, the only state that provides all three FDA-approved MAT medications in prisons and jails, found that fatal opioid related overdoses dropped by almost two-thirds in the first year of screening and providing MAT to all state inmates.²⁰ One study found that patients who have only received behavioral therapy are twice as likely to overdose after treatment than those treated with MAT, and abstinence-based residential treatment without MAT has limited effectiveness.²¹
- Reducing risk of relapse: Individuals who receive MAT are half as likely to suffer relapse than those who receive other types of therapy.²² One review of multiple studies determined that individuals treated with methadone were more likely to remain in treatment compared to individuals not receiving it.²³ Buprenorphine, likewise, reduces both opioid cravings and opioid use.²⁴ Another study showed that individuals treated with buprenorphine had better outcomes than individuals who were tapered off opioid medications.²⁵ This study also determined that individual opioid dependence counseling in addition to buprenorphine-naloxone did not improve outcomes.²⁶

- Reducing risky activities: Treatment with methadone or buprenorphine has been consistently shown to decrease behaviors that increase risk of physical and other harms, including illicit opioid use, injecting drugs, sharing needles, and engaging in high risk sexual activity.²⁷ For these reasons, MAT treatment leads to decreases in both HIV and Hepatitis C risk.²⁸
- Reducing costs: Methadone and buprenorphine are highly cost-effective and much more effective than abstinence-based therapy.²⁹ A study of Vermont's MAT program found that MAT is associated with reduced health care use and costs, including those not related to OUD.³⁰ In general, one dollar spent on SUD prevention and treatment leads to between two and ten dollars of savings in health care, criminal justice, and educational costs.³¹

Barriers to MAT

At both the federal and state levels, unnecessary laws and regulations make it more difficult to access MAT for OUD than the opioid medications that cause it.³² Under federal law, while methadone for pain treatment can be dispensed from any pharmacy, methadone for MAT may only be dispensed from a specially licensed clinic.³³ Patients must typically travel to the clinic to take their dose while supervised every day.³⁴ Patients receiving methadone for MAT must also participate in behavioral therapy.³⁵ These restrictions make it very difficult for many employed people to receive methadone treatment. State and local laws often add additional restrictions, including limiting the locations in which methadone clinics can operate. Clinics are unwelcome in many neighborhoods, even though studies show that methadone treatment centers are not associated with crime.³⁶

Buprenorphine also faces unnecessary restrictions. While any pharmacy may dispense the medication, it can only be prescribed by practitioners specifically "waivered" to do so. Physicians must complete an 8-hour training or hold certain certifications to qualify for the waiver. A waivered practitioner may treat 30 patients with buprenorphine in the first year of waiver, after which the practitioner must apply for another year with a limit of 100 patients. They may then apply for permission to treat up to 275 patients. Nurse practitioners and physician assistants may apply for a waiver of up to 30 patients in the first year, but must complete a 24-hour training to do so and are often subject to other limitations under state law.³⁸

These limitations unnecessarily restrict access to MAT for many people with OUD. Almost half of America's 3,100 counties has no doctor authorized to prescribe buprenorphine, including over 60 percent of rural counties. Some prescribers who are waivered do not prescribe any buprenorphine at all. This may in part be due to concern about treating patients with OUD due to community judgment, lack of access to substance-abuse counseling for patients, or regulatory audits. Including education on the treatment of addiction in medical school core curriculum, requiring evidence-based continuing education on addiction medicine, and incorporating MAT into general practice could help lift these misconceptions and stigma and increase quality and availability of care.

Naltrexone may be prescribed by any health care provider licensed to prescribe medications, but because it is an opioid antagonist the patient must have abstained from opioid use before beginning treatment, which limits its usefulness.⁴³ It is also quite expensive, around \$1,000 per month.⁴⁴

Because OUD is a chronic condition, MAT must typically be delivered over a long period of time, much like insulin for diabetes. ⁴⁵ Unfortunately, even with the Affordable Care Act's expanded parity protections, MAT coverage is often subject to lifetime limits, preauthorization requirements, and "fail first" requirements. ⁴⁶ Due to poor enforcement of the law, network adequacy and reimbursement rate disparities are still a barrier to care. ⁴⁷

Conclusion

Increased access to MAT is urgently needed. While stigma surrounding OUD remains a key barrier to evidence-based treatment, many access issues can be addressed through legislation. For example, states and the federal government can require that MAT medications be covered by nearly all public and private insurance plans without cost sharing, prior authorization, or other barriers. Additionally, Congress can remove the requirement that prescribers be waivered to prescribe buprenorphine, and the cap on the number of patients that can be seen. Likewise, the cumbersome restrictions on methadone maintenance treatment can and should be modified. States and the federal government can use numerous means to ensure that health care providers receive evidence-based education in the appropriate treatment of SUD.⁴⁸ Finally, increasing Medicaid funding and encouraging states to expand the Medicaid program will allow states to cover more MAT and reduce the need for costly inpatient treatment; in fact, states that expanded Medicaid had a 200 percent increase in MAT.⁴⁹

Like many conditions, SUD may require lifelong treatment. Luckily, effective evidence-based treatment is available. MAT improves quality of life and is key to allowing Americans with OUD to hold down jobs, connect with friends and family, and function in day to day life. Not only does MAT improve lives, it saves them, and it is key to reversing the fatal overdose epidemic that is devastating our communities.

ENDNOTES

¹ Centers for Disease Control and Prevention, *U.S. drug overdose deaths continue to rise; increase fueled by synthetic opioids* (Mar. 29, 2018), https://www.cdc.gov/media/releases/2018/p0329-drug-overdose-deaths.html.

² Rachel N. Lipari & Struther L. Van Horn, *Trends in Substance Use Disorders Among Adults Aged 18 or Older*, THE CENTER FOR BEHAVIORAL HEALTH STATISTICS AND QUALITY REPORT (Jun. 29, 2017), https://www.samhsa.gov/data/sites/default/files/report 2790/ShortReport-2790.html.

³ Josh Katz, *Drug Deaths in America are Rising Faster Than Ever*, N.Y. TIMES (June 5, 2017), https://www.nytimes.com/interactive/2017/06/05/upshot/opioid-epidemic-drug-overdose-deaths-are-rising-faster-than-ever.html; Deborah Dowell, *Underlying Factors in Drug Overdose Deaths*, 318 JAMA 2295 (Dec. 19, 2017).

⁴ Holly Hedegaard, et al., *Drug Overdose Deaths in the United States, 1999-2016.* NATIONAL CENTER FOR HEALTH STATISTICS, Data Brief No. 294, 1-8 (Dec. 2017); Medication-Assisted Treatment Improves Outcomes for Patients with Opioid Use Disorder, THE PEW CHARITABLE TRUSTS (Nov. 22, 2016) http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2016/11/medication-assisted-treatment-improves-outcomes-for-patients-with-opioid-use-disorder.

⁵ Marc A. Schuckit, *Treatment of Opioid-Use Disorders*, N. ENGL. J. MED. (July 28, 2016) http://www.nejm.org/doi/full/10.1056/NEJMra1604339.

⁶ U.S. Department of Health and Human Services, Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health (Nov. 2016), https://addiction.surgeongeneral.gov/executive-summary#1; Christopher M. Jones, et al, National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment, 105 Am. J. Pub. HEALTH 55 (Aug. 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4504312/.

⁷ Hannah K. Knudsen et al., *Adoption and Implementation of Medications in Addiction Treatment Programs*, 5 J. OF ADDICT MED. 21, 21 (2011), https://www.ncbi.nlm.nih.gov/.
⁸ Id.

⁹ While many definitions of MAT include counseling, Opioid Treatment Providers that dispense methadone are the only places legally required to provide counseling as part of MAT. See generally 42 C.F.R. § 8.

¹⁰ Corey S. Davis & Derek H. Carr, *The Law and Policy of Opioids for Pain Management, Addiction Treatment, and Overdose Reversal*, 14 IND. HEALTH L. REV. 1, 24 (2017).

Methadone, Substance Abuse and Mental Health Services Administration https://www.samhsa.gov/medication-assisted-treatment/treatment/methadone; see also Buprenorphine, Substance Abuse and Mental Health Services Administration https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine (last visited Apr. 26, 2018).

¹² Davis & Carr, *The Law and Policy of Opioids for Pain Management, Addiction Treatment, and Overdose Reversal* at 37.

¹³ Buprenorphine, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine.

¹⁴ Hillary Smith Connery, *Medication-Assisted Treatment of Opioid Use Disorder: Review of the Evidence and Future Directions*, 23 HARVARD REV. OF PSYCH. 63, (Mar./Apr. 2015).

¹⁵ *Naltrexone*, Substance Abuse and Mental Health Services Administration, https://www.samhsa.gov/medication-assisted-treatment/reatment/naltrexone.

¹⁶ Hillary Smith Connery, *Medication-Assisted Treatment of Opioid Use Disorder: Review of the Evidence and Future Directions*, 23 HARVARD REV. OF PSYCH. 63, (Mar./Apr. 2015); German Lopez, *There's a highly successful treatment for opioid addiction. But stigma is holding it back.*, Vox (Nov. 15, 2017), https://www.vox.com/science-and-health/2017/7/20/15937896/medication-assisted-treatment-methadone-buprenorphine-naltrexone.

- 17 Medication-Assisted Treatment Improves Outcomes for Patients with Opioid Use Disorder, THE PEW CHARITABLE TRUSTS (Nov. 22, 2016) http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2016/11/medication-assisted-treatment-improves-outcomes-for-patients-with-opioid-use-disorder; German Lopez, There's a highly successful treatment for opioid addiction. But stigma is holding it back., Vox (Nov. 15, 2017), https://www.vox.com/science-and-health/2017/7/20/15937896/medication-assisted-treatment-methadone-buprenorphine-naltrexone.

 18 Rachel Roubein, HHS chief pitches new measures to expand opioid addiction treatment, THE HILL (Feb. 24, 2018), https://thehill.com/policy/healthcare/375455-hhs-chief-pitches-new-measures-to-expand-opioid-addiction-treatment.
- ¹⁹Luis Sordo et. al., *Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies*, THE BMJ (March 17, 2017) https://www.bmj.com/content/bmj/357/bmj.j1550.full.pdf.
- ²⁰ Traci C. Green, et al., Postincarceration Fatal Overdoses After Implementing Medications for Addiction Treatment in a Statewide Correctional System, 75 JAMA PSYCHIATRY 4 (2018); Christine Vestal, *New Momentum for Addiction Treatment Behind Bars*, STATELINE (Apr. 04, 2018) http://www.pewtrusts.org/en/research-amd-analysis/bogs/stateline/2018/04/04/new-momentum-for-addiction-treatment-behind-bars.
- ²¹ Matthias Pierce et al., *Impact of treatment for opioid dependence on fatal drug-related poisoning: a national cohort study in England*, ADDICTION (2015) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4950033/pdf/ADD-111-298.pdf; Connery at 69. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4950037/pmc/articles/PMC4950037/pmc/articles/PMC4950037/pmc/articles/PMC4
- ²² James. R Roberts, *Buprenorphine: A Drug You Need to Know About*, 30 EMERGENCY MED. NEWS, Dec. 2008, at 7-8.
- ²³ R.P. Mattick et. al., *Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence (Review)*, THE COCHRANE LIBRARY 1 (2009).
- ²⁴ Paul J. Fudala et al., *Office-Based Treatment of Opiate Addiction with a Sublingual-Tablet Formulation of Buprenorphine and Naloxone*, THE NEW ENG. J. OF MED. 949 (2003).
- ²⁵ Roger D. Weiss et. al., *Adjunctive Counseling During Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence*, ARCH. GEN. PSYCHIATRY 1238 (2011). ²⁶ *Id.*
- ²⁷ Monique E. Wilson et al., *Impact of Interim Methadone Maintenance on HIV Risk Behaviors*, 87 J URBAN HEALTH 586 (2010); Linda Gowing et al., *Oral Substitution Treatment of Injecting Opioid Users for Prevention of HIV Infection*, 8 COCHRANE DATABASE OF SYSTEMATIC REVIEWS CD004145 (2011). ²⁸ Connerv at 66.
- ²⁹ Martin Connock, et al., *Methadone and Buprenorphine for the Management of Opioid Dependence: A Systematic Review and Economic Evaluation*, 11 HEALTH TECHNOLOGY ASSESSMENT 1 (2007).
- ³⁰ Mary Kate Mohlman et al., *Impact of Medication-Assisted Treatment for Opioid Addiction on Medicaid Expenditures and health Services Utilization Rates in Vermont*, 67 JOURNAL OF SUBSTANCE ABUSE TREATMENT 9 (Aug. 2016).
- ³¹ Mary E. O'Connell et al., *Preventing Mental, Emotional, and Behavioral Disorders Among Young People: Progress and Possibilities*, NATIONAL RESEARCH COUNCIL AND INSTITUTE OF MEDICINE (2009).
- ³² Corey Davis, Traci Green, and Leo Beletsky, *Action, Not Rhetoric, Needed to Reverse the Opioid Overdose Epidemic*, J. OF LAW, MED. & ETHICS, 20 (2017).
- 33 42 C.F.R. § 8.12 (2018).
- ³⁴ After a certain period of treatment, they may qualify for "take-home" doses on weekends or for special occasions, but this is at the discretion of the provider. 42 C.F.R. § 8.12(i) (2018). ³⁵ 42 C.F.R. § 8.12(f)(5) (2018).
- ³⁶ Susan J. Boyd, et al.; *Use of a 'microecological technique' to study crime incidents around methadone maintenance treatment centers*, 107 ADDICTION 1632 (Sep. 2012), https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1360-0443.2012.03872.x.

- ³⁷ 21 U.S.C.A. § 823(B)(iii); 42 C.F.R. § 8.610.
- ³⁸ 21 U.S.C.A. § 823(B)(iii)(I); 42 C.F.R. § 8.610; *Resources*, AMERICAN SOCIETY OF ADDICTION MEDICINE https://www.asam.org/resources/practice-resources/nurse-practitioners-and-physician-assistants-prescribing-buprenorphine.
- ³⁹ Shane Shiflett, Hilary Fung, Nicky Forster, and Jason Checkris, *Not Enough Doctors Are Treating Heroin Addiction With A Life-Saving Drug*, THE HUFFINGTON POST http://projects.huffingtonpost.com/dying-to-be-free-heroin-treatment/opioid-abuse-outpace-treatment-capacity; National Council on Alcoholism and Drug Dependence, Inc., *Increasing Availability of Medication-Assisted Treatment Using Buprenorphine* (Sep. 6, 2017), https://www.ncadd.org/blogs/in-the-news/increasing-availability-of-medication-assisted-treatment-using-buprenorphine.
- ⁴⁰ Mark Moran, *Why Aren't More Physicians Prescribing Buprenorphine?*, PSYCHIATRIC NEWS (Mar. 4, 2016), https://psychnews.psychiatryonline.org/doi/full/10.1176/appi.pn.2016.PP3a2.
- ⁴¹ Mark Moran, *Why Aren't More Physicians Prescribing Buprenorphine?*, PSYCHIATRIC NEWS (Mar. 4, 2016), https://psychnews.psychiatryonline.org/doi/full/10.1176/appi.pn.2016.PP3a2, Dan Mangan, *Many doctors don't prescribe medication for opioid addiction despite epidemic*, CNBC (Sep. 20, 2016), https://www.cnbc.com/2016/09/20/many-doctors-do-not-prescribe-medication-for-opioid-addiction-despite-epidemic.html.
- ⁴² Corey S. Davis & Derek Carr, *Physician continuing education to reduce opioid misuse, abuse, and overdose: Many opportunities, few requirements*, 163 DRUG AND ALCOHOL DEPENDENCE 100(2016), http://dx.doi.org/10.1016/j.drugalcdep.2016.04.002.
- ⁴³ *Naltrexone*, Substance Abuse and Mental Health Services Administration https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone.
- ⁴⁴ Alec MacGillis, *Addiction Drug's Side Effect: More Overdoses?*, PROPUBLICA (April 3, 2018), https://www.propublica.org/article/vivitrol-addiction-drug-side-effect-more-overdoses.
- ⁴⁵ U.S. Department of Health and Human Services, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health* at 4/21, https://addiction.surgeongeneral.gov/sites/default/files/chapter-4-treatment.pdf.
- ⁴⁶ Nora D. Volkow, et al., *Medication-Assisted Therapies—Tackling the Opioid-Overdose Epidemic*; 370 NEW ENGLAND JOURNAL OF MEDICINE 2063 (May 29, 2014).
- ⁴⁷ Stephen P. Melk et al., *Addiction and mental health vs. physical health: Analyzing disparities in network use and provider reimbursement rates*, MILLIMAN RESEARCH REPORT (Dec. 2017), http://www.milliman.com/uploadedFiles/insight/2017/NQTLDisparityAnalysis.pdf.
- ⁴⁸ Corey S. Davis & Derek Carr, *Physician continuing education to reduce opioid misuse, abuse, and overdose: Many opportunities, few requirements*, 163 DRUG AND ALCOHOL DEPENDENCE 100 (2016), http://dx.doi.org/10.1016/j.drugalcdep.2016.04.002.
- ⁴⁹ Alana Sharp et al., *Impact of Medicaid Expansion on Access to Opioid Analgesic Medications and Medication-Assisted Treatment*, 108 Am. J. Pub. Health 642 (May 2018),
- https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2018.304338; Medication and Counseling Treatment, Substance Abuse and Mental Health Services Administration
- https://www.samhsa.gov/medication-assisted-treatment/treatment/ (last visited May 15, 2018).