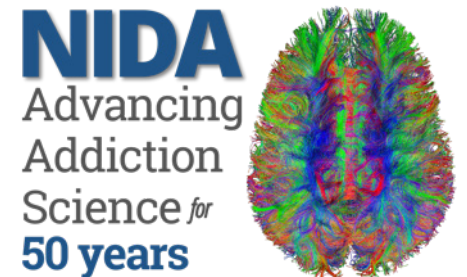


HEAL
INITIATIVE

*Providing Scientific Solutions to
the Opioid & Overdose Crisis*

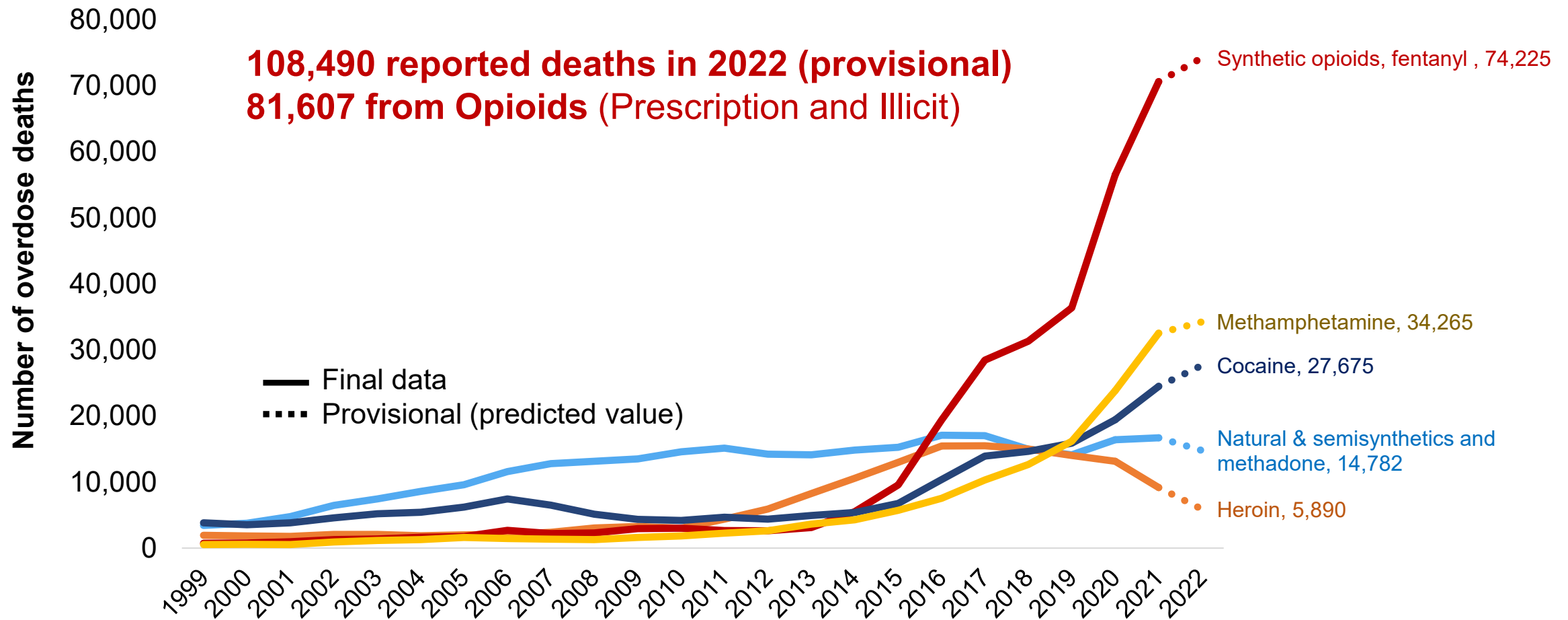
Nora D. Volkow M.D.

Director



Evolution of Drivers of Overdose Deaths, All Ages

Analgesics → Heroin → Fentanyl → Stimulants

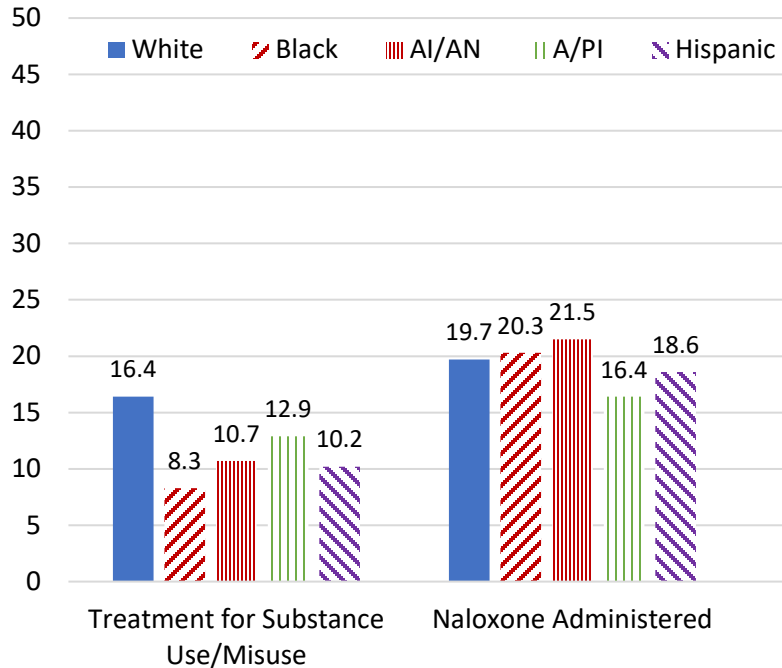


Note: Final and provisional data cannot be compared because some states have not reported final data. Numbers of deaths reported here are from the CDC multiple cause of death files and represent deaths in US residents, whereas other provisional data may include all overdose deaths in the US including those in foreign residents. Provisional data is included here to provide an estimate of what the final data may show.

Source: [The Multiple Cause of Death](#) data are produced by the Division of Vital Statistics, NCHS, CDC, US DHHS.

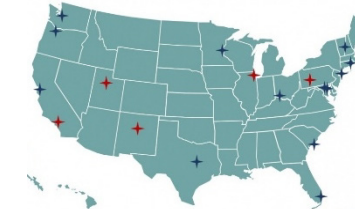
Implementation Science

Drug Overdose Deaths: 2019–2020



Kariisa M et al., MMWR Morb Mortal Wkly Rep. 2022

NIDA Clinical Trials Network



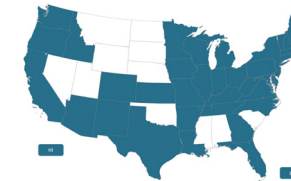
HEALTHCARE

Effectiveness of treatments in diverse clinical settings and populations

HEAL
INITIATIVE

JCOIN
JUSTICE COMMUNITY OPIOID INNOVATION NETWORK

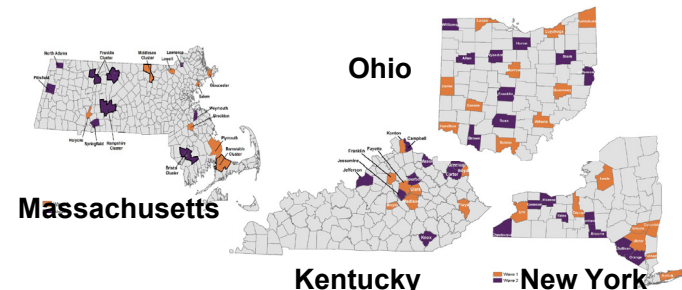
Build Evidence for OUD treatment in justice populations



JUSTICE

HEAL
INITIATIVE

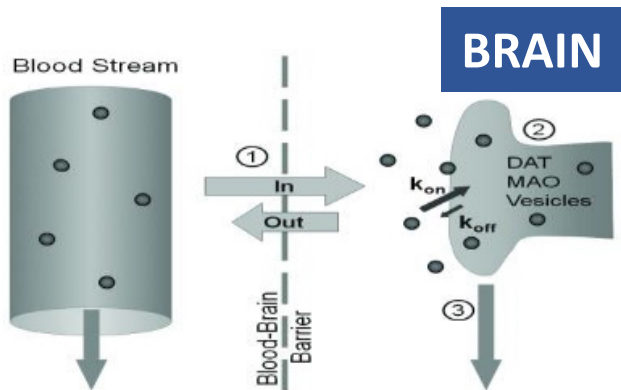
Healing Communities Study



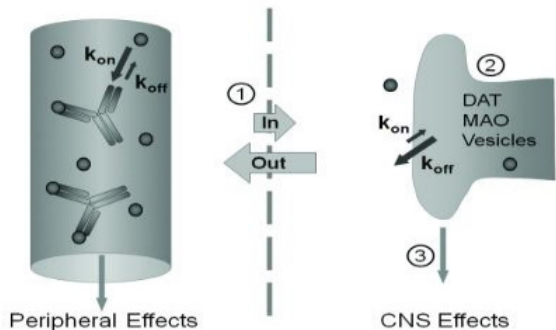
COMMUNITIES

Medications Development: Immunotherapies

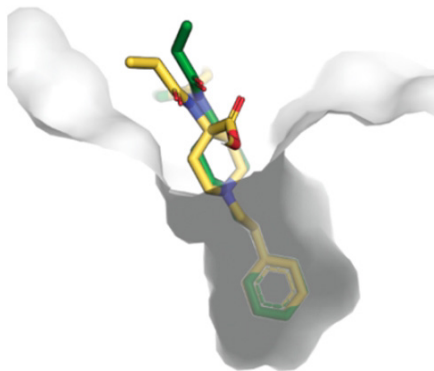
BEFORE Anti-Meth Antibody Treatment



AFTER Anti-Meth Antibody Treatment



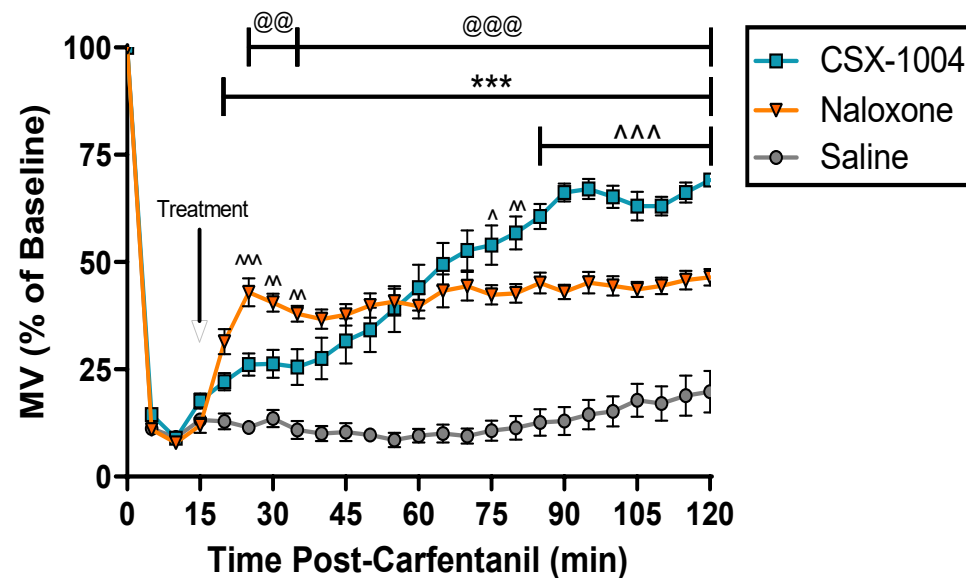
Fentanyl Carfentanil



CSX-1004 binds to fentanyl with picomolar affinity developed for prevention of fentanyl overdose

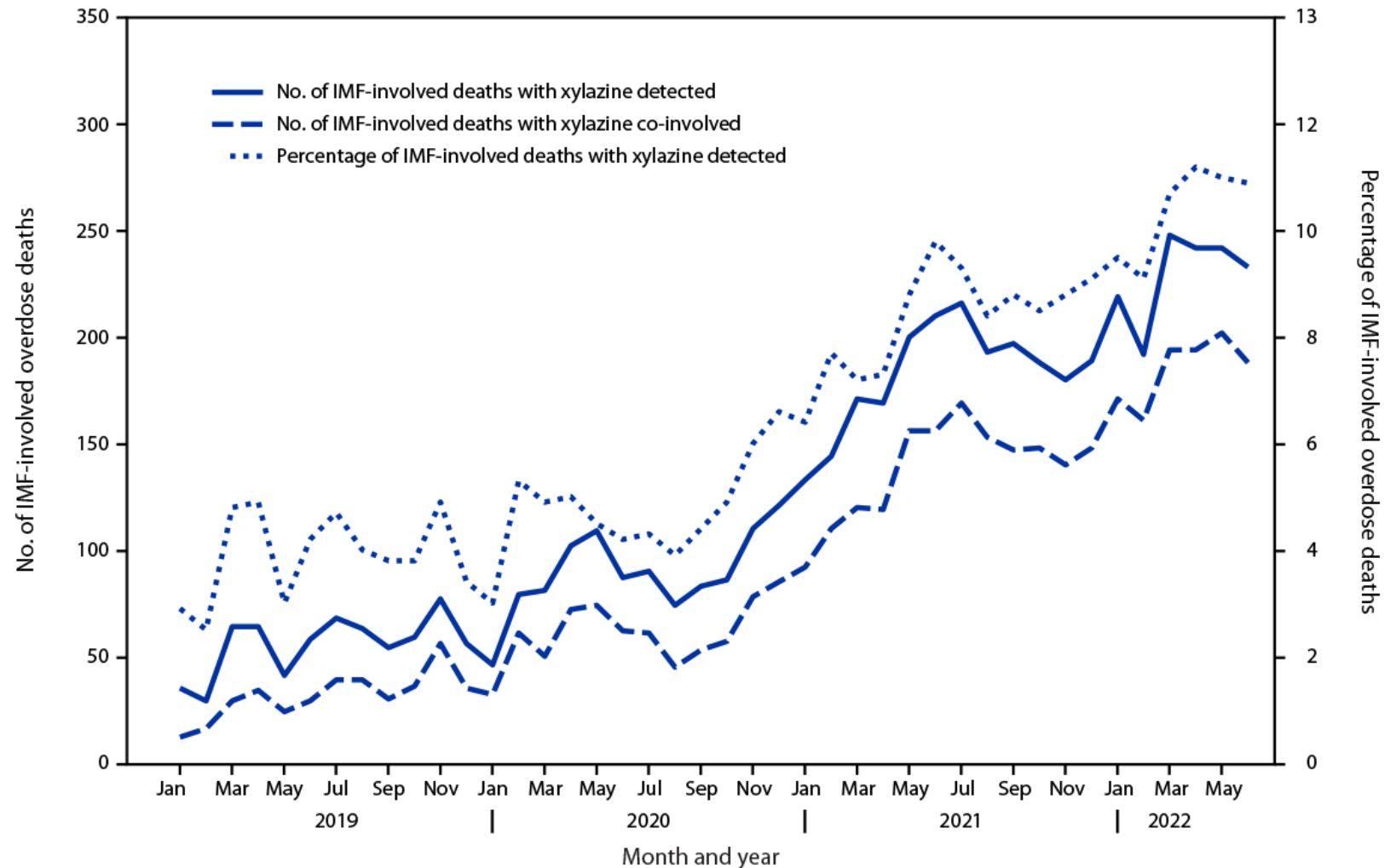
Cessation Therapeutics Announces FDA Authorization for First-in-Human Clinical Trial of Antibody for Prevention of Fentanyl Overdose

Trial to start August of 2023



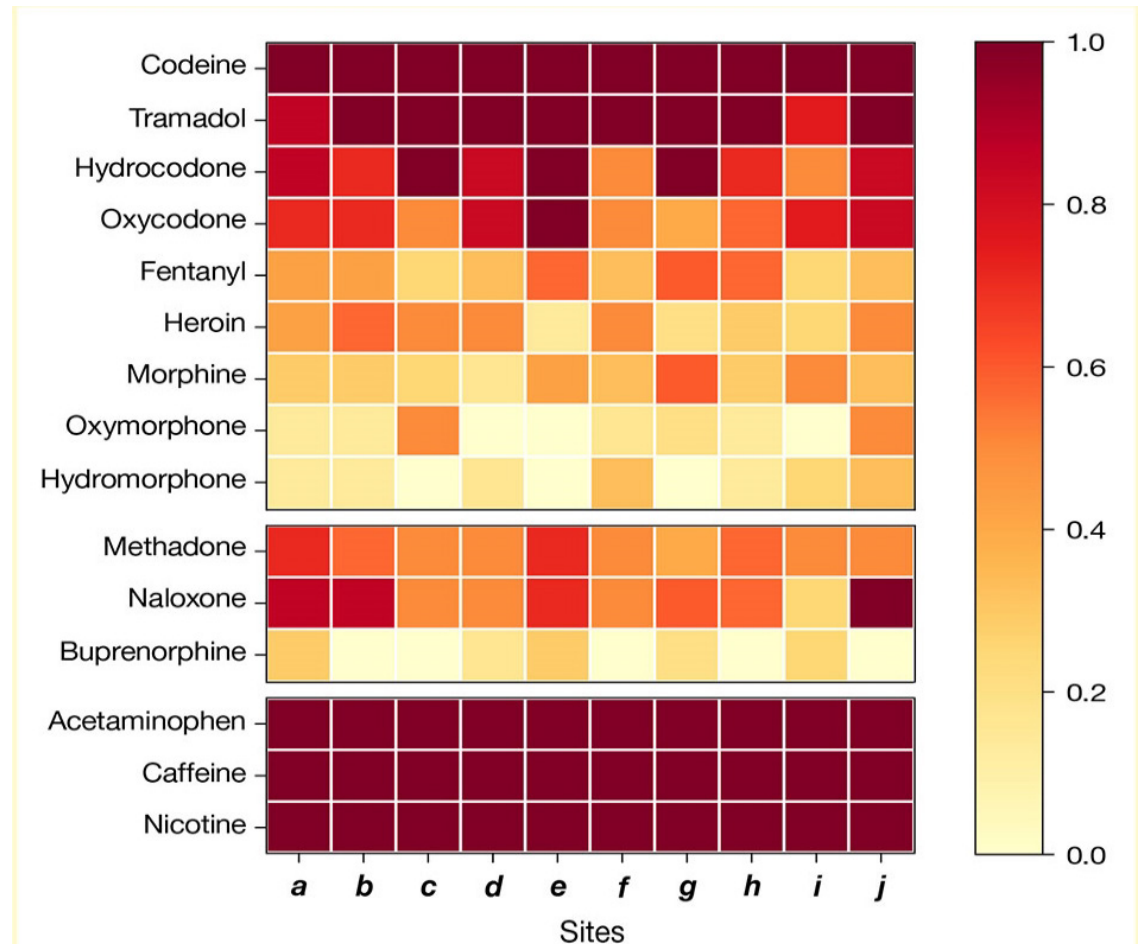
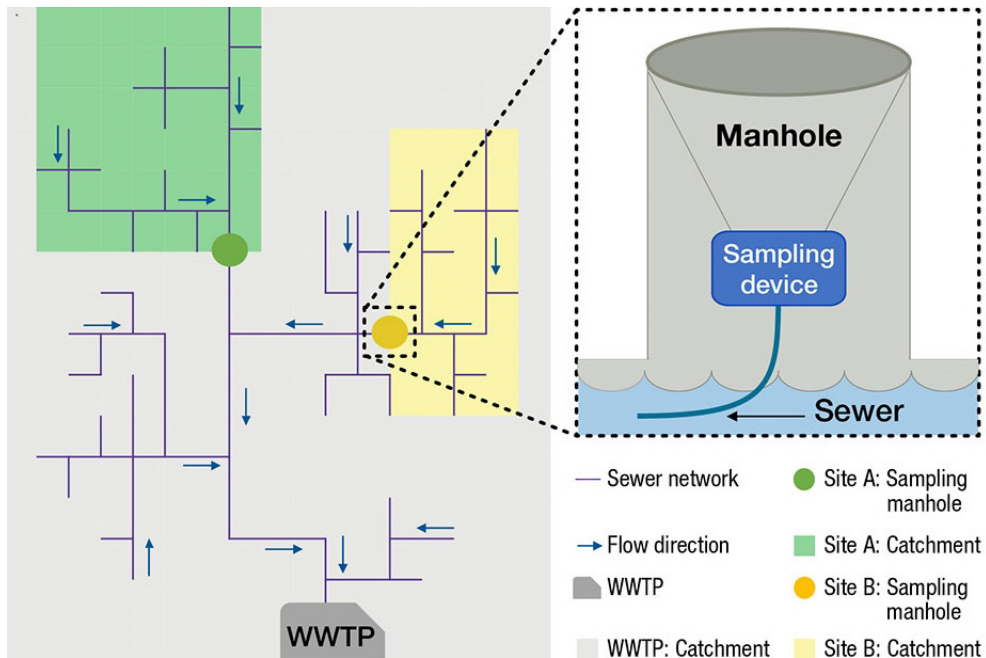
Co-Involvement of Emerging Drug, Xylazine, and Fentanyl

- Number and percentage of drug overdose deaths involving illicitly manufactured fentanyls.
- By month and xylazine detection or co-involvement
- State Unintentional Drug Overdose Reporting System, 21 jurisdictions, January 2019–June 2022.

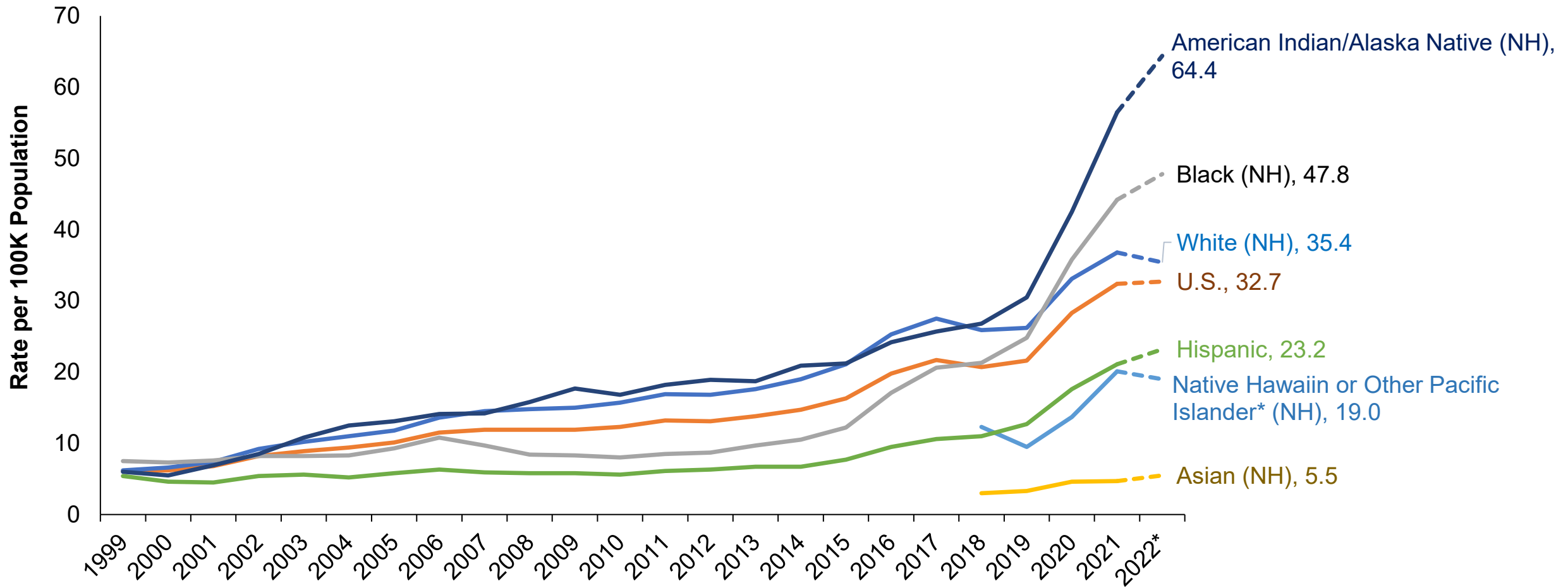


Translational Science

Drug Exposures in the Community Can Be Measured Using Wastewater



Drug Overdose Death Rates by Race/Ethnicity



NCHS, National Vital Statistics System. Estimates for 2022 are based on provisional data.

Native Collective Research Effort to Enhance Wellness

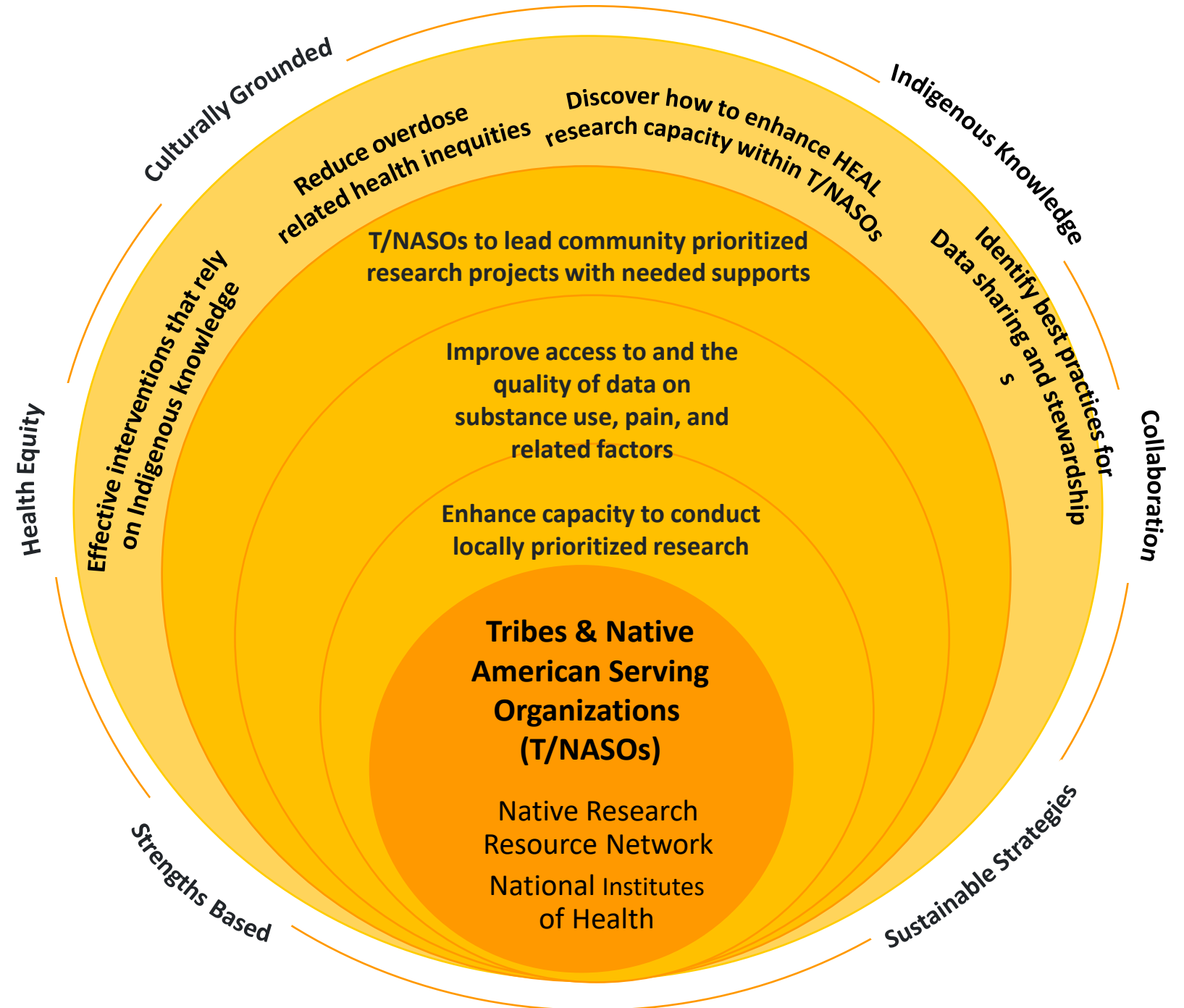
(N CREW): Addressing Overdose, Substance Use, Mental Health, & Pain

Phase I Development and Planning
FY24-25 \$~25 million

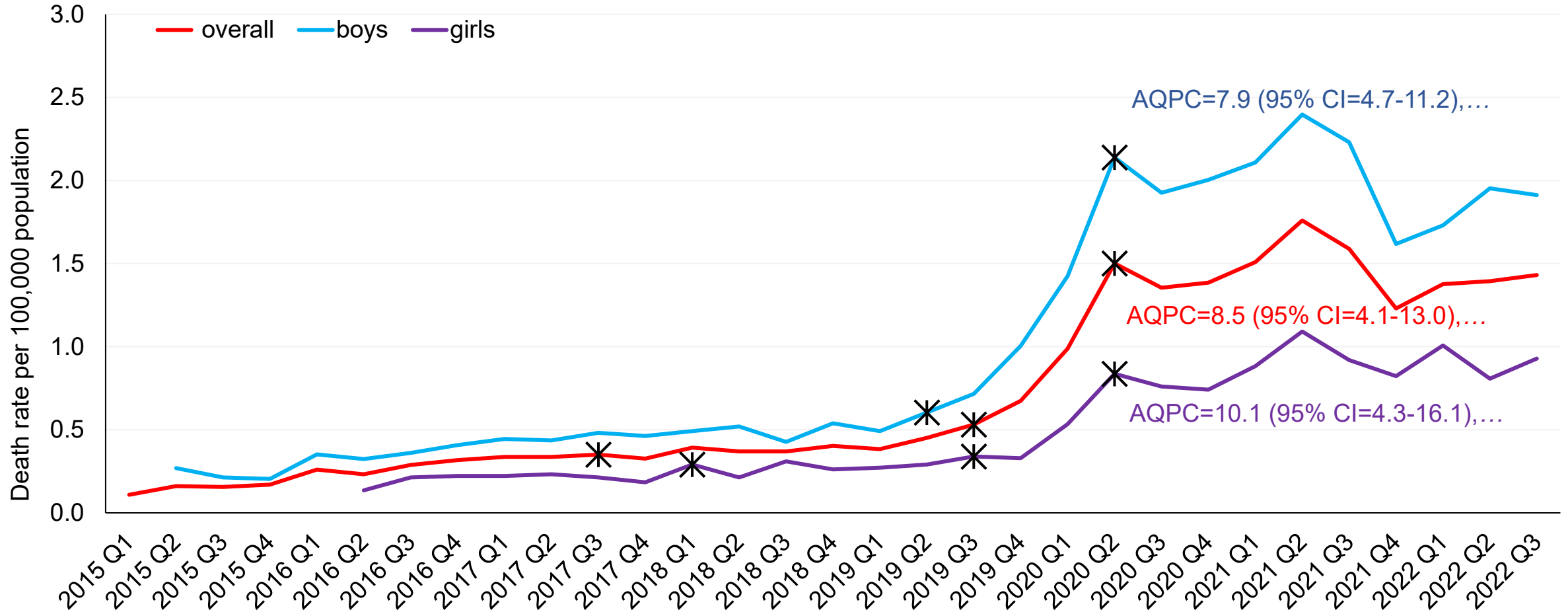
- ROA OTA 23-007: **T/NASOs** will plan, develop, pilot, and/or implement research and/or data improvement projects.
- ROA OTA 23-008: T/NASOs and Ally Organizations will form a **Native Research Resource Network (NRRN)** to provide comprehensive training, resources, and program coordination.

Phase II will build on Phase I
FY26-30 \$~240 million

Contact: NCREW@NIH.GOV



UNINTENTIONAL FENTANYL-CATEGORY-INVOLVED OVERDOSE DEATH RATES AMONG US YOUTH AGED 15-19 REMAIN ELEVATED



Data sources: National Vital Statistics System multiple-cause-of-death 2015-2021 final and 2022 provisional data and the U.S. census monthly data. *: Joinpoints identified indicate significant change in nonlinear trends using Bayesian Information Criterion. AQPC=average quarter percentage change during 2015 Q1-2022 Q3 (overall), 2015 Q2-2022 Q3 (boys), and 2016 Q2-2022 Q3 (girls). ICD-10 cause of death code: synthetic opioids other than methadone (T40.4, primarily fentanyl and analogs).

Blueprint for a National Prevention Infrastructure for Behavioral Health Disorders

NASEM ad hoc committee to develop a blueprint for building and sustaining an infrastructure for delivering prevention interventions for behavioral health disorders.

- **Best practices** to create and sustain behavioral health prevention infrastructure
- **Funding needs and strategies**
- **Research gaps**
- **Actionable recommendations** on policies

Very Few Adolescents with Substance Use Disorders Receive Treatment

8.7% (2.2 million) adolescents aged 12 to 17 had a SUD in the past year, USA 2022.

0.5% (n=8,000) sought treatment

2.0% (n=34,000) did not seek treatment but thought they should get it

97.5% (1.7 million) did not seek treatment or think they should get it.

Limited Treatments for Adolescents with SUD

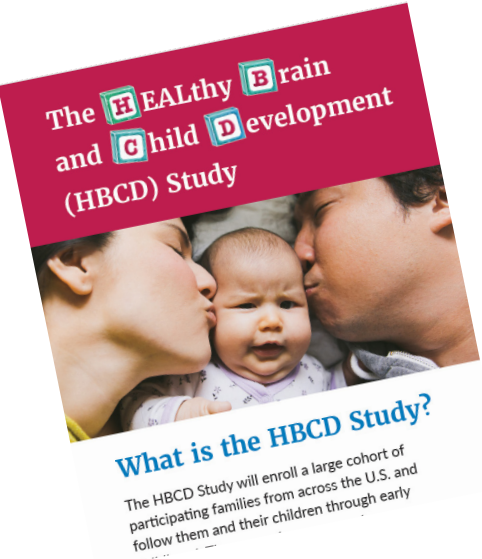
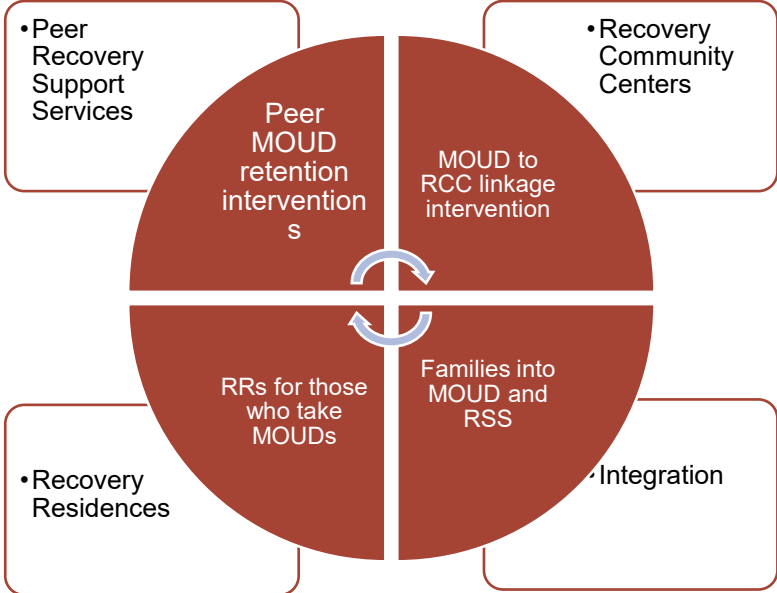
Psychosocial treatments: motivational, cognitive-behavioral, family-oriented therapies and contingency management (CM) are efficacious, but effect sizes are small to modest.

Medications: Few clinical trials have evaluated FDA approved medications for SUD

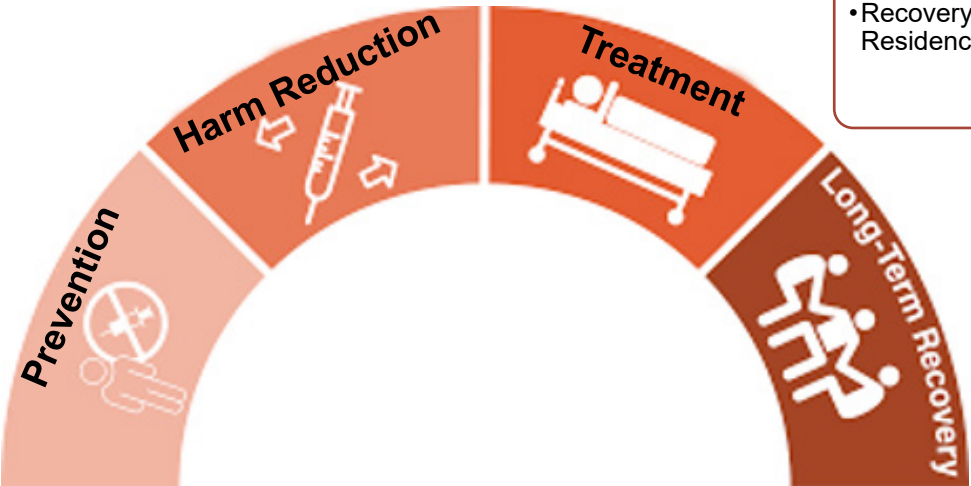
For OUD, buprenorphine was approved by FDA for 16 years of age or older and has evidence of benefit in adolescents with more severe SUD. Naltrexone (oral or XR) merits further investigation.

Research Across the Cascade of Care for Opioid Use Disorder

Novel harm reduction approaches	Understanding and addressing barriers
Novel settings for and modes of service delivery	Reaching understudied populations



Longitudinal (n=7,500 infants) normative neurodevelopment study from birth to 9-10 years to investigate impact of drug exposures and social determinants of health factors and genes throughout childhood



THANKS!

HHS Overdose Prevention Strategy



Harm Reduction

Model of substance use care created by and for people who use drugs, that aims to reduce health and safety issues from drug use

Syringe Exchanges and Syringe Services Programs (SSPs)



SSPs save lives by lowering the likelihood of deaths from overdoses.



Providing testing, counseling, and sterile injection supplies helps prevent outbreaks of other diseases. For example, SSPs are associated with a **50% decline** in the risk



Users of SSPs were **three times more likely** to stop injecting drugs.



Naloxone



Overdose Prevention Centers



Drug Testing

Fentanyl and Xylazine Test Strips

Others????

Harm Reduction Research Network

Purpose: Increase our understanding of effectiveness, implementation, and impact of existing and new harm reduction strategies

Novel harm reduction approaches

- Community drug checking
- Overdose prevention centers
- Meth sobering center
- Contingency management

Novel settings for and modes of service delivery

- Emergency department
- Mobile apps
- Hotline
- Text messages
- Mail delivery
- Secondary distribution
- Remote lockboxes

Understanding and addressing barriers

- Limited access
- Not using naloxone when it is available
- Burnout & trauma from responding to overdose
- State-level policy barriers

Reaching understudied populations

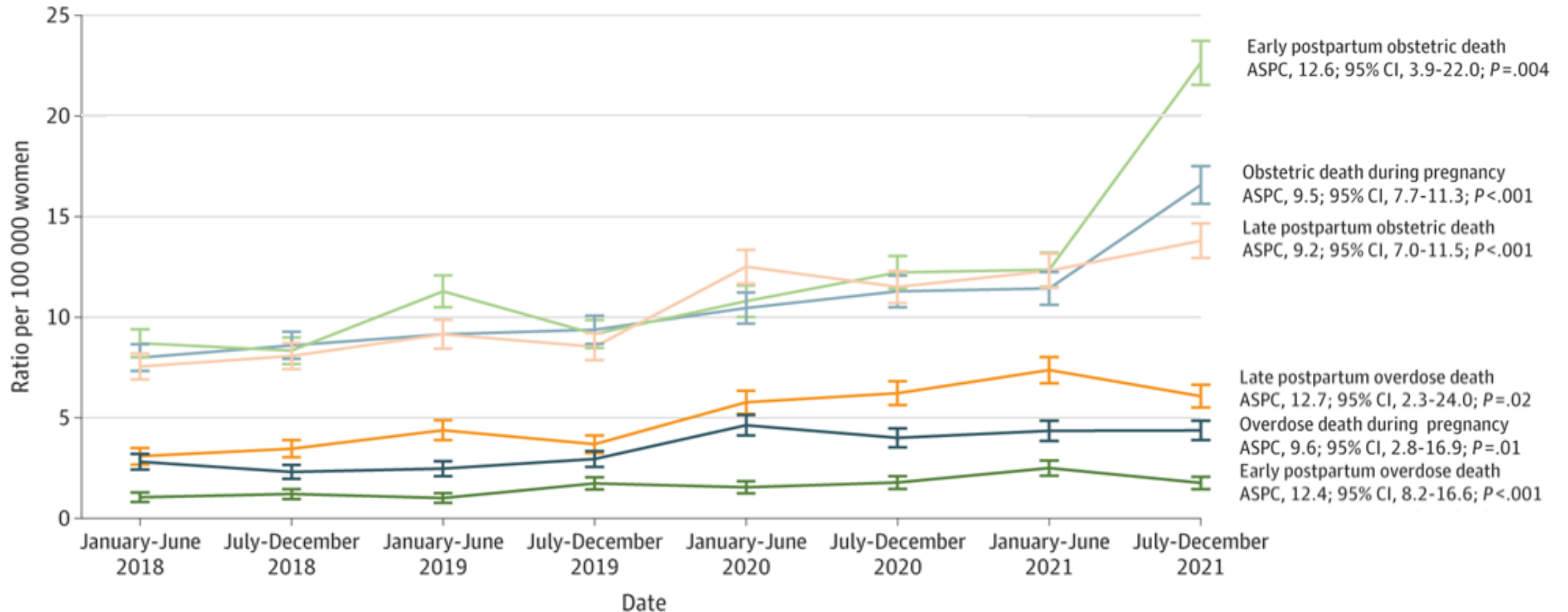
- Racial/ethnic minority groups
- Women
- Rural communities
- People who use stimulants

Coordination Center – 4 cores

- Communication and Coordination
- Data Harmonization and Methodology
- Community and Stakeholder Engagement
- Dissemination and Translation

(10 R01s, 1 R24)

Trends in Pregnancy-Associated Drug Overdose or Obstetric Mortality Rates in Women Aged 10 to 44 Years by Pregnancy Timing



2022-2023: Provisional* Drug Overdose Deaths 12-months ending in select months

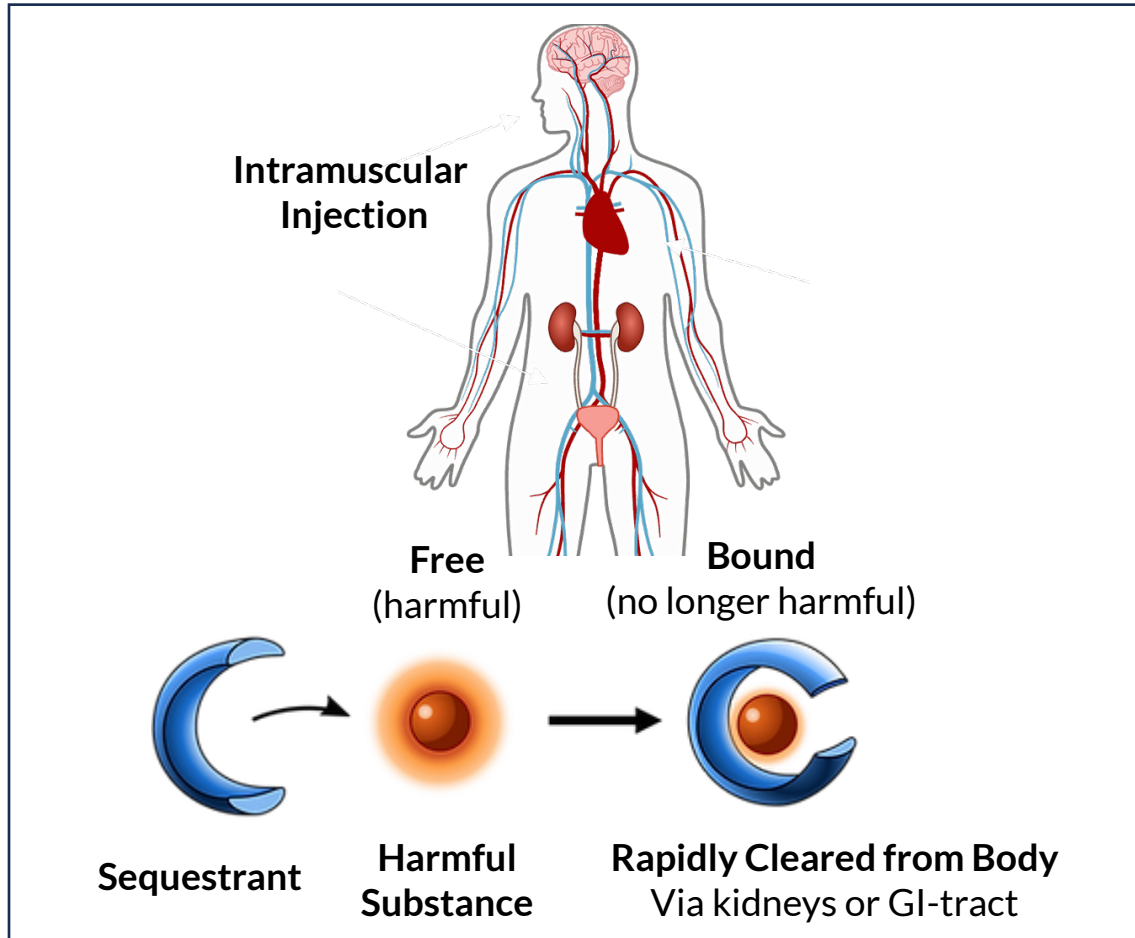
	ALL DRUGS	HEROIN	NAT & SEMI SYNTHETIC	METHADONE	SYNTHETIC OPIOIDS (mainly illicit fentanyl)	COCAINE	OTHER PSYCHO-STIMULANTS (mainly meth)
7/2022*	109,416	7,190	12,707	3,443	74,048	26,989	34,724
1/2023*	110,784	5,753	11,917	3,362	76,438	28,607	35,766
7/2023*	111,964	4,768	11,076	3,405	78,287	30,290	36,937
Percent Change 7/22-7/23	2.3%	-33.7%	-12.8%	-1.1%	5.7%	12.2%	6.4%

*NCHS Provisional drug-involved overdose death counts are PREDICTED VALUES, 12 months ending in select months. The numbers for 2022 differ from final data in slide 1 because provisional data includes all deaths that occurred in the US including foreign residents. Final data through 2021 on slide 1 is limited to deaths in US residents.

<https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

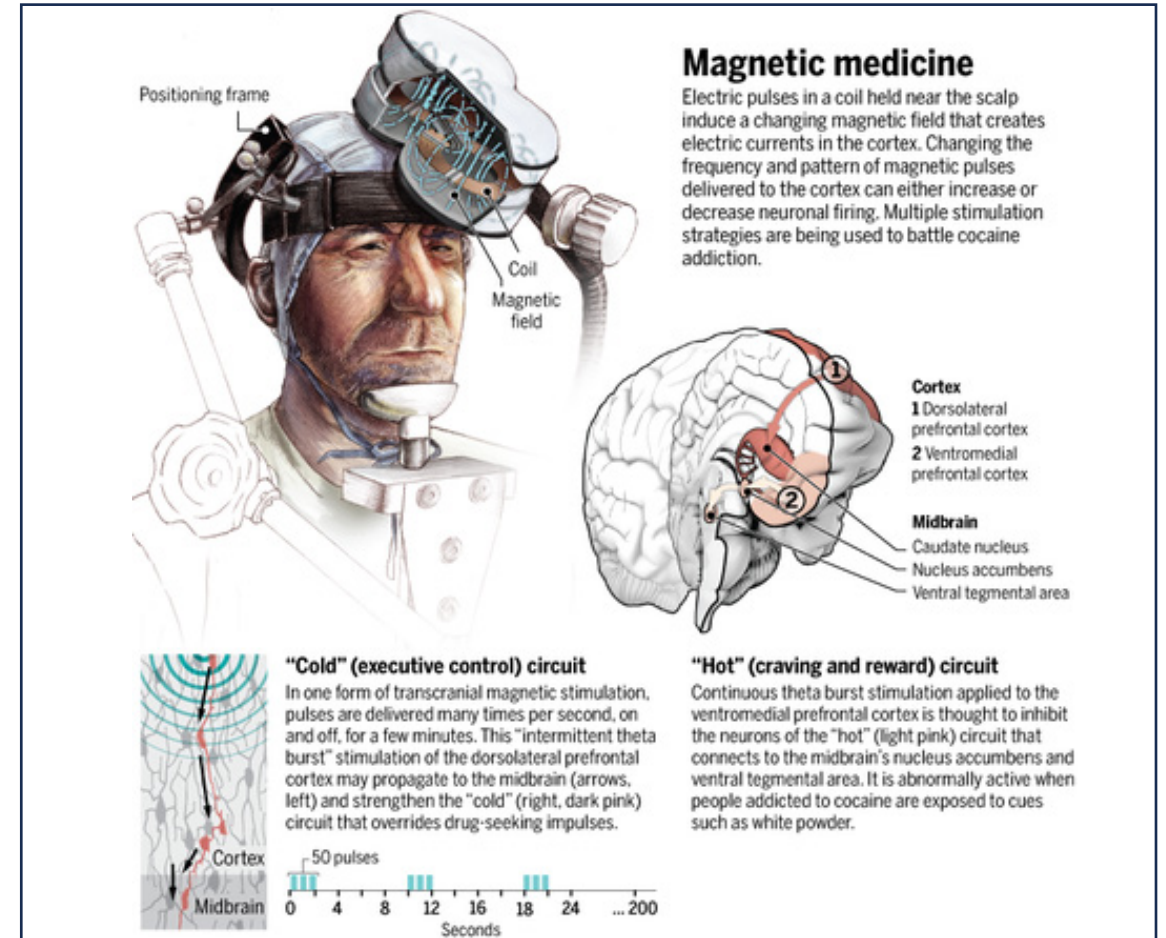
Developing Novel Approaches to Address Polysubstance Use

Drug Sequestrants



Clear Scientific, LLC

Transcranial Magnetic Stimulation



M Wadman, (2017) *Science*