NIH Pragmatic Trials Collaboratory Grand Rounds

January 24, 2025

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HEALing Communities Study
Massachusetts

The HEALing Communities Study – 10 Million People, 67 Communities

A Community-based Cluster Randomized Trial to Reduce Opioid Overdose Deaths

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

No Disclosures to Report

Introduction

- Opioid overdose (OD) mortality - 8,050 (1999) to 82,136 (2022)
- US Surgeon General (2016) & National Academy of Medicine (2017) urged medical professionals to address the opioid crisis through:
  - Advocacy
  - Stigma reduction
  - Uptake of opioid use disorder (OUD) treatment
  - Safer opioid prescribing
  - Evidence-based practices (EBPs) to prevent or reverse opioid OD

RFA-DA-19-016

Department of Health and Human Services

Part 1. Overview Information

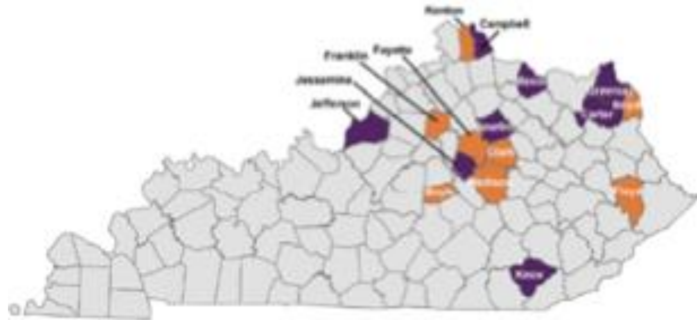
Participating Organization(s)	National Institutes of Health (NIH) Substance Abuse and Mental Health Services Administration (SAMHSA)
Components of Participating Organizations	National Institute on Drug Abuse (NIDA)
Funding Opportunity Title	HEALing Communities Study: Developing and Testing an Integrated Approach to Address the Opioid Crisis (Research Sites) (UM1 - Clinical Trial Required)

HEALing Communities Study (HCS) Goal

To reduce opioid OD deaths through implementation of evidence-based practices

- Increase overdose education & naloxone distribution (OEND)
- Increase access to medications for opioid use disorder (MOUD)
- Increase safer opioid prescribing & dispensing practices

HEALing Communities Study



Intervention

Control

April 2019: Funded by NIDA and SAMHSA

67 Communities:

- Implemented in 4 states
- Total population 10 million

Primary Outcome:

- Opioid overdose fatalities

Secondary Outcomes:

- Naloxone distribution
- Access/utilization of MOUD

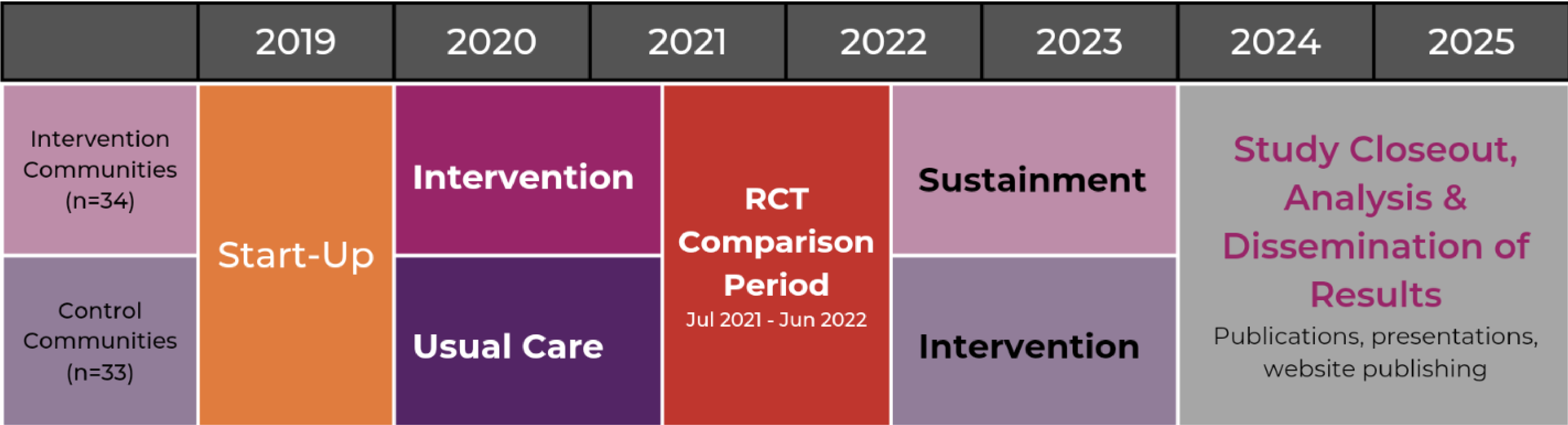
Baseline Communities Characteristics (2019)

	Overall	KY	MA	NY	OH
Total HCS community population	10,144,261	1,823,027	875,086	2,357,192	5,088,956
Opioid overdose death rate (per 100,000)	33.4	38.2	40.6	28.3	27.5
Number of communities by rural vs urban	29 rural 38 urban	7 rural 9 urban	5 rural 11 urban	8 rural 8 urban	9 rural 10 urban
Medicaid expansion?		Yes	Yes	Yes	Yes

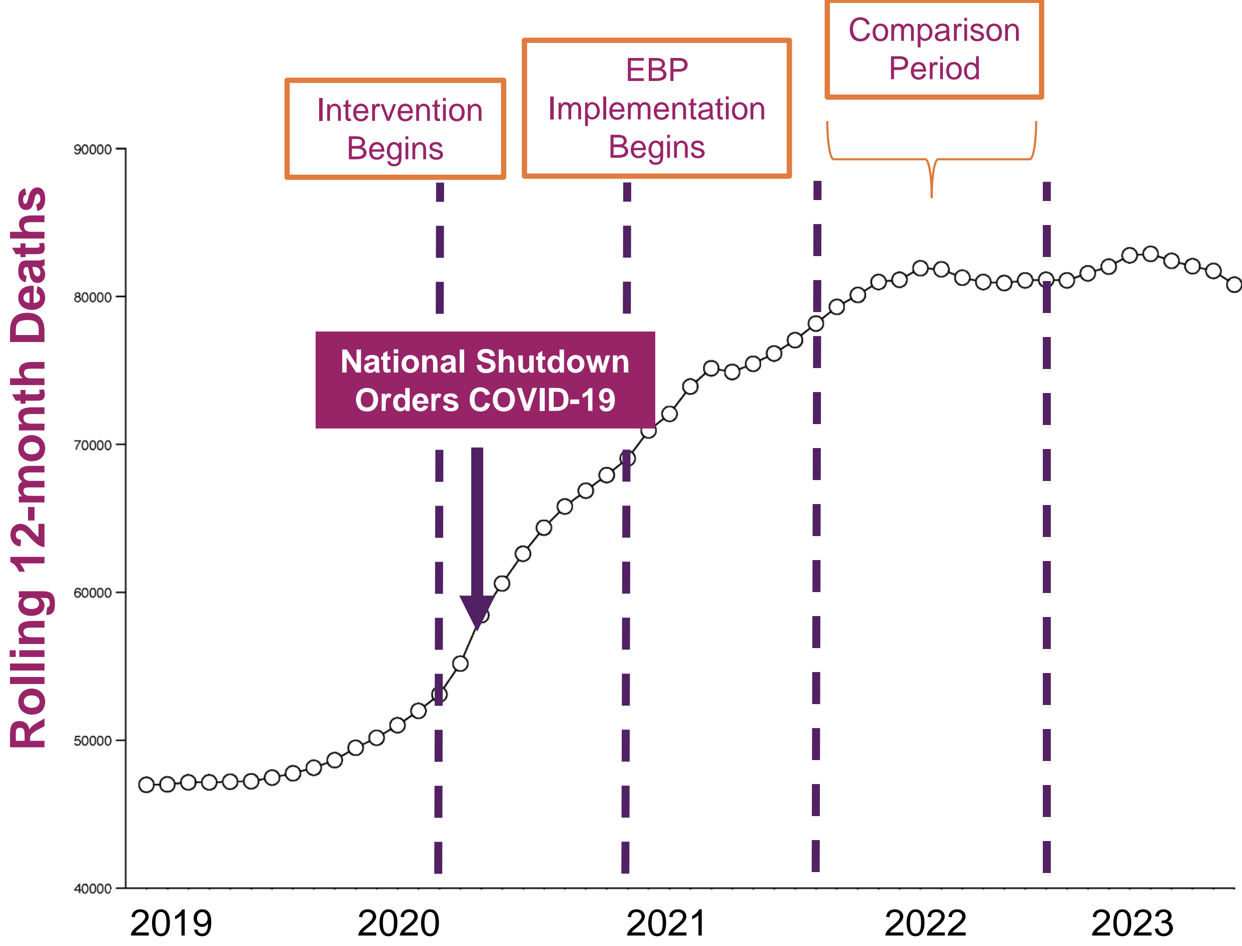
HEALing Communities Study Design

- Multi-site, parallel arm, cluster randomized, wait-list controlled trial
- 67 communities randomized to the **intervention** arm or to the **control** arm
- Communities balanced within state by: urban/rural, number of deaths, population size
- Primary and secondary outcomes compared between the intervention & control groups

Timeline



U.S. Opioid Overdose Deaths and HCS Milestones



Communities that HEAL (CTH) Intervention

3 Components

Community Engagement

The Opioid Reduction Continuum of Care Approach (ORCCA)

Community-Based Health Communications Campaigns

Increase awareness and adoption of evidence-based practices to *save lives!*

Community Engagement - Coalitions

- Coalitions formed across communities
  - KY/OH used existing coalitions
  - NY/MA built coalitions
- Examine data, select EBPs, identify partner organizations, implement EBPs, and monitor progress
- Support communication campaigns
- Received HCS funds
  - Average per community:
    NY $672,000; OH $922,500;
    KY $1.69M; MA $1.72M

Community Coalitions

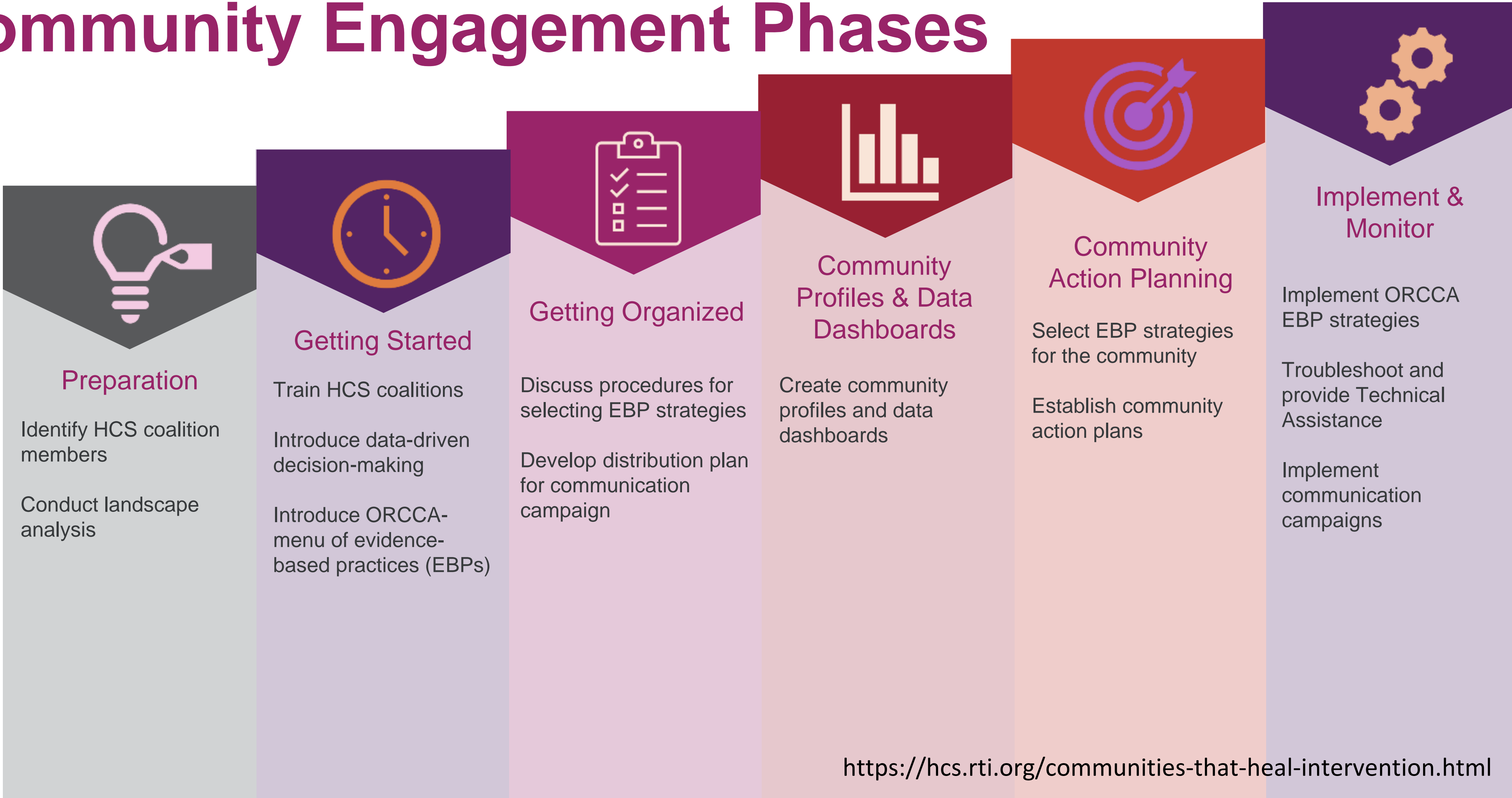
Infrastructure

- **25-40 members** with diverse expertise and perspectives
  - **Leadership:** program manager, data coordinator, community engagement facilitator, communications champion
  - **Other members:** policymakers, providers, people with living experience (PWLE), loved ones of PWLE, local government leaders, local organizations and media

Responsibilities

- Serve on the coalition
- Conduct a **community needs assessment**
- Data-driven selection and implementation of **evidence-based practices**

Community Engagement Phases



https://hcs.rti.org/communities-that-heal-intervention.html

Sustainability

Community Advisory Board (CAB)

- Advise on study design, opioid trends, equity, implementation
- Examples of members experiences: people in recovery and with active drug use, family members, harm reduction providers, legal system workers, public health professionals, veterans, housing services experts
- CABs provide an opportunity to align academic health care research with the needs and vision of the community and to advance health equity

What is the ORCCA?

Opioid-overdose Reduction Continuum of Care Approach:
A menu of strategies to support implementation of EBPs

EBPs:

Opioid overdose prevention education and naloxone distribution (OEND) in high-risk populations

Effective delivery of MOUD maintenance treatment

Safer opioid prescribing and dispensing

Implementation Settings:

Health and Public Health

Criminal Justice

Behavioral Health

Communications Campaign

Topics

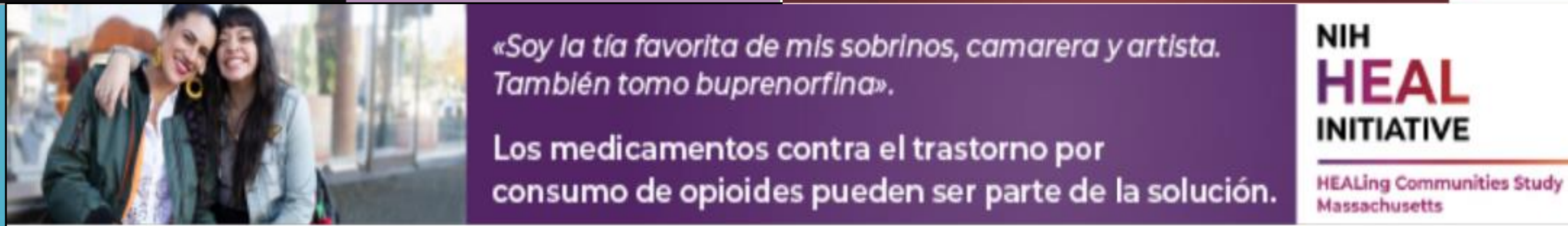
- Naloxone, MOUD, Stay on MOUD

Goals

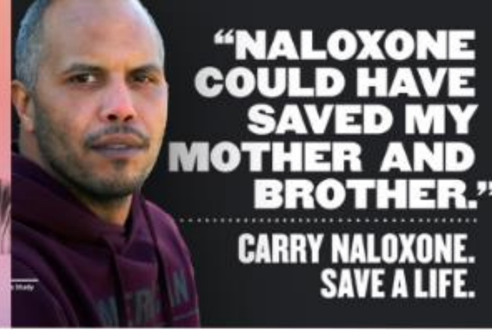
- Increase adoption of evidence-based practices
- Reduce stigma

Priority Audience Groups

- Providers, community leaders, people with lived experience



KY



MA

NY

OH

HEALing Communities Study *Outcomes*

- Primary - number of opioid OD deaths among community adults
  - Determined from death certificates
  - Deaths attributed to communities based on death certificate address
- Secondary:
  - OEND
  - MOUD – receipt, linkage, retention
  - Opioid and stimulant OD deaths
  - Non-fatal overdose events

HCS Objectives

To compare **the number of outcome events** during the comparison period (July 2021 - June 2022) between Intervention and Control Communities

Rate Ratio (RR):

< 1 means fewer outcome events in Intervention Communities

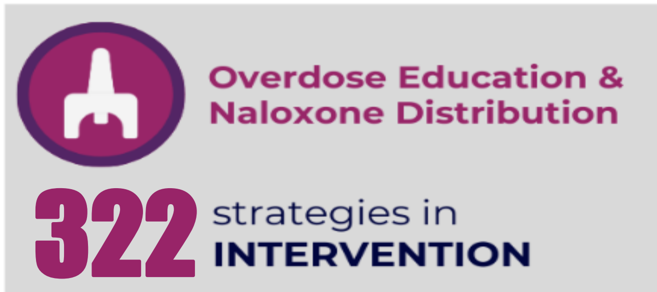
> 1 means more outcome events

Statistical Methods

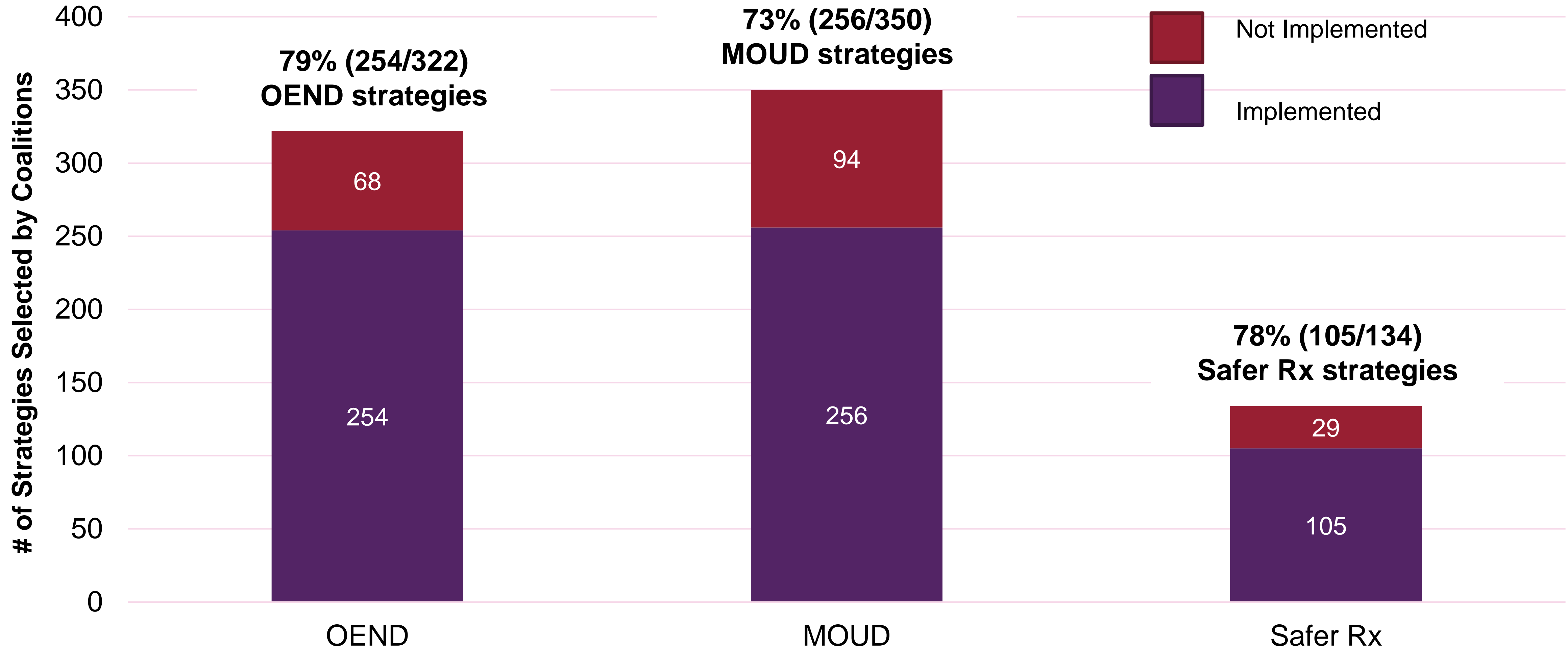
- Intention-to-treat principle for 67 randomized communities.
- Negative binomial regression analysis modeled population-averaged rate of outcomes, adjusting for state, urban/rural, & community baseline rates.
- Power was 99% and 83% to detect the pre-specified 40% and 20% lower opioid OD death rate (primary outcome) between intervention & control arms, respectively.

Results

Evidence-Based Practice (EBP) Strategies Selected



76% (615/806) Strategies Implemented* by 6/30/22**



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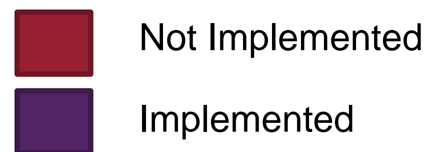
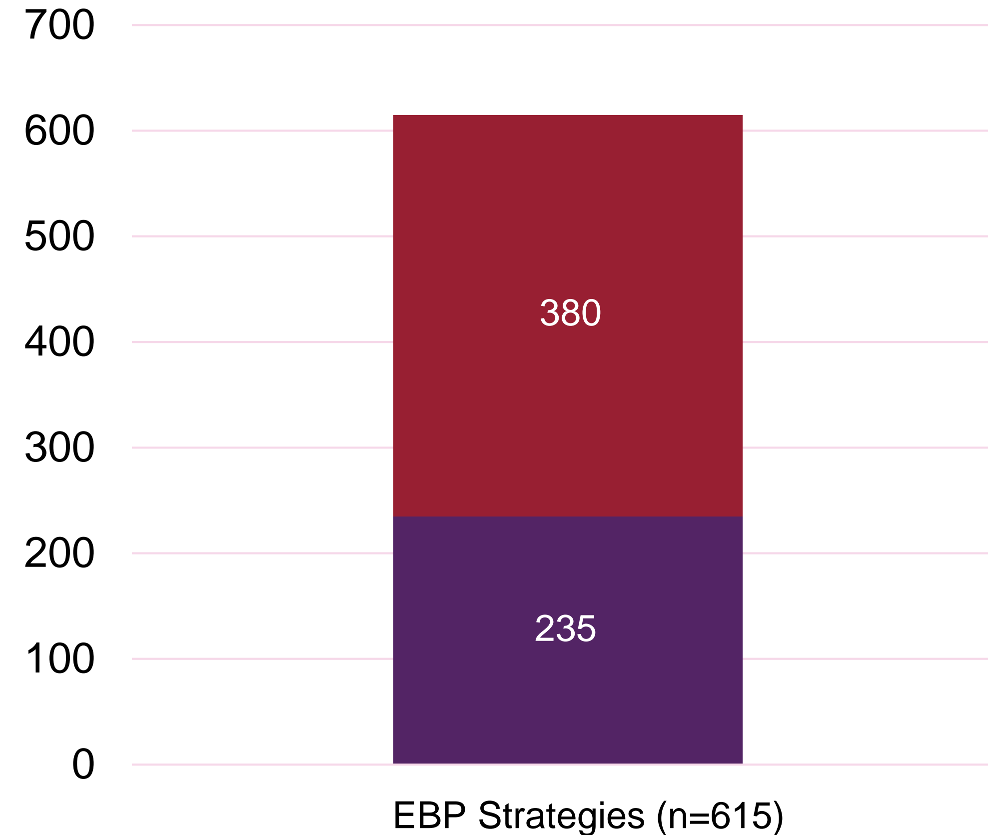
*Implemented if ≥1 service was delivered
**End of the comparison period

EBP Strategies Implemented by July 2021

- **Only 38%** (235/615) of strategies were implemented **prior to the beginning of the comparison period**



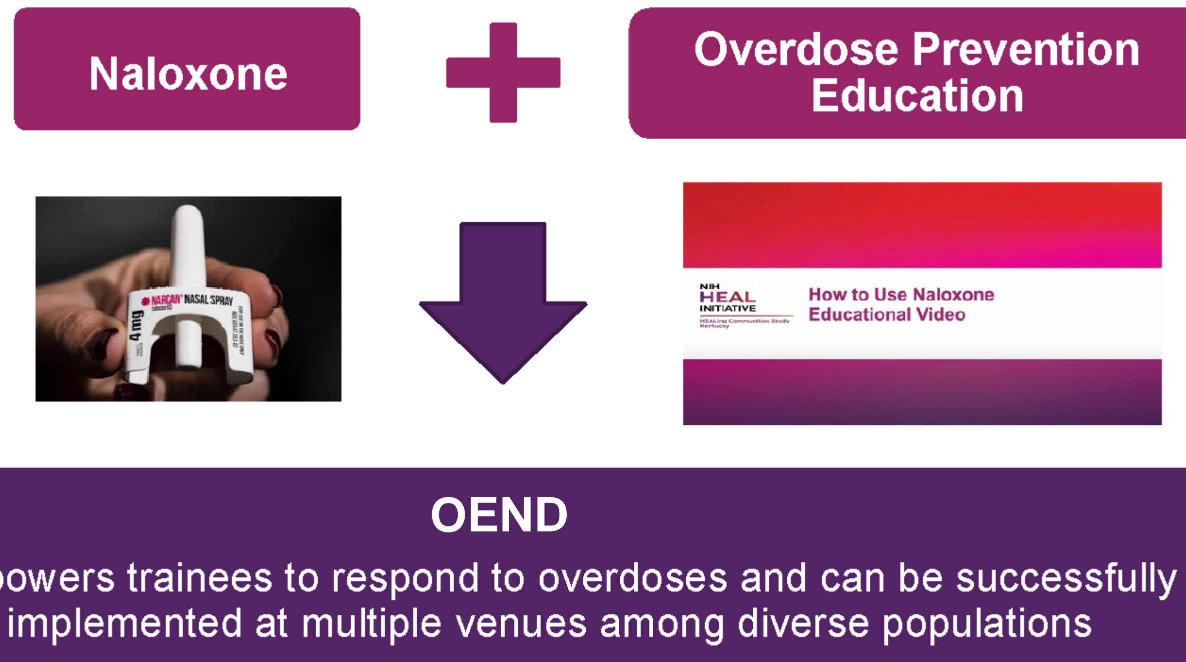


Overdose Education & Naloxone Distribution (OEND)

Secondary Outcome

OEND

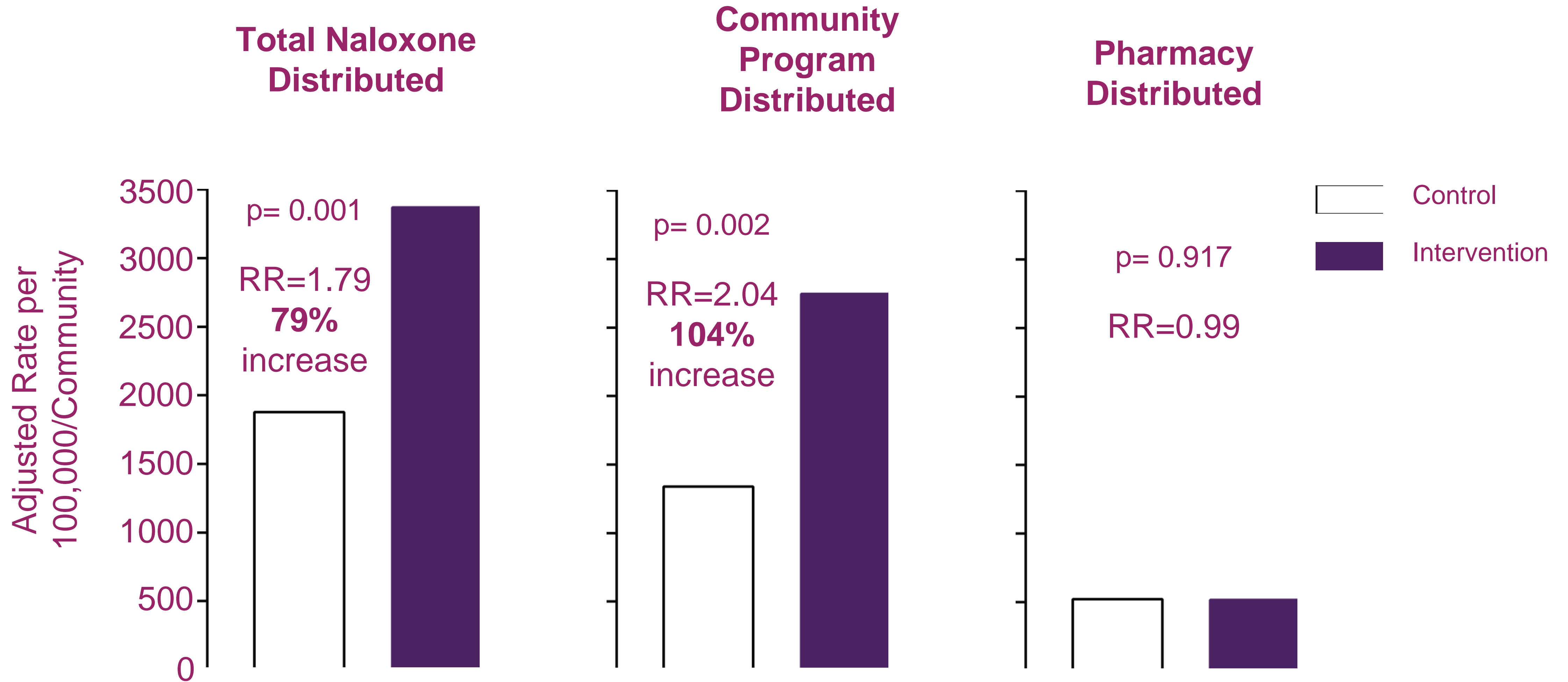
- Naloxone is an opioid antagonist that can reverse opioid ODs
- Bystander administration increases survival[1]
- Communities with OEND programs have lower rates of opioid OD deaths[2,3]



1. Giglio RE, Li G. & DiMaggio CJ. *Inj Epidemiol*. 2015.
2. Walley AY, Xuan Z, Hackman HH, et al. *BMJ*. 2013.
3. Naumann, RB et al. *Drug Alcohol Depend*. 2019.

Do communities implementing the CTH intervention have higher rates of Overdose Education and Naloxone Distribution (OEND)?

OEND - Effective Naloxone Distribution



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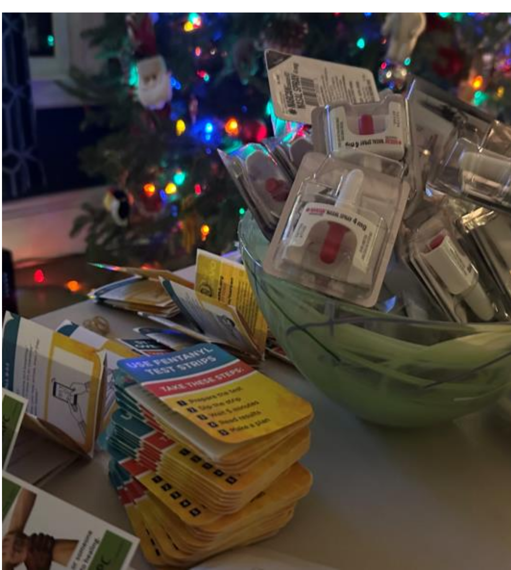
Freeman PR, Walley AY, Winhusen TJ, et al. *Am J Public Health. 2025.*



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Medications for Opioid Use Disorder (MOUD)

Secondary Outcome

Rationale

- Buprenorphine and methadone decrease opioid OD by 59%[1]
- OD survivors are at significantly increased risk for repeat OD[2]
- Only 13-28% of individuals with OUD are linked to MOUD[3]
- MOUD retention is also suboptimal[4]
  - 57% for buprenorphine and 65% for methadone at 4-6 months

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1. Santo T, Clark B, Hickman M, et al. *JAMA Psychiatry*. 2021.
2. Crystal S, Nowels M, Samples H, et al. *Drug Alcohol Depend*. 2022.
3. Mauro PM, Gutkind S, Annunziato EM, et al. *JAMA Netw Open*. 2022.
4. Klimas J, Hamilton M, Gorfinkel L, et al. *Syst Rev*. 2021.

Methods

- The Opioid-overdose Reduction Continuum of Care Approach (ORCCA) guided selection of EBPs to:

  1. Expand MOUD treatment availability
  2. Link individuals with OUD to MOUD treatment
  3. Improve MOUD retention

Outcome – Receipt of MOUD

- Community members (18-64 years) who received buprenorphine, methadone, naltrexone, or any of MOUD at least once during the comparison period (Medicaid and PDMP data).
- Limited to individuals with an ICD-10 diagnosis of opioid dependence or abuse

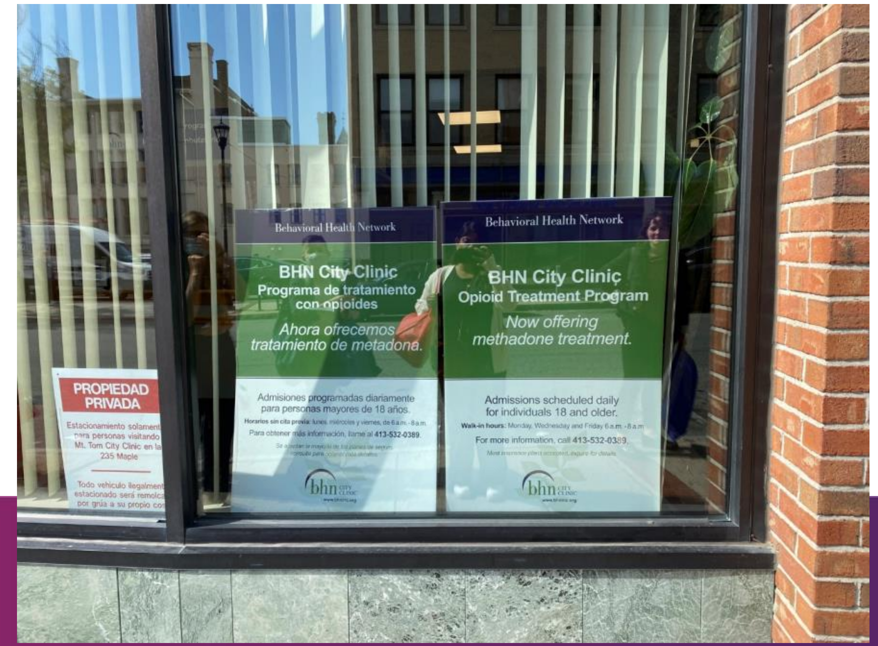
Outcome – Linkage to MOUD

- Linkage after ED or hospital encounter for OD or opioid-related conditions (i.e., abscess, cellulitis, infection-related arthritis, or endocarditis)
- Linkage to MOUD was defined as having $\geq$1 Medicaid claim for methadone, buprenorphine, or naltrexone in the 31 days following a qualifying ED or hospital encounter

Outcome – MOUD Retention

- Numerator: individuals receiving MOUD continuously for at least 180 days during or ending in the comparison period
- Denominator: individuals receiving MOUD at least once from 180 days before to 180 days after the start of the comparison period
- Continuous receipt was defined as no gap in medication coverage greater than 7 days

Opioid Treatment Programs



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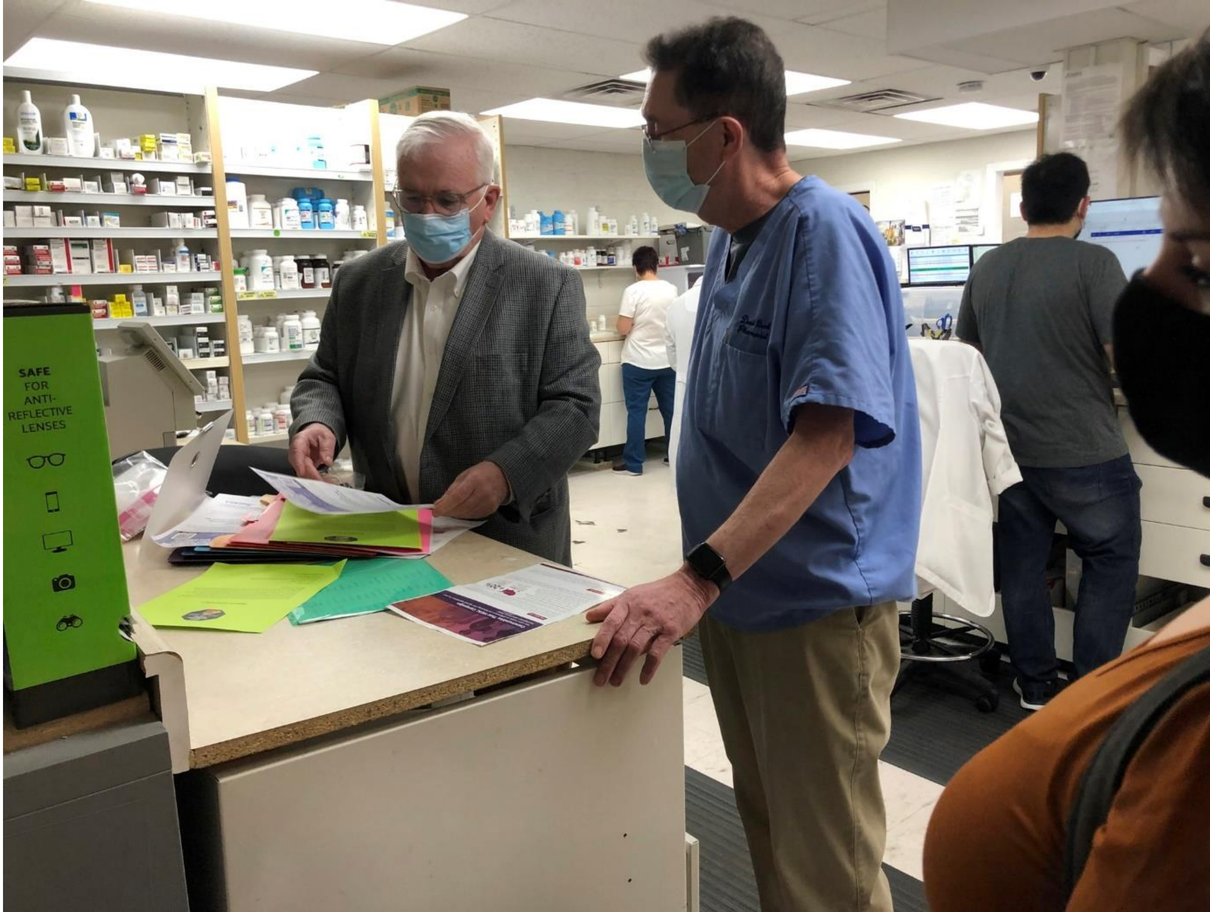
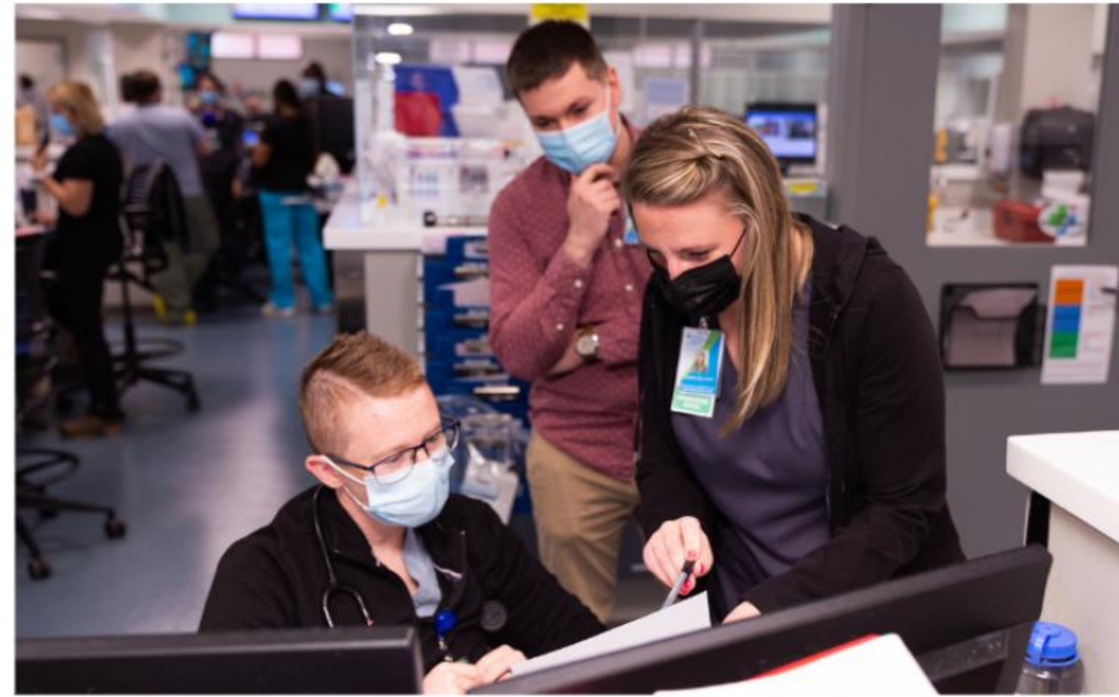
Academic Detailing





Holyoke Medical Center Addiction Consult Service (in MA)

Vans/mobile units to facilitate MOUD appointments

Do communities implementing the CTH intervention have higher rates of MOUD?

Opioid Overdose Mortality:
Primary Outcome

Primary Objective

To *compare* **the number of** ***opioid overdose deaths (OOD)*** **in adults** during the comparison period (July 2021 – June 2022) between Intervention and Control Communities

Rate Ratio (RR) < 1 means fewer deaths in Intervention Communities

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Community-Based Cluster Randomized Trial to Reduce Opioid Overdose Deaths

The HEALing Communities Study Consortium

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New England Journal of Medicine Authors

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Primary Outcome: Intervention Communities had no statistically significant Opioid OD deaths reduction compared to Control Communities

Adjusted Rate Ratio During the Evaluation Period (July 1, 2021 - June 30, 2022)

Model	Intervention	Control	Adjusted Rate Ratio (95% CI)	P-value
	Adjusted Rate	Adjusted Rate		
Primary Model – Negative binomial, Marginal GEE-type (standard covariates*)	47.15	51.73	0.91 (0.76, 1.09)	0.30

**Standard covariates: research site, urban/rural, baseline rate*

Primary Model: Opioid-overdose Deaths

Overall and by State Mortality - 4,517 total OOD across both arms

Group	Intervention		Control		Adjusted Rate Ratio
	Total Events	Adjusted Rate Per 100K	Total Events	Adjusted Rate Per 100K	
Overall	**2,220**	**47**	**2,297**	**52**	**0.91 (0.76, 1.09)**
Kentucky	391	60	609	59	1.01 (0.56, 1.81)
Massachusetts	201	45	241	52	0.86 (0.54, 1.37)
New York	472	46	543	53	0.87 (0.56, 1.35)
Ohio	1,156	39	904	43	0.91 (0.58, 1.44)

Pre-specified Stratified Analyses by Age, Sex

Group	Intervention		Control		Adjusted Rate Ratio
	Total Events	Adjusted Rate Per 100K	Total Events	Adjusted Rate Per 100K	
Overall	2,220	47	2,297	52	0.91 (0.76, 1.09)
Age					
18-34 Years	599	46	645	51	0.90 (0.72, 1.13)
35-54 Years	1,101	70	1,111	77	0.91 (0.73, 1.15)
55+ Years	520	34	541	39	0.86 (0.59, 1.23)
Sex					
Male	1,528	61	1,602	69	0.88 (0.71, 1.08)
Female	692	34	695	37	0.91 (0.71, 1.18)

Pre-specified Stratified Analyses by Race/Ethnicity

Group	Intervention		Control		Adjusted Rate Ratio
	Total Events	Adjusted Rate Per 100K	Total Events	Adjusted Rate Per 100K	
Overall	2,220	47	2,297	52	0.91 (0.76, 1.09)
Race/Ethnicity					
Hispanic	137	39	177	46	0.85 (0.46, 1.57)
Non-Hispanic White	1,583	45	1,538	48	0.95 (0.72, 1.26)
Non-Hispanic Black	462	70	534	77	0.91 (0.59, 1.40)

Opioid-related Deaths with Other Substances: *Secondary Outcomes*

Non-fatal Overdose Events: *Secondary Outcome*

Factors Impacting Results & Limitations

Factors impacting results:

- Complex array of strategies for high-risk populations in healthcare, behavioral health, and criminal legal sectors
- Not enough time from implementation of EBPs to achieve full benefit of reducing overdose fatalities
- COVID demands on coalition members and healthcare personnel
- Increasing fentanyl in drug supply with stimulant contamination
- Statistical power

Study Limitations (OEND)

- No uniform/centralized system for collecting community-level data for naloxone distribution
- Some states had other efforts underway for OEND that were not fully captured

Study Limitations (MOUD)

- Medicaid data – findings might not generalize to non-Medicaid enrollees
- Community-level administrative data limits the research questions that can be addressed:
  - ORCCA is designed to reach populations at heightened risk for OOD; it is unknown if intervention communities were more effective in engaging higher-risk populations with MOUD

Study Limitations (OD Outcomes)

- Variation in # of persons in each community who could benefit from HCS resources
- Contamination of control communities to EBP strategies possibly attenuated the CTH effect
  - Control communities could access non-HCS funds (available in the Covid era) to address the opioid epidemic
- HCS did not consistently assess the # of persons who were affected by the strategies implemented in intervention communities

Conclusions

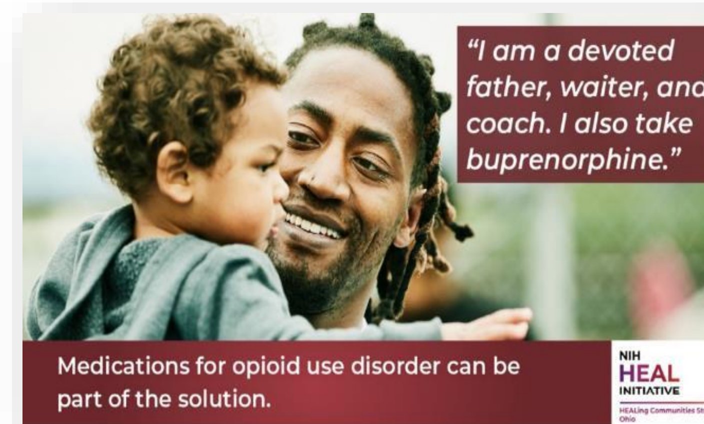
Conclusions – Successes & shortcomings of CTH intervention

- Opioid OD deaths – no difference
- OD deaths involving opioids and psychostimulants (excluding cocaine)
- Non-fatal overdoses
- Naloxone availability – 79% increase
- MOUD receipt, linkage, and retention

- *Mitigating factors of CTH intervention impact:*
  - *Complexity of many of the EBPs*
  - *Insufficient time to implement EBPs*
  - *Covid competing priorities*

Other Take Home Conclusions

- HCS is the largest implementation science study funded by NIDA
- CTH provides an approach to implement OUD EBPs
- Multi-level partnerships are critical to community-engaged research success
- Communication campaigns are a way to energize communities
- Great importance of social determinants of health, especially transportation and housing



Thank You

- Community Advisory Boards
- Key Governmental Officials
- Coalitions
- Community Partners
- Investigators and Staff

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Acknowledgement

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Thank you!

Questions & Answers