

Lessons Learned from COVID-19 and Regulatory Change in the Wake of Necessity

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I have no conflicts to disclose

Decades of research have found that strict methadone regulations cause tremendous **burden**, **stigma**, and **burnout** among persons with opioid use disorder

“That was one of the things that drove me away, that I would rather be on heroin than be on methadone. Cuz I wanted to be free to do what I want to do when I want to do it, and I – and could take them with me, and go where I want... [When I was on MMT] I was like a double slave. Like, you're a slave to the heroin already. And you're on methadone, you're a slave to the methadone and the clinic.”

- “Nina,” 63, previously on MMT

COVID-19 is our critical chance to evaluate outcomes of more flexible methadone regulations



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COVID-19 Could Change the
to the Opioid Crisis—for the

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Yuhua Bao, Ph.D., Arthur Robin Williams, M.D.

Opioid Policy Changes During the COVID-19

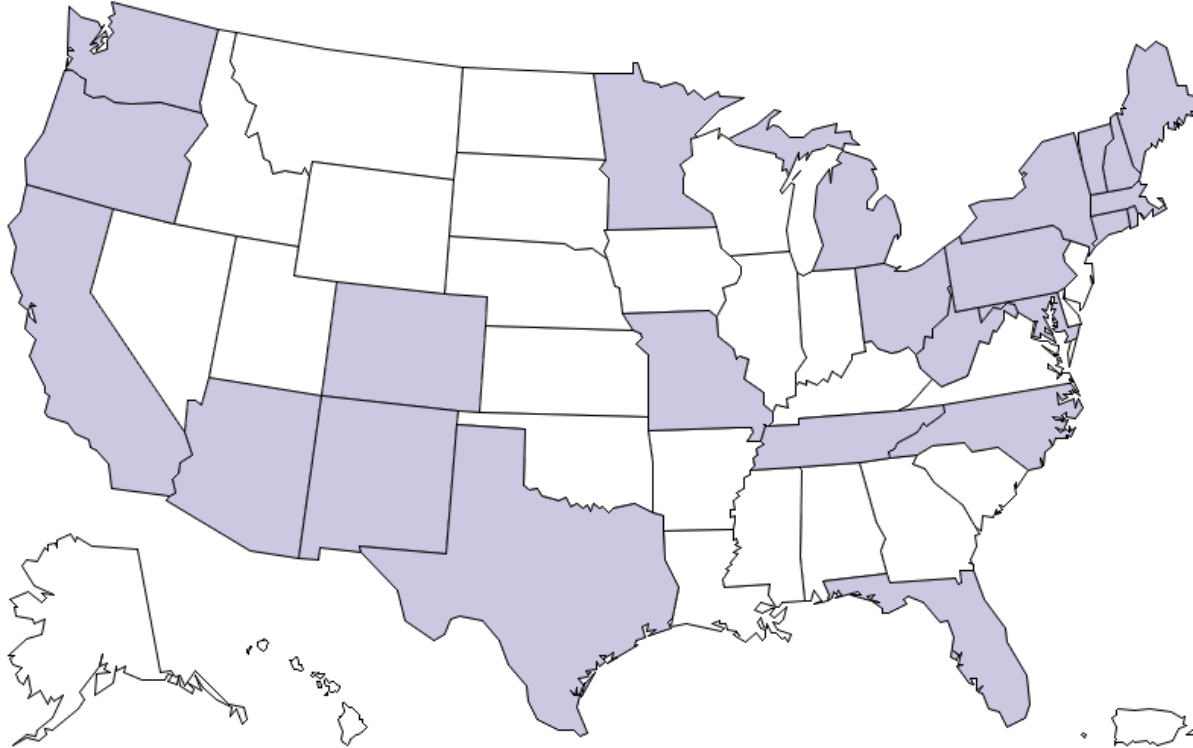
[Corey S. Davis](#), JD, MSPH and [Elizabeth A. Samuels](#), MD

THE METHADONE MANIFESTO

<https://sway.office.com/UjvQx4ZNnXAYxhe7?ref=Link>



Gathered *published* evidence from ~30 U.S. based publications that include data from OTPs across >25 States



Summarize findings on **3 key questions** on COVID-19 extended-take home regulations in the U.S.:

1. How have these new regulations been **implemented** in practice?
2. How have they impacted **overdose** and **diversion**?
3. How have they impacted patient **treatment experience** and **quality of life**?

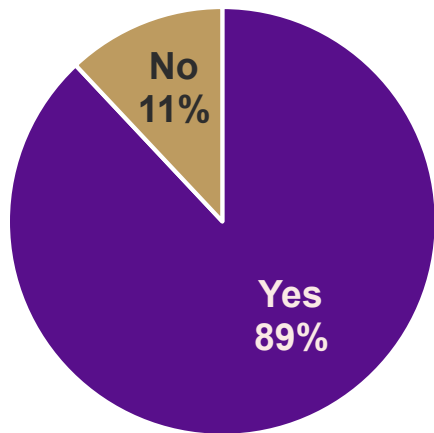
Limitations

- Rapidly evolving pandemic and policies, slow research & peer-review process
- COVID-19 “natural experiment” felt neither natural nor like an experiment
- Published research and data is only one piece of the story

Research Question 1:

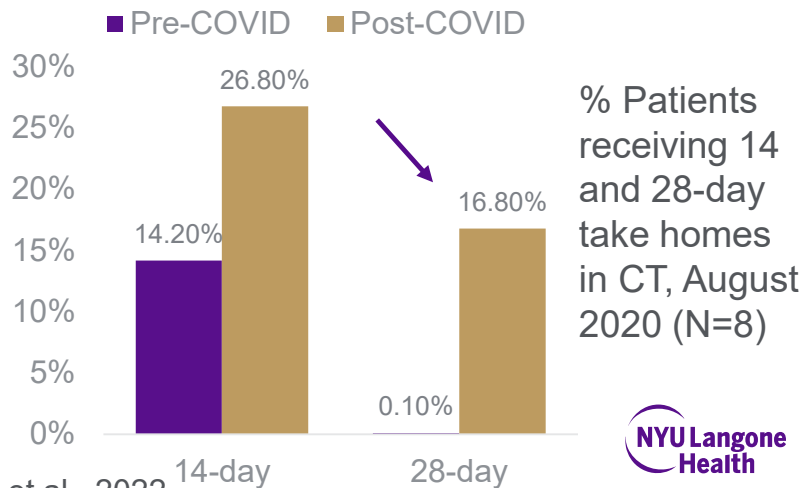
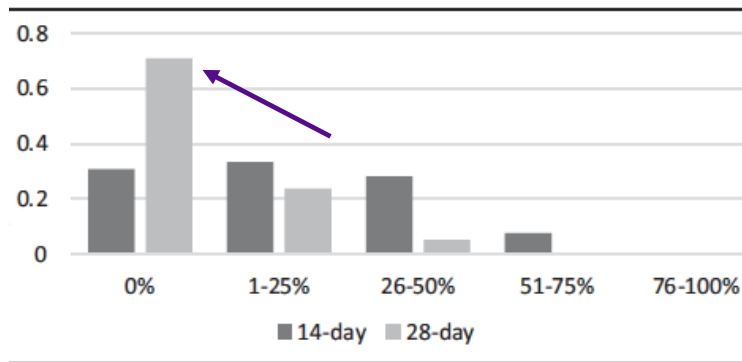
How have new take-home methadone regulations been implemented in practice?

% OTPs reporting increased take-home doses. April 2020 (N=142)



Most OTPs are providing **more take-home doses**, but a minority of patients receive a 14 or 28 day supply

Percent of PA OTPs endorsing none, some, or most patients receiving 14 and 28-day take-homes, Nov 2020 (N=39)

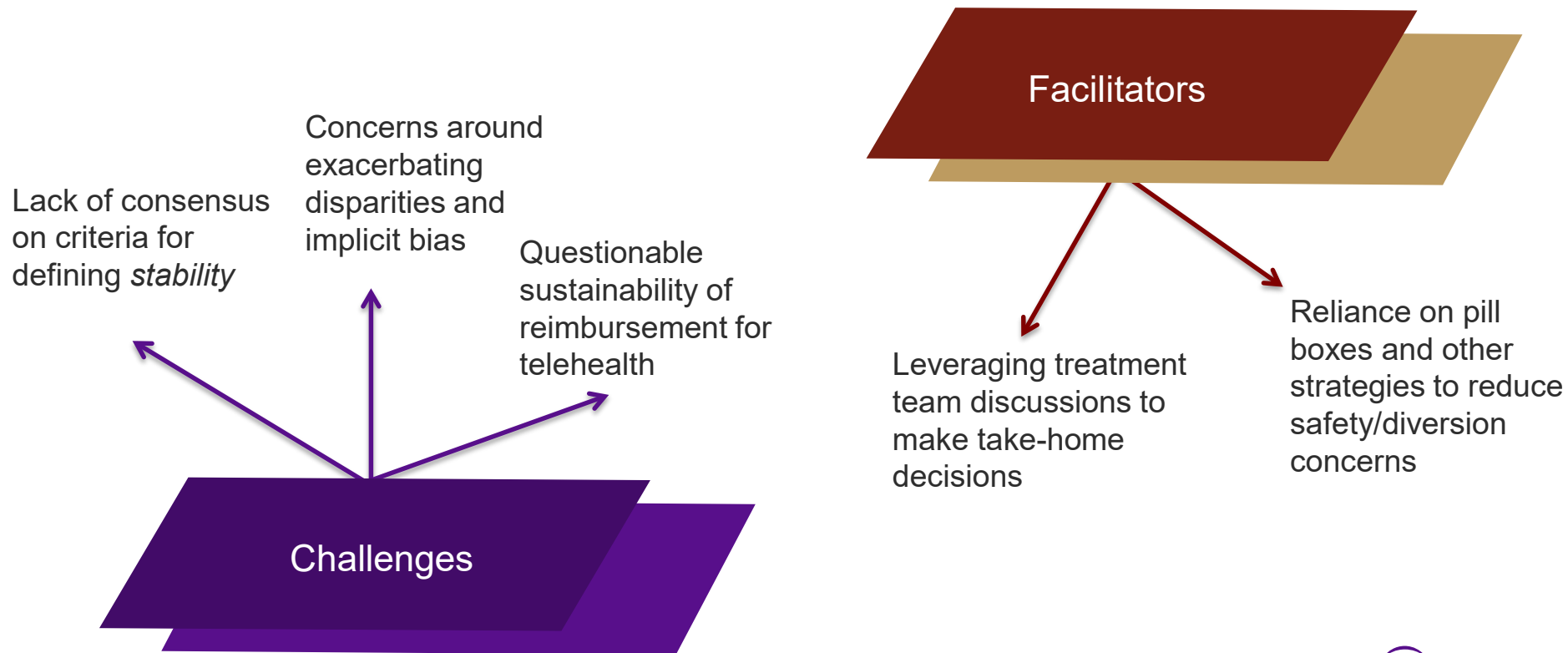


OTP providers were generally supportive of new regulations, with some expressing apprehension

“It’s proven in a lot of case[s] that [patients] could handle the methadone and it’s been nice to give them more trust in managing their methadone and not having to come in every day. I think it’s beneficial for the relationship”

“We have very strict policies, and I think we just follow that policy...The chances of abuse of the medication itself is so much higher ... we just find it to be a huge liability on our part”

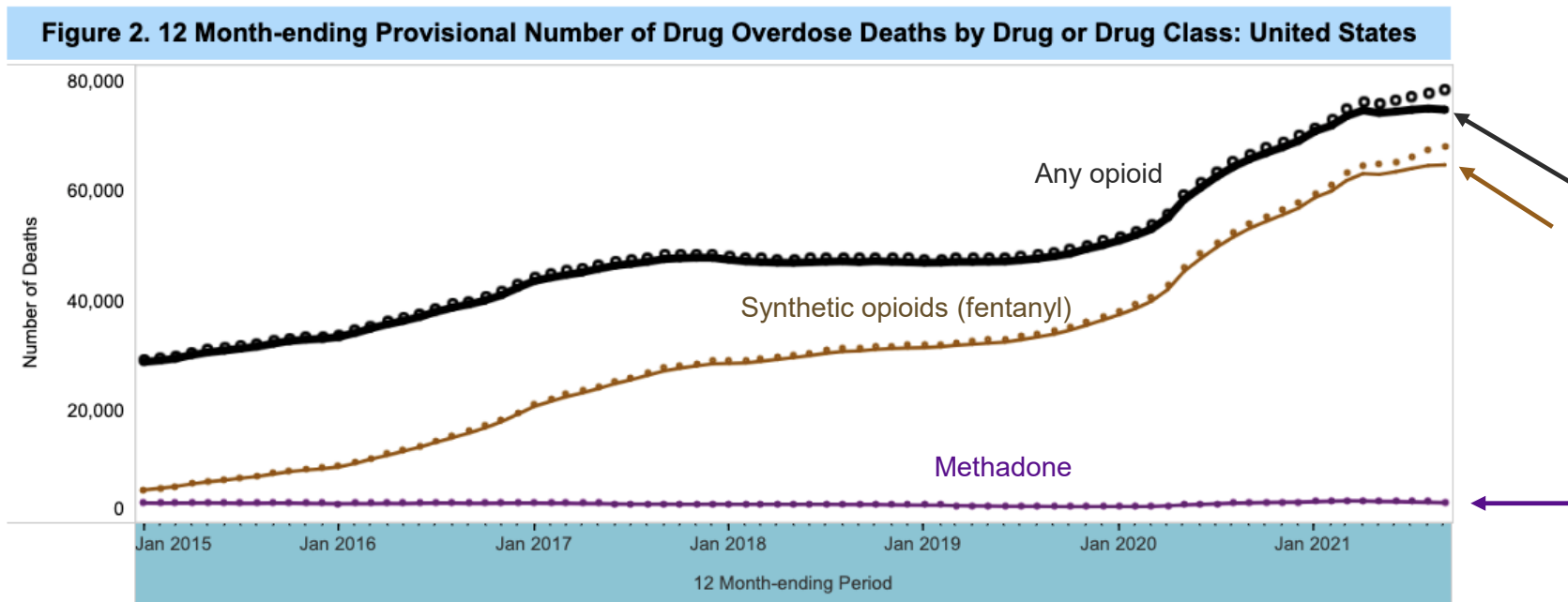
Challenges and facilitators to implementing longer take-homes



Research Question 2:

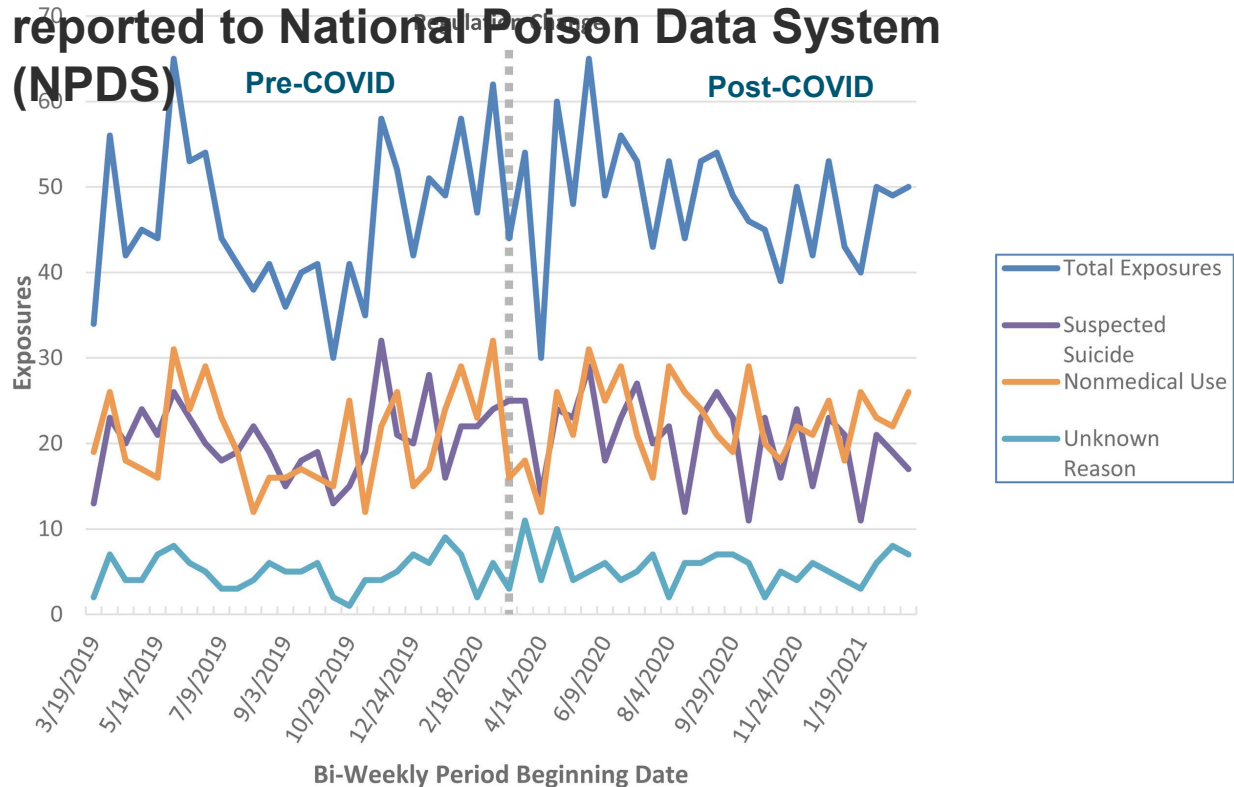
How have new take-home methadone regulations impacted overdose and diversion?

Methadone (including for pain) continues to be involved in only 5% of opioid overdose deaths



Intentional exposures involving methadone reported to National Poison Data System (NPDS)

- Calls to NPDS involving methadone (including for pain) increased only 5% from 1,199 to 1,262
- No increases in severity of outcomes, including death



Overdose and diversion outcomes reported in studies conducted in single or multiple OTPs

- **No increased overdose** deaths observed following COVID-19 regulations
- **Little to no diversion observed** following COVID-19 regulations

Research Question 3:

How have new take-home methadone regulations impacted patients' treatment experience and quality of life?

Theme 1: Longer take-homes provided a chance for greater autonomy and normalcy

“Not having to come in. I feel a little more independent. I feel when I do get a job it will be a lot easier...I just enjoy being able to be more like a normal person, just having my medication at home.”

“When you get your take-homes it’s like you feel you are being trusted to take care of yourself, and do the right thing...it felt great...that I was on the right track in my recovery.”

Theme 2: Individualized care was key, with option of more frequent contact viewed as beneficial for some

“I would like to see is maybe not having to come in quite as often...Everybody is different. Everybody should be looked at on an individual basis”

“I basically told on myself and told [the clinic] that I was having trouble with the take-homes, so they stopped giving them to me...I like it better because [going to the clinic] gets me up and ready for the day.”

Theme 3: Increased flexibility and independence supported patient treatment goals

“[Having take-homes is] a blessing because I wasn’t [off heroin] before the COVID started. I wasn’t getting to the clinic every day; now I’m able to get there so it’s helped a lot to get stable, stabilized and get off of the drugs.”

What about the effect on the gold standard of treatment success: Methadone retention?

- No empirical evidence as of yet...
- Large NIDA Clinical Trials Network (CTN) study in progress: **Optimal Policies to Improve Methadone Maintenance Long-Term (CTN-0112)**
 - Quasi experimental study assessing pre-post retention outcomes in a random sample of ~2500 patients across 10 large OTPs in 10 states.

Three “take-homes” from the early research:

- 1) Most OTPs adopted take-home changes, but more *work is needed* to determine best practices for implementing new regulations widely and equitably.
- 2) Overdoses involving methadone remain rare. OTPs have *not* reported significant increases in methadone overdose or diversion.
- 3) Increased take-homes *improve* patient autonomy and support treatment goals. *Option* to access daily services may benefit patients who prefer more structured treatment.

Implications for Policy and Practice

- Increasing flexibility around methadone **take-homes** should be sustained and expanded beyond the COVID-19 pandemic
- Greater **flexibility** should be extended to all aspects of methadone treatment (e.g. counseling; drug testing) so treatment plans can be individually tailored to patient needs and goals
- Such reforms must be **combined with other strategies to expand access** to medications for opioid use disorder, including:
 - Expanded access to methadone via pharmacies (proposed pathway via *Opioid Treatment Access Act*)
 - Expanded access to methadone via primary care
 - Extending buprenorphine flexibilities (telehealth) and elimination of waiver requirements
 - Increased access to medications in the criminal legal system
 - Ensuring all licensed treatment programs offer and encourage use of evidence based medications for OUD

Thank you!

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Magdalena Cerdá

All authors and participants of referenced studies

NASEM and ONDCP for bringing us together for this long awaited conversation

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Appendix data

