

NIH · Helping to End Addiction Long-term

### **Session B:**

### MOUD Pre- and Postrelease: System, Client, and Cost Perspectives

Moderator: John Schneider MAARC

NIH HEAL Initiative and Helping to End Addiction Long-term are service marks of the U.S. Department of Health and Human Services.

### **Presentations by:**

1. Peter Friedmann – Massachusetts Hub

2. Sean Murphy – Health Economics Team – Weill Cornell Medicine

3. Lisa Marsch – New York University Hub

4. Thomas Blue – Friends Research Institute Hub

5. Lisa Puglisi – Yale-TCN Hub

6. Jonathan Ozik - MAARC



MOUD in Massachusetts' County Houses of Correction: Preliminary Findings on Postrelease MOUD Treatment, Reincarceration, Overdose and Mortality

> Elizabeth A. Evans PhD, MA Peter D. Friedmann MD, MPH

> > No conflicts to report



& Health Sciences

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#### JUSTICE COMMUNITY OPIOID INNOVATION NETWORK

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### Background

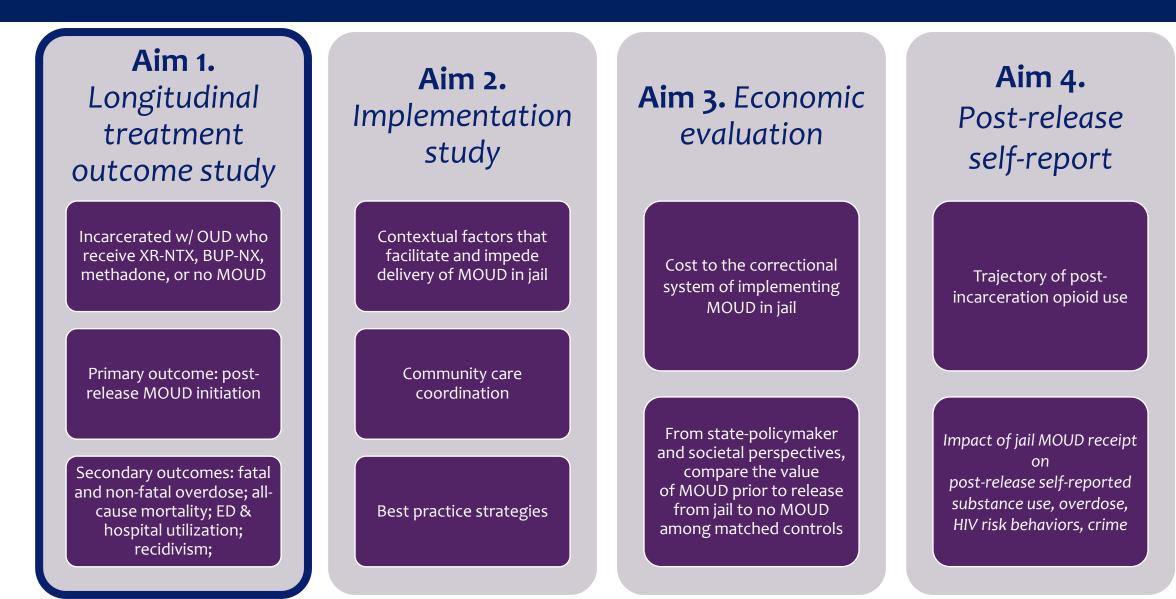
- Legislative mandate (CARE Act) created Massachusetts Chapter 208
- Required jails\* to implement a pilot program for all FDA-approved types of MOUD no later than 09/01/2019
  - o medication maintenance at intake
  - induction w/in 30 days of release
- Pilot program included 7 jails (in red)



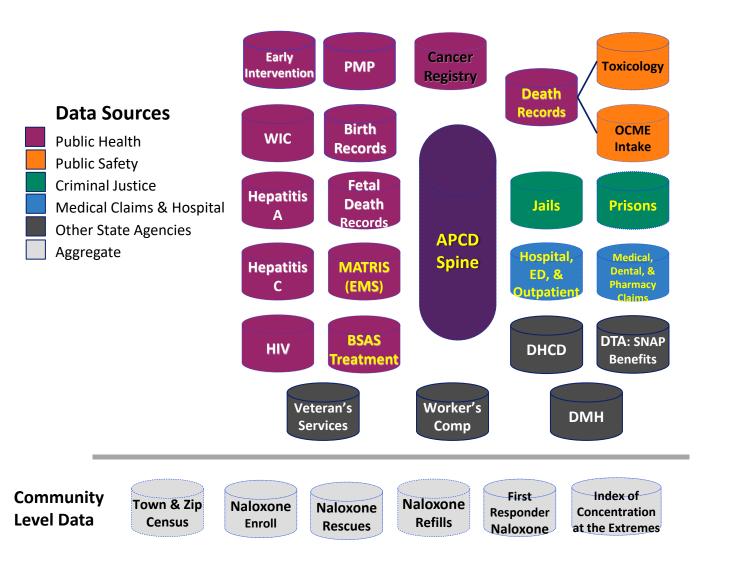




### Type 1 hybrid effectiveness-implementation study



### **Data Source: Public Health Data Warehouse (PHD) 2.0**



#### **Analytic Environment**

- SAS datasets
- Secure, remote server
- Analysis via SAS Studio

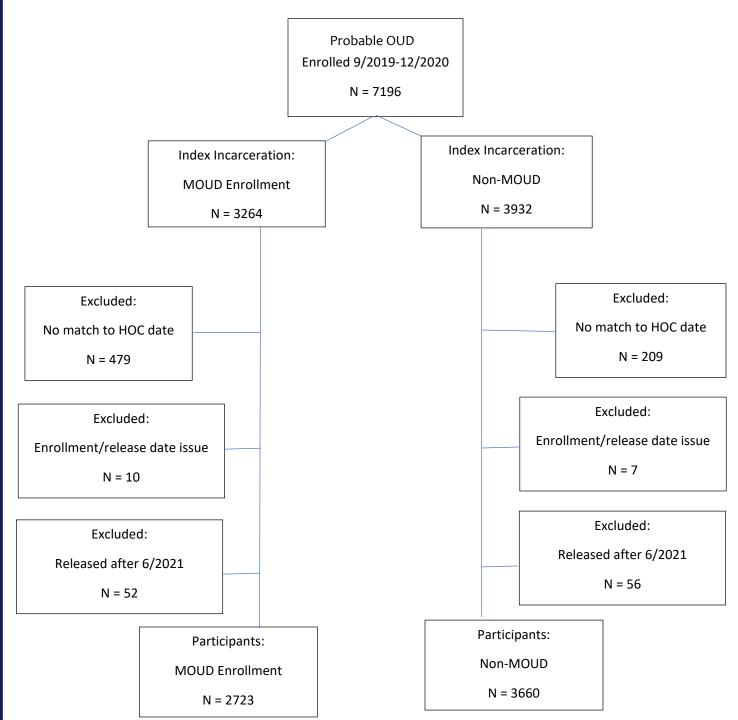
#### **System Attributes**

- Linkage at individual level
- Longitudinal (2011-2020)
- Data encrypted in transit & at rest
- Datasets unlinked at rest
- Linking and analytics "on the fly"
- No residual files after querying
- Analysts can't see data
- Automatic cell suppression

# Sampling

- 7 Jails/HOCs
- Probable OUD
  - Enrolled between Sept 2019- Dec 2020
  - Exited pre-July 2021 (i.e. >180 days of post-release community follow-up)
- n= 6,383 jailed persons with OUD

   Received MOUD while
   incarcerated: n=2,723; 42%
   Did not receive MOUD while
   incarcerated: n=3,660; 58%



### **Probable OUD**

Site	Source for determining Probable OUD
1.	<ul> <li>Self reports recent opioid use or SUD during medical/mental health intake and/or</li> <li>Screened for OUD via TCUD</li> </ul>

- 2. Self report of recent opioid use during medical/ mental health intakes and/or,
  - DAST-10 screening (>2-10)
- 3. iCup drug screen and/or,
  - OUD diagnosis assessed during mental health assessment
- Diagnosed with any SUD during Mental Health Evaluation and self-reported recent opioid use
- Self report of substance use history/disorder and OUD diagnosis during mental health assessment
- 6. PHD algorithm due to inconsistent screening onsite.
- Self-report of history of substance use and/or MAT use during medical/ mental health intakes and/or
  - Positive for OUD (TCUD), or recent reported opioid use

## **OUD Algorithm**

- Defines 3 types of historical indicators to identify persons with probable opioid use disorder:
  - Indicator of opioid overdose
  - Indicator of opioid abuse or dependence
  - Indicator of MOUD treatment
- Uses DPH's Public Health Data Warehouse to find indicators for any of the above before the index jail intake
  - PHD Data Sources: SPINE overdose, BSAS, APCD (medical and pharmacy), Casemix (emergency dept, hospital discharge, outpatient observation), DMH, PMP



### **Methods**

### **Outcomes:**

- Post-release MOUD treatment
- Reincarceration
- Non-fatal and fatal opioid overdose
- All-cause mortality

### Analysis: Propensity score (PS) weights adjusted for selection effects...

- Age
- Sex
- Race
- Educational attainment
- HOC county
- Adjudication status

- Veteran status
- Homeless history
- Pre-incarceration overdose
- MOUD at jail entry
- Days incarcerated



### **Results – Baseline Differences**

Table 1	MOUD, N=2723	Non-MOUD, N=3660
Age		
median [IQR]	36 [31, 42]	35 [29, 43]
mean (std)	37.0 (8.8)	36.7 (10.1)
Female Sex, N (%)	695 (25.5)	916 (25.0)
Race/Ethnicity, N (%)		
White non-Hispanic	2044 (75.1)	2137 (58.4)
Black non-Hispanic	158 (5.8)	596 (16.3)
Asian/PI non-Hispanic		15 (0.4)
Hispanic	500 (18.4)	883 (24.1)
American Indian or Other	16 (0.6)	29 (0.8)
Pre-incarceration overdose, N (%)	1239 (45.5)	1306 (35.7)
MOUD at jail entry, N (%)	1975 (72.5)	628 (17.2)
MOUD type (enrollment), N (%)		
Methadone	699 (25.7)	
Buprenorphine (Suboxone)	1855 (68.1)	
Naltrexone (Vivitrol)	169 (6.2)	
Adjudication status, N (%)		
Pre-trial	1754 (64.4)	2981 (81.5)
Sentenced	938 (34.5)	501 (13.7)
Safekeep	22 (0.8)	158 (4.3)
Unknown/Missing	ns	20 (0.5)
Days incarcerated		
median [IQR]	51 [14, 140]	17 [2, 63]
mean (std)	109.3 (149.7)	53.8 (94.4)

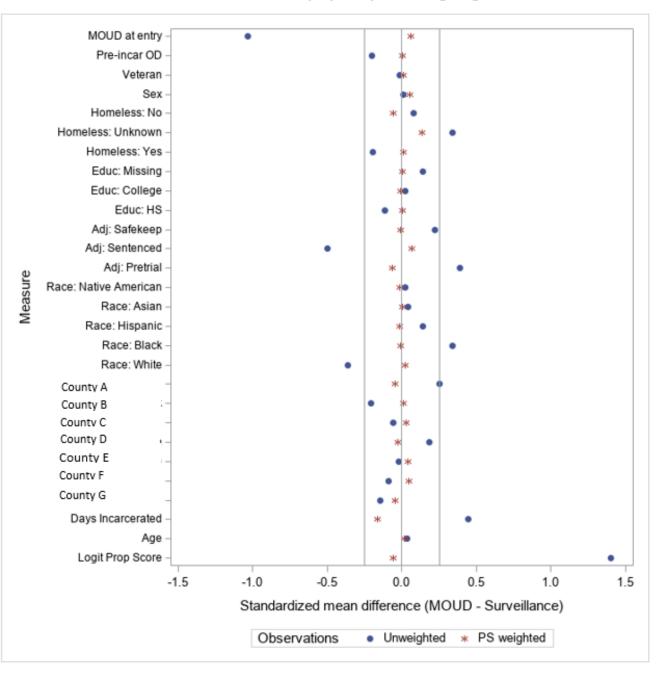


INNOVATION NETWORK (JCOIN)

### Results

### Propensity Score weights balanced baseline differences.

Standardized mean differences before and after propensity score weighting.

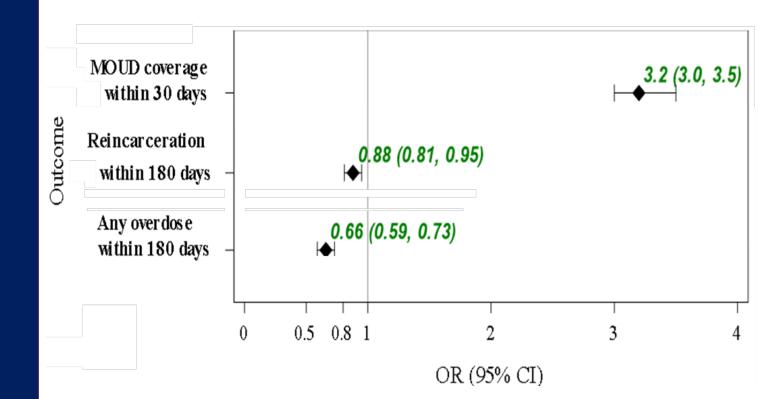


### Results

# • Those treated with MOUD in jail had...

- Three-fold greater odds of linkage to community MOUD in first 30 days post-release
- Lower odds of reincarceration or any overdose within 180 days

### MOUD vs. non-MOUD, PS weighted

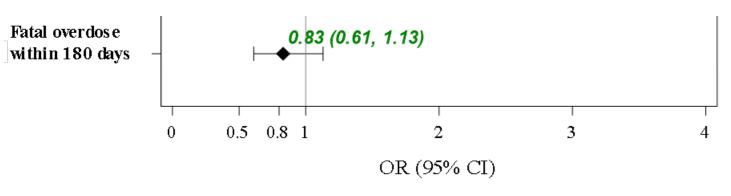


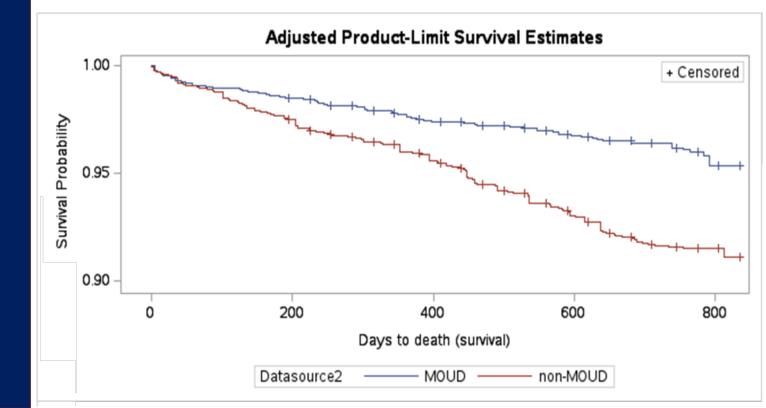
### Results

 No significant effect on 180-day overdose fatality detected (aOR 0.83, 95% 0.61-1.13)

• All-cause mortality was reduced over the entire follow-up period (adjusted hazard ratio 0.48, 95% 0.41-0.56).

### MOUD vs. non-MOUD, PS weighted





### Limitations

- Identification of non-MOUD arm not standardized
   Sensitivity analyses using OUD algorithm for all
- Varied MOUD access in communities  $\rightarrow$  jails
  - Entry disparities reflect community practices
- Data quality and matching challenges

   Analyst unable to see data directly per PHD policy
- COVID-19 may have distorted outcomes



### Conclusion

- Jail-based MOUD treatment is associated with... Higher rates of post-release MOUD treatment in the community Lower rates of total opioid overdose Lower rates of reincarceration Lower rates of all-cause mortality
- Racial and ethnic disparities in MOUD treatment access merit intervention



### Acknowledgments

**Data analyst** Donna Wilson

#### **Co-Investigators**

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NNOVATION NETWORK (JCOIN)

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#### **Correctional Partners**

**Essex:** Sheriff Coppinger, Jason Faro, Dr. Christopher Gudas Franklin: Sheriff Donelan, Ed Hayes, Dr. Ruth Potee Hampden: Sheriff Cocchi, Cassandra Sarno, Dr. Thomas Lincoln, Sally Johnson Van Wright, Marty Lyman Hampshire: Sheriff Cahillane, Mindy Cady, Bridget Szawlowski Middlesex: Sheriff Koutoujian, Kashif Siddigi, Dan Lee, Crystal Miske, Ashley Witts Norfolk: Sheriff McDermott, Erika Sica, Tara Flynn Suffolk: Sheriff Tompkins, Rachelle Steinberg, Marjorie Bernadeau-Alexandre ... and many more!

#### Funding: NIDA 1UG1DA050067-01 (Friedmann, Evans), K23DA049953 (Pivovarova)

Rebecca Rottapel

### Cost Analysis of MOUD Implementation and Sustainability in Massachusetts Jails

JCOIN Steering Committee June 11<sup>th</sup>, 2024





JUSTICE COMMUNITY OPIOID INNOVATION NETWORK (JCOIN)



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**CHERISH** 

## **Funding & Declarations**

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- Declarations of interest: NA



### **Presentation Outline**

- Overview
- Objective
- Methods
- Findings
- Insights
- Questions



Substance Use Disorder, HCV, and HIV

### Overview

- Resources required to implement MOUD programs in jails/prisons can vary widely due to the myriad of possible combinations of existing services and potential delivery models
  - <u>Examples of existing services</u>: no MOUD; offering MOUD upon release from incarceration; continuing coverage of MOUD for those entering facility with a Rx, etc.
  - Examples of delivery models: medication provided by the facility's healthcare team; vendor-based delivery; combination of in-house and vendor services
- Uncertainty regarding the resources/costs needed to implement & sustain an MOUD program can be a significant barrier to adoption



# Objective

### The objectives of this study were to:

- i. identify the types of MOUD models deployed by the jails serving as research sites for the MA JCOIN Hub,
- ii. determine which resources were utilized at each stage of development, and
- iii. estimate the associated costs



## Methods

- A detailed microcosting analysis was conducted at 6/7 of the participating jails
- Microcosting entailed systematically capturing, cataloging, & valuing changes in resources resulting from the intervention
  - <u>Accounting costs</u> = the actual expenditures of all resources used by the site for the intervention
  - <u>Economic costs</u> = accounting costs + opportunity costs (e.g., donated/subsidized services, volunteer effort, etc.)
- Quantitative resource utilization data were collected through a combination of administrative sources and semi-structured interviews of relevant personnel
  - <u>Included</u>: clinicians, social workers, managers/directors, IT staff, administrators, counselors, superintendents, deputies, and sheriffs
- Our customizable budget impact tool, designed to assist jails/prisons with assessing the viability of alternative MOUD models, was used to organize each site's resources and estimate their associated costs

# **Budget Impact Tool**

> J Subst Use Addict Treat. 2023 Mar:146:208943. doi: 10.1016/j.josat.2022.208943. Epub 2023 Jan 26.

### Budget impact tool for the incorporation of medications for opioid use disorder into jail/prison facilities

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The BIT and associated manuscript are available *open access* via JSAT, and on the CHERISH website: <u>https://cherishresearch.org/tools-and-resources/budget-impact-tool/</u>



### Methods

- Resources/costs are categorized as "fixed start-up", "timedependent", or "variable"
  - <u>Fixed start-up</u>: resources/costs that are incurred only once, and are not directly related to the number of participants
  - <u>Time-dependent</u>: resources/costs that are recurring, but fixed over a given time-period
  - <u>Variable</u>: resources/costs that are a direct function of the number of participants



### Methods

- **Implementation**: costs incurred for purposes of start-up, and over the timeperiod required for facility to hit a steady-state with regard to intervention
  - We assumed fixed costs would be distributed over the course of the first 12 months following start-up, for budgeting purposes
- **Sustainment:** costs required to continuously operate the intervention over time

Imp	lementation Phase	
	Sustainmen	t Phase
Fixed Start-up	Time-Dependent	Variable
Equipment	Meetings	OUD Medications
Start-up Meetings	Trainings	OUD Assessments
Trainings	Accreditation and Licensing Fees	Medication Dosing
Information Technology Services (ITS)	Contracted Vendor Fees	Counseling
Construction/Renovation		<b>Testing Supplies</b>
Application Process		
Interim Medication Delivery		

# **Characteristics of HOCs**

		Model 1: Contract for Methadone Maintenance		Model 2: Contract for All Induction & Maintenance		Iail OTP ation
	Site A	Site B	Site C	Site D	Site E	Site F
Average Daily Population	613	381	>1,000	>1,000	149	143
Switched MOUD Program Type During Implementation		NO	NO	NO	NO	YES
Setting <sup>*18</sup>	Major Metro*	Major Metro*	Major Metro*	Large Metro**	Nonmetro***	Small Metro****
Monthly Average Number of Patients Receiving MOUD						
Methadone	19	11	21	48	21	6
Buprenorphine	32	26	44	75	11	6
Extended-Release Naltrexone	5	1	3	2	2	1
Total Monthly Average Number of Patients Receiving MOUD	56	38	68	125	34	12

\*Major Metropolitan area is considered a population of 1 million or more

\*\*Large Metropolitan area is a population of 250,000-1 million

\*\*\*Nonmetro area has a population of 20,000 or more

\*\*\*\*Small metro has a population fewer than 250,000



Substance Use Disorder, HCV, and HIV

### Model 1: Contract for Methadone Maintenance

- Certified vendor hired to deliver and administer methadone daily for incarcerated individuals who entered the facility with an existing prescription from a community provider
- Clinical jail staff were in charge of facilitating induction and/or maintenance of buprenorphine and extended-release naltrexone



### Model 1: Contract for Methadone Maintenance

	Site A	Site B
Fixed-Start Up	\$1,351,271	\$332,968
Costs in Previous Model	\$1,324,895	
Renovation		\$65,277
Meetings and Trainings	\$21,776	\$39,829
Supplies and Equipment	\$4,600	\$227,862
Time-Dependent	\$650,083	\$433,191
Vendor/Accreditation Fees	\$596,575	\$382,044
Meetings and Trainings	\$53,508	\$51,147
Variable	\$298,206	\$213,427
OUD Medications <sup>1</sup>	\$20,872	\$13,687
OUD Assessments & Testing Supplies	\$80,466	\$64,708
Medication Dosing	\$180,728	\$135,032
Counseling (Group & Individual)	\$16,140	

Implementation	\$2,299,560	\$979 <i>,</i> 586
Sustainment	\$948,289	\$646,618
Annual Per Patient	\$1,411	\$1,418
Monthly Per Patient	\$117	\$118

- Site A initially implemented Model 2 and accounted for ~\$1.3 million
- Site B renovated an existing space to accommodate MOUD



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# Model 2: Contract for All Induction & Maintenance

 Hired a certified vendor to operate an in-house opioid treatment program (OTP) to oversee the induction and maintenance of all three types of MOUD



# Model 2: Contract for All Induction & Maintenance

	Site C	Site D
Fixed-Start Up	\$893,371	\$1,857,376
Dispensary	\$834,618	\$973 <i>,</i> 955*
Meetings & Trainings specifically for Jail staff	\$10,551	\$838,424
Supplies/equipment	\$13,000	
Interim Medication Delivery	\$23,202	
Information Technology Services	\$12,000	\$44,997
Time-Dependent	\$1,695,432	\$2,268,157
Vendor/Accreditation Fees	\$1,602,800	\$2,235,792
Meetings and Trainings	\$81,112	\$32 <i>,</i> 365
Information Technology Services	\$11,520	
Variable	\$286,946	\$70 <i>,</i> 875
OUD Treatment	\$259 <i>,</i> 053	\$16,510
Medication Dosing	\$15,214	\$15,071
Counseling (Group & Individual)	\$12,679	
Miscellaneous Costs		\$39,294

Implementation	\$2,875,749	\$4,196,408
Sustainment	\$1,982,378	\$2,339,032
Annual Per Patient	\$2,429	\$1,559
Monthly Per Patient	\$202	\$129

- Site C used outside vendors to create a dispensary and used the contracted vendor's software for MOUD status; Site D used their own jail staff
- While the dispensary was being built in Site C, the jail had an interim medication delivery
- Site C paid an administrative fee to operate the OTP and an additional per-patient cost for medication and dosing
- Site D Bundled services included vendor staffing, medication, counseling, dosing, and discharge planning



# Model 3: Jail OTP certification

- Underwent the OTP certification process to operate their own in-house OTP
- Manage all factors relating to the MOUD program, including induction and maintenance for all medications



### Model 3: Jail OTP certification

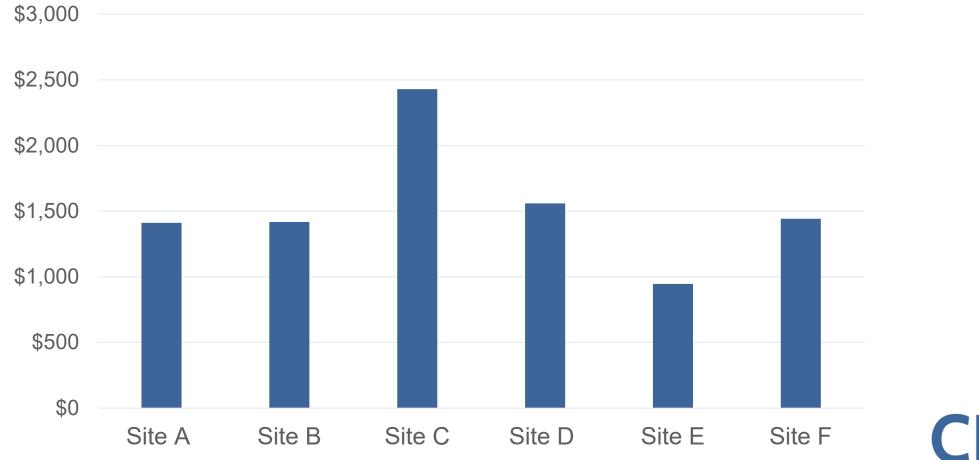
	Site E	Site F
Fixed-Start Up	\$120,573	\$733,651
Costs in Previous Model		\$438,885
OTP Application Process	\$62 <i>,</i> 565	\$130,439
Meetings and Trainings	\$41,508	
Supplies and Equipment	\$16,500	\$164,327
Time-Dependent	\$82,610	\$55,902
Accreditation Fees	\$6 <i>,</i> 865	\$7,395
Renewal of Accreditation	\$13,440	
Meetings and Trainings	\$59 <i>,</i> 377	\$47,737
Information Technology Services	\$2,928	\$770
Variable	\$303,629	\$151,785
OUD Medications	\$34,989	\$4,372
OUD Assessments & Testing Supplies	\$100,871	\$39,004
Medication Dosing	\$152,764	\$102,627
Counseling (Group & Individual)	\$15,005	\$5,782

Implementation	\$506,812	\$941,338
Sustainment	\$386,239	\$207,687
Annual Per Patient	\$946	\$1,442
Monthly Per Patient	\$79	\$120

- Site E initially certified as an OTP and obtained the costs for a renewal process of OTP
- Site F initially contracted with a vendor which amounted to \$438,885
  - Was in the process of renewing their license, so were unable to obtain that cost



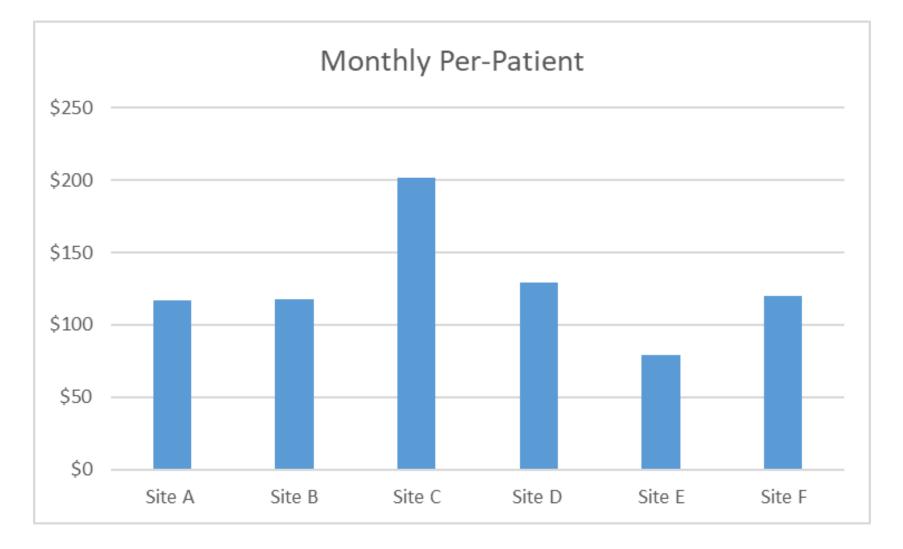
### **Annual Per Patient Cost Across Sites**





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### Monthly Per Patient Cost Across Sites





### Insights

### (1) Engage jails with MOUD experience & similar characteristics (e.g., average daily census, number of facilities, proximity to OTP)

- Could reduce likelihood of switching models
- Inform processes, such as those required for licensing and accreditation
- Vendor recommendations

#### (2) Build relationships with your local OTPs

· Open communication and knowledge of structure/business model can facilitate patient transitions upon release

### (3) Understand vendor services and pricing options

- E.g., administrative fee + fee-for-service, vs. bundled services (i.e., will vendor ensure medication continuity post release?)
- If bundled, which services are included (e.g., vendor staffing, medication, counseling, dosing, discharge planning)
- Use vendor IT systems, vs. creating/purchasing your own

#### (4) Educate/Train staff on OUD

Think carefully about who should attend, who should lead the trainings, how frequently should they occur, etc.

#### (5) Space considerations

- Are there specific requirements for the models being considered
- Costs associated with a dedicated dispensary space, vs. multipurpose room, vs. medicine cart



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# THANK YOU! Any Questions?

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# Factors contributing to the expansion of medication for opioid use disorder (MOUD) within the New Hampshire Department of Corrections (NH DOC)

### Dr. Lisa A. Marsch Dartmouth College

### **Dr. Pracha Peter Eamranond**

New Hampshire Department of Corrections, Wexford Health, Harvard Medical School



AT UNE CONTRACTOR

### NIH HEAL INITIATIVE

JUSTICE COMMUNITY OPIOID INNOVATION NETWORK (JCOIN)

### ACKNOWLEDGEMENTS

Funding from NIDA (NIH HEAL) U01DA047982 Contact PI: Dr. Joshua D. Lee.

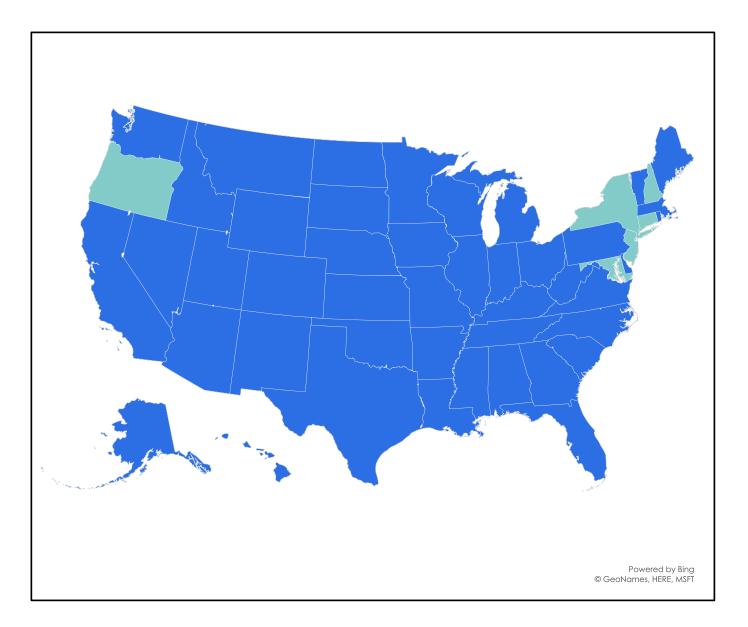
MPIs: Dr. David Farabee; Dr. Jan Gryczynski; Dr. Lisa A. Marsch; Dr. Amesika Nyaku; Dr. Donald Reeves; Dr. Sandra A. Springer; Dr. Elizabeth N. Waddell.

### **PRESENTATION AIM**

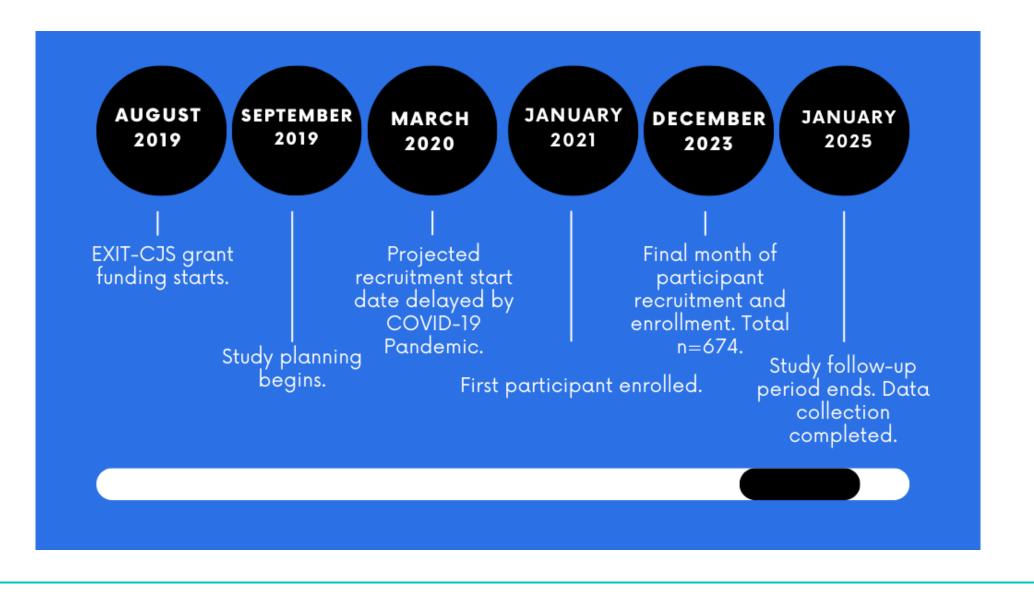
To describe the confluence of factors contributing to the expansion of the medication for opioid use disorder (MOUD) program at the New Hampshire Department of Corrections (NHDOC) and the synergy between NHDOC program expansion and the "Long-acting buprenorphine vs. naltrexone opioid treatments in criminal justice system-involved adults (EXIT-CJS)" study implementation

### EXIT-CJS STUDY OVERVIEW

- Multistate randomized controlled trial with quasi-experimental, treatment-as-usual arm (PI: Joshua D. Lee)
- Aim: Compare the effectiveness of two MOUD for persons involved in the carceral system:
  - Extended-release buprenorphine (XR-B; Sublocade)
  - Extended-release naltrexone (XR-NTX; Vivitrol)



### **EXIT-CJS STUDY TIMELINE**



# NEW HAMPSHIRE SITE OVERVIEW

• Partnership between:

O Dartmouth College (research team)

• New Hampshire Department of Corrections (recruitment, carceral treatment provider)

• ROAD to a Better Life (community treatment provider)

### COLLABORATED WITH NHDOC LEADERSHIP

Collaborated with leadership to plan study.

Received support from NH Attorney General's office

**Executed BAA** 

### PROVIDER TRAINING AND ENGAGEMENT

Bi-weekly Zoom meetings with medical team leadership.

Annual in-person trainings.

Bi-monthly study clinician call.

### STAFF TRAINING AND ENGAGEMENT

Visited NHDOC facilities and engaged in planning with staff.

Held annual in-person trainings.

STUDY

IMPIFMENTATION

AT NHDOC

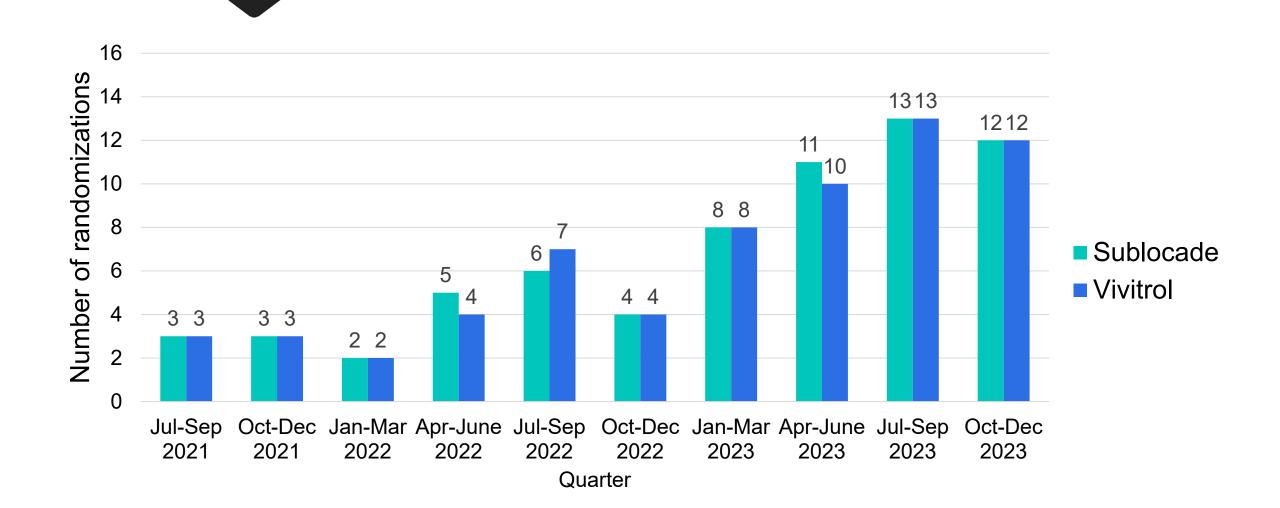
Weekly Zoom meeting.

### PATIENT NAVIGATOR

Located onsite at NHDOC facilities to answer staff/provider questions and meet with participants

Liaison between participants, NHDOC, and research team.

# Quarterly randomizations to XR-B and XR-NTX in the NH EXIT-CJS study site: 2021-2023



## NHDOC MOUD PROGRAM

• Comprehensive program to:

• Screen all individuals for OUD

• Provide behavioral treatment

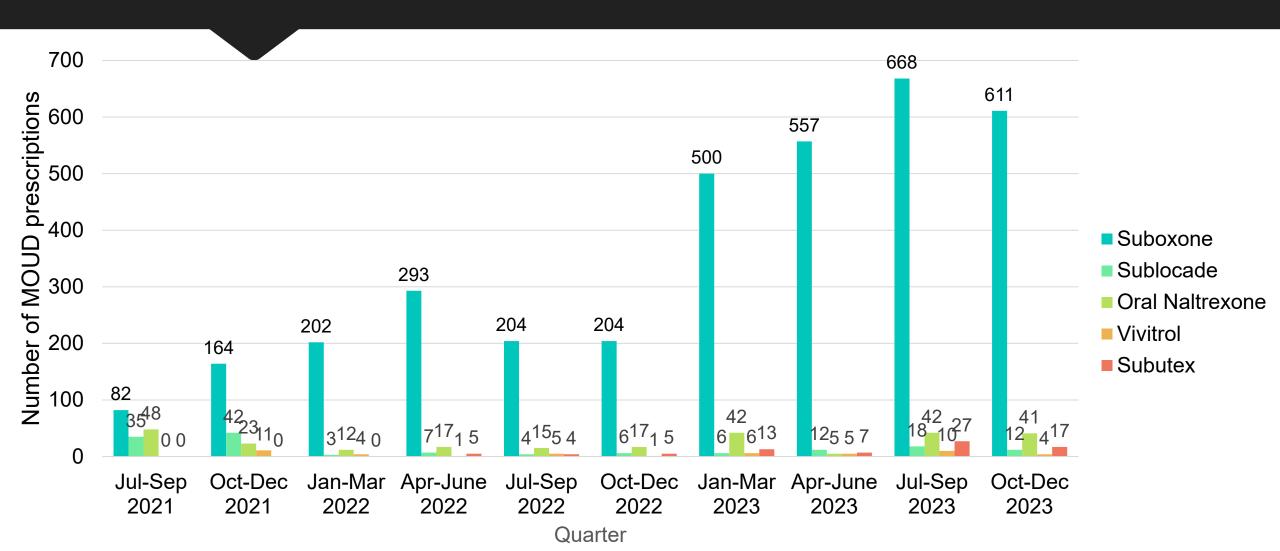
• Offer treatment with FDA-approved medications

• Provide linkage to community treatment at release

 Multidisciplinary MOUD Team meets weekly to discuss cases, program operations, and policy
 Includes medical, mental health, nursing, pharmacy,

and security staff

# Quarterly MOUD prescriptions at the New Hampshire Department of Corrections (NHDOC): 2021-2023



# FACTORS CONTRIBUTING TO NHDOC MOUD PROGRAM EXPANSION

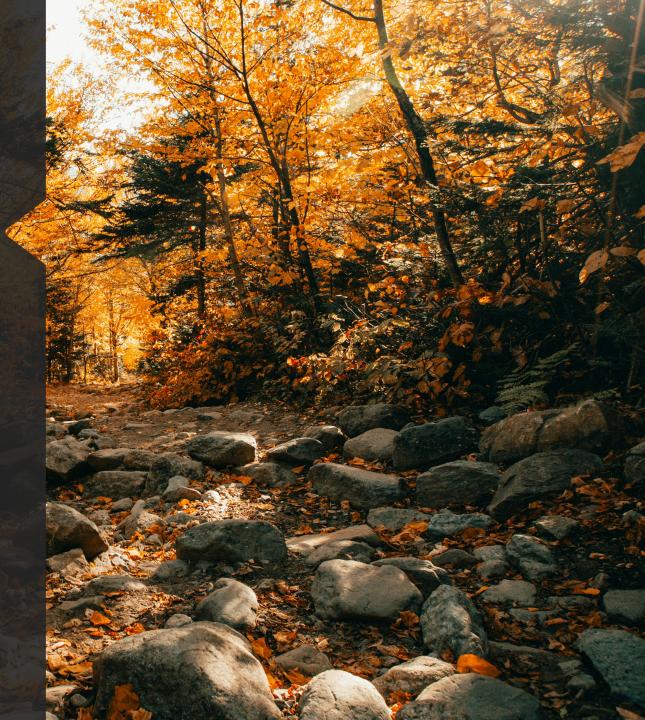
TYPE OF FACTOR								
External factors	<ul> <li>Elimination of the DATA-Waiver (X-Waiver) Program.</li> <li>Expanded funding for MOUD through State Opioid Response grant.</li> </ul>							
Internal factors	<ul> <li>Support from NH DOC leadership, including Medical &amp; Forensics and the Commissioner's Office.</li> <li>Culture change within the NHDOC facilities through education provided by the NHDOC MOUD Team and the EXIT-CJS study.</li> <li>Expansion of the medical and mental health workforce.</li> <li>Engagement of experts in addiction treatment through the EXIT-CJS study.</li> <li>Simultaneous ramp-up of EXIT-CJS recruitment bringing awareness to patients and staff.</li> </ul>							
Individual factors	<ul> <li>Shift in staff perceptions of MOUD via education of security, nursing, administration, others.</li> <li>Programmatic focus on overcoming individual challenges such as dealing with drug diversion, addressing knowledge deficits in prescribing, weekly case reviews on specific barriers to care</li> <li>Enhanced trust in MOUD from residents through engagement with the EXIT-CJS study.</li> </ul>							

# CONCLUSIONS

 Comprehensively addressing barriers at multiple levels is necessary to effectively expand MOUD prescribing in carceral settings.

 Synergy with the EXIT-CJS study also contributed to program expansion.

 Partnerships with academic institutions and research teams can support MOUD program expansion.

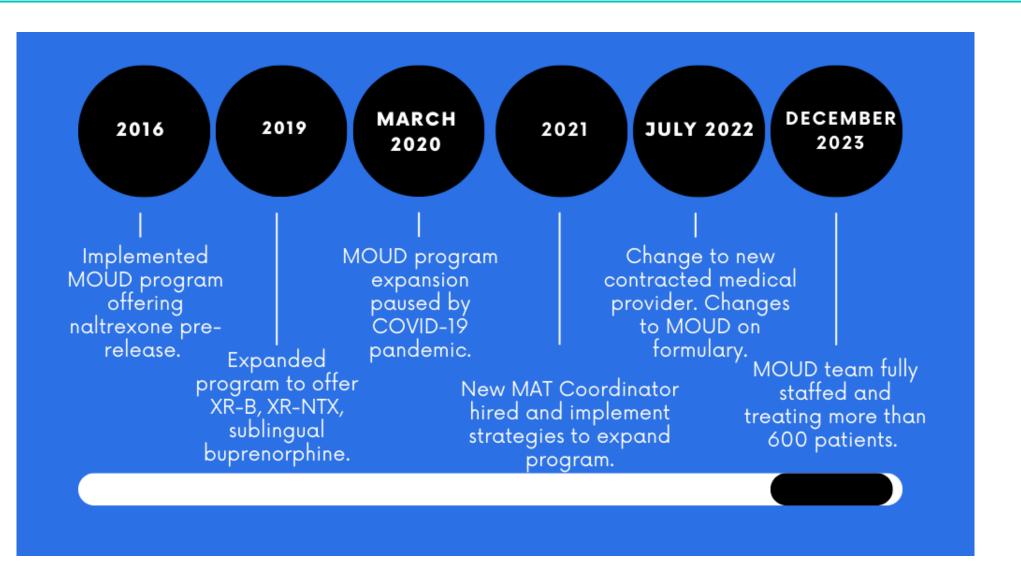




# Thank you!



### NHDOC MOUD PROGRAM TIMELINE



A Naturalistic Study of Individuals Involved in the Justice System Who Experienced Both Formulations of Extended-release Buprenorphine

> T. R. Blue<sup>1</sup>, M.S. Gordon<sup>1</sup>, F.J. Vocci<sup>1</sup>, M.J. Fishman<sup>3</sup>, S.G. Mitchell<sup>1</sup>, & K. Wenzel<sup>2</sup> <sup>1</sup>Friends Research Institute, Baltimore, MD <sup>2</sup> Mountain Manor Treatment Center, Baltimore, MD





FRIENDS RESEARCH INSTITUTE

Steering Committee for the Justice Community Opioid Innovation Network (JCOIN) on June 11-13 in Bethesda, MD

> National Institutes of Health (NIH) National Institute on Drug Abuse (NIDA) Grant Number: 1UG1DA050077-01

### **Acknowledgments/Disclosures**



- Study funded by the National Institutes of Health, National Institute on Drug Abuse Grant # UG1DA050077 (MPI contact: Michael S. Gordon)
- Drs. Gordon, Vocci and Blue receive in-kind study drug from Braeburn and Alkermes
- Dr. Mitchell receives in-kind study drug from Braeburn
- Dr Fishman has been a consultant for Indivior, Alkermes, Drug Delivery LLC, has been the recipient of a research grant from Alkermes, and has received study drug from Alkermes, Indivior and Braeburn.

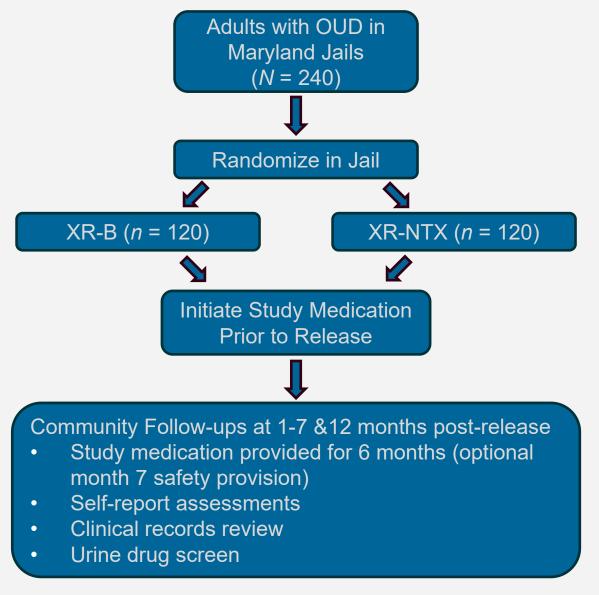
### **Background – XR-B**



- Extended-release injectable buprenorphine (XR-B) is a promising intervention for the treatment of opioid use disorders (OUDs) in carceral settings because it cannot be diverted and does not require daily administration.
- Monthly formulations may improve medication coverage and continuity of care during community re-entry, when individuals are at the highest risk for overdose.
- Currently, there are two FDA approved formulations of XR-B available in the U.S.
  - SUBLOCADE was approved by the FDA in 2017 and comes in two dosage strengths (300mg and 100mg) delivered subcutaneously.
  - BRIXADI was approved by the FDA in May of 2023, is administered by subcutaneous injections, and is available in weekly (8mg, 16mg, 24mg, 32mg) and monthly (64mg, 96mg, 128mg) strengths.
- Compared to SUBLOCADE, BRIXADI has a smaller injection volume and no requirement for refrigeration.

### **Background – Parent Study**





(See Gordon et al. 2021 for more detail.)

### **Background – Parent Study**



A Comparative Effectiveness Trial of Extended-Release Naltrexone vs. Extended-Release Buprenorphine with Individuals Leaving Jail

**Aim 1.** To determine the effectiveness of XR-B compared to XR-NTX in terms of:

**Primary Outcome.** (a) pharmacotherapy adherence (number of monthly injections received).

**Secondary Outcomes.** (b) illicit opioid urine test results; (c) self-reported illicit opioid use; (d) overdose events (non-fatal and fatal); (e) quality of life (i. physical health; ii. mental health); (f) HIV risk behaviors (i. sexual behavior; ii. needle use or sharing); and (g) criminal activity (i. crime days; ii. re-arrest; iii. re-incarceration).

### **Present Study – Premise**

- In the Spring of 2022, our remaining supply of BRIXADI was exhausted/expired.
   Because BRIXADI was not fully FDA approved there was a lengthy process to import BUVIDAL (European trade name for BRIXADI) to bridge the gap in our study supply.
- Recruitment was halted in April of 2022, but 12 participants were due for their monthly BRIXADI injection. With IRB approval, we offered them SUBLOCADE instead.
- After we obtained more BRIXADI, all 12 resumed BRIXADI treatment the following month.
- We conducted semi-structured interviews with 10 of these participants to gauge their experiences with both medications (2 could not be located for follow-up).
- Because of the limited uptake of BRIXADI at the time, these individuals were some of the only people with lived experience in carceral settings in the U.S. to have received both medications.



### Interviews



- Previous experience with SUBLOCADE (yes/no)
- Reaction to being told there would be a switch in medication
- Preference for BRIXADI or SUBLOCADE at the time of the switch
- Overall experience with the injection (any difference)
- Cravings
- Medication wearing off
- Withdrawal symptoms
- Helpfulness with recovery
- Medication preference for future treatment (BRIXADI vs. SUBLOCADE)

### **Participants**



Age	Race	Sex	Carceral Status at enrollment	Days Incarcerated at baseline	Previous Experience with Sublingual Bup	Previous Experience with SUBLOCADE
22.60	W	Μ	Pre-trial	115.00	Yes	No
24.94	W	Μ	Sentenced	77.00	Yes	No
23.26	W	М	Pre-trial	153.00	No	No
44.99	W	М	Sentenced	84.00	No	Yes
43.47	W	F	Pre-trial			No
45.76	W	М	Pre-trial	83.00	Yes	No
38.41	W	Μ	Pre-trial	79.00	Yes	No
36.78	В	Μ	Pre-trial	108.00	Yes	No
40.88	W	F	Sentenced	68.00	Yes	No
38.41	W	Μ	Pre-trial	789.00	No	No



- Previous experience with SUBLOCADE
  - Participant #4 reported previous experience with SUBLOCADE prior to enrolling in this study
  - This participant reported a positive prior experience with the medication and reported that they only discontinued the medication because they were arrested and incarcerated



- Reaction to being told there would be a switch in medication
  - Participants were generally not concerned about switching between medications.
  - However, one participant was "not happy" [#5] with the switch, and another was "confused" [#8] by the switch
  - The participant who had received SUBLOCADE previously was "completely fine" [#4] with switching medications



- Preference for BRIXADI or SUBLOCADE at the time of the switch
  - Five-point Likert scale ranging from "strongly prefer SUBLOCADE" to "strongly prefer BRIXADI" with three being "no preference"
  - Five indicated that they "strongly preferred" and one indicated that they "somewhat preferred" BRIXADI
  - Three participants indicated that they had "no preference"
  - The participant with previous experience with
     SUBLOCADE indicated that they "somewhat preferred"
     SUBLOCADE



- Overall experience with the injections (any differences)
  - Nine out of 10 participants reported differences between the feelings of the BRIXADI and SUBLOCADE injections
  - All nine reported greater discomfort and pain with the SUBLOCADE injection compared with the BRIXADI injection
  - Two participants indicated that they had injection site reactions to SUBLOCADE that they did not have with BRIXADI such as "bruising, swelling, and itching" [#5] and a "burning feeling" [#1]
  - Multiple participants reported feeling a "lump" or a "knot" after the SUBLOCADE injection
  - Five-point Likert scale ranging from "strongly prefer SUBLOCADE" to "strongly prefer BRIXADI" with three being "no preference"
  - seven reported they "strongly preferred" BRIXADI, 2 reported "no preference", and the one participant with previous SUBLOCADE experience reported "somewhat preferring" SUBLOCADE



- Cravings
  - Five-point Likert item about cravings, ranging from "much stronger cravings on SUBLOCADE" to "much stronger cravings on BRIXADI" with three being "no difference in cravings
  - half of the participants reported "no difference" in cravings between the two medications
  - one participant reported slightly more cravings on BRIXADI, and one participant reported slightly more cravings on SUBLOCADE
  - Three reported no feelings of cravings on either medication



- Medication wearing off
  - Five-point Likert item about medication duration ranging from "SUBLOCADE wore off much more quickly" to "BRIXADI wore off much more quickly" with three being "SUBLOCADE and BRIXADI wore off in the same way"
  - four participants reported that they felt BRIXADI wear off "somewhat quicker", while two reported that they felt SUBLOCADE wore off "somewhat quicker" than the other medication
  - Two participants reported that the two medications wore off "in the same way"
  - Two participants reported not feeling either medication wear off before their next injection



- Withdrawal Symptoms
  - Five-point Likert item about symptoms ranging from "many more withdrawal symptoms on SUBLOCADE" to "many more withdrawal symptoms on BRIXADI" with three being "no difference in withdrawal symptoms"
  - four participants reported no differences between the medications in terms of their withdrawal symptoms (if any were experienced), while three reported no withdrawal symptoms on either medication
  - Two participants reported feeling a few more withdrawal symptoms while on BRIXADI compared to SUBLOCADE, including "Cramping in legs when sleeping" [#3] and "Sweating, headaches, hot and cold spells" [#2]
  - One participant reported experiencing a few more symptoms while on SUBLOCADE compared to BRIXADI, including "Nausea and headaches" [#1]



- Helpfulness with recovery
  - Five-point Likert item about the helpfulness of the medications with their recovery ranging from "SUBLOCADE was much more effective" to "BRIXADI was much more effective" with three being "equally effective"
  - Three participants reported that BRIXADI was "much more effective" in helping with their recovery, while one reported that BRIXADI was "somewhat more effective"
  - The other six participants said the medications were "equally effective"



- Medication preference for future treatment
  - five-point Likert item about which medication they would prefer in the future ranging from "strongly prefer SUBLOCADE" to "strongly prefer BRIXADI" with three being "no preference"
  - seven participants indicated that they "strongly prefer" BRIXADI to SUBLOCADE for their OUD treatment
  - For one participant "BRIXADI lasted longer" and they experienced "no withdrawal symptoms" [#1]
  - One participant reported that "BRIXADI was more effective in helping with cravings" and that "it stung less and lasted longer than SUBLOCADE" [#6]
  - Another participant "did not like the side effects of SUBLOCADE" and felt that the "BRIXADI needle hurts less" [#5]
  - Two participants expressed no preference between the two medications
  - The participant with previous SUBLOCADE experience "somewhat preferred" SUBLOCADE because "BRIXADI wore off faster which meant more injections" [#4]

### Discussion



- We were able to successfully transition 12 participants from BRIXADI to SUBLOCADE and back to BRIXADI
- Most participants expressed a preference for BRIXADI in the future
- several participants indicated that they believed BRIXADI was more effective at helping with their recovery
- Reports of greater injection site discomfort with SUBLOCADE may be driving this effect.
  - In clinical settings, the issue of injection site discomfort could be addressed through the use of topical or sub-cutaneous anesthetic
- While there was no overall difference between the two formulations in terms of self-reported cravings or withdrawal symptoms, four participants reported that BRIXADI wore off somewhat more quickly and two participants reported that SUBLOCADE wore off somewhat more quickly
  - In clinical settings, these issues could be addressed through the use of supplemental doses of weekly BRIXADI formulations or by increasing injection frequency (for patients on BRIXADI) or supplemental prescriptions of (SL-B) (for patients on either medication)

# Thank you!





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> National Institutes of Health (NIH) National Institute on Drug Abuse (NIDA) Grant Number: 1UG1DA050077-01

Factors Associated with Alignment Between MOUD Preference and Treatment for People with OUD who have been Incarcerated

> Lisa Puglisi, MD Associate Professor SEICHE Center for Health and Justice Yale University TCN PATHS (Wang) Yale Site







### Acknowledgements

We would like to acknowledge and thank:

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- Dr. Haseena Rajeevan
- The team at Friends Research Institute
- The team at NYU Langone
- The team at MAARC
  - Phil Schumm
  - Mike Kranz

### Declarations

Conflicts of Interest. The authors declare that they have no conflict of interest.

## Background

- For MOUD in non-incarcerated people, treatment preferences have been identified and include in part route of administration and symptoms during induction
- In carceral settings patient preferences for MOUD are rarely considered or core to program implementation
- Newer qualitative work in carceral settings shows patient preference in medication is affected by side effects, route of administration, delivery in the community, and stigma.
- Preference likely affects treatment retention even post incarceration
- In this study, we seek to investigate the factors associated with MOUD participant preference alignment among individuals recently released from jails.

Muthulingam JSAT 2023, Puglisi Current Addiction Reports 2019, Kaplowitz JSAT 2022

### Hypothesis

Overall, we hypothesize that having current treatment aligned with preference will be associated with increased retention in care post-release.

At baseline, we are starting by looking at what factors are associated with alignment of treatment with stated preference.

### TCN PATHS: STUDY DESIGN and Hypotheses

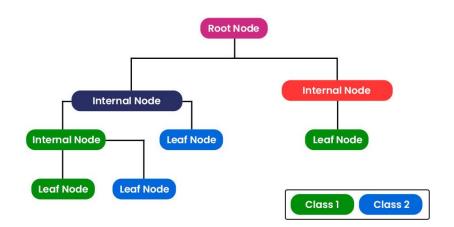
Bridgeport TCN on OUD outcomes TCN or OUD outcomes	SPC TCN SPC	Caguas, PR	Minneapolis, MN	New York City, NY
Aim 1: TCN impact on       TCN = ↑ OUD treatment engagement and retention, MOUD retention, ↓         OUD treatment       Mediators: social support, housing stability, food insecurity, criminal justice				
Aim 2: TCN cost- effectiveness analysis	TCN =   cost-per-OALY   societal costs			
Aim 3: TCN facilitators and barriers	<u>Quantitative</u> ILA 🕺 🖈 🕇		Qualitativ	· *

## Methods- Variable Definition

- Patient Preference: Which OUD medication treatement type would you most prefer to receive if it were available to you now?
- Treatment history: Which medications are you currently on to treat OUD?
- Demographic characteristics
- Opioid Severity:
  - Last opioid overdose
  - Last used opioid
  - Last withdrawal
  - Last drug use
- CJS History
  - Age first arrest
  - Age first convicted
  - Jail length

## Methods-Statistical Analysis: Classification and Regression Trees (CART)

- A decision tree algorithm used in machine learning for classification and predictive modeling
- Can capture complex non-linear relationships and interactions between input variables
- Can handle both numerical and categorical data



## Results

- 90% of pt have been on MOUD previously
- Buprenorphine/Suboxone was the preferred MOUD (52%) and 78% of those preferred had received treatment
- 50% of pt had their preferred MOUD align with their MOUD tx Alignment by site:
  - MN 53.4%
  - NC 50%
  - CT-36.7%
- Factors associated with better alignment:
  - Any history of withdrawal
  - Last opioid use not recent (not in the past month)
  - Current jail length <= 50 days
  - Race (among current jail length <= 50.5, White is more likely than other race to align MOUD for longer stays Black and other race are more likely to align)
  - Last opioid overdose more than a year ago.

## **Next Steps**

- Collaborating with NYU and FRI Hubs through the MAARC
- Additional core measures
- Manuscript

## Questions?

## Jail-based MOUD and post-release linkage to care reduces opioid-related overdose mortality in in-silico modeling and analysis

Presented by Jonathan Ozik - The University of Chicago / Argonne

In collaboration with:

Eric Tatara, Charles Macal – University of Chicago / Argonne

Harold Pollack, John Schneider, Anna Hotton, Ellen Almirol, Olga Morozova – University of Chicago

Samuel Friedman – NYU Grossman School of Medicine

Basmattee Boodram, Mary Ellen Mackesy-Amiti, Larry Ouellet – University of Illinois Chicago

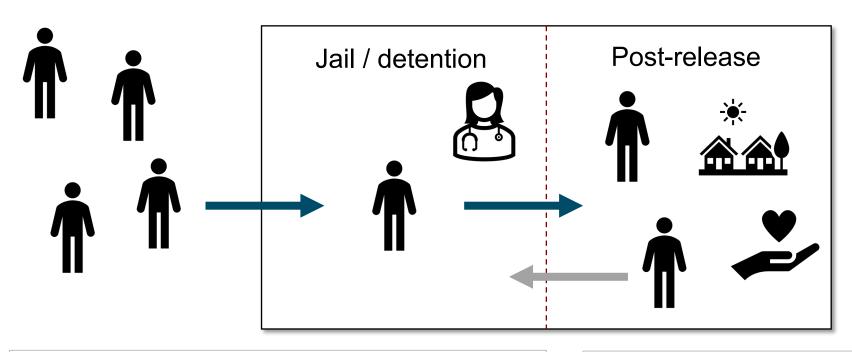
Elizabeth Salisbury-Afshar – University of Wisconsin

Nina Harawa – David Geffen School of Medicine at UCLA





## Modeling jail-based MOUD initiation with the Justice-Community Circulation Model (JCCM)



#### **Policy space (future work)**

- Sustainability of grant funding
- Support for sustained investments to support this population

#### Institutional factors

- How long individuals need to wait for OUD screening?
- What MOUDs are locally available to persons with OUD?
- Post-release linkage to care

#### Local contextual factors

- Rates of Opioid-related overdose in local population
- Number of local population with OUD
- Recidivism
- Community-based naloxone distribution

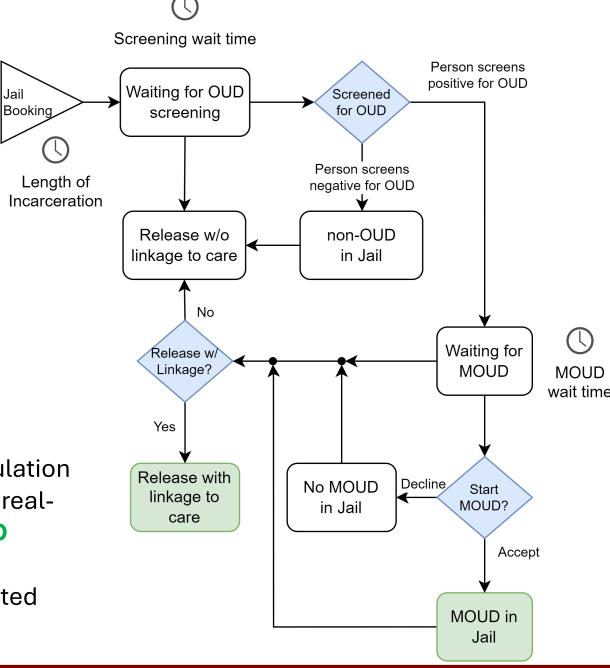
## We designed the JCCM to address the following research questions

- What is the impact on OD mortality risk of intervening at various points in the MOUD treatment process - e.g., increasing the ability of jails to offer treatment, intervening at an optimal time during jail stay - to increase the proportion who initiate OUD from a baseline level to a higher level?
- 2. What is the impact on OD mortality risk of increasing the proportion who **initiate treatment in jail**? With different types of **linkage to care** post-release?
- 3. What is impact on OD mortality risk of offering **different types of OUD treatments**, would this increase the proportion of people starting treatment if they had more acceptable options?



### Modeling Jail-Based **MOUD** Initiation

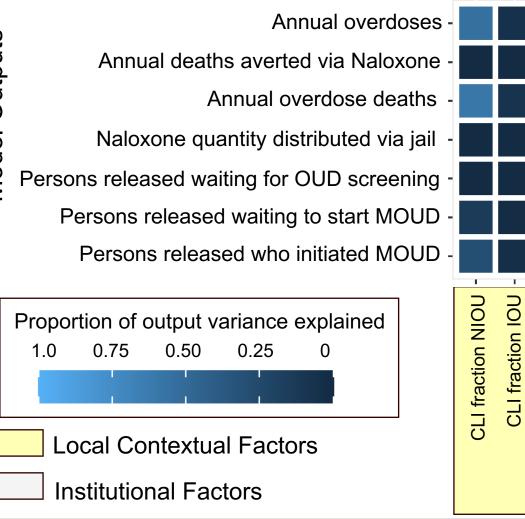
- The JCCM includes state transitions for determining what happens to persons at time of booking into jail.
- Key modeled institutional factors (blue diamonds):
  - Post-booking OUD screening rate
  - Percent of persons who initiate MOUD in jail
  - Wait times for OUD screening and MOUD initiation post-booking
- The modeled institutional factors are varied via simulation sensitivity analysis to examine a range of potential realworld implementations that affect jail-based MOUD initiation and post-release linkage to care (green rectangles), and ultimately, post-release opioid-related overdose mortality.



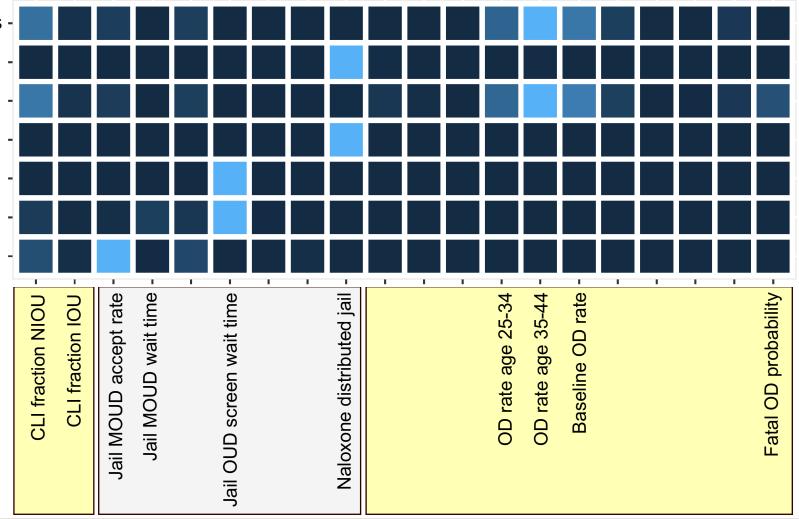
Jail

## Sensitivity analysis identifies which model input parameters have the greatest influence on model output variance

Model Outputs



Model Input Parameters

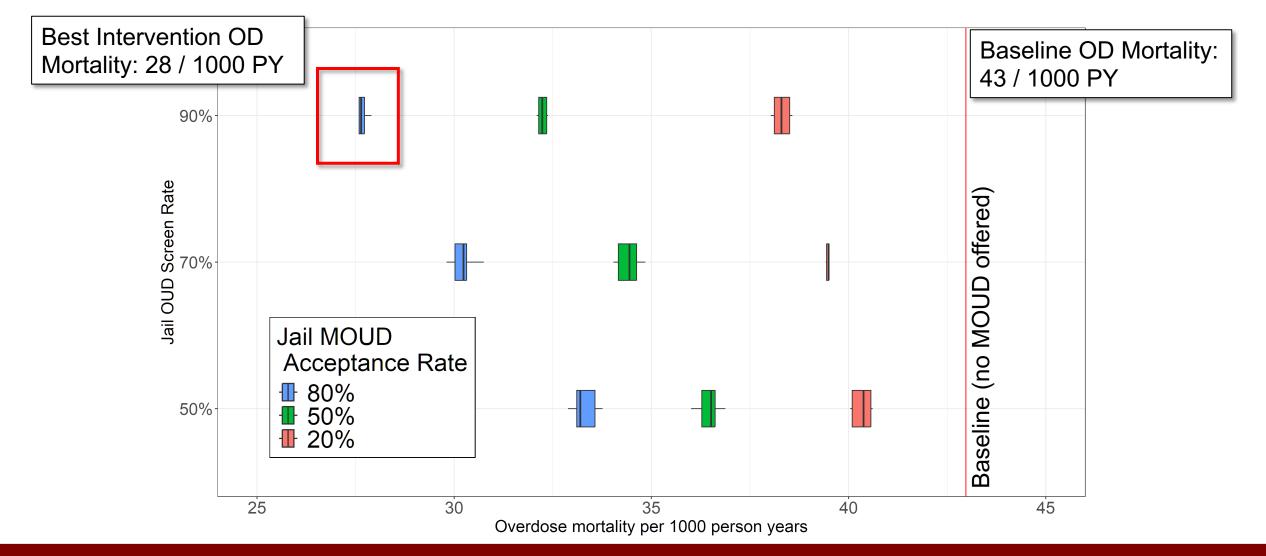


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## Sensitivity analysis helps to identify which model input parameters have the greatest influence on model outputs

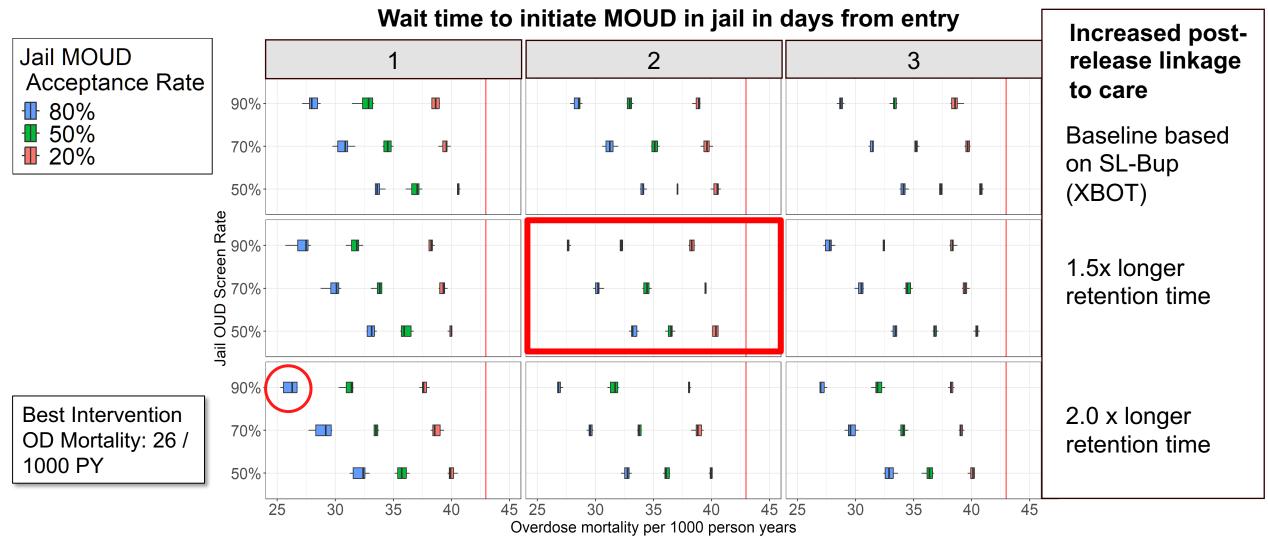
Outcome	Greatest impact - local	Greatest impact - institutional
Overdoses (fatal and non-fatal) among persons released from jail	<ul> <li>Baseline overdose rate</li> <li>Percent CLI with OU/D</li> <li>Age-related OD risks</li> </ul>	<ul> <li>MOUD acceptance rate in jail</li> <li>OUD screening rate in jail</li> <li>Linkage to care post release</li> </ul>
Overdose deaths among released persons from jail	<ul> <li>Baseline overdose rate</li> <li>Probability that overdose will be fatal</li> </ul>	<ul> <li>MOUD acceptance rate in jail</li> <li>OUD screening rate in jail</li> <li>Linkage to care post release</li> <li>Naloxone distribution at release</li> </ul>

## Increased jail-based OUD screening and initiation reduces post-release overdose mortality with XR Buprenorphine



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#### Reduced waiting time, increased screening rate, and post-release linkage to care increase the effectiveness of MOUDs for reducing postrelease Opioid Overdose (OOD) mortality



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## Conclusions

- Our simulation studies show that when XR-buprenorphine is offered, estimated OOD mortality can be markedly reduced given high rates of OUD screening and MOUD acceptance.
- **OOD mortality rates were reduced by 40%** relative to baseline, to 26 deaths per 1,000 person years given 90% rates of OUD screening and 80% rates of MOUD acceptance.
- Improved post-release linkage to care that enhances MOUD time-on-treatment (adherence) can further reduce overdose mortality.
  - This highlights the need for people to easily continue medication post release.
  - Medicaid waivers for persons leaving jail can help with linkage to post-release care.
- Changes in how jails organize the **administration of MOUDs can have important effects** on outcomes, though local contextual factors could impact the extent of those effects.
- Our next steps include a comparative analysis to determine if different MOUDs are better or worse at reducing OOD mortality under different combinations of institutional and local contextual factors.



## Thank you!

# The next session will begin at 3:00.

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