07.18.22

Background:

There is a shortage of access to methadone treatment for opioid addiction within the US. The Opioid Treatment Access Act (OTAA) included the following modest reforms to expand methadone access and save lives:

1) Allow pharmacy-based dispensing and office-based prescribing of methadone outside of OTPs to physicians board-certified in addiction psychiatry or addiction medicine;
2) End registration requirements for mobile methadone vans connected to OTPs; and
3) Modestly increase flexibility surrounding take-home methadone requirements.

Methadone treatment saves lives by treating the symptoms of opioid use disorder and substantially reducing overdose risk. Expanding access to methadone treatment is more important than ever given the deadly fentanyl in the illicit drug supply that is ravaging American communities.

AATOD is a national organization representing opioid treatment programs (OTP) (i.e. methadone clinics). AATOD recently published **misleading statements about methadone inconsistent with scientific and medical consensus**. As experts in addiction medicine and research, we correct these misleading statements so the public and Congress understands why expanding methadone access will save lives.

Misleading AATOD statement	**Corrections**
[The OTAA bill] will result in physicians prescribing a powerful medication with no effort to limit diversion, no counseling, no drug testing and no outcome reporting to evaluate effectiveness - exactly how we got into the current opioid epidemic and record numbers of deaths.	All of the same controls and safeguards we have for opioid prescribing would still apply to methadone prescribing for addiction including state prescription monitoring programs. These same controls have lowered opioid prescribing in the US for several years.[1] **Rather the bill would expand methadone treatment to jurisdictions that do not have access to an OTP, reducing overdose risk from deadly illicit fentanyl use.**
Board certified physicians are well trained; however, training alone is necessary but not sufficient to provide safe TREATMENT. TREATMENT is comprised of much more than just prescribing more opioids	Canada, Australia, and the UK all provide methadone treatment for addiction without the unaccommodating structure of OTPs, including providing the medication in primary care settings and pharmacies.[2] US clinicians are just as capable as clinicians in these nations. These nations have lower opioid overdose death rates compared to the US. Methadone and other medications for opioid use disorder are highly effective on their own, even when not accompanied by other psychosocial interventions.[3]
The OTP structure is what makes methadone safe and effective for OUD. Suggesting that methadone is safe and effective for OUD in any	A National Academy Sciences, Engineering, and Medicine Consensus report concluded in 2019 that **methadone treatment should not be contingent on the availability of other services**

other setting is scientific appropriation: it is not evidence-based.	and that methadone should be available in all treatment settings.[4] This would save lives by preventing people from using deadly illicit fentanyl.
Five federal agency reports issued in the 2000s (SAMHSA, 2004; DOJ, 2007; SAMHSA, 2007; GAO, 2009; SAMHSA, 2010) found that the majority of methadone mortality is attributed to physician's prescribing methadone in private practices.	The rise in methadone associated mortality in the 2000s was associated with prescribing for pain NOT addiction.[5] With new safeguards opioid prescribing for pain is now declining and illicit fentanyl is now driving the epidemic. Methadone prescribing for addiction can prevent fentanyl use, which will save lives.
Buprenorphine and methadone are very different medications, hence different FDA scheduling. Buprenorphine is unlikely to cause respiratory depression like methadone. Methadone is slow to act and accumulates in the body, making it especially lethal if misused. Moreover, despite exponential increases in buprenorphine prescriptions over the past 20 years, ODs and deaths have notched record levels every year. More opioid prescriptions doesn't stop ODs. Buprenorphine is one of the most diverted medications in the U.S. because it is widely distributed by physicians with no diversion control effort. Methadone diversion rates have declined significantly over the last 20 years.	Both buprenorphine and methadone prevent deaths by treating the symptoms of opioid use disorder and providing a safe alternative to fentanyl and other dangerous opioids. Research has found diversion to be a consequence of inadequate access to these medications.[6] Overdoses continue to rise largely due to inadequate access to methadone and buprenorphine. Removing restrictions on methadone during the COVID-19 pandemic did NOT result in increased overdose deaths.[7] Expanding methadone to pharmacies has the potential to increase access to treatment, reduce overdose risk, and reduce demand for diverted medications.
Strang study (2010) found that the "Introduction of supervised methadone dosing was followed by substantial declines in deaths related to overdose of methadone in both Scotland and England." Supervised dosing refers to the dispensing and monitoring process required at OTPs, where patients consume treatment medication onsite in presence of medical personnel. Pharmacy-filled prescriptions do not require this consumption monitoring process. Furthermore, a Canadian study found that when methadone is prescribed for OUD and picked up at a pharmacy, patients getting medication from a clinic demonstrated a one-year retention rate of 57.3% compared to 11.9% retention rate at the pharmacy	The referred to Strang study analyzed data in two European countries between 1993 and 2008, during a period of time and context that did not include deadly fentanyl. Moreover, the described supervised methadone dosing did in fact occur in pharmacies (not OTPs) and supervised dosing introduced in pharmacies only applied to a segment of methadone patients (33% in Scotland and 65% in England). A study published in 2022 and conducted within the US, recently demonstrated pharmacy dispensing of methadone for addiction is safe. Patients who received methadone at the pharmacy reported high patient satisfaction.[8] In the current emergency state of the overdose crisis, expanding access to treatment must be the main priority.

07.18.22

Authors:

- Paul Joudrey, MD, MPH, Assistant Professor, Yale Program in Addiction Medicine;
- Noa Krawczyk, PhD, Assistant Professor, Center for Opioid Epidemiology, NYU Grossman School of Medicine; and
- Ruth A. Potee, MD, FASAM, Medical Director, Behavioral Health Network.

References:

1. Guy GP, Zhang K, Bohm MK, et al. Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015. *MMWR Morb Mortal Wkly Rep*. 2017;66(26):697-704. doi:10.15585/mmwr.mm6626a4.
2. Joudrey PJ, Bart G, Brooner RK, et al. Research priorities for expanding access to methadone treatment for opioid use disorder in the United States: A National Institute on Drug Abuse Clinical Trials Network Task Force report. *Substance Abuse*. 2021;42(3):245-254. doi:10.1080/08897077.2021.1975344.
3. Rice D, Corace K, Wolfe D, Esmaeilisaraji L, Michaud A, Grima A, et al. Evaluating comparative effectiveness of psychosocial interventions adjunctive to opioid agonist therapy for opioid use disorder: a systematic review with network meta-analyses. *PLoS ONE*. 2020.
4. Leshner AI, Mancher M. Medications for Opioid Use Disorder Save Lives. *National Academies of Sciences, Engineering, and Medicine*. Published online 2019.
5. Kuehn BM. Methadone Overdose Deaths Rise With Increased Prescribing for Pain. *JAMA*. 2012;308(8):749. doi:10.1001/jama.2012.9289.
6. Williams AR, Mauro CM, Feng T, et al. Non–prescribed buprenorphine preceding treatment intake and clinical outcomes for opioid use disorder. *Journal of Substance Abuse Treatment*. 2022;139:108770. doi:10.1016/j.jsat.2022.108770.
7. Jones CM, Compton WM, Han B, Baldwin G, Volkow ND. Methadone-Involved Overdose Deaths in the US Before and After Federal Policy Changes Expanding Take-Home Methadone Doses From Opioid Treatment Programs. *JAMA Psychiatry*. Published online July 13, 2022. doi:10.1001/jamapsychiatry.2022.1776.
8. Wu LT, John WS, Morse ED, et al. Opioid treatment program and community pharmacy collaboration for methadone maintenance treatment: results from a feasibility clinical trial. *Addiction*. 2022;117(2):444-456. doi:10.1111/add.15641.