Evidence-Based Methadone Treatment

Lessons Learned from the COVID-19 Pandemic

SAMHSA's Proposed Regulatory Changes

Disclosure Information

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Learning Objectives

Upon completion, participants will be able to:

- Describe pre-pandemic U.S. methadone treatment infrastructure, how federal and state agencies regulated treatment, and how these regulations impacted treatment access.
- Summarize federal COVID-19 methadone treatment regulation relaxations and preliminary evidence of positive outcomes arising from them.
- List actionable steps U.S. addiction treatment providers can take to increase methadone treatment access through both medical practice and advocacy.

Polling Questions

What is your relationship with methadone clinics (OTPs)? (raise hand for all that apply)

a. I work at an OTP

b. I refer patients to OTPs from my inpatient practice

c. I refer patients to OTPs from my outpatient practice

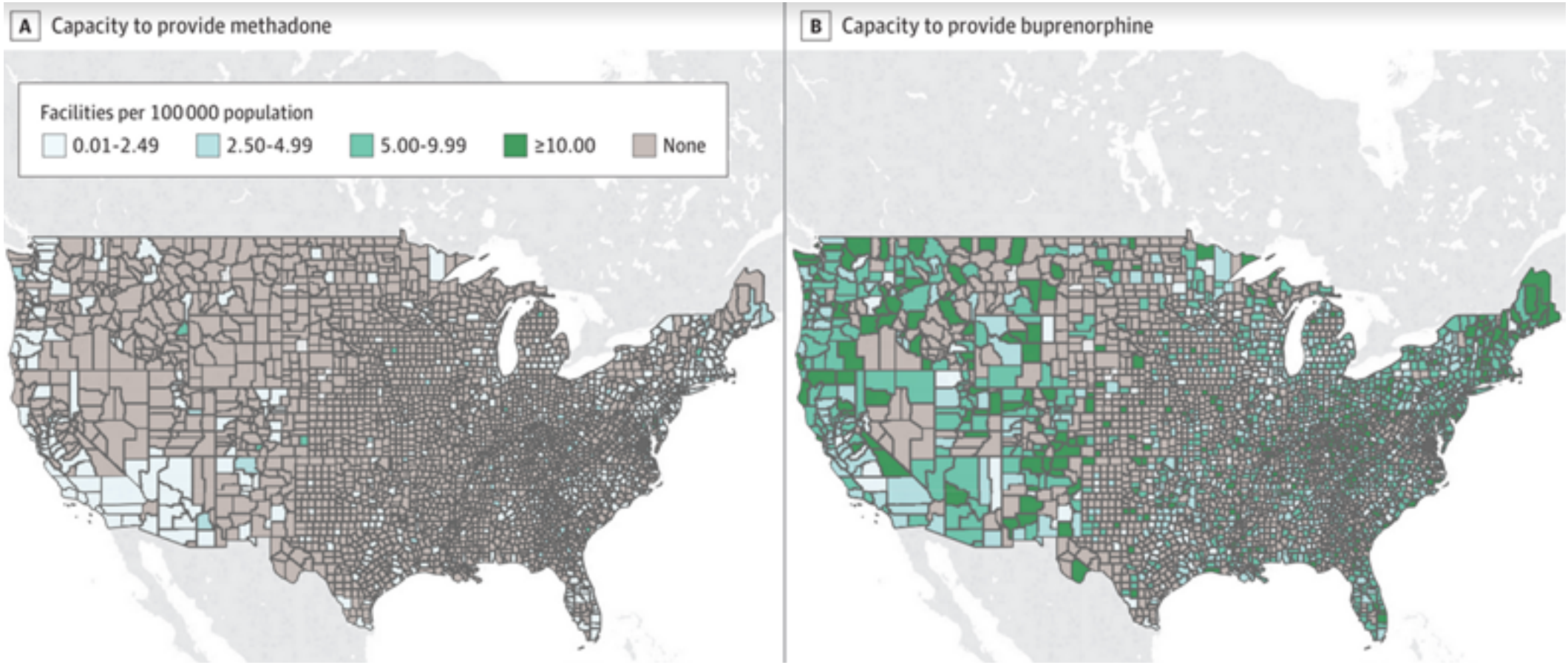
d. I care for patients who attend OTPs

e. I am a patient myself or friend/family member of a patient at an OTP

Narcotic Addiction Treatment Act of 1974

Peterkin. J Addict Med 2022

Racial Segregation of Treatment



Goedel et al. JAMA Network Open 2020

Peterkin. J Addict Med 2022

The 8-Point Criteria = How to Earn Take Homes

1. Absence of recent use of drugs or alcohol
2. Regularity of clinic attendance
3. Absence of serious behavioral problems at the clinic
4. Absence of known recent criminal activity, e.g., drug dealing
5. Stability of the patient's home environment and social relationships
6. Length of time in comprehensive maintenance treatment
7. Assurance that take-home medication can be safely stored within the patient's home
8. Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion

Substance Abuse and Mental Health Services Administration. Federal Guidelines for Opioid Treatment Programs. HHS Publication No. (SMA) XX-XXXX. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015.

Time in Treatment for Take Homes

- Day 1-90 – take-homes limited to 1 dose each week
- Day 91-180 – 2 doses per week
- Day 181-270 – 3 doses per week
- Day 271-365 – 6 doses per week
- Day 366-730 (Year 2) – 13 doses every 14 days
- Day 731 (year 3) and beyond – 27 doses per 28 days

Most clinics have loss of take homes result in return to the first phase and work their way back through

COVID-era Flexibilities

SAMHSA
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane • Rockville, MD 20857
www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

3/16/2020 (Updated 3/19/2020)

Opioid Treatment Program (OTP) Guidance

SAMHSA recognizes the evolving issues surrounding COVID-19 and the emerging needs OTPs continue to face.

SAMHSA affirms its commitment to supporting OTPs in any way possible during this time. As such, we are expanding our previous guidance to provide increased flexibility.

FOR ALL STATES

The state may request blanket exceptions for all stable patients in an OTP to receive 28 days of Take-Home doses of the patient's medication for opioid use disorder.

The state may request up to 14 days of Take-Home medication for those patients who are less stable but who the OTP believes can safely handle this level of Take-Home medication.

Polling Questions

What changes have you noticed in take home policies at methadone clinics (OTPs) since the start of the COVID-19 Pandemic? (choose 1)

a. More take homes in general these past 3 years

b. More take homes at first, but now back to basically pre-pandemic levels

c. More take homes, but only ever for patients who were already stable/abstinent

d. No meaningful change

e. What are take homes?

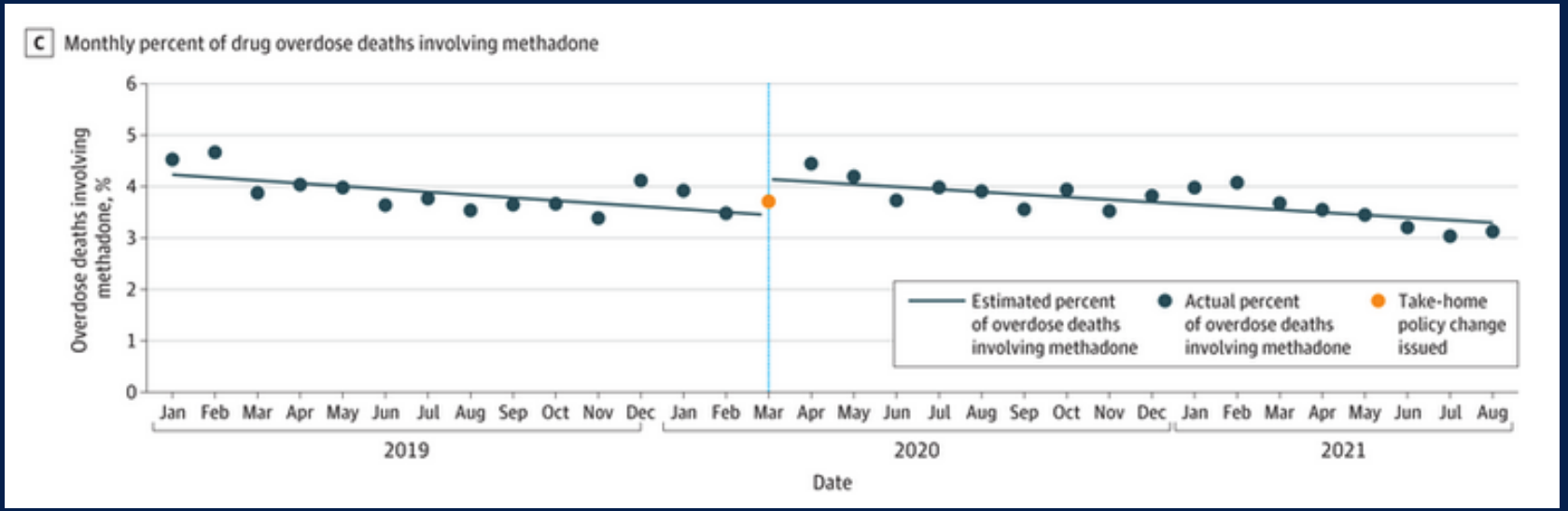
Polling Questions

What other overall changes have you noticed at OTPs since the start of the pandemic?

COVID-era Flexibilities

Did <u>overdose deaths</u> involving methadone increase?

- Deaths involving methadone remained ~3-5% of total overdoses
- Did not significantly increase when comparing the 12-months before/after flexibilities enacted



Jones JAMA Psychiatry 2022

COVID-era Flexibilities

Did methadone diversion increase?

Limited area of study. Two main studies:

- North Carolina OTP found little to no diversion among patients in 2020
- Hennepin Health Care in Minnesota found urine drug tests negative for methadone increased in July 2020 vs July 2019
  - Unclear if related to diversion vs barriers in treatment access
  - Local law-enforcement reports of methadone diversion during this period did not increase

Figgatt JSAT 2021; Bart JSAT 2022

COVID-era Flexibilities

How was quality of care impacted?

Multiple qualitative studies of patients, OTP clinicians, policymakers found:

- Longer take-homes provided a chance for greater autonomy and normalcy
- Individualized care was key, with option of more frequent contact viewed as beneficial for some
- Increased flexibility and independence supported patient treatment goals

Krawcyzk NASEM 2022, Hunter 2021, Levander ASCP 2021, Suen 2022

COVID-era Flexibilities

- However, a minority of OTPs adopted these flexibilities
  - A multi-state survey found that around half of OTP providers gave 14 day and 28 day take homes (THs) to eligible patients
  - State specific findings support this:
    - CT: patients receiving 14 day THs increased from 14 to 27%, those receiving 28 day THs increased from 0.1 to 17%
    - PA: <50% receive 14 day THs, <25% receive 28 day THs
- OTP characteristics (clients served, for-profit status, urbanicity) do not appear to influence take home practices

Levander 2021, Brothers 2021, Krawczyk 2022

Proposed Changes to 42 CFR 8.12

Expanded the definition of “Practitioner”: Intake physicals, evaluations, and dose changes can be done by physician assistants, nurse practitioners, nurse midwives, physicians, and others.

CHANGE

OTPs could be staffed many days a week, accepting walk-ins and transfers.

OTPs could provide basic primary care, wound care, Hepatitis C and HIV treatment

OTPs could change doses for patients every day

NO CHANGE

Days or weeks for appointments

Wait lists

Methadone dispensing only

Dose adjustments only 1-2 times a week

Proposed Changes to 42 CFR 8.12

Increase the availability of Take Home Bottles:

Days 1 - 14	=	7 Take Home Bottles
Days 15 - 30	=	14 Take Home Bottles
Days 31 +	=	28 Take Home Bottles

First Take Home Bottle could start on Day 1

CHANGE	NO CHANGE
People transferring from jail or other clinics could start THB immediately	Clinic rules supercede the federal guidance and nothing changes
People could go to work/school and not dose at clinic every day	Payment structure influences THB

Proposed Changes to 42 CFR 8.12

Counselling is as clinically necessary and mutually agreed-upon, including harm reduction education and recovery oriented counseling.

Patient refusal of counseling shall not preclude them from receiving MOUD.

Proposed Changes to 42 CFR 8.12

Expands options for split dosing

Split dosing is indicated among, but not limited to, those patients who: possess a genetic variant which increases methadone metabolism; concurrently use other medications or alcohol that also induce hepatic enzymes leading to more rapid metabolism of methadone; who are pregnant; or for whom methadone or buprenorphine are being used to treat a concurrent pain indication in addition to the diagnosis of OUD. This leads to more stable, steady-state medication levels.

CHANGE

Individualization of dosing could include twice daily dosing for some patients

NO CHANGE

Clinic rules supercede the federal guidance and nothing changes.

Continued mandate of the peak and trough testing

Language is not clear and exceptions need to be filed at the SAMHSA Extranet site which is burdensome

Proposed Changes to 42 CFR 8.12

Credentialing agencies must add one licensed physician "with experience treating OUD with MOUD" to accreditation body applicant's staff

CHANGE

Knowledgable patient-oriented doctor could shift the survey to focus more on patient outcomes in clinic

NO CHANGE

Surveys by the six credentialing agencies is unchanged and the new SAMHSA regulations are not enforced at the clinic level

Proposed Changes to 42 CFR 8.12

Removes the “one year” rule, meaning that patients can enroll in a methadone clinic if they have had less than one year of OUD

Proposed Changes to 42 CFR 8.12

Admission exams are accepted from providers outside the OTP. Examples would be a physical done during a hospital admission, ED visit, or primary care provider. This screening exam needs to document OUD and be current no more than 7 days from the admission to the OTP. The written results, narrative,

and available lab testing must be verified by an OTP practitioner.

CHANGE

Lower barrier entry to the OTP

No longer need to wait for "Doctor Day"

Relies on other community clinicians to understand methadone and direct into the clinic

NO CHANGE

Continued waits for appointments and delayed access to treatment

42 CFR 8.12 - UNCHANGED

First Day Dosing = 30 mg + 10 mg

Eight Drug Screens a Year

Methadone dispensing only at fully licensed OTPs

No improved access to people incarcerated

Relies on credentialing agencies to enforce

42 CFR Part 8 RIN 0930-AA39 Medications for the Treatment of Opioid Use Disorder NPRM

“The methadone manifesto: treatment experiences and policy recommendations from methadone patient activists”

Abby Coulter, National Survivors Union methadone liaison abby@urbansurvivorsunion.org
Caty Simon, National Survivors Union leadership team member caty@urbansurvivorsunion.org

Editorial:
Simon, C., Vincent, L., Coulter, A., Salazar, Z., Voyles, N., Roberts, L., Frank, D., & Brothers, S. (2022). The Methadone Manifesto: Treatment Experiences and Policy Recommendations From Methadone Patient Activists. *American journal of public health*, *112*(S2), S117–S122. https://doi.org/10.2105/AJPH.2021.306665

Unabridged Methadone Manifesto living document:
https://sway.office.com/UjvQx4ZNnXAYxhe7?ref=Link&mc_cid=9754583648&mc_eid=51fa67f051 Google “the Methadone Manifesto”

Community driven methodology we adapted to create the Methadone Manifesto :
Simon, C., Brothers, S., Strichartz, K., Coulter, A., Voyles, N., Herdlein, A., & Vincent, L. (2021). We are the researched, the researchers, and the discounted: The experiences of drug user activists as researchers. *The International journal on drug policy*, *98*, 103364. https://doi.org/10.1016/j.drugpo.2021.103364

We’ll also refer to: Brothers, S., Palayew, A., Simon, C., Coulter, A., Voyles, N., Vincent, L. (in press) Patient experiences of methadone treatment changes during the first wave of COVID-19: A national community driven survey. *Harm Reduction Journal*

Methadone patient activist perspectives on counseling-related rule changes

- "The proposed rule change expands the definition of 'counseling services' to include psychoeducational services, harm reduction and recovery-oriented services, and linkage to treatment …"

Many methadone clinic counselors **exclusively promote abstinence models, which have been shown to promote overdose risk upon termination**. (Cousins et al. 2011)

- "Language…is revised to promote a patient-centered approach to care that does not make medication continuity contingent upon involvement in counseling services."

Many states mandate weekly or biweekly counseling and groups sessions, **though there's mixed evidence to support that mandatory counseling contributes to positive outcomes and some evidence that it influences clients negatively toward treatment.** (WHO 2009, Schwartz et al. 2012)

Methadone clinic counselors frequently determine federally mandated treatment plans that outline patients' short-term goals, influence dosing decisions, and are periodically reassessed. **These treatment plans rarely reflect patients' actual goals and are often written without our input**.

Methadone clinic counselors also often lack the cultural competency to treat particularly vulnerable patient populations, such as patients in the sex trade. Street sex working women report not feeling safe in group counseling sessions (Jeal et al. 2017)

Cousins, G., Teljeur, C., Motterlini, N., McCowan, C., Dimitrov, B. D., & Fahey, T. (2011). Risk of drug-related mortality during periods of transition in methadone maintenance treatment: a cohort study. *Journal of substance abuse treatment*, *41*(3), 252-260.

Jeal, N., Macleod, J., Salisbury, C., & Turner, K. (2017). Identifying possible reasons why female street sex workers have poor drug treatment outcomes: a qualitative study. *BMJ open*, *7*(3), e013018. https://doi.org/10.1136/bmjopen-2016-013018

Schwartz, R. P., Kelly, S. M., O'Grady, K. E., Gandhi, D., & Jaffe, J. H. (2012). Randomized trial of standard methadone treatment compared to initiating methadone without counseling: 12 -month findings. *Addiction*, *107*(5), 943-952.

World Health Organization. (2009) Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence. Geneva, CH: WHO;. ISBN-13: 978-92-4-154754-3. https://www.ncbi.nlm.nih.gov/books/NBK143185/.

Patient activist perspectives on drug toxicology requirements remaining static

- The proposed rule change will not affect federal drug toxicology requirements for methadone patients, which will remain static at 8 mandated drug tests a year.
- We believe patients should be treated based on their behavior as a whole, not based on the chemical content of their urine. A review of sixty articles found a lack of evidence demonstrating an association between positive health-related outcomes for people in opioid agonist treatment and frequent urine testing (McEachern et al. 2019)
- Urine screening in particular is retraumatizing to many patients. We recommend OTPs switch to mouth swab testing while toxicology requirements are active.
- In our experience, punitive measures based on toxicology also do not result in positive outcomes.
- We recommend the elimination of state and federal policies mandating drug screening requirements in favor of patient-reported outcome measures.

McEachern, J., Adye-White, L., Priest, K. C., Moss, E., Gorfinkel, L., Wood, E., Cullen, W., & Klimas, J. (2019). Lacking evidence for the association between frequent urine drug screening and health outcomes of persons on opioid agonist therapy. *The International journal on drug policy*, *64*, 30–33. https://doi.org/10.1016/j.drugpo.2018.08.006

Patient activist perspectives on uneven COVID-19 relaxation implementation

Our national survey (Brothers et al., in press) found **patients experienced inconsistent COVID 19 methadone regulation relaxations implementation** during the first wave of the pandemic, as a contemporary North Carolina study also found (Figatt et al. 2021). Studies later in 2020 on OTP perspectives also found relaxations were unevenly implemented (Levander et al. 2022, Madden et. al 2022)

Some respondents to our study said that their clinics had already revoked COVID take-homes during the time of our survey (June/July 2020), only months after SAMHSA had first issued its guidance. Some patients even reported *increased* in-person requirements.

In late spring 2021, many MMT programs and an entire state rescinded COVID take-homes with the rationale that vaccines were now available.

These experiences have taught us to expect the rule changes will cause few improvements in methadone treatment access, unless the federal government creates a mechanism to incentivize states and individual OTPs to change their policy and practices. In the long term, it is critical for people with lived and living experience as methadone patients to occupy roles with decision making power in the creation and approval of quality metrics and OTP accreditation bodies.

Brothers, S., Palayew, A., Strichartz, K., Simon, C., Coulter, A., Voyles, N., Herdlein, A., Vincent, L. (in press)Changes in methadone treatment during COVID-19 in the United States: National online methadone patient survey. *Harm reduction journal*.

Figgatt, M. C., Salazar, Z., Day, E., Vincent, L., & Dasgupta, N. (2021). Take-home dosing experiences among persons receiving methadone maintenance treatment during COVID-19. Journal of substance abuse treatment, 123, 108276. https://doi.org/10.1016/j.jsat.2021.108276

Levander, X. A., Hoffman, K. A., McIlveen, J. W., McCarty, D., Terashima, J. P., & Korthuis, P. T. (2021). Rural opioid treatment program patient perspectives on take-home methadone policy changes during COVID-19: a qualitative thematic analysis. Addiction science & clinical practice, 16(1), 72. https://doi.org/10.1186/s13722-021-00281-3

Madden, E. F., Christian, B. T., Lagisetty, P. A., Ray, B. R., & Sulzer, S. H. (2021). Treatment provider perceptions of take-home methadone regulation before and during COVID-19. *Drug and alcohol dependence*, *228*, 109100. https://doi.org/10.1016/j.drugalcdep.2021.109100

Meyerson, B. E., Bentele, K. G., Russell, D. M., Brady, B. R., Downer, M., Garcia, R. C., Garnett, I., Lutz, R., Mahoney, A., Samorano, S., Arredondo, C., Andres, H. J., Coles, H., & Granillo, B. (2022). Nothing really changed: Arizona patient experience of methadone and buprenorphine access during COVID. *PloS one*, *17*(10), e0274094. https://doi.org/10.1371/journal.pone.0274094

Calls to Action

- If you or someone you know is experiencing inequitable methadone treatment, file complaints to accreditation bodies:
  - CARF International
    - 888-281-6531 or Emily Hosea (ext 7193) ehosea@carf.org
    - 520-495-7077 (TTY)
    - 520-318-1129 (Fax)
  - Council on Accreditation
    - 866-262-8088 (ext 234) or 212-797-3000 (ext 234)
    - Alisha Phillip, MSW (aphillip@coanet.org)
  - The Joint Commission
    - 630-792-5800
    - 630-792-5005 (Fax)
    - Peter Vance, LPCC, CPHC (pvance@jointcommission.org)
  - National Commision on Correctional Health Care
    - 773-880-1460
    - Amy Panagopoulos (amyp@ncchc.org)

Calls to Action

- Join the National Coalition to Liberate Methadone
  - Scan this QR code to fill out a form to join or email liberatemethadone@gmail.com

    [insert QR code to link https://forms.gle/nFmmMakXiZcEmjfx5]
  - Follow on social media:
    - Facebook: National Coalition to Liberate Methadone
    - Twitter: @methadonelib
    - LinkedIn: National Coalition to Liberate Methadone

Final Takeaways

- Current methadone treatment is rooted in the racist War on Drugs
- COVID-19 flexibilities to OTP care did NOT result in harm, and many of these changes may soon become permanent
- However these changes were unevenly implemented
- As addiction providers we must strive to provide patient-centered care including
  - Advocating for our patients and within our treatment systems to take full advantage of these flexibilities and push for further change

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