

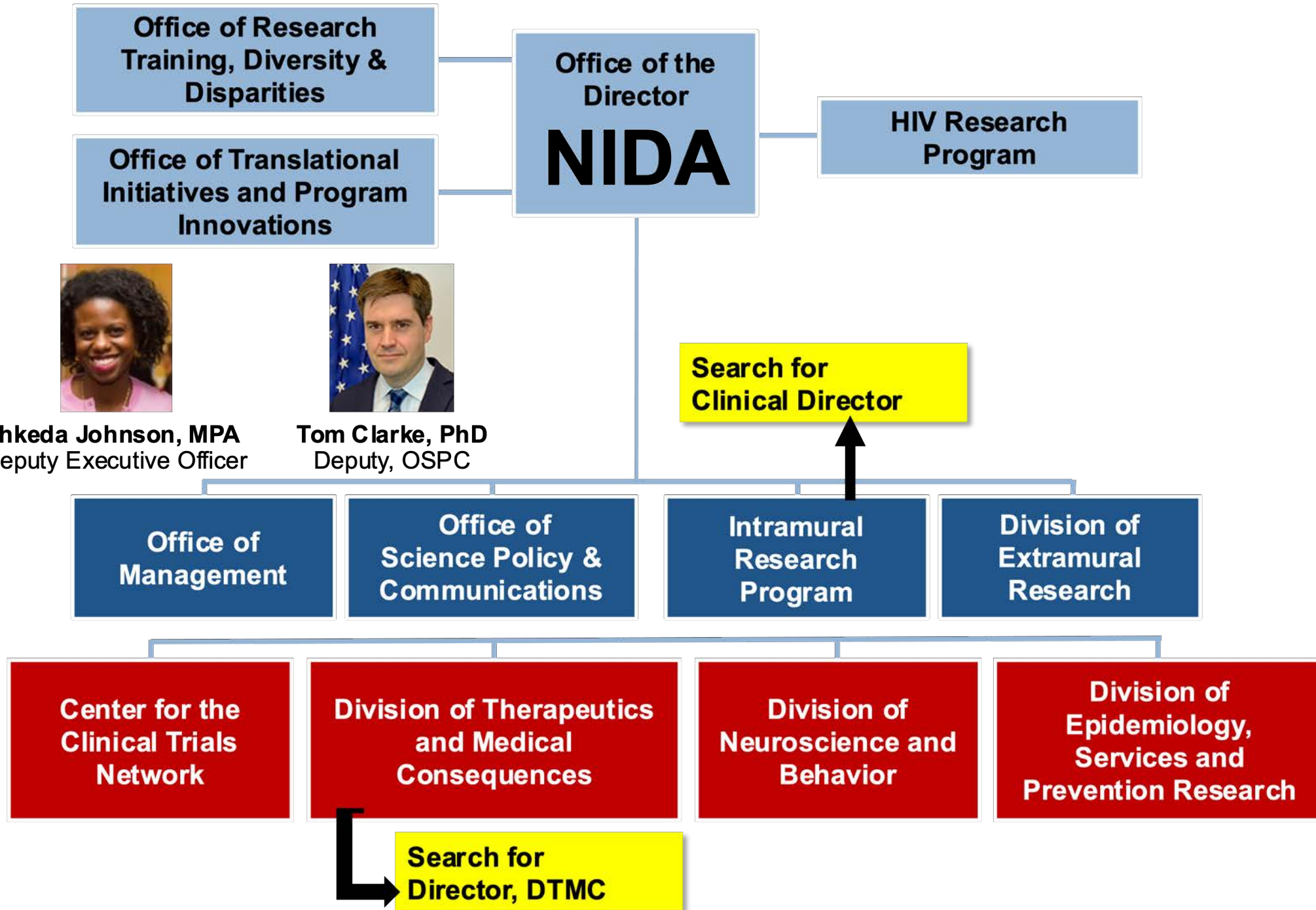
Director's Report to the National Advisory Council on Drug Abuse

Nora D. Volkow, M.D.

Director

National Institute on Drug Abuse

September 13, 2022



NIDA BUDGET

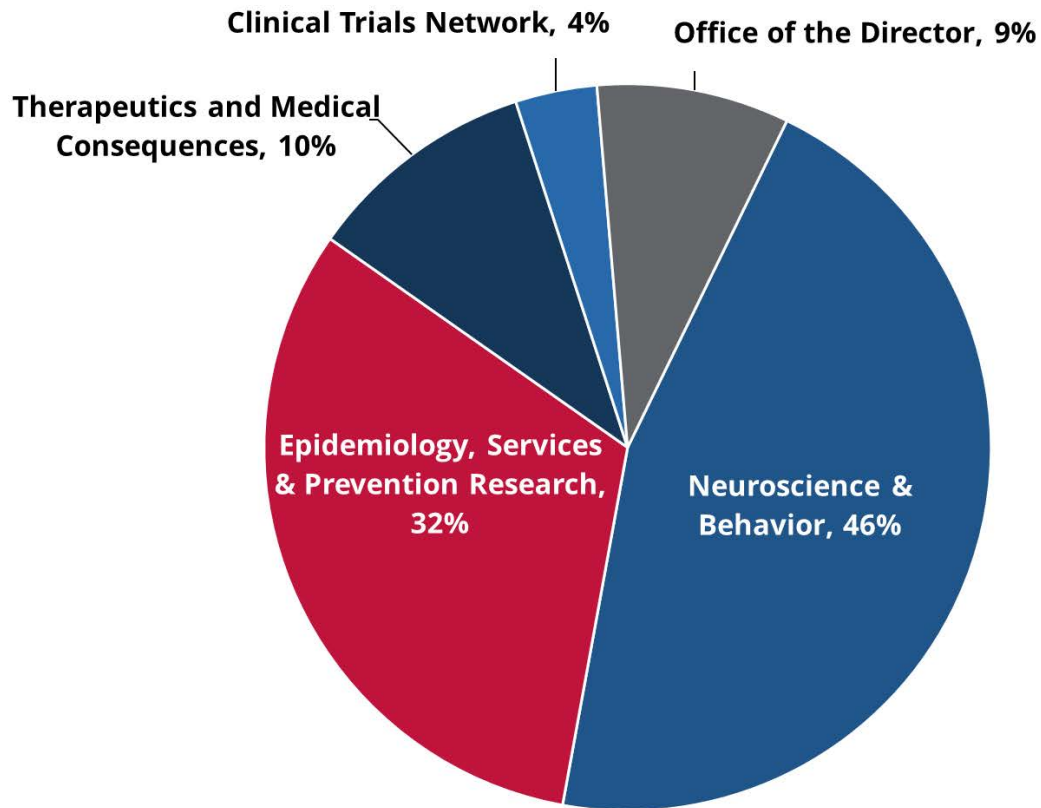
(all dollars are in \$k)

	FY 2021 Final	FY 2022 Enacted	FY 2023 PB*
Base	\$1,206,321	\$1,250,828	\$1,437,883
HEAL	\$269,484	\$345,295	\$405,443
Total	\$1,475,805	\$1,596,123	\$1,843,326

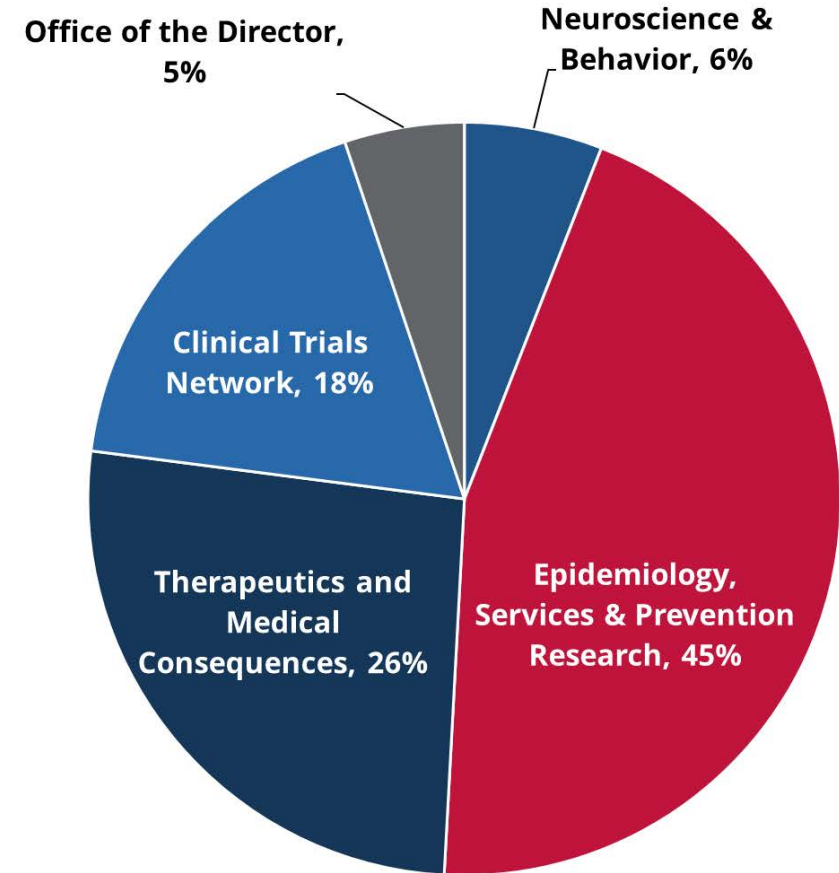
* The FY 23 President's Budget proposal was released prior to the receipt of a full year FY 22 appropriation. The proposed budget included a \$364m increase over the FY 22 Continuing Resolution level and contained a request for \$196.3m in support of non-HEAL opioid and pain research.

FY 21 Funding Overview

Non-HEAL Research



HEAL Research*



*Includes all NIDA HEAL projects regardless of funding source

New FOAs

Next-Gen Non-invasive Imaging [due Oct 2022]

- [RFA-EB-22-001](#): Transformative Brain Non-invasive Imaging Technology Development [UG3/UH3]

Quantifying Behavior [due Feb 2023]

- [RFA-MH-22-240](#): Brain Behavior Quantification and Synchronization [R61/R33]

Recent Reissues

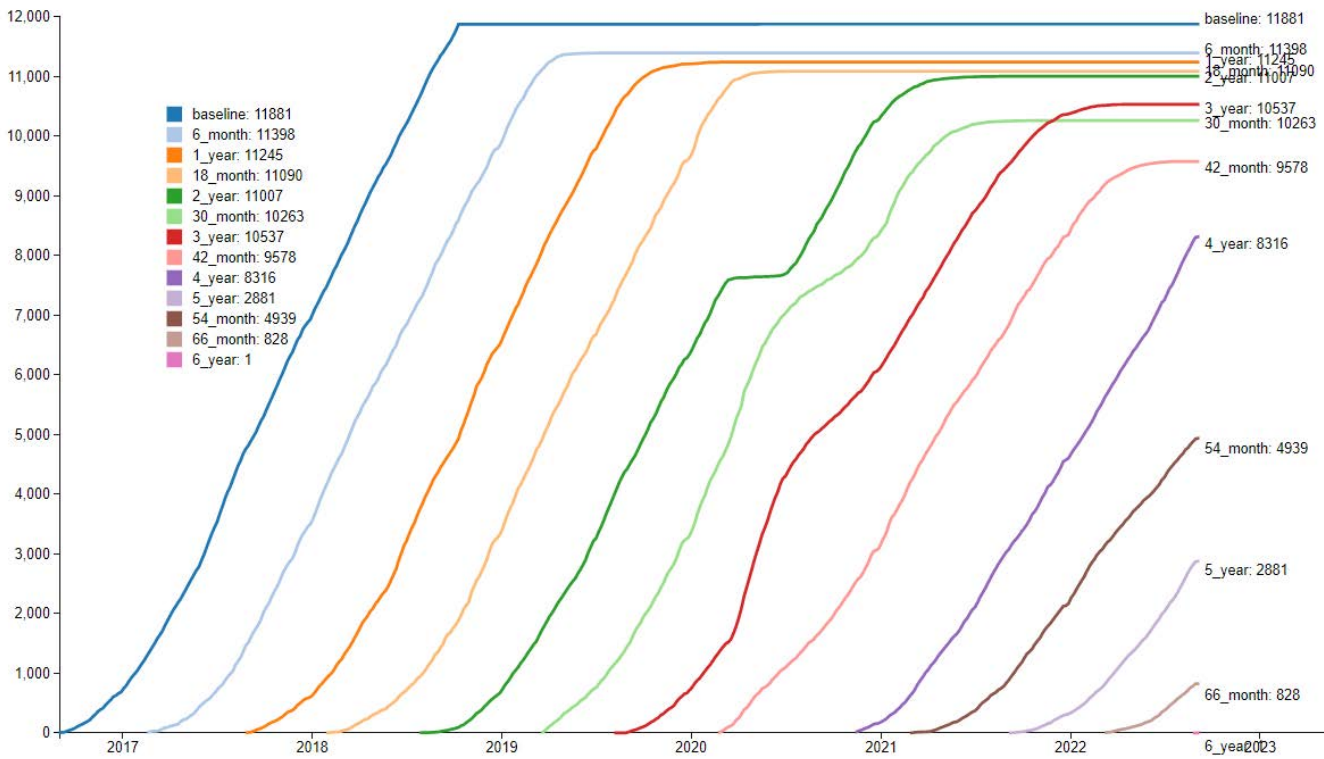
Brain Circuits [due Sept 2022]

- [RFA-NS-22-039](#): Team-Research BRAIN Circuit Programs [U19] (Basic Experimental Studies with Humans Required)
- [RFA-NS-22-040](#): Team-Research BRAIN Circuit Programs [U19] (Clinical Trial Not Allowed)
- [RFA-NS-22-041](#): Research Opportunities Using Invasive Neural Recording and Stimulating Technologies in the Human Brain [U01] (Basic Experimental Studies with Humans Required)



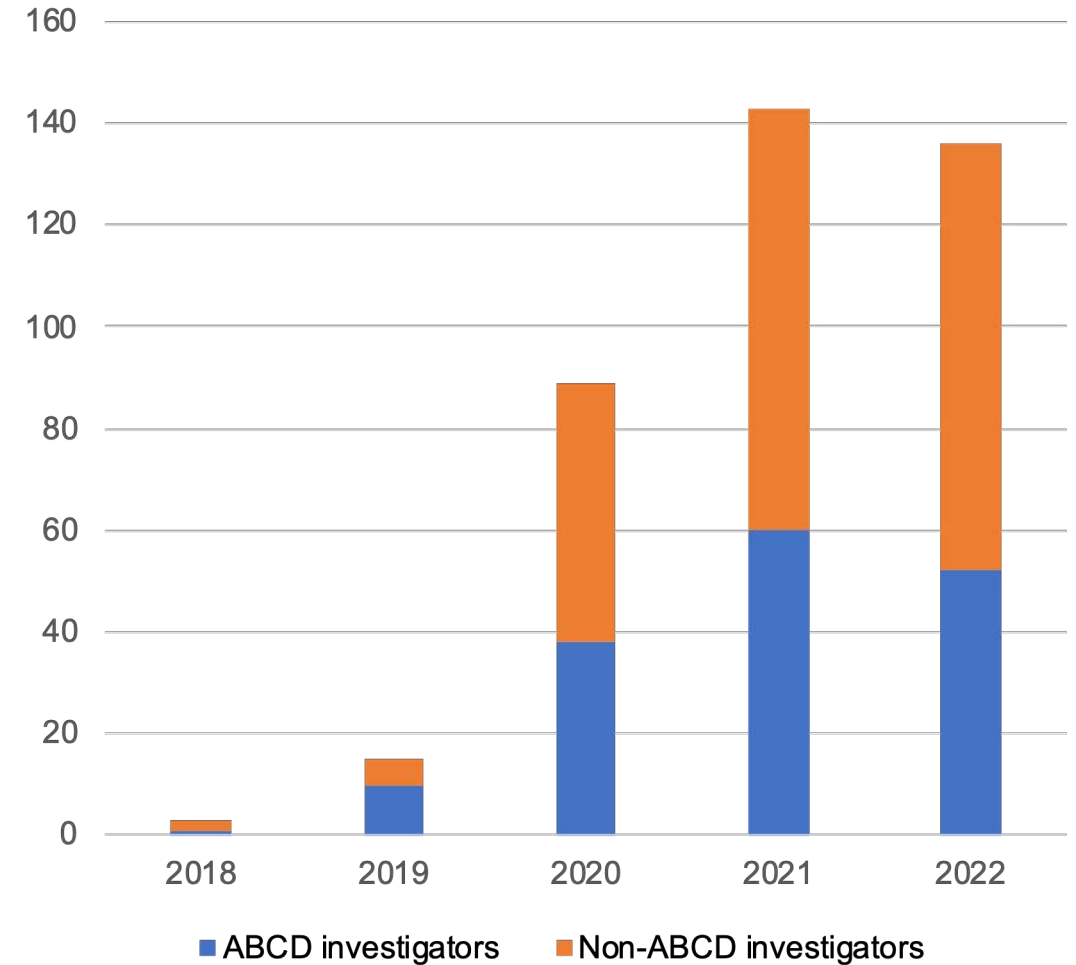
Adolescent Brain Cognitive Development Study

98.0 Percent Retained



Publications Using ABCD Data

N=386

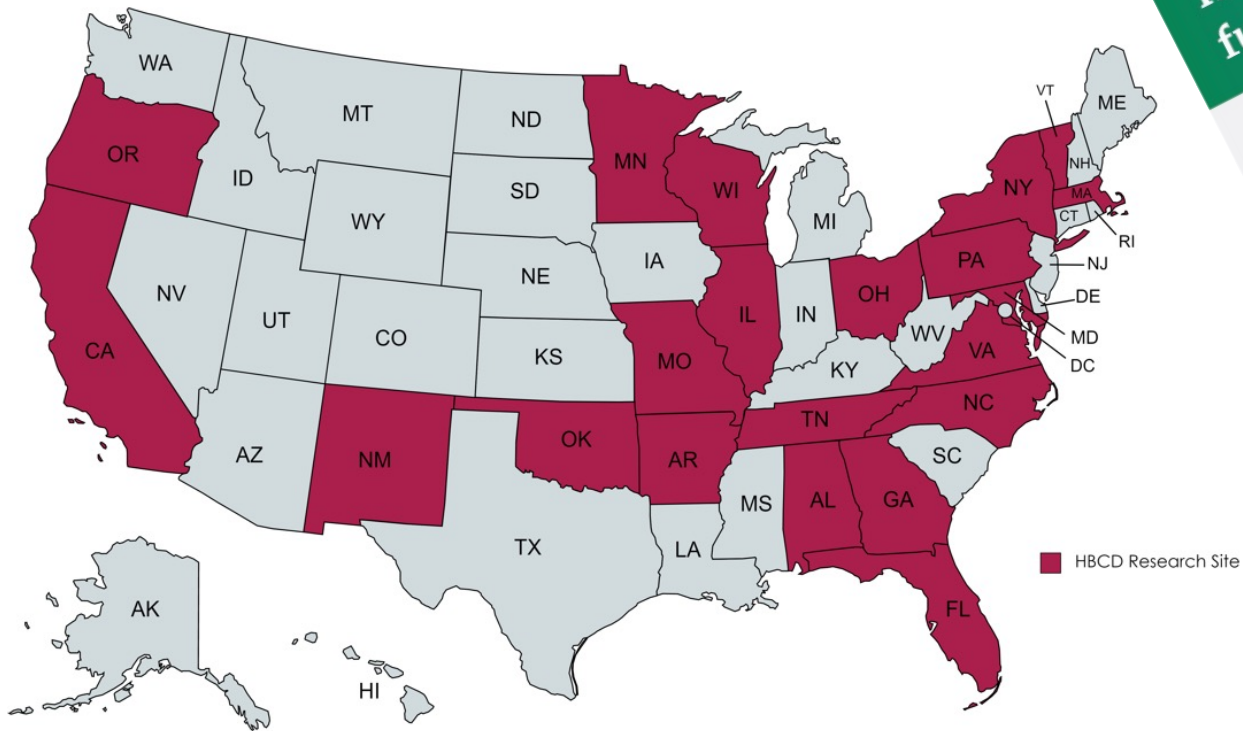


As of September 2022

HEALthy Brain and Child Development Study



10 sites ready to begin pilot testing



Help create a healthy future for your child!

The HEALthy Brain and Child Development (HBCD) Study is enrolling pregnant volunteers to understand how the brain develops during pregnancy, infancy, and childhood.

You may be eligible to participate in your area. Visit HBCDStudy.org to learn how.

HEALthy Brain and Child Development
Babies · Brains · Bright Futures

The **H**EALthy **B**rain and **C**hild **D**evelopment (HBCD) Study

What is the HBCD Study?

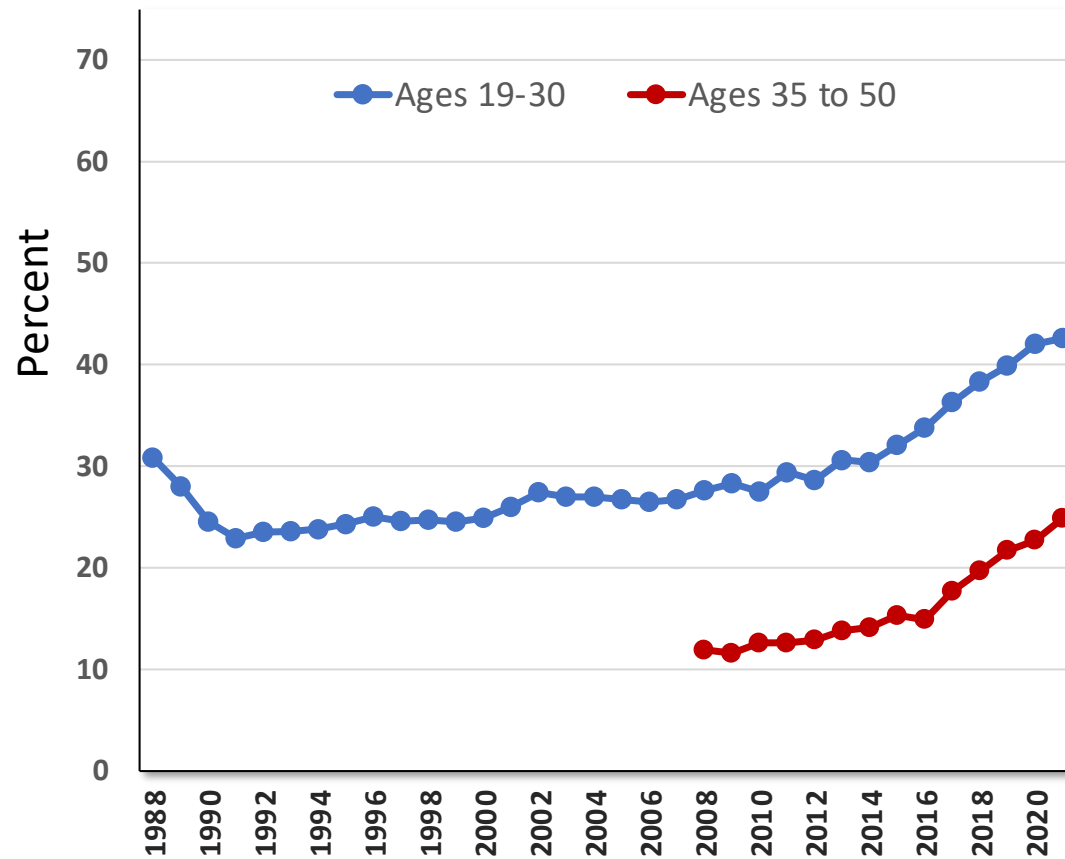
The HBCD Study will enroll a large cohort of participating families from across the U.S. and follow them and their children through early

<http://hbcdstudy.org>

National Data on Substance Use Among Adults Ages 19-30 and 35-50, 1988-2021

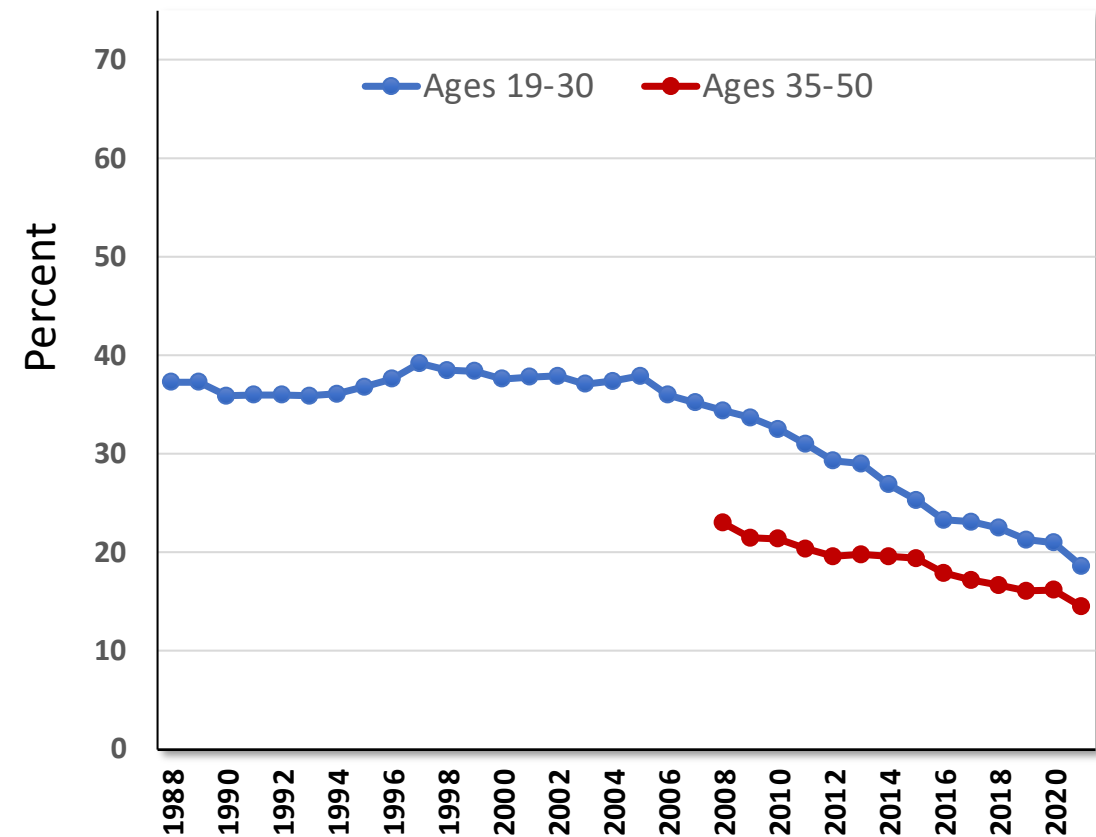
MARIJUANA

Trends in 12 Month Prevalence
Among Ages 19-30 and 35-50



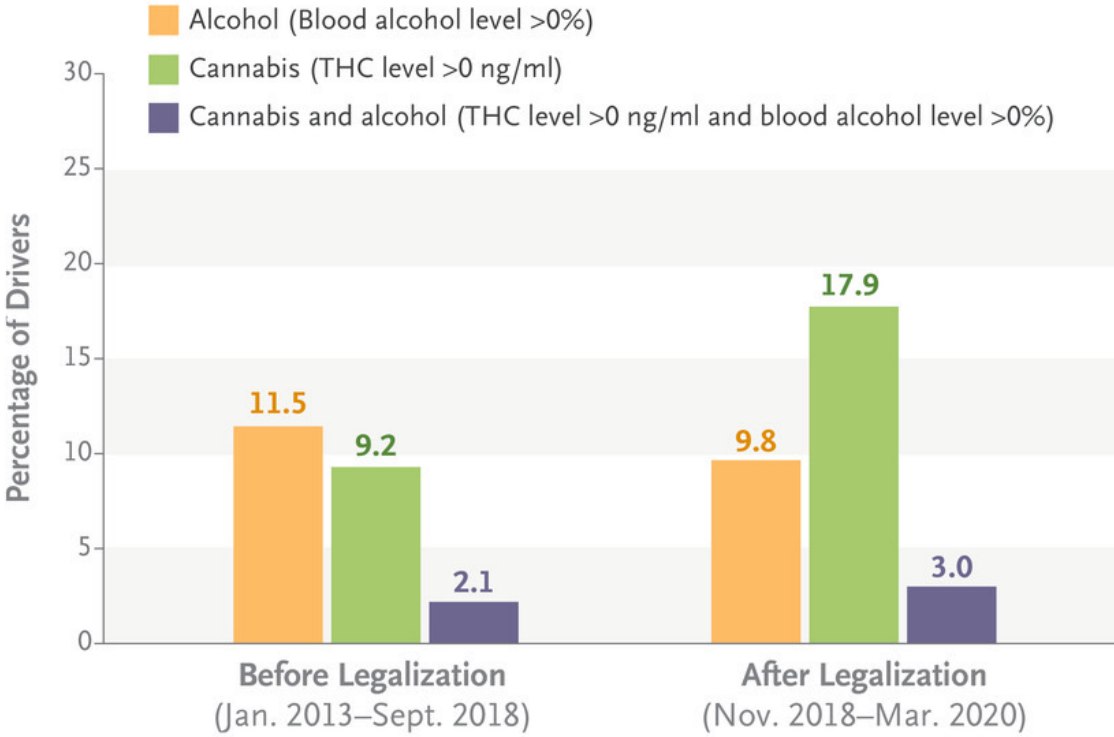
CIGARETTES

Trends in 12 Month Prevalence
Among Ages 19-30 and 35-50



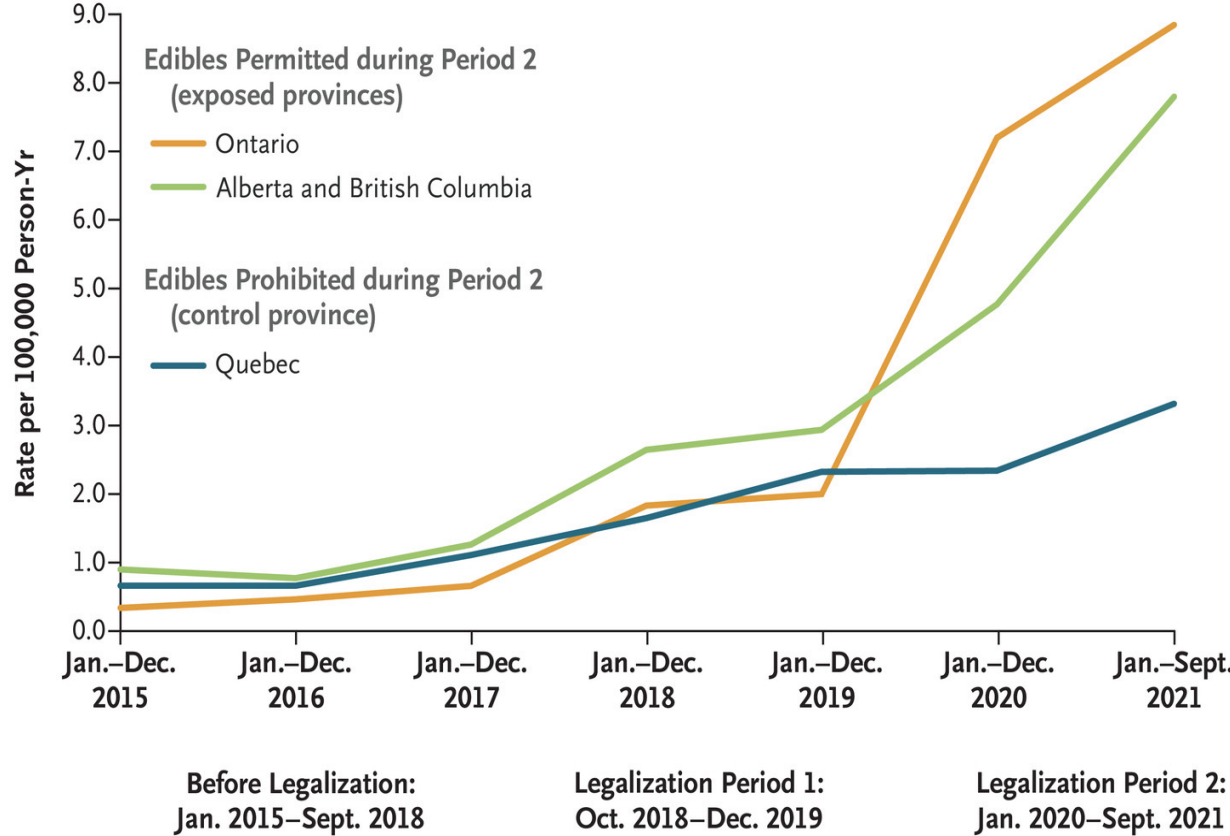
Cannabis Legalization and Detection of THC in Injured Drivers

Substance Levels in Moderately Injured Drivers before and after Cannabis Legalization



CONCLUSIONS
 The percentage of moderately injured drivers who had THC levels above the legal limit more than doubled after cannabis legalization in Canada

Rates of Hospitalization for Cannabis Poisoning in Children 0 to 9 Years of Age in Four Canadian Provinces, 2015–2021



Before Legalization: Jan. 2015–Sept. 2018
 Legalization Period 1: Oct. 2018–Dec. 2019
 Legalization Period 2: Jan. 2020–Sept. 2021

Significant increases in ED visits due to cannabis exposures among children after legalization of recreational cannabis

Brubacher JR et al., N Engl J Med 2022; 386:148-156.

Myran DT et al., JAMA Network Open 2022.



**Intersection
Between
COVID-19 and
Substance Use
Disorders**

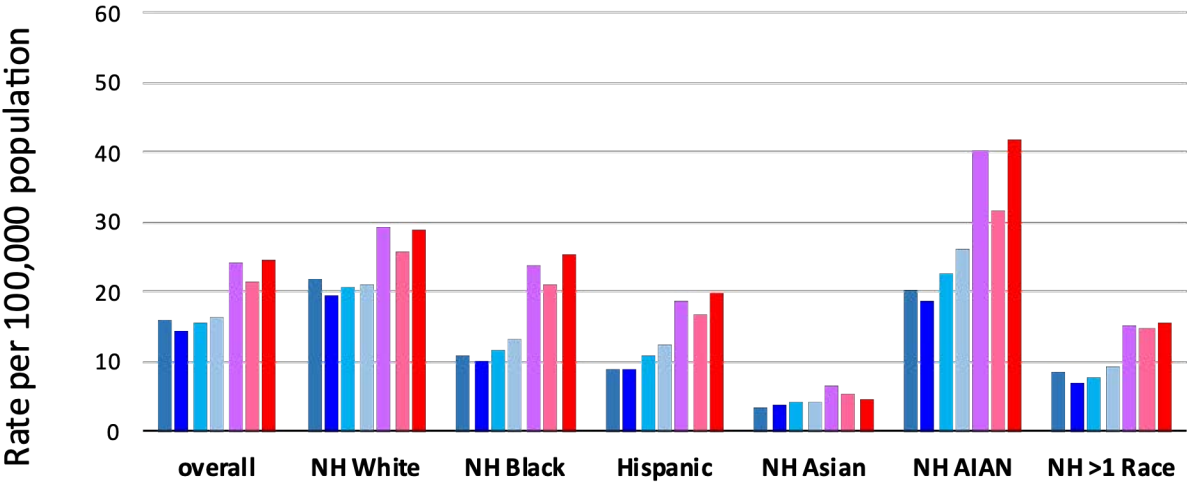
Drug Overdose Deaths* Continue to Increase

	ALL DRUGS	HEROIN	NAT & SEMI SYNTHETIC	METHADONE	SYNTHETIC OPIOIDS (mainly illicit fentanyl)	COCAINE	OTHER PSYCHO-STIMULANTS (mainly meth)
3/2021*	99,567	12,733	14,061	3,893	63,389	20,780	27,435
9/2021	105,654	10,227	14,023	3,733	68,880	23,127	31,647
3/2022*	109,247	8,328	13,376	3,527	73,473	25,959	33,994
Percent Change 3/21–3/22	9.7%	-34.6%	-4.9%	-9.4%	15.9%	24.9%	23.9%

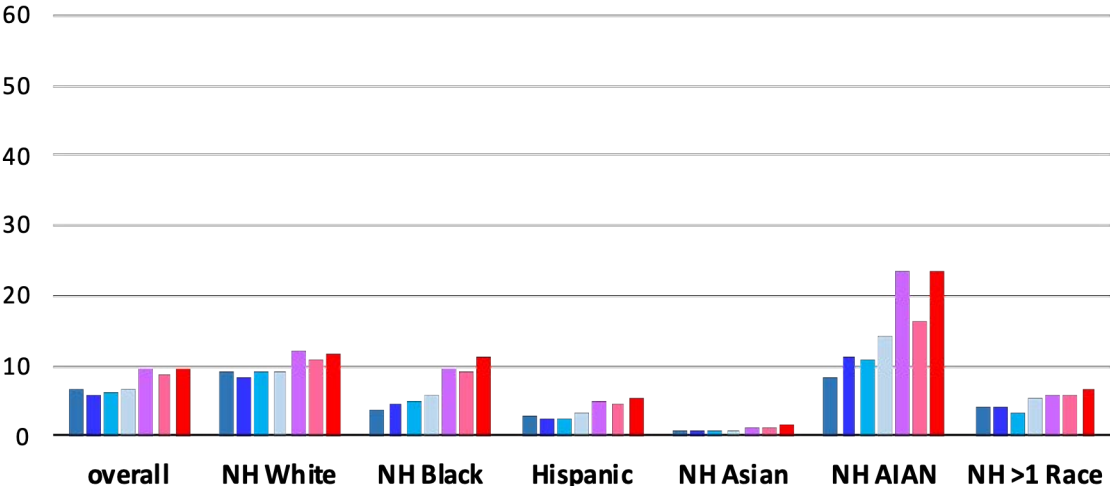
*NCHS Provisional drug-involved overdose death counts are PREDICTED VALUES, 12 months ending in select months.
<https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

Overdoses Before and During the COVID-19 Pandemic

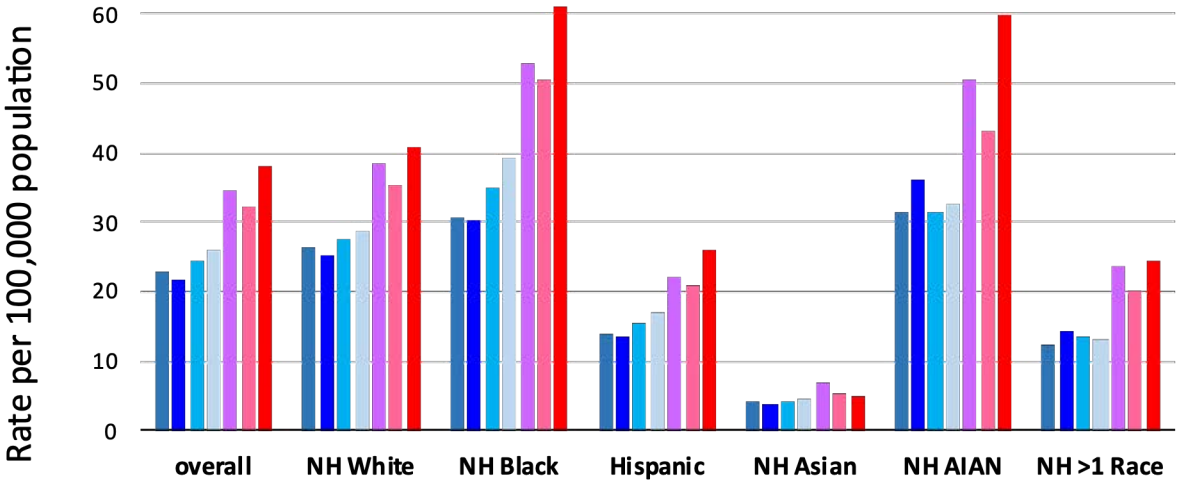
Men aged 15-34



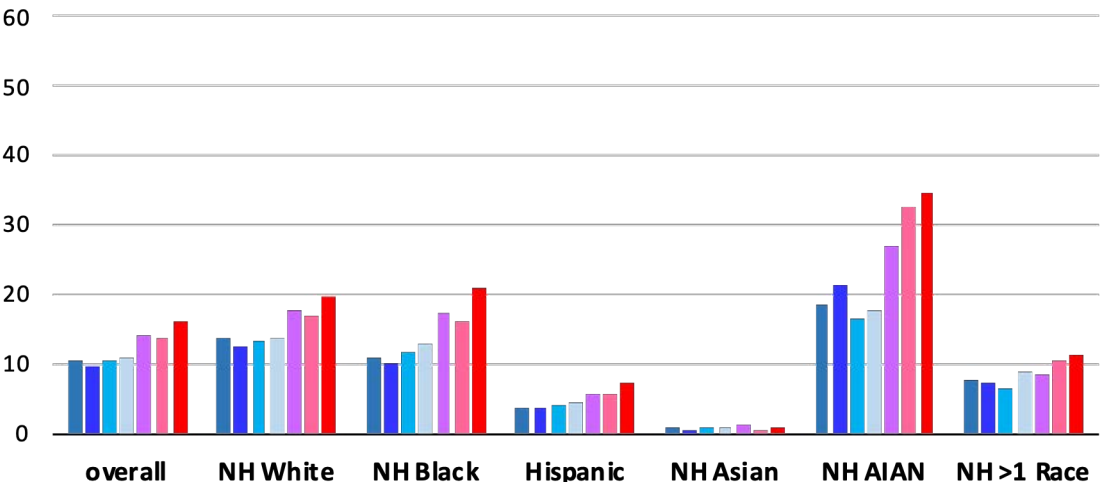
Women aged 15-34



Men aged 35-64



Women aged 35-64

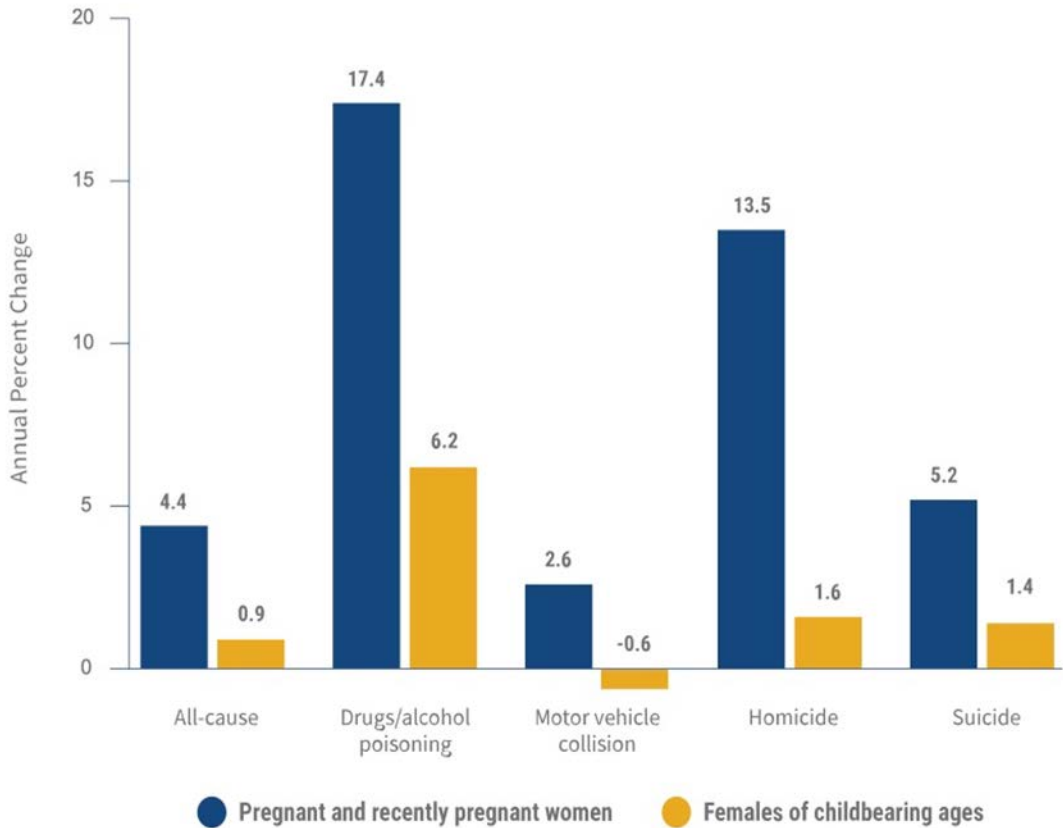


■ Mar-Aug 2018 ■ Sep 2018-Feb 2019 ■ Mar-Aug 2019
■ Sep 2019-Feb 2020 ■ Mar-Aug 2020 ■ Sep 2020-Feb 2021

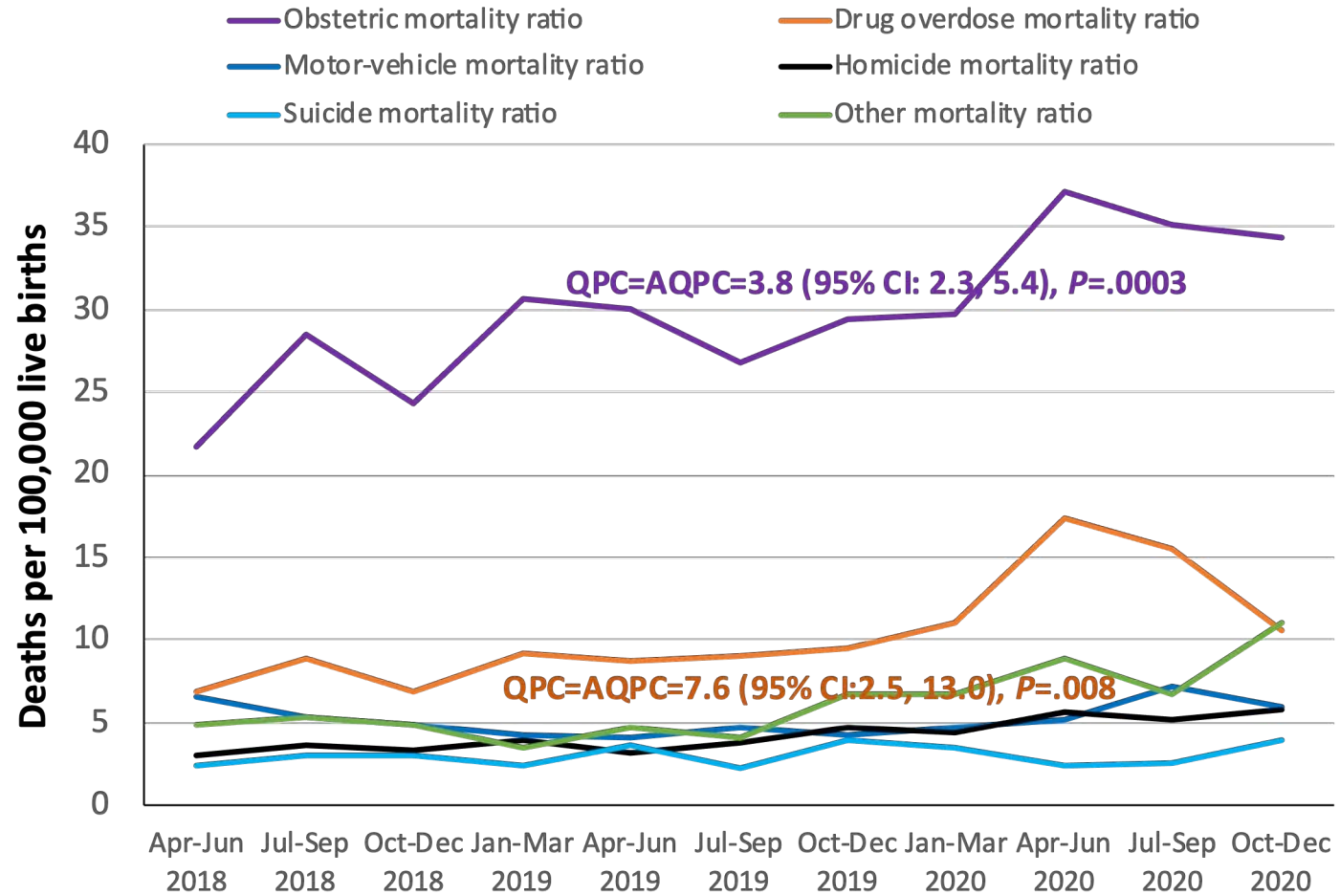
NH: non-Hispanic.
 AIAN: American Indian/Alaska Native.
 March–August 2020: COVID-19 pandemic.

Han et al., unpublished

Mortality from Alcohol and Drugs Increased Sharply in Pregnant Women Between 2015 and 2019

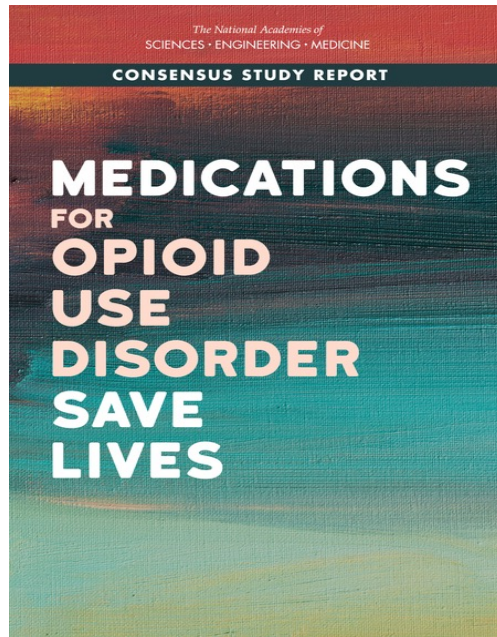


Trends In Pregnancy-Associated Mortality Ratios By Causes In US

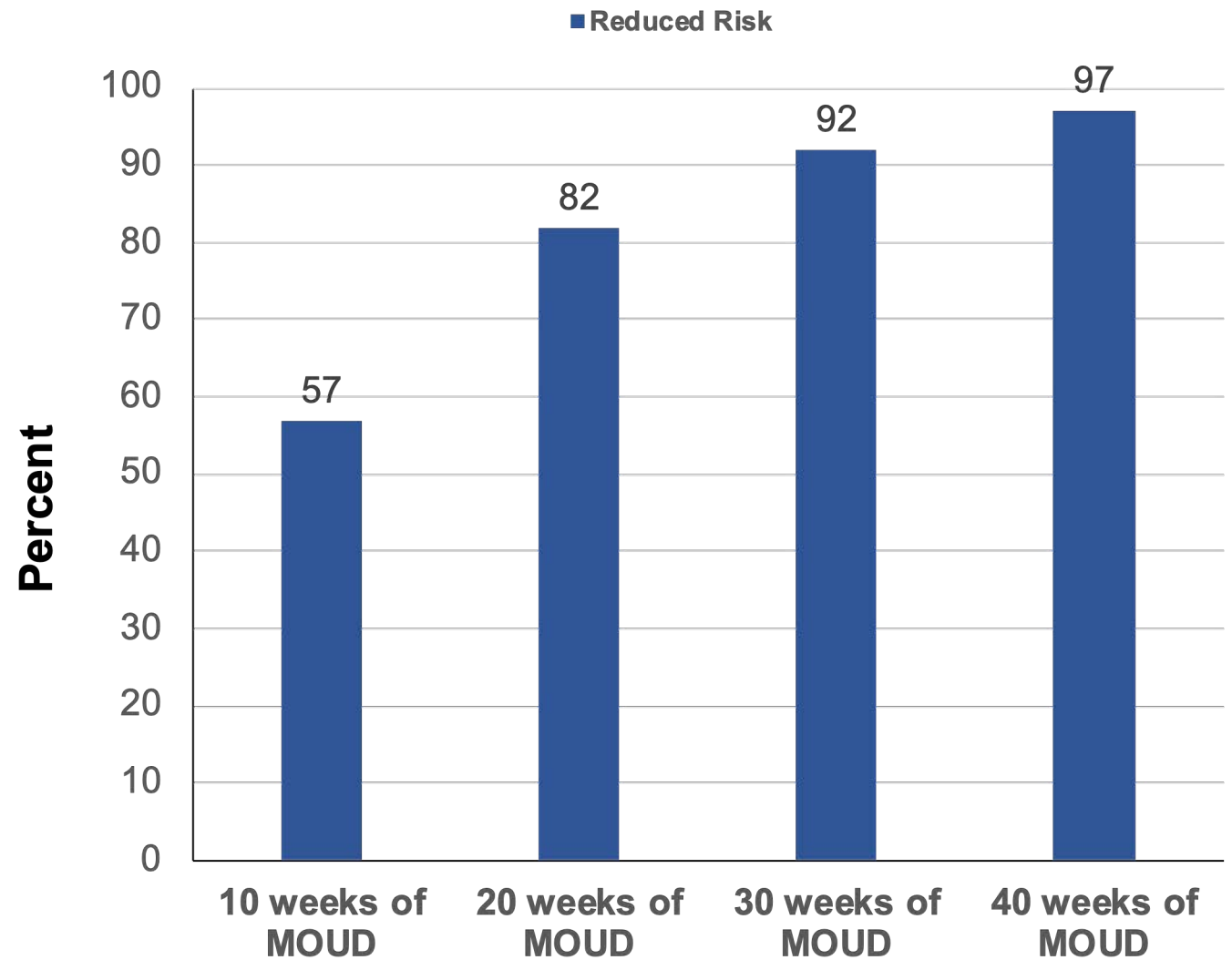


Jeffrey et al., *JAMA*326, no. 16 (2021): 1631–33

Data sources: National mortality and birth data. Pregnancy-associated death is defined as a maternal death attributable to a condition unaffected by the pregnancy per se and occurs while pregnant or within 12 months end of pregnancy.



Reduced Risk Overdose in Pregnant Women Given Medications for OUD



FDA-Approved Medications

Methadone



In use since the 1960s, the slow-acting synthetic opioid agonist effectively treats moderate to severe heroin addiction. It is only available in heavily regulated clinics.

Buprenorphine/Suboxone



Approved in 2002, the long-acting opioid agonist relieves drug cravings with fewer side effects than other opioids and is available by prescription from certain doctors. Suboxone is designed to deter illicit use.

Naltrexone/Vivitrol



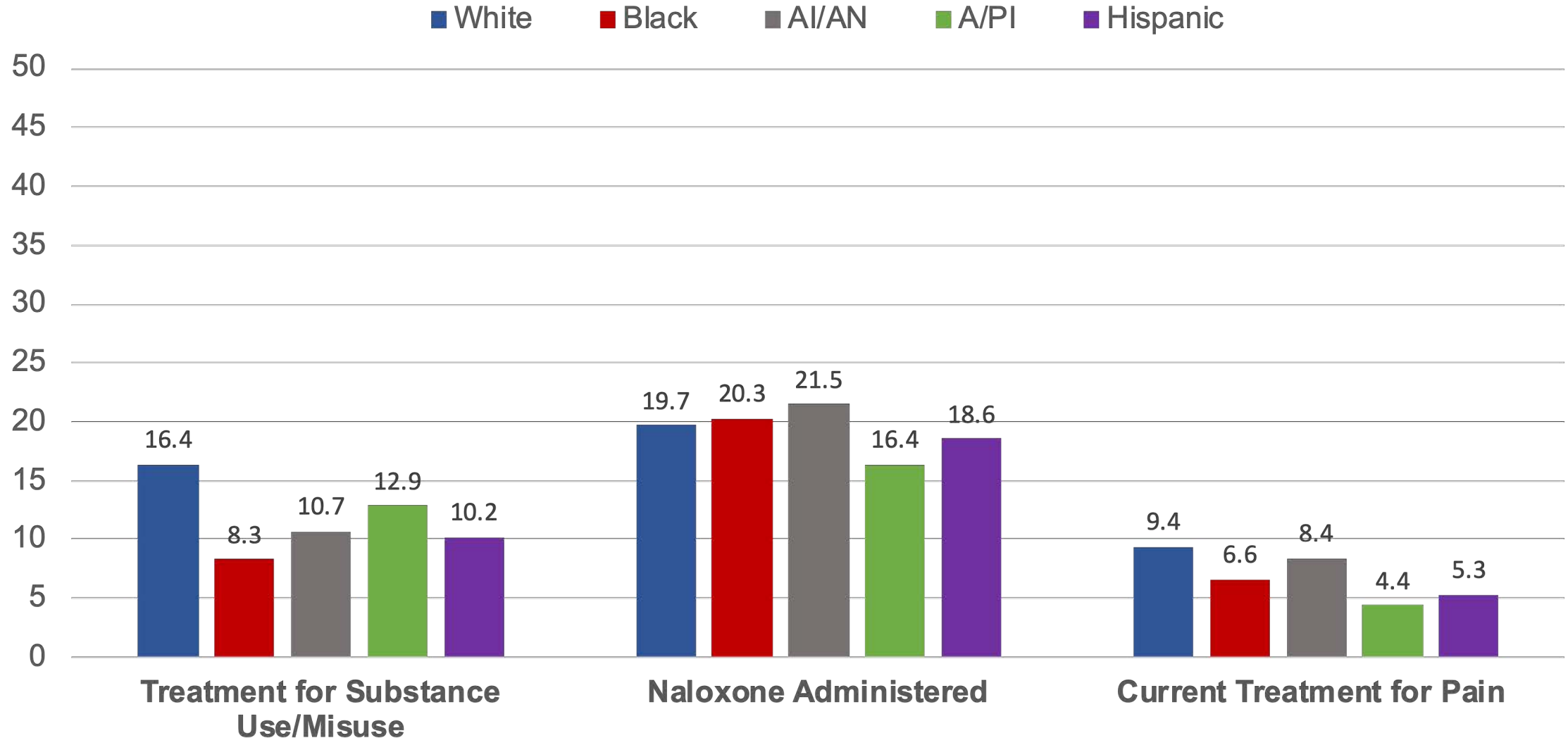
Approved in pill form in 1984, it has been available since 2010 as a 30-day time-release injectable medication called Vivitrol. Patients must be completely off all opioids for seven to 10 days. Both block the effect of opioids, do not activate the opioid receptor system, and do not cause physical dependence.

Naloxone



Approved in 1971, the short-acting medication, also known as Narcan and Evzio, reverses opioid overdoses but does not treat opioid addiction.

Characteristics Of Drug Overdose Deaths, Overall and By Race and Hispanic Origin — 25 States and The District Of Columbia, 2019–2020



Implementation Science: CTN, JCOIN, HCS, Prevention



NIH
HEAL
INITIATIVE

JCOIN
JUSTICE COMMUNITY OPIOID INNOVATION NETWORK

NIH
HEAL
INITIATIVE

HEALing
Communities
Study

[Enhancing the National Drug Abuse Treatment Clinical Trials Network to Address Opioids](#) Expand research conducted by NIDA CTN to address emergent needs presented by the opioid crisis.

[Justice Community Opioid Innovation Network](#) Study quality care for OUD in justice populations. Help create partnerships between local and state justice systems and community-based treatment providers.

[HEALing Communities Study](#) is investigating coordinated approaches for deploying evidence-based strategies to prevent and treat OUD in 67 communities in 4 states.

HEAL Harm Reduction Approaches to Reduce Overdose Deaths

Harm reduction approaches connect people who use drugs with services and resources they need (ie naloxone, SEP, fentanyl test strips). Research is to identify ways to enhance access and to measure effectiveness. Program will establish:

- 1) **National network of research projects** to improve effectiveness, implementation, and impact of existing and new harm reduction policies and practices, to be done in **real-world settings with a diverse range of stakeholders** to ensure strategies are sustainable and scalable.
- 2) **Coordinating center to support the research projects** by streamlining communication, supporting data needs, engaging community stakeholders, and translation of findings for use.

HEAL Recovery Research Networks

Recovery support services provide a variety of non-clinical services over the long-term to address loss of jobs, homes, relationships, or the effects of justice system involvement, but their effectiveness has not been adequately studied. Program will establish:

- 1) **Multi-stakeholder networks** (researchers, payors, providers, people in recovery) to build infrastructure to set research agendas; build tools, methods, and relationships; and train researchers. Will address *peer recovery support, recovery community centers, active recovery communities, continuing care, or integrated networks*. Support to prepare for clinical trials testing specific services.
- 2) **Consortium on Addiction Recovery Science** (CoARS), to coordinate cross-project activities

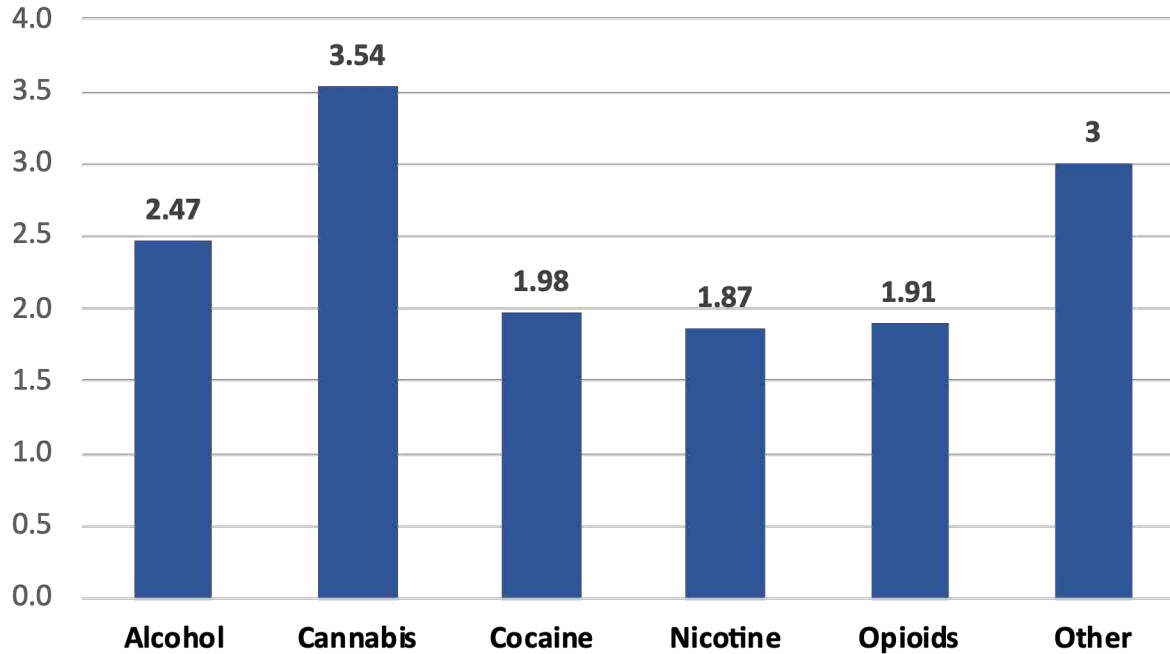
NIDA Division of Therapeutics and Medical Consequences Funding Opportunity Announcements

- Grand Opportunity Med Development for SUD (U01 Clinical Trial Optional; 5M direct q/y, max 3y) <https://grants.nih.gov/grants/guide/pa-files/PAR-22-202.html>
- Development of Medications to Prevent and Treat Opioid and/or Stimulant Use Disorders and OD (UG3/UH3 - Clinical Trial Optional; 3M direct q/y up to 5y) <https://grants.nih.gov/grants/guide/pa-files/PAR-22-200.html>
- Behavioral & Integrative Treatment Development Program (R01 Clinical Trial Optional) <https://grants.nih.gov/grants/guide/pa-files/PAR-22-182.html>
- Device-Based Treatments for SUD (UG3/UH3, Clinical Trial Optional; 500k UG3 phase; no limit UH3) <https://grants.nih.gov/grants/guide/pa-files/par-20-279.html>
- Developing Digital Therapeutics for SUD (UG3/UH3 Clinical Trial optional) <https://grants.nih.gov/grants/guide/pa-files/PAR-21-183.html>

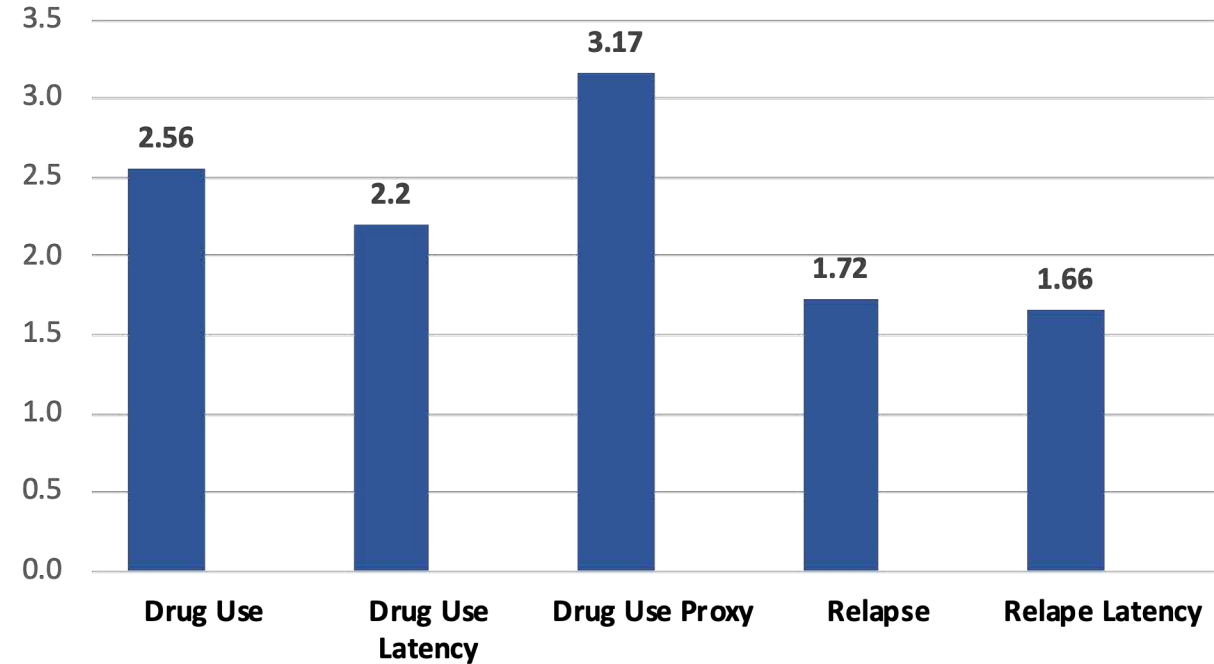
Alternative Outcomes for Medication Development

Reducing Craving Reduces Relapse Risk

Drug Type



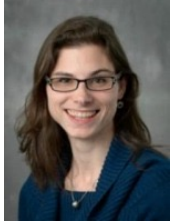
Outcome



Significant prospective association of craving with drug use/relapse was found (OR, 2.05; 95% CI, 1.94-2.15)

Use of craving as a measurable variable to estimate risk of drug use/relapse across clinical settings and to serve as an outcome variable to evaluate medication for SUD.

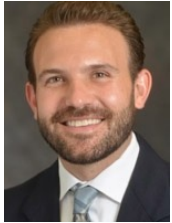
HIV Avenir Research



Jacqueline Linnes, PhD,

Purdue University

Towards Acute HIV Infection Detection at the Point-of-Use



Ian Holloway, PhD,

University of California, Los Angeles

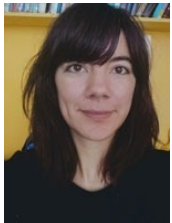
uTECH: ML for HIV Prevention Among Men Who Have Sex With Men Who Use Substances



Gregg Gonsalves, PhD,

Yale University

An Adaptive Approach to Active Surveillance for HIV (and SARSCoV2)



Annick Bórquez, PhD,

University of California, San Diego

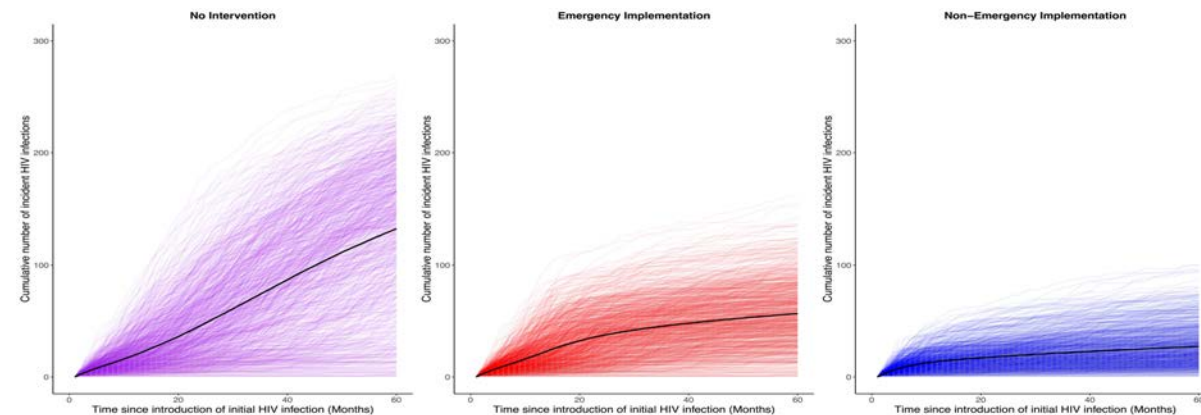
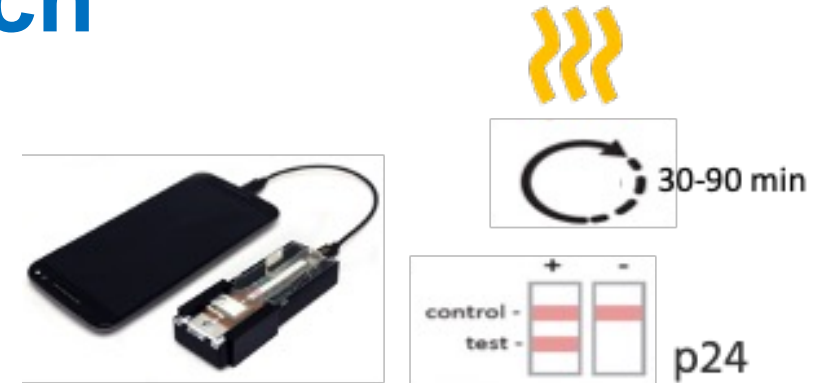
Predicting drug-related epidemics in US



Brandon Marshall, PhD,

Brown University

Agent-based modeling to estimate impact Of SSP on HIV transmission among PWID



NIDA Racial Equity Initiative Status Update

- The workplace workgroup mission will fall under the Racial and Ethnic Equity Plan (REEP) that all ICs are establishing as part of the UNITE initiative. Results from the second NIDA Climate Survey were presented to NIDA staff yesterday
- **New** NIDA, NIMH, NINR, and NINDS Research Opportunities for New and "At-Risk" Investigators to Promote Workforce Diversity [PAR-22-181](#)
- Coordinated suite of [FOAs](#) have been released focused on:
 - Community-engaged research projects
 - HIV and substance use
 - Neurocognitive mechanisms of structural racism
 - Racial Equity Visionary Award Program
 - Coordinating Center
- RFI and listening session feedback are being synthesized to inform REI Action Plan
- [Virtual Meeting on the Neurocognitive Mechanisms of Structural Racism](#) held in May
 - Attended by more than 900 neuroscientists and psychiatrists
 - Interdisciplinary speakers explored how to be anti-racist as neuroscientists

NACDA Future of MERIT Awards Workgroup

Charge:

The working group will review the current criteria for the award and consider if changes are needed, if the criteria should remain the same, or if the MERIT award should be discontinued. Suggestions on the future of the award will be presented to the NACDA for consideration.

Working Group Members:

Sara Becker – Northwestern

Debra Furr-Holden – NYU

Brandon Henderson – Marshall University

Paul Kenny (NACDA member) – Mount Sinai

Melissa Walls (NACDA member) – Johns Hopkins University

Sharon Walsh (NACDA member) – University of Kentucky

National Institutes of Health (NIH)/National Institute on Drug Abuse (NIDA) and Food and Drug Administration (FDA)/Center for Devices and Radiological Health (CDRH) Public Workshop: Diagnostic and Monitoring Medical Devices for Opioid Use

November 7, 2022 | 10:00 a.m. – 4:30 p.m. EST

Natcher Conference Center, Building 45
NIH Campus, Bethesda, MD

[WELCOME](#)

[AGENDA](#)

[REGISTRATION](#)

[DAY 2 WORKSHOP](#)

[COVID PROTOCOLS](#)

[LOCATION INFORMATION](#)

[CONTACT](#)

Welcome

Welcome to the Public Workshop: Diagnostic and Monitoring Medical Devices for Opioid Use, sponsored by the National Institute on Drug Abuse and the Food and Drug Administration. This is a hybrid Workshop. This is a hybrid Workshop to be held on November 7th. In-person attendance will be at the [Natcher Auditorium](#) on the National Institutes of Health main campus, and virtual attendance will be via the Zoom Meeting platform.

A second virtual workshop will be held on November 8th:

Food and Drug Administration (FDA)/Center for Devices and Radiological Health (CDRH) and National Institutes of Health (NIH)/National Institute on Drug Abuse (NIDA)

Public Workshop:

Risk Prediction Devices of Opioid Use and Opioid Use Disorder (OUD)- Opportunities and Challenges

November 8, 2022: 10 a.m. – 4 p.m. EST

Virtual Meeting

FY 2022-2026 NIDA Strategic Plan



Thank you!