Innovative Models of Initiation under Existing Regulations – Inpatient and Outpatient Settings

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Methadone Treatment for Opioid Use Disorder:
Examining Federal Regulations and Laws
Session 4: Expanding Access to Methadone through Regulatory Innovation
Friday, March 4, 2022

CARE
Clinical Addiction Research and Education

Grayken Center for Addiction
Boston Medical Center

Disclosures – Alex Walley

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I lead education efforts funded by the Health Resources and Services Administration and have received honoraria for teaching about overdose prevention from the American Society of Addiction Medicine

2004-2006 – Dimock Center Detox medical director
2007-2014 – Boston Public Health Commission OTP medical director
2014-2016 - Healthcare Resource Centers Bradston Street OTP medical director
2015 – present BMC Addiction Consult Service and bridge clinic attending physician

Accessing Methadone: Running a Gauntlet

There has to be a better way

SAMHSA Regulations

State Regulations

STIGMA

Initial in-person visit requires:
To be in withdrawal
3+ interviews (Counselor, RN, and MD)
Toxicology testing
+/- Abstinence from other substances
Medication review
Double enrollment search
Informed consent/Release of Information
Commitment to counseling
Daily in-person attendance
Picture identification
…Dosing typically at the end
First day dose is capped at 30-40mg
---After many hours

DEA Regulations

Clinic Requirements

STIGMA

What is required now? Initial in-person visit

Under 42 C.F.R. § 8.12(f)(2): (f) Required services— . . .
Initial medical examination services. OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a *primary care physician*, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

April 2020, SAMHSA re-affirmed:
For new OTP patients that are treated with methadone, the requirements of an in-person medical evaluation will remain in force.

What is allowed now?

Direct Admission = “Regulatory opportunity not currently understood or leveraged… under the existing regulatory framework”

Treating with methadone outside of an OTP and linking to an OTP

1. Medically managed withdrawal program (aka **detox**) -> link to OTP day after discharge
2. General **hospital ->** link to OTP day after discharge
3. **Outpatient** or emergency department -> link to an OTP under “72 hour rule”

Key Caveat:

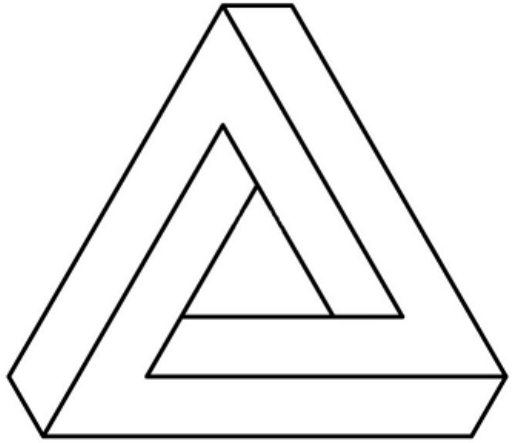
Direct admission hinges on an existing, trusting relationship with at least one OTP that will accept patients initiated and titrated at an outside venue

What is allowed now? Directly admit to OTP from detox

Paradox:

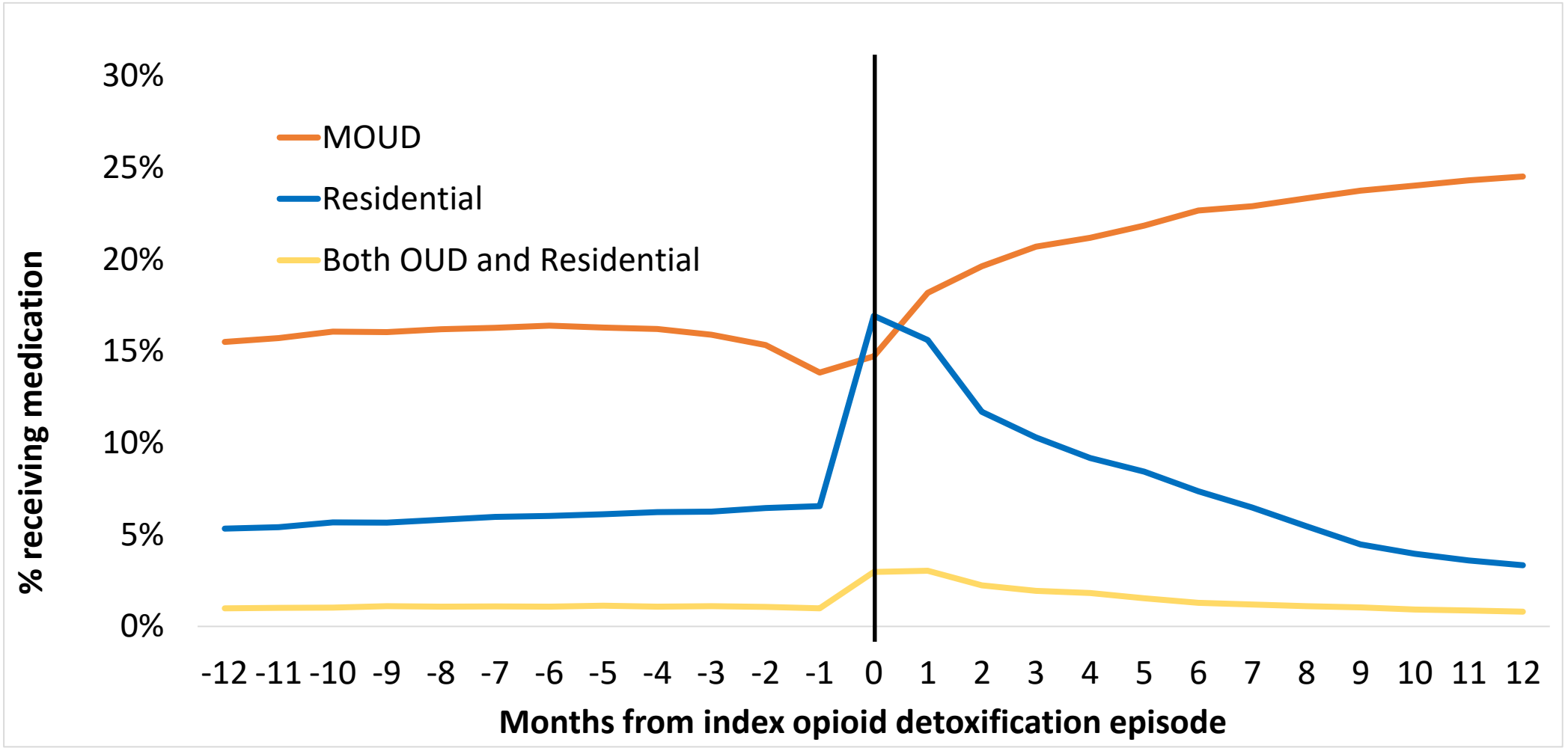
Many seek detox for treatment, reduce their use, and reduce their overdose risk

Yet, detox is followed by low treatment, high relapse and high overdose death



After detox, most do not receive treatment

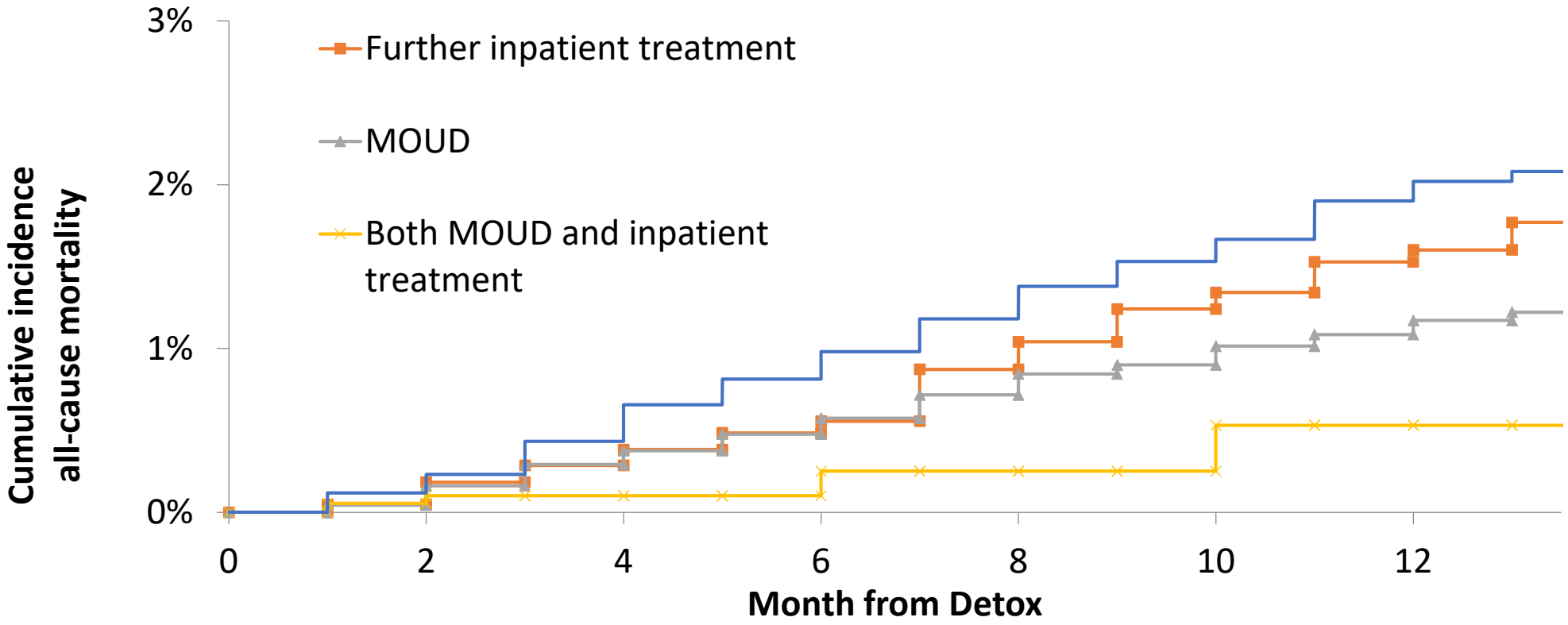
Cohort of 61,819 OUD detox encounters in MA, 2012-2014



Walley AY, Lodi S, Li Y, Bernson D, Babakhanlou-Chase H, Land T, Larochelle MR. Association between mortality rates and medication and residential treatment after in-patient medically managed opioid withdrawal: a cohort analysis. Addiction. 2020 Aug;115(8):1496-1508.

Detox patients who receive further treatment have better survival

Cohort of 61,819 detox encounters in MA, 2012-2014



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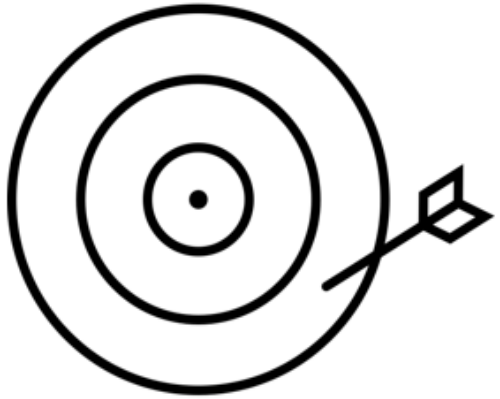
What is allowed now? Directly admit to OTP from detox

Paradox:
Many seek detox for treatment, to reduce use, to reduce overdose risk
Yet, detox is followed by low treatment, high relapse and high overdose death
-> Detox without further treatment = malpractice

Missed Opportunity! *Detox programs that provide methadone are already licensed as OTPs and can serve as methadone induction centers!*



What is allowed now? Directly admit to OTP from hospital

Only federally certified and accredited OTPs can dispense methadone for the treatment of OUD, but…

Controlled Substances Act has **exceptions** from the requirement to provide methadone through an OTP

1. **Physician or authorized hospital staff [may] administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction.**

- Title 21 Code of Federal Regulations § 1306.07 C

Direct Admission from hospital: High methadone linkage

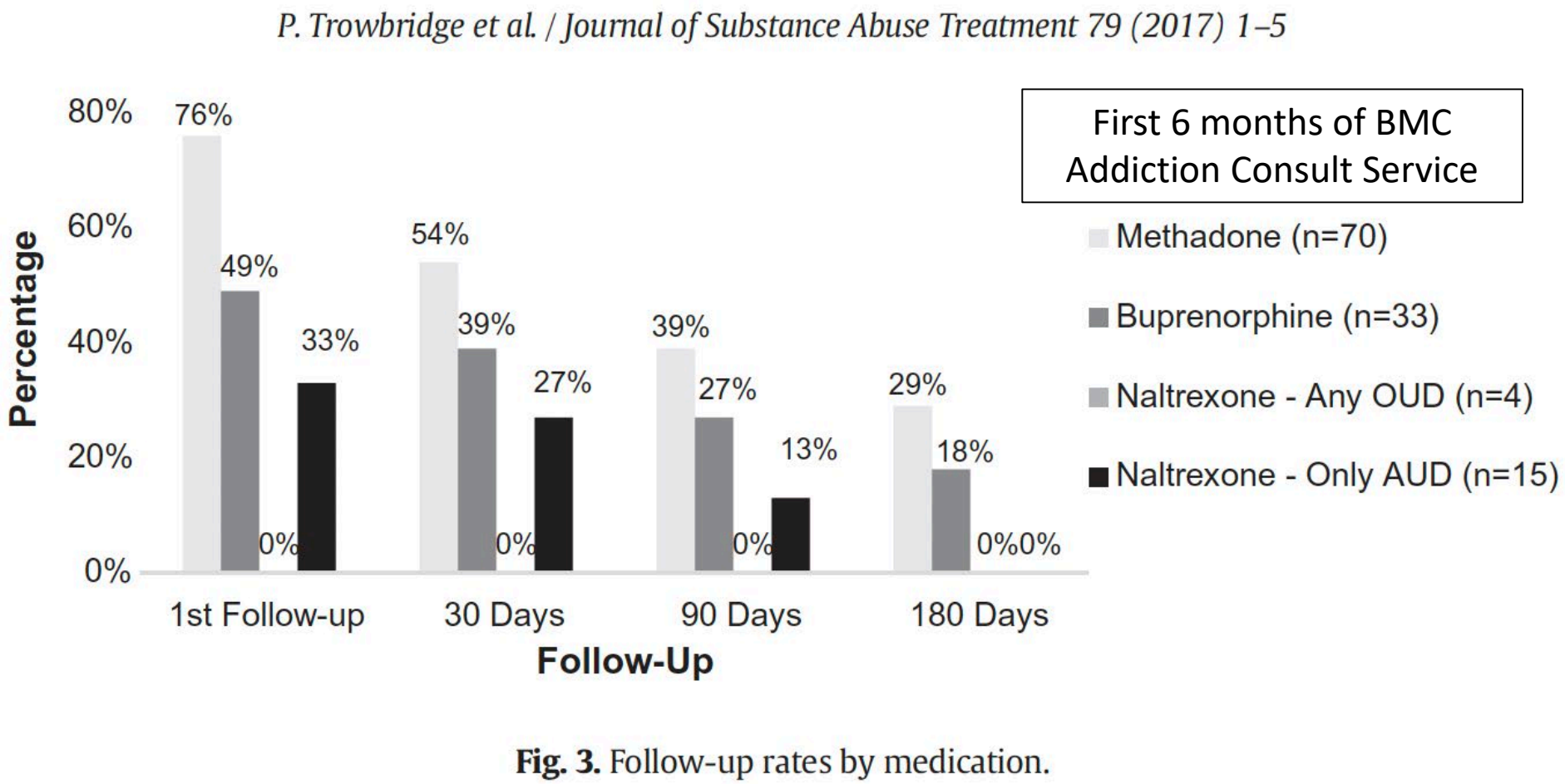


Fig. 3. Follow-up rates by medication.

Trowbridge P, Weinstein ZM, Kerensky T, Roy P, Regan D, Samet JH, Walley AY. Addiction consultation services - Linking hospitalized patients to outpatient addiction treatment. J Subst Abuse Treat. 2017 Aug;79:1-5.

What is allowed now? Directly admit outpatients in withdrawal

Only federally certified and accredited OTPs can dispense methadone for the treatment of OUD, but…

Controlled Substances Act has **exceptions** from the requirement to provide methadone through an OTP

2. **A physician not specifically registered to conduct a narcotic treatment program [may] administer (but not prescribe) narcotic drugs to a person for the purpose of relieving acute withdrawal while arrangements are being made for referral for treatment**
   - **Not more than one day's medication at a time.**
   - **Not more than three days**
   - **Not be renewed or extended**

- Title 21 Code of Federal Regulations § 1306.07 C

www.deadiversion.usdoj.gov/pubs/advisories/emerg_treat.htm

Direct Admission: 72-hour rule in a bridge clinic

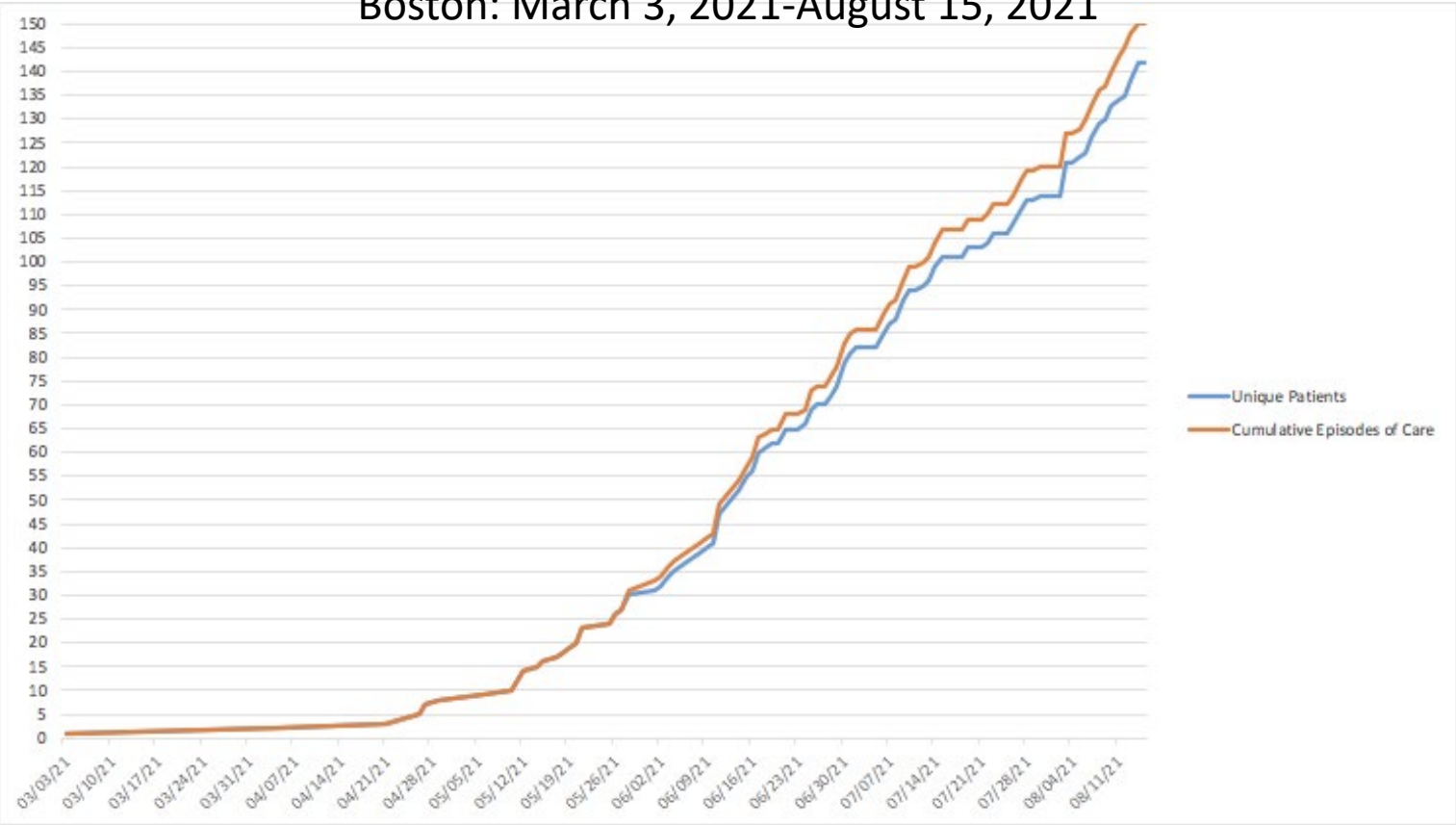
Low Barrier Bridge Clinic
March – August 2021:

- 150 treatment episodes in 138 patients
  - 12 loss to follow-up
  - 4 referred to inpatient
  - 1 admitted to hospital
  - 4 already enrolled at OTP
- 129 referred to OTP

Among 121 for the 2 main OTP partners:

- 87% (105) linked to the OTP
- 58% (70) retained at OTP at 1 month

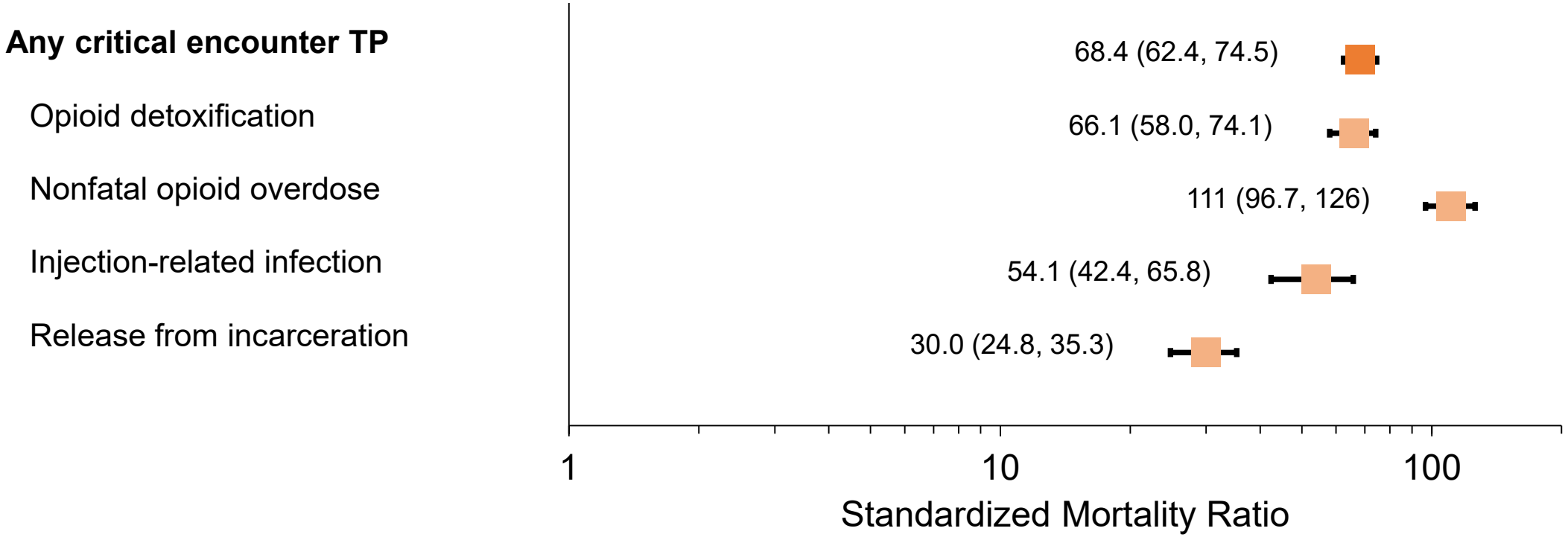
Cumulative number of treatment episodes and individuals treated for emergency opioid withdrawal in a low-barrier bridge clinic in Boston: March 3, 2021-August 15, 2021



Laks J, Kehoe J, Farrell NM, Komaromy M, Kolodziej J, Walley AY, Taylor JL. Methadone initiation in a bridge clinic for opioid withdrawal and opioid treatment program linkage: a case report applying the 72-hour rule. Addict Sci Clin Pract. 2021 Dec 28;16(1):73.
Taylor, J et al. Bridge clinic implementation of "72-hour rule" methadone for opioid withdrawal management: impact on opioid treatment program linkage and retention in care. *In Preparation.*

Overdose Death is very high within 1 year of high-risk touchpoints

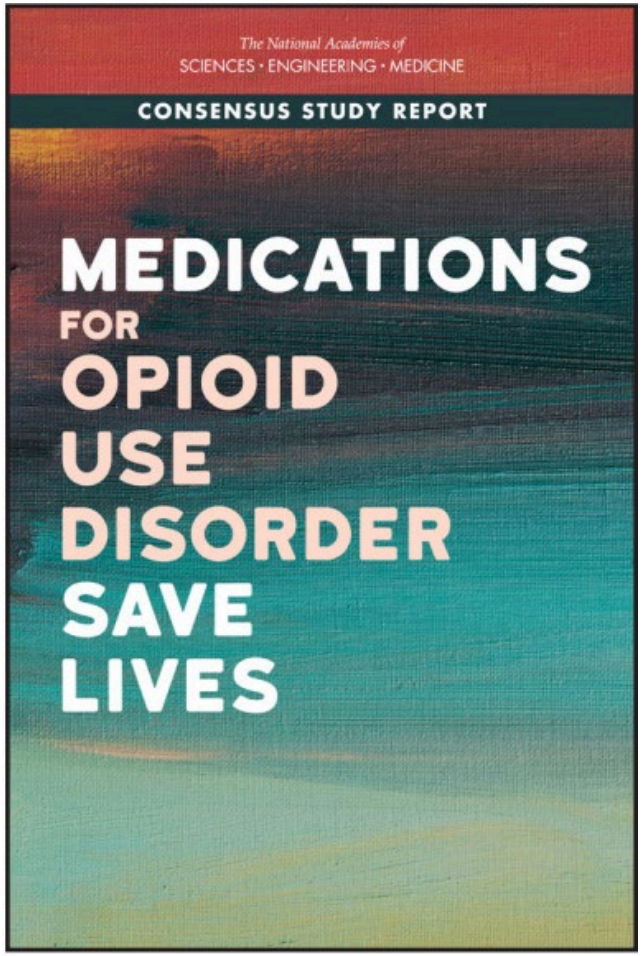
Massachusetts, 2014, n=1,315 opioid-related deaths



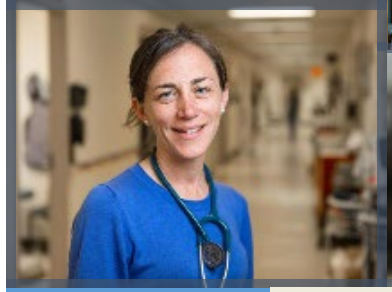
Larochelle MR, Bernstein R, Bernson D, Land T, Stopka TJ, Rose AJ, Bharel M, Liebschutz JM, Walley AY. Touchpoints - Opportunities to predict and prevent opioid overdose: A cohort study. Drug Alcohol Depend. 2019 Nov 1;204:107537.

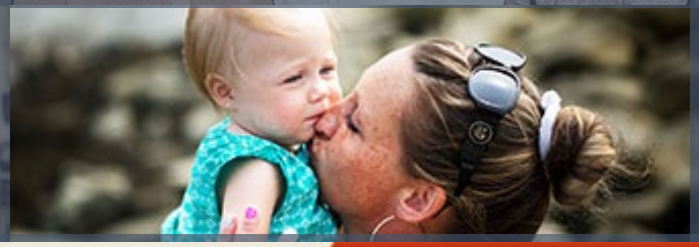
Facilitating Admission to Methadone: Concrete Action Steps Now

1. Issue and promote guidance for OTP direct admission approaches that already exist under current regulations – (detox, hospital, outpatient)
2. Incentivize partnerships with detox, hospitals, outpatient clinics and EDs
3. Transform detox into induction venues via regulation and funding incentives
4. Redesign OTP intakes to welcome rather than gauntlet patients
   a) True treatment on demand
   b) Start methadone for withdrawal within 1 hour
   c) Liberalize dose titration and take-home access
   d) Integrate, not fragment, methadone into the rest of healthcare
5. Fund research that evaluates innovative methadone initiation approaches
   - RCTs show that initiating buprenorphine in these settings work. Methadone RCTs have not been done



NASEM 2019 Consensus Conclusion:
"Witholding or failing to have all classes of FDA-approved MOUD in any care settings is denying appropriate medical treatment."





ADDICTION IS **HERE** SO IS **BOSTON MEDICAL CENTER.**

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References

Broers B, Giner F, Dumont P, Mino A. Inpatient opiate detoxification in Geneva: follow-up at 1 and 6 months. Drug Alcohol Depend. 2000;58(1-2):85-92.

D'Onofrio G, O'Connor PG, Pantalon MV, Chawarski MC, Busch SH, Owens PH, Bernstein SL, Fiellin DA. Emergency department-initiated buprenorphine/naloxone treatment for opioid dependence: a randomized clinical trial. JAMA. 2015 Apr 28;313(16):1636-44. doi: 10.1001/jama.2015.3474. PMID: 25919527; PMCID: PMC4527523.

Larochelle MR, Bernstein R, Bernson D, Land T, Stopka TJ, Rose AJ, Bharel M, Liebschutz JM, Walley AY. Touchpoints - Opportunities to predict and prevent opioid overdose: A cohort study. Drug Alcohol Depend. 2019 Nov 1;204:107537. doi: 10.1016/j.drugalcdep.2019.06.039. Epub 2019 Sep 3. PMID: 31521956; PMCID: PMC7020606.

Liebschutz JM, Crooks D, Herman D, Anderson B, Tsui J, Meshesha LZ, Dossabhoy S, Stein M. Buprenorphine treatment for hospitalized, opioid-dependent patients: a randomized clinical trial. JAMA Intern Med. 2014 Aug;174(8):1369-76. doi: 10.1001/jamainternmed.2014.2556. PMID: 25090173; PMCID: PMC4811188.

National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on Medication-Assisted Treatment for Opioid Use Disorder. Medications for Opioid Use Disorder Save Lives. Mancher M, Leshner AI, editors. Washington (DC): National Academies Press (US); 2019 Mar 30. PMID: 30896911.

Noska A, Mohan A, Wakeman S, Rich J, Boutwell A. Managing Opioid Use Disorder During and After Acute Hospitalization: A Case-Based Review Clarifying Methadone Regulation for Acute Care Settings. J Addict Behav Ther Rehabil. 2015;4(2):1000138. doi: 10.4172/2324-9005.1000138. PMID: 26258153; PMCID: PMC4527170.

Mark TL, Vandivort-Warren R, Montejano LB. Factors affecting detoxification readmission: analysis of public sector data from three states. J Subst Abuse Treat. 2006;31(4):439-45.

Physicians in an inpatient setting can legally order methadone administration to patients admitted primarily for other reasons – TIP 63, Administering or dispensing of narcotic drugs, 21 CFR § 1306.07 (2005).

Shanahan CW, Beers D, Alford DP, Brigandi E, Samet JH. A transitional opioid program to engage hospitalized drug users. J Gen Intern Med. 2010 Aug;25(8):803-8. doi: 10.1007/s11606-010-1311-3.Epub 2010 Mar 17. PMID: 20237960; PMCID: PMC2896583.

Spear SE. Reducing readmissions to detoxification: an interorganizational network perspective. Drug Alcohol Depend. 2014;137:76-82.

References

Stein M, Herman D, Conti M, Anderson B, Bailey G. Initiating buprenorphine treatment for opioid use disorder during short-term in-patient 'detoxification': a randomized clinical trial. Addiction. 2020;115(1):82-94.

Stein MD, Anderson BJ, Bailey GL. Preferences for Aftercare Among Persons Seeking Short-Term Opioid Detoxification. J Subst Abuse Treat. 2015;59:99-103.

Stein MD, Flori JN, Risi MM, Conti MT, Anderson BJ, Bailey GL. Overdose history is associated with postdetoxification treatment preference for persons with opioid use disorder. Subst Abus. 2017;38(4):389-93.

Strang J, McCambridge J, Best D, Beswick T, Bearn J, Rees S, et al. Loss of tolerance and overdose mortality after inpatient opiate detoxification: follow up study. Bmj. 2003;326(7396):959-60.

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.

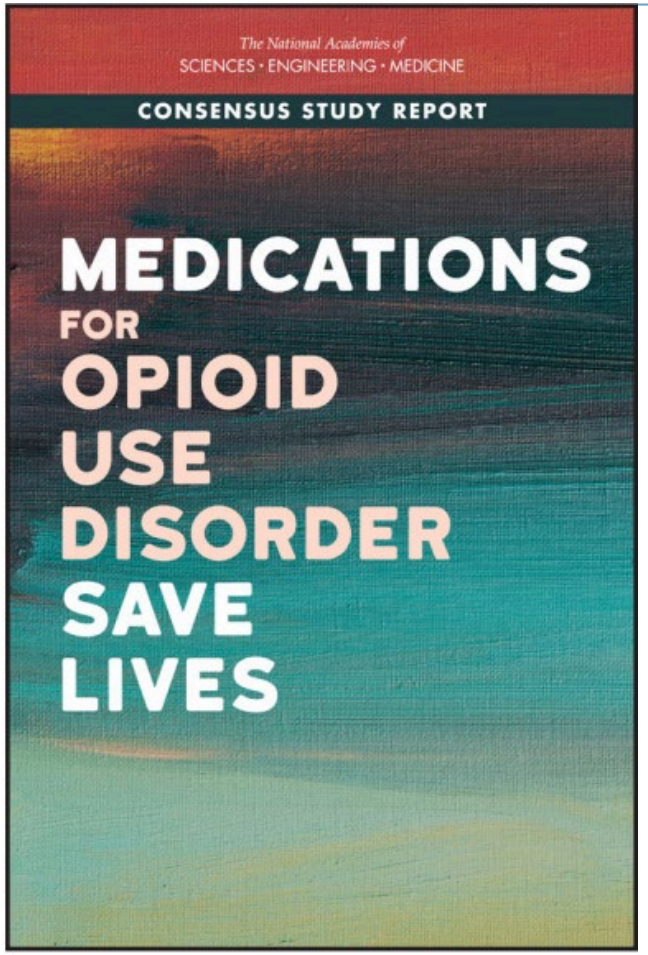
Trowbridge P, Weinstein ZM, Kerensky T, Roy P, Regan D, Samet JH, Walley AY. Addiction consultation services - Linking hospitalized patients to outpatient addiction treatment. J Subst Abuse Treat. 2017 Aug;79:1-5. doi: 10.1016/j.jsat.2017.05.007. Epub 2017 May 11. PMID: 28673521; PMCID: PMC6035788.

Wakeman SE, Larochelle MR, Ameli O, Chaisson CE, McPheeters JT, Crown WH, et al. Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder. JAMA Netw Open. 2020;3(2):e1920622.

Walley AY, Lodi S, Li Y, Bernson D, Babakhanlou-Chase H, Land T, Larochelle MR. Association between mortality rates and medication and residential treatment after in-patient medically managed opioid withdrawal: a cohort analysis. Addiction. 2020 Aug;115(8):1496-1508. doi: 10.1111/add.14964. Epub 2020 Feb 25. PMID: 32096908; PMCID: PMC7854020.

https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf
https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8
https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP21-02-01-002.pdf

National Academy of Sciences, Engineering, and Medicine 2019



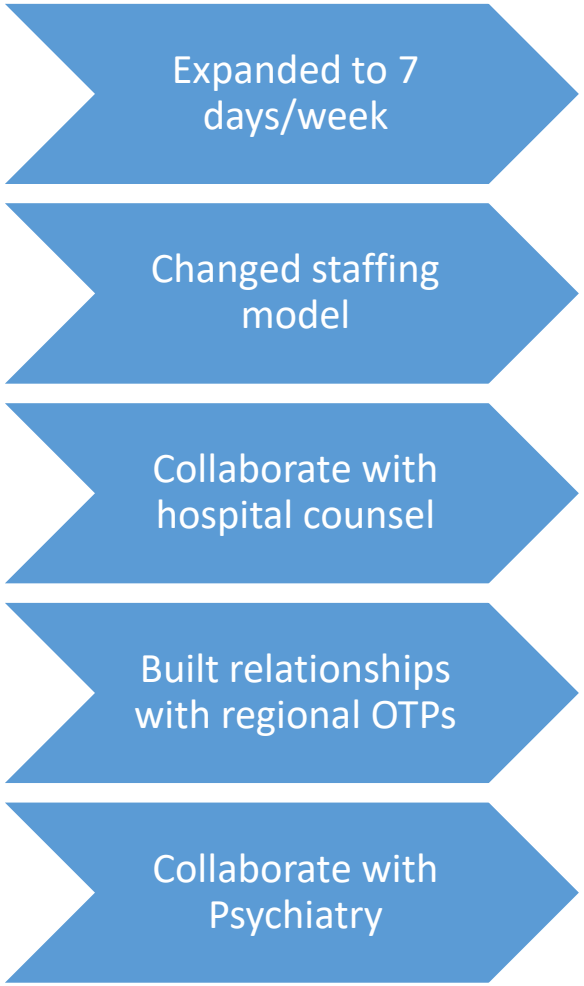
OVERVIEW OF CONCLUSIONS

To read the full text of the committee's conclusions, visit nationalacademies.org/OUDtreatment.

1. Opioid use disorder is a treatable chronic brain disease.
2. FDA-approved medications to treat opioid use disorder are effective and save lives.
3. Long-term retention on medications to treat opioid use disorder is associated with improved outcomes.
4. A lack of availability of behavioral interventions is not a sufficient justification to withhold medications to treat opioid use disorder.
5. Most people who could benefit from medication-based treatment for opioid use disorder do not receive it, and access is inequitable across subgroups of the population.
6. Medication-based treatment is effective across all treatment settings studied to date. Withholding or failing to have available all classes of FDA-approved medication for the treatment of opioid use disorder in any care or criminal justice setting is denying appropriate medical treatment.
7. Confronting the major barriers to the use of medications to treat opioid use disorder is critical to addressing the opioid crisis.

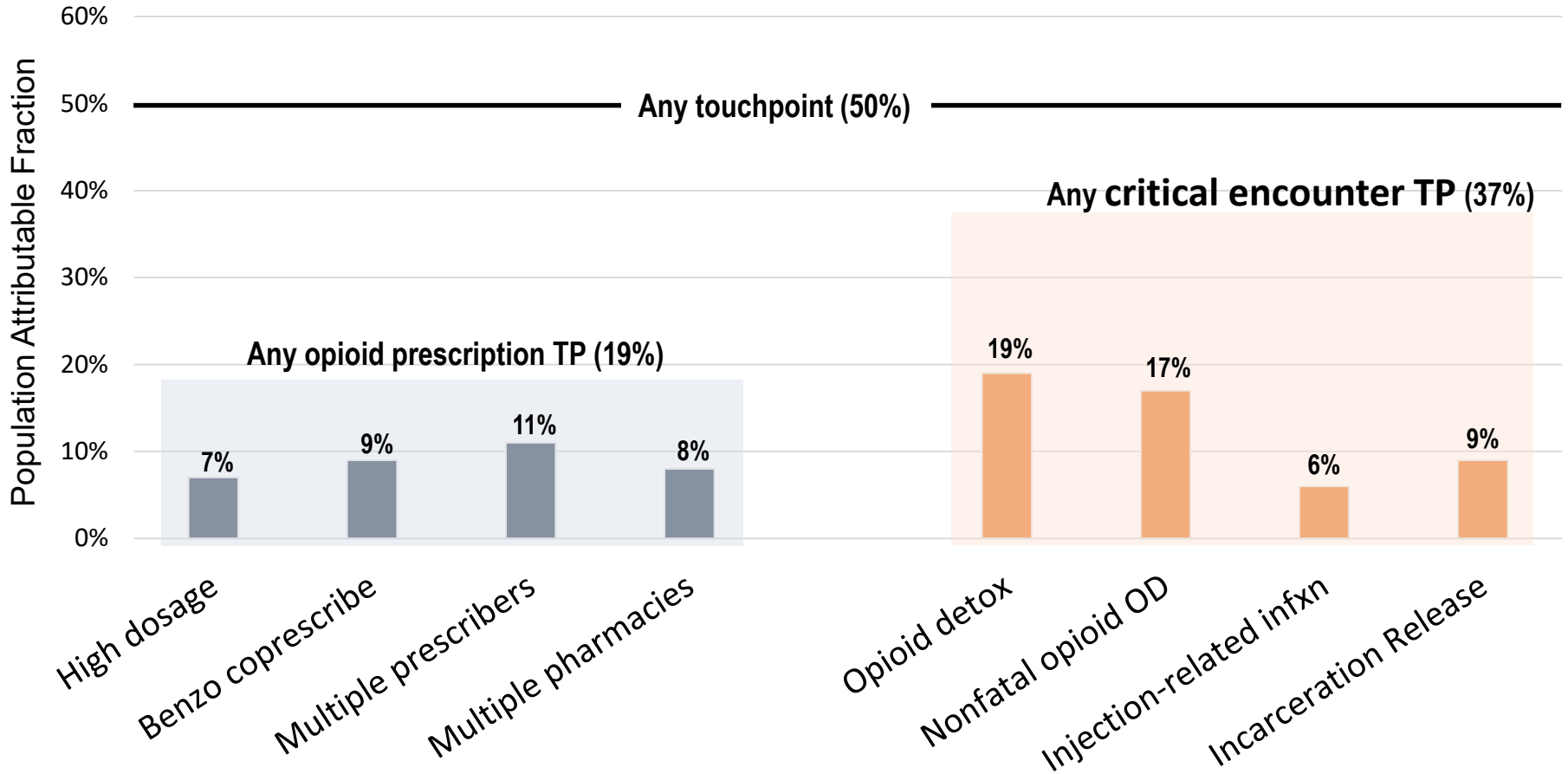
72 hour methadone challenges and solutions

- Very high demand, rapid increase in clinical volume
- Labor-intensive, time-pressured referrals process
- Limited OTP capacity for new patients over weekend
- Lack of precedent
- Patient preference for linkage outside the area
- High medical and psychiatric complexity



Looking back….Half of OD decedents touch our systems < 12 months
Population attributable fractions for pre-OD touchpoints

(Massachusetts, 2014, n=1,315 opioid-related deaths)



Source: Table 1. Larochelle et al. *Drug and Alcohol Dependence 2019*

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