

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

Nora D. Volkow, M.D.

Director, National Institute on Drug Abuse

May 7, 2024

Pay Level Increases for Pre- and Postdoctoral Scholars

- NIH will increase annual pay levels over the next 5 years for predoctoral and postdoctoral scholars at NIH-funded institutions recipients of the Ruth L. Kirschstein National Research Service Awards (NRSA).
- Applies to >17,000 research trainees
 - Predoctoral scholars: ~4% increase, bringing it to \$28,224
 - Postdoctoral scholars: ~8% increase with pay starting at \$61,008 and adjusted based on years of experience.
 - For eligible recipients: \$500 increase for childcare and \$200 for training-related expenses. This is the largest year-over-year update since 2017.

Establishing a Research Network in Primary Care Settings

NIH Common Fund Program to Support Clinical Research in Primary Care Settings

Problem: The health of the U.S. population is declining. Decline is steepest among the underserved and underrepresented.

Goals:

- Establish a **primary care-focused** clinical research network that is disease-agnostic, facilitating clinical research **in mission areas across all ICs**
- **Integrate innovative research** with routine clinical care in real-world settings
- Create a foundation for sustained **engagement with communities underrepresented in clinical research**

Anticipated Budget: OD funds \$5M in FY24, \$25M in FY25; anticipate ramp up of ~\$50-100M/year after assessing feasibility and budget requirements

Timeline: Gather Feedback in Spring 2024 → Quick Launch in 2024 → Expand in 2025 and Beyond

10th Annual BRAIN Initiative Conference

Register Soon!

June 16, 2024: Early career researcher evening networking event

June 17 – June 18, 2024: Plenary talks, posters, symposia sessions, and more

A forum for:

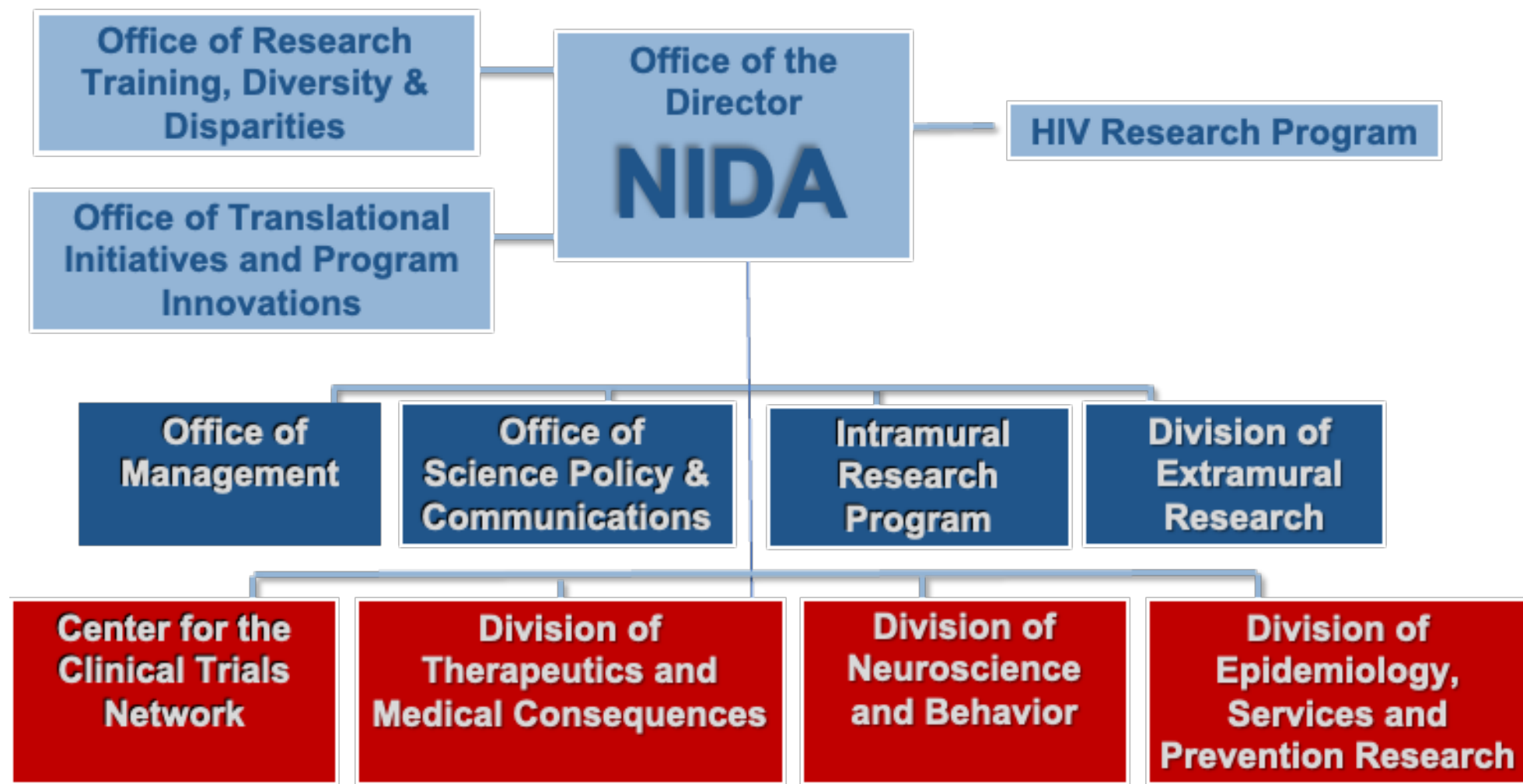
- sharing exciting scientific developments
- discussing potential new directions
- identifying areas for collaboration & research coordination



NIDA BUDGET

(All dollars are in thousands)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget
Base	\$1,250,828	\$1,308,070	\$1,308,070
HEAL	\$345,295	\$355,295	\$355,295
Total	\$1,596,123	\$1,663,365	\$1,663,365

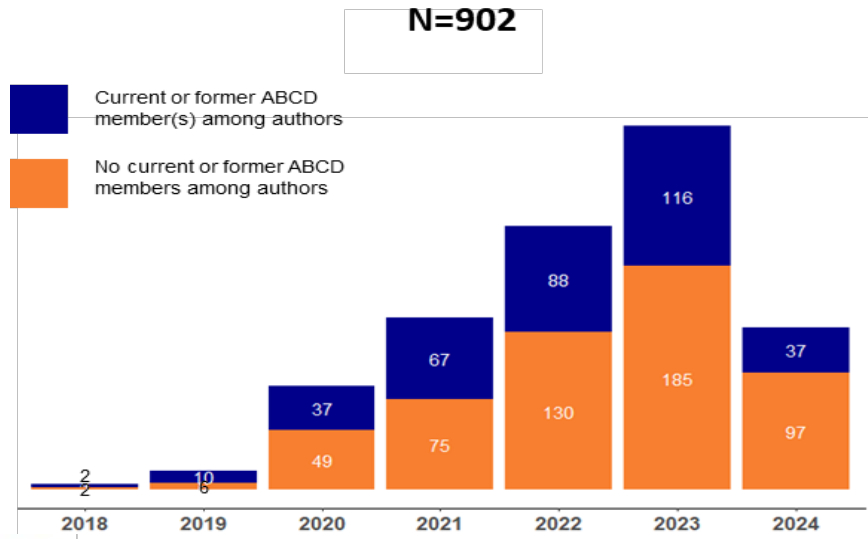


Iván D. Montoya, M.D., M.P.H.
Director
Division of Therapeutics and
Medical Consequences

Adolescent Brain Cognitive Development Study

Current visit – 6 & 7-year follow-ups (youth ages 15-18), 96% retained (as of 4/18/24)

Empirical Publications by ABCD Membership



60% by Non-ABCD scientists



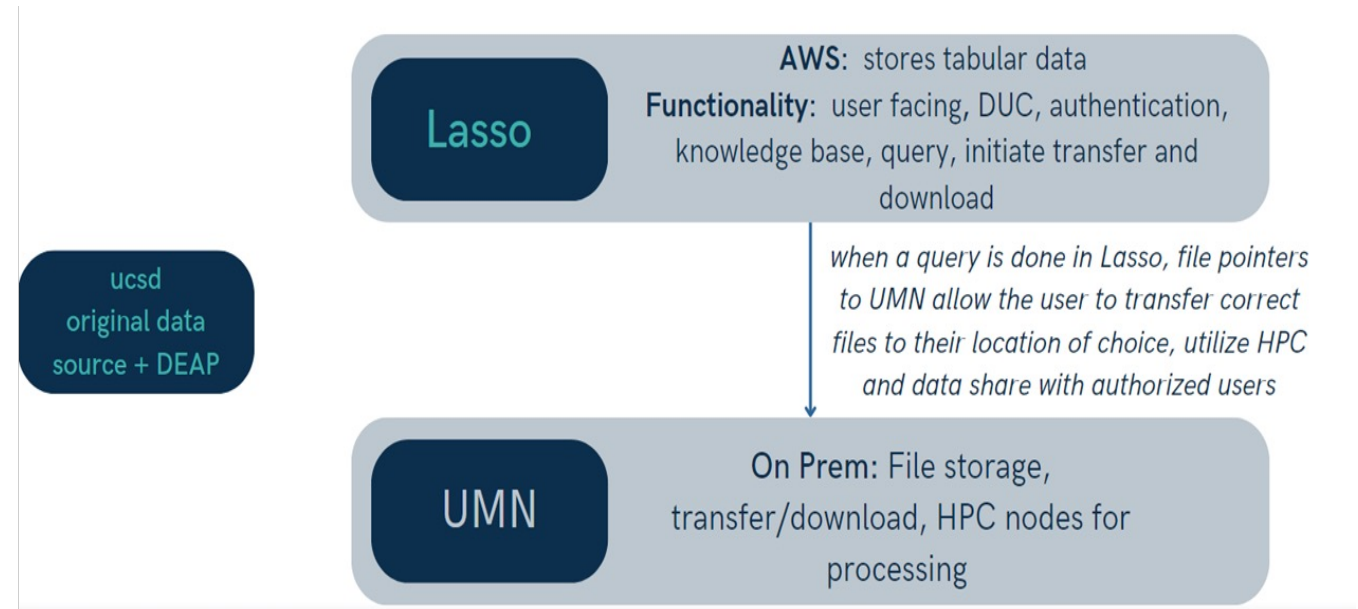
Summer 2024 NIH Brain Development Cohorts Data Sharing Platform

- Optimized for large datasets, including neuroimaging and genomics data
- Provides scalable data ingestion, integrated data analytics, customized user experience
- Provides homogenous solution for harmonizing with planned data from the HBCD Study

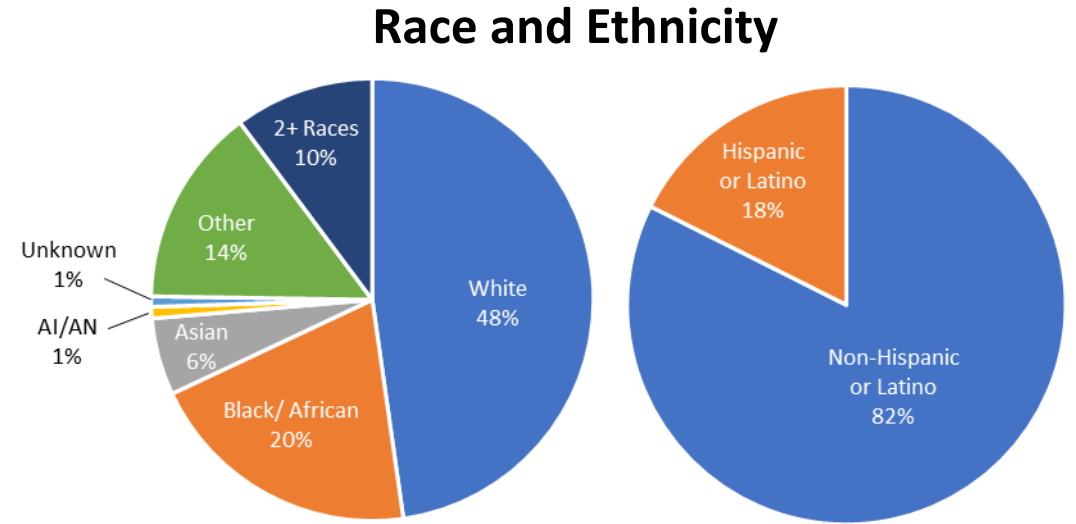
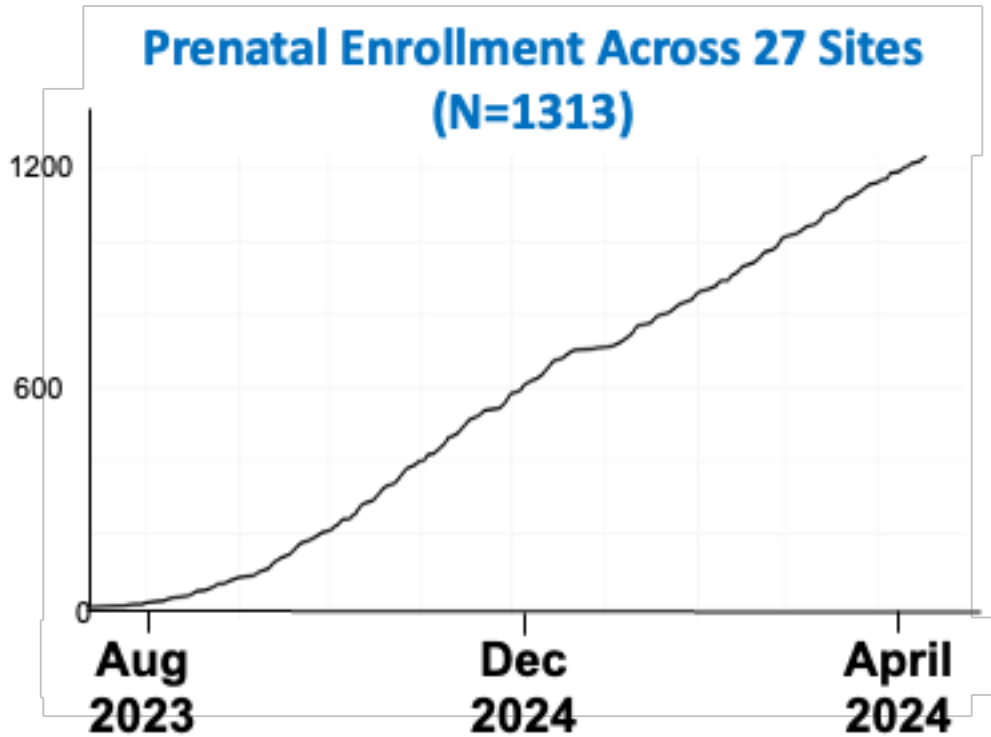


NIH Brain Development Cohorts (NBDC) Biospecimen Access Program

Scan for more information on the NBDC BAP

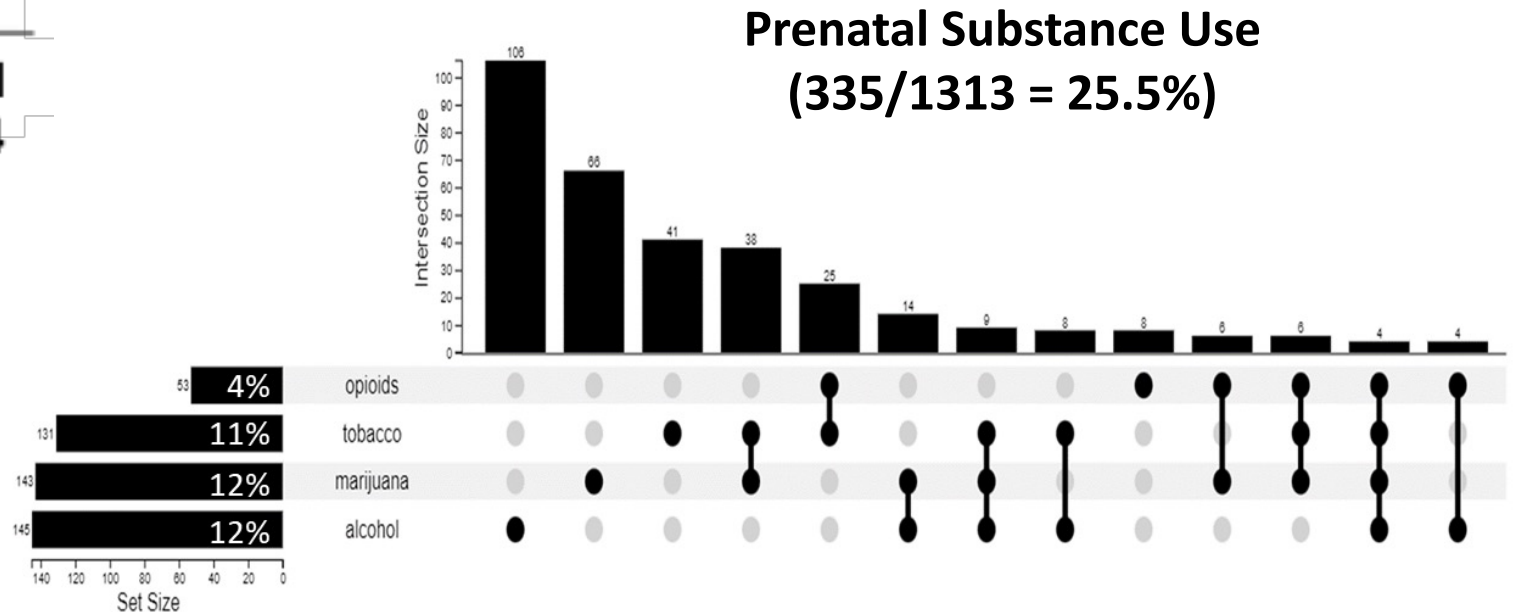


HEALTHY Brain and Child Development Study



Data Release Timeline

Summer/Fall 2024 – Freeze data
 Fall/Winter 2024 – Beta Release
 End of 2024/Early 2025 – Full Release



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

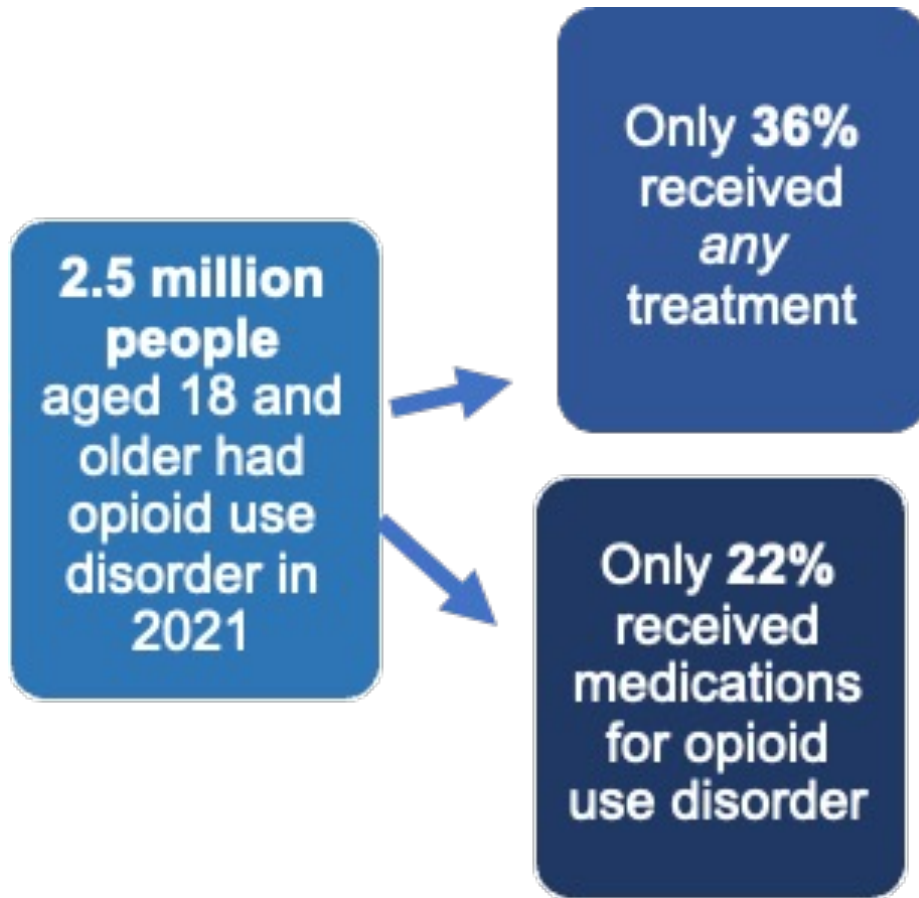
	ALL DRUGS	HEROIN	NAT & SEMI SYNTHETIC	METHADONE	SYNTHETIC OPIOIDS (illicit fentanyl)	COCAINE	OTHER PSYCHO-STIMULANTS (meth.)
11/2022*	110,063	6,198	12,197	3,426	75,418	27,991	35,001
5/2023*	113,127	5,170	11,695	3,514	78,947	30,346	37,141
11/2023*	109,527	4,249	10,448	3,396	76,303	30,326	36,836
Percent Change 11/22-11/23	-0.49%	-31.45%	-14.34%	-0.88%	1.17%	8.34%	5.24%

*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 2022 on slide 1 is limited to deaths in U.S. residents.

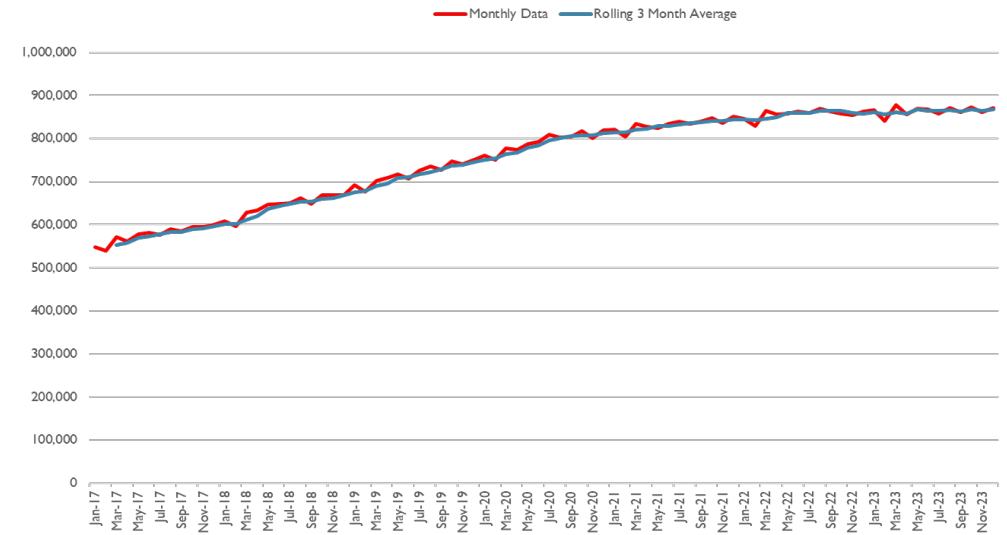
<https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

Use of Medication for Opioid Use Disorder Among Adults With Past-Year Opioid Use Disorder in the US, 2021

Christopher M. Jones, PharmD, DrPH, MPH; Beth Han, MD, PhD, MPH; Grant T. Baldwin, PhD, MPH; Emily B. Einstein, PhD; Wilson M. Compton, MD, MPE

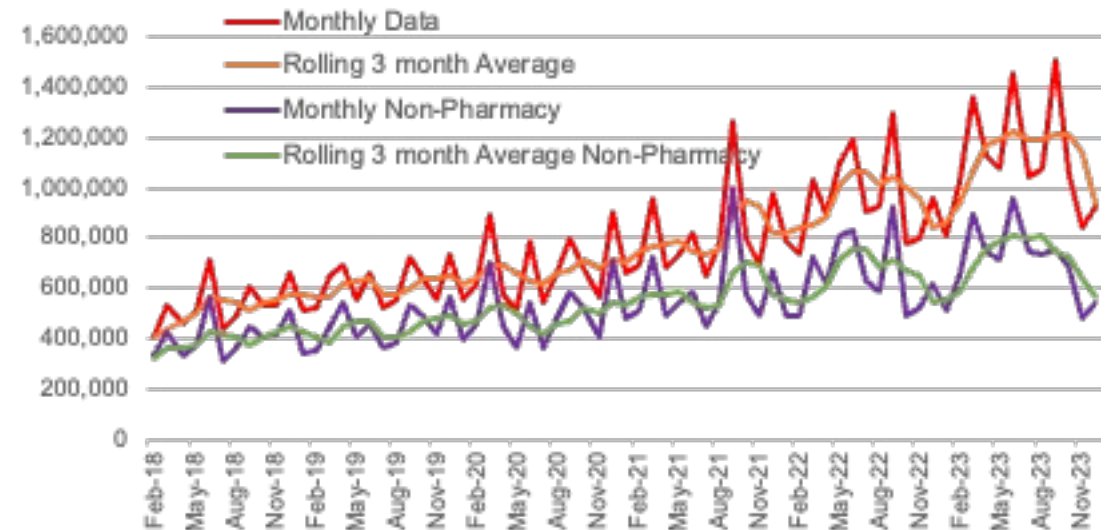


Unique Patients Receiving Buprenorphine



Source: IQVIA Total Patient Tracker. March 7, 2024. TPT measures prescriptions dispensed through retail

Naloxone Units Sold



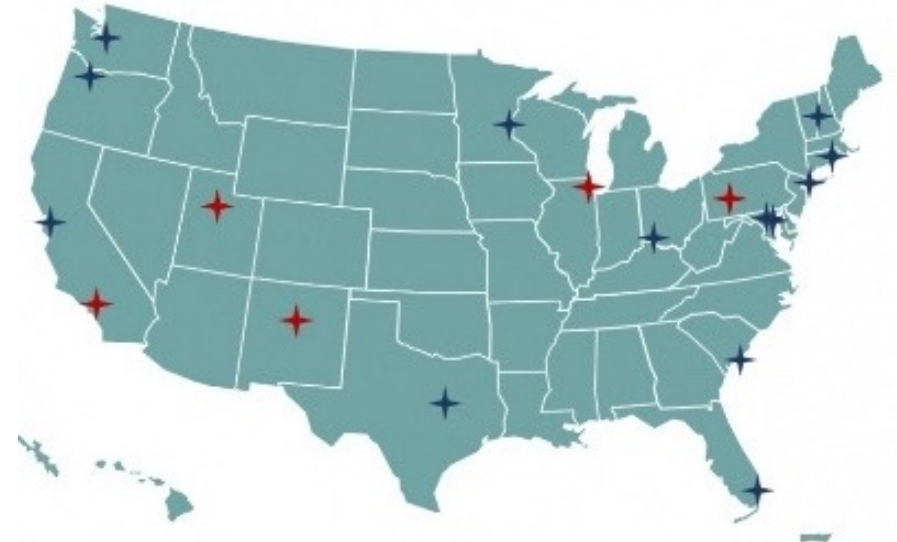
IQVIA National Sales Perspectives. March 6, 2024.



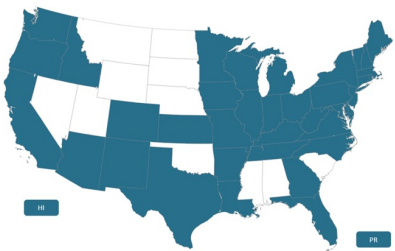
NIDA Clinical Trials Network

Effectiveness of treatments in diverse clinical settings and populations

- Emergency Department initiated MOUD
- Primary Care for Screening and OUD Treatment
- Integrating HIV and OUD care
- Spokes and Hub Model
- Pharmacy Delivery of MOUD
- Mobile Delivery of MOUD
- Telehealth for OUD treatment and care



The healthcare system represents the most impactful infrastructure to prevent and treat substance use disorders including interventions to address the overdose crisis.



Bridging the Research-Practice Gap

Building the Evidence Base

- 83 Research protocols
 - 13 Multisite clinical trials
 - >23,000 participants
 - 14 Small grant awards
 - 14 Modeling + mapping studies
 - 6 National surveys
 - 6 Diversity supplements
- 140 counties across 38 states
- 165+ publications
- Coordination with ONDCP, BJA, BJS, SAMHSA, BOP

Building Capacity

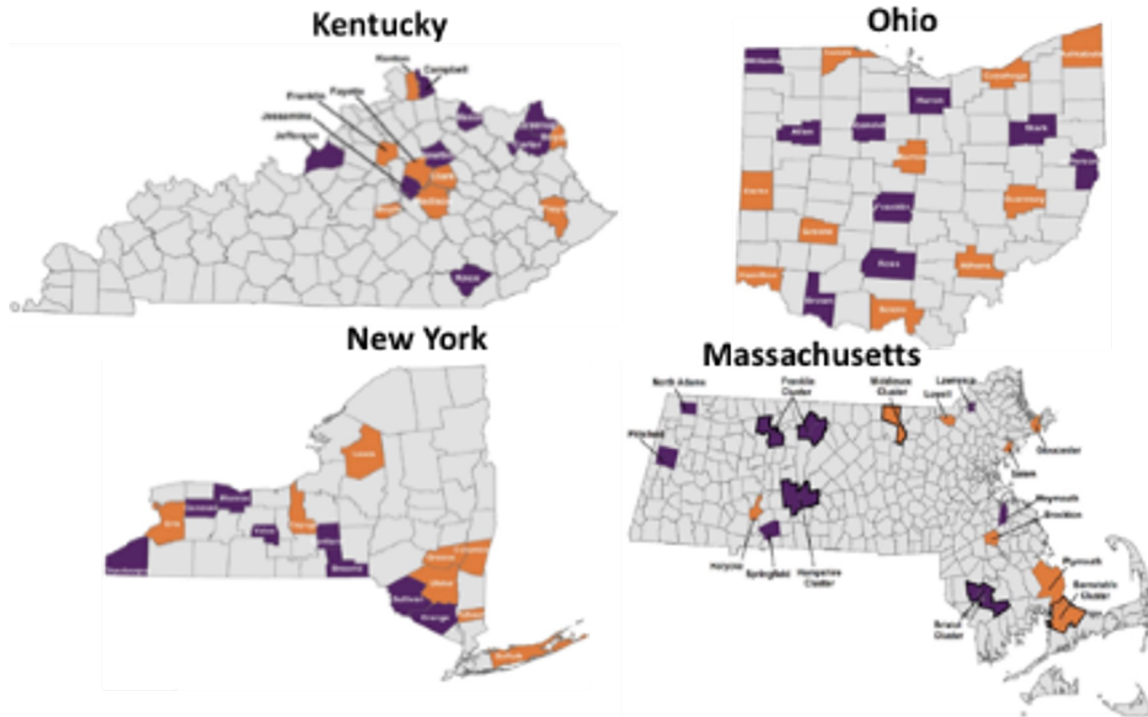
- LEAP R25 Training Program
 - 71 practitioner & ESI
- Online course catalog
 - 50+ courses
 - 6,500+ enrolled
 - 15,000+ podcast downloads
- Dozens of webinars & research translation products for diverse audiences
- Technical assistance platform
 - 93 engagements across the country

HEALing Communities Study

67 Communities:

- Implemented in 4 states
- Total population >10 million

Empower communities with data and support to partner with healthcare, justice, and State leaders to address overdose crisis



Goal: Reduce overdose deaths

Secondary Outcomes:

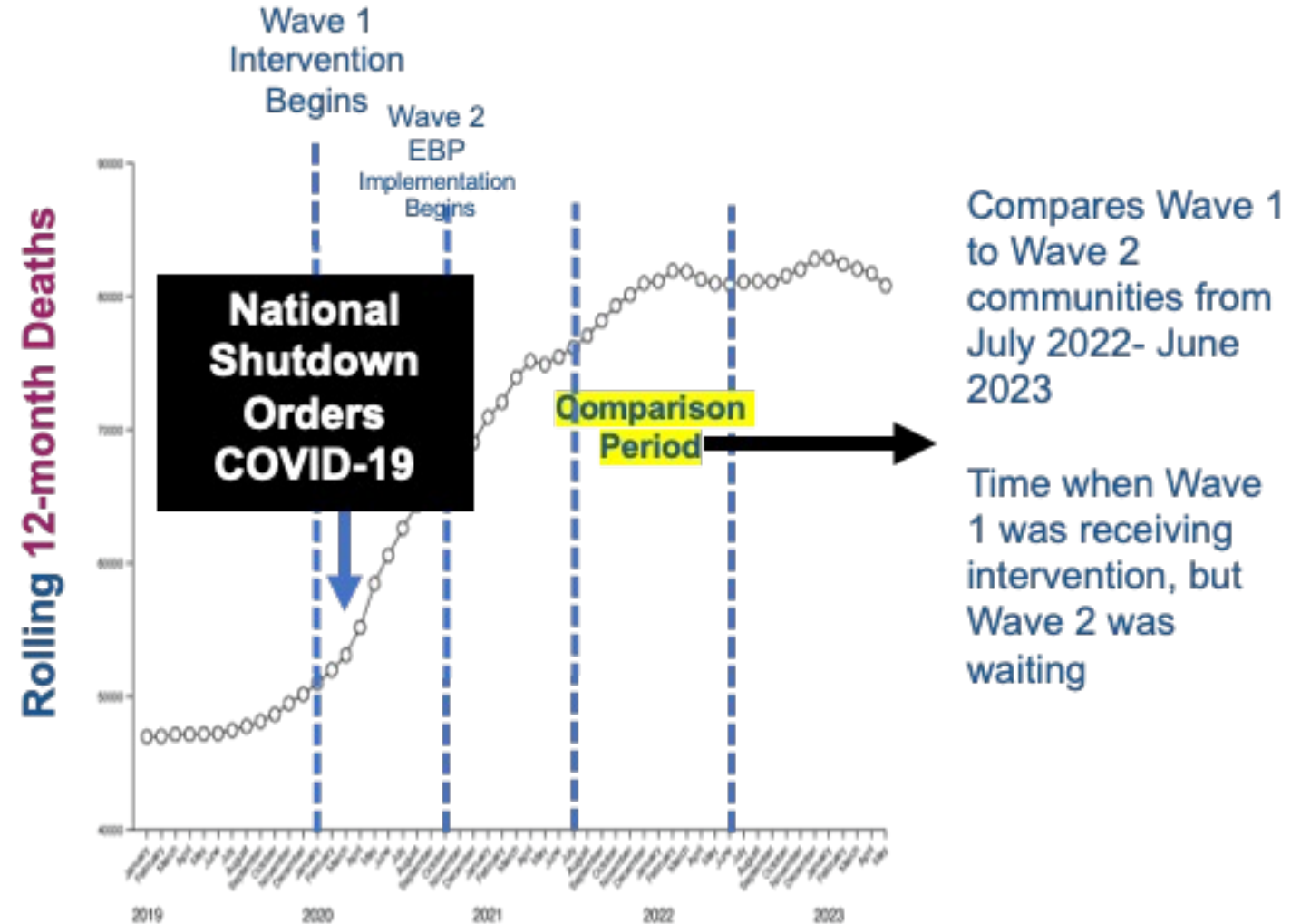
- Increase naloxone distribution
- Increase access/utilization of MOUD
- Decrease high risk opioid prescribing



Conclusions

- **9% reduction** opioid OD deaths (NS)
- **37% reduction** opioid + psychostimulant (excluding cocaine) deaths
- 525 total OD deaths averted W1
- Factors impacting results:
 - Increase in poly drug use
 - Increase of fentanyl
 - COVID
 - Limited time period from implementation of EBPs to see benefit in overdose death



Opioid Overdose Deaths and HCS Milestones





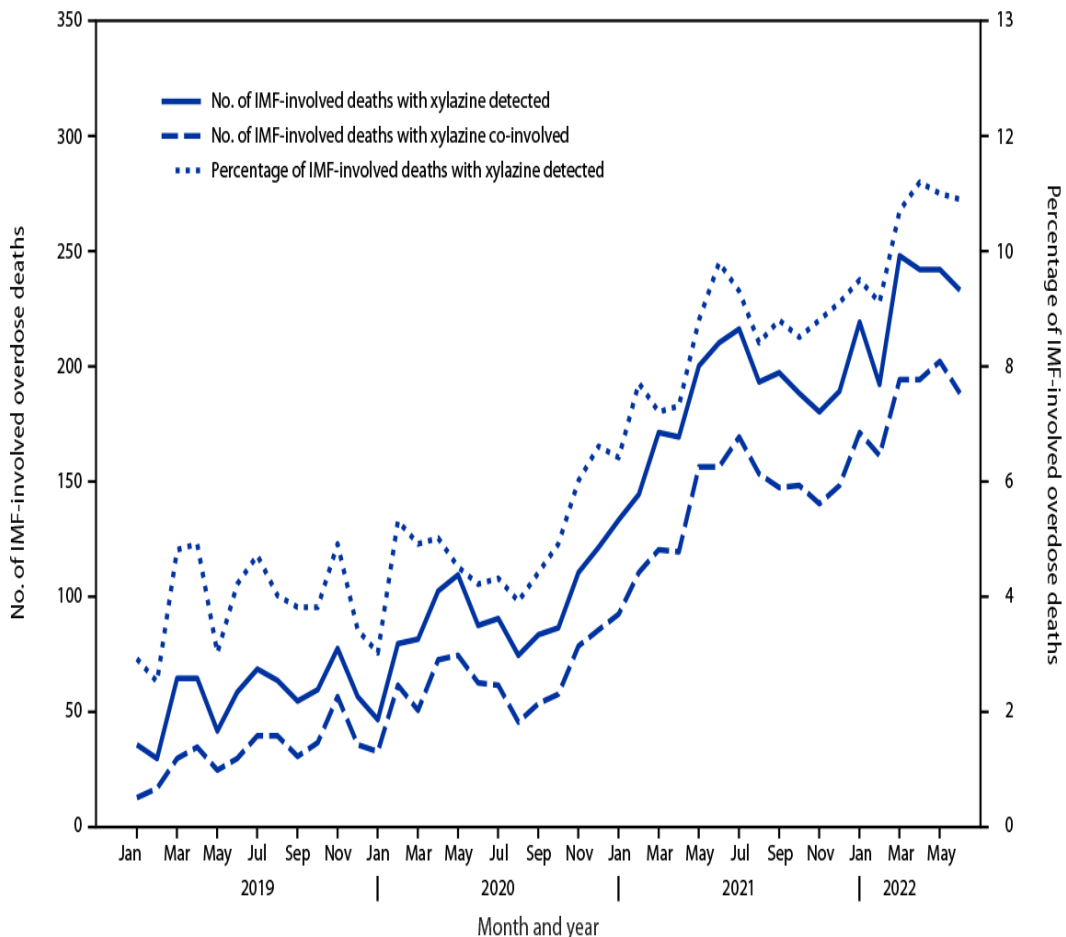
Toxicology/Review Article

National Institute on Drug Abuse Clinical Trials Network Meeting Report: Managing Patients Exposed to Xylazine-Adulterated Opioids in Emergency, Hospital and Addiction Care Settings

Jeanmarie Perrone MD^a  , Rachel Haroz MD^b, Joseph D'Orazio MD^b, Giacomo Gianotti DVM, DVSc^c, Jennifer Love MD^d, Matthew Salzman MD^e, Margaret Lowenstein MD, MSHP^f, Ashish Thakrar MD^g, Stephanie Klipp RN, CARN^h, Lisa Rae MDⁱ, Megan K. Reed PhD, MPH^j, Edward Sisco PhD^k, Rachel Wightman MD^l, Lewis S. Nelson MD, MBA^m

Identified research areas:

- fentanyl-xylazine overdose,
- xylazine dependence and withdrawal,
- xylazine-associated dermal manifestations,
- xylazine surveillance and detection in clinical and nonclinical settings.



FTS Update

 U.S. Department of Health & Human Services


Overdose Prevention Strategy

Facilitate evidence-based use of Fentanyl Testing Strips (FTS) and drug checking utilization in community and clinical settings

Because the presence of fentanyl mixed with other types of drugs poses a significant risk of accidental overdose and is often hard to detect, NIDA

Lead Agencies:
NIH, FDA



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June 10, 2023

SPECIALTIES ▾ TOPICS ▾ MULTIMEDIA ▾ CURRENT ISSUE ▾ LEARNING/CME ▾ AUTHOR CENTER PUBLICATIONS ▾

PERSPECTIVE

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Testing for Fentanyl — Urgent Need for Practice-Relevant and Public Health Research

Authors: Nora D. Volkow, M.D., Robert M. Califf, M.D., Marta Sokolowska, Ph.D., Lawrence A. Tabak, D.D.S., Ph.D., and Wilson M. Compton, M.D., M.P.E. [Author Info & Affiliations](#)

Published June 10, 2023 | N Engl J Med 2023;388:2214-2217 | DOI: 10.1056/NEJMp2302857

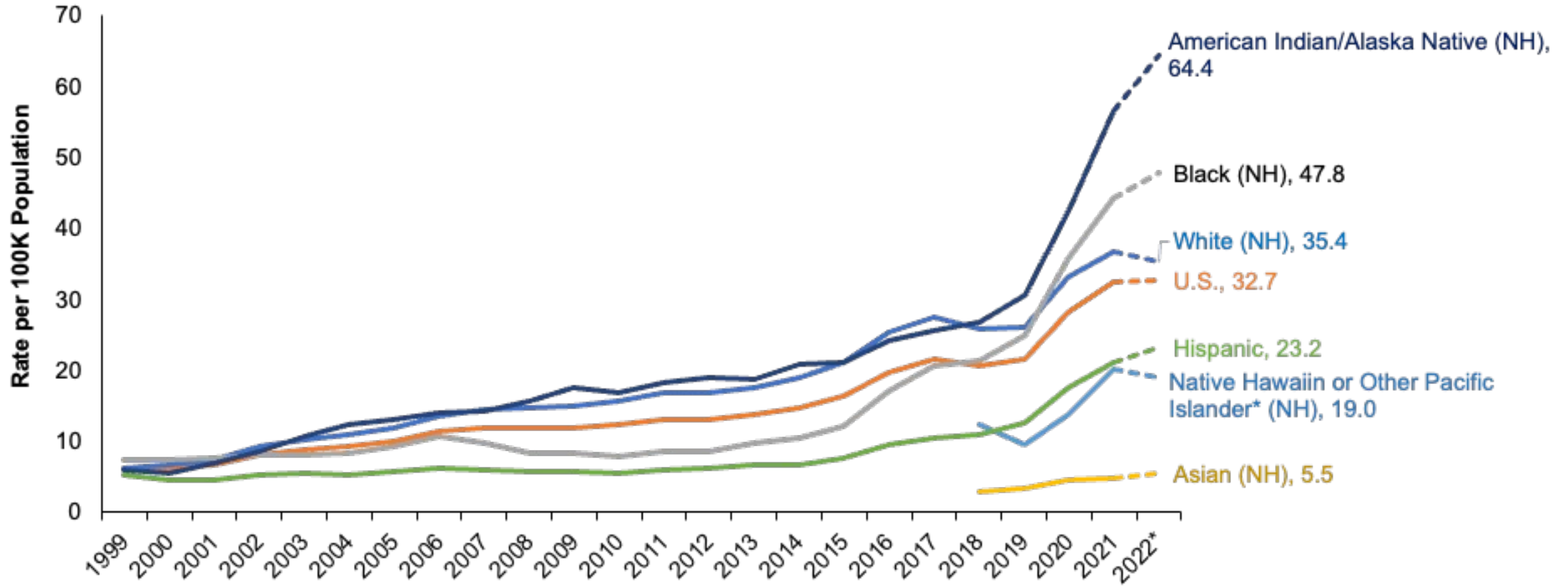
INSTAN SIS

- A Lateral Flow Assay for Rapid Saliva Fentanyl Detection (sFENTANYL) (PI: Uddin; PO: Dan Kostov, OTIPI)
- Rapid, Instrument-free and High Sensitivity Over-the-counter Urine Fentanyl Testing (PI: Xia; PO: Dan Kostov, OTIPI)



- FDA Breakthrough Device Designation: Oct 25, 2023
- FDA 510(k) approval: March 28, 2024

Drug Overdose Death Rates by Race/Ethnicity



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

N-CREW

Phase I Development and Planning

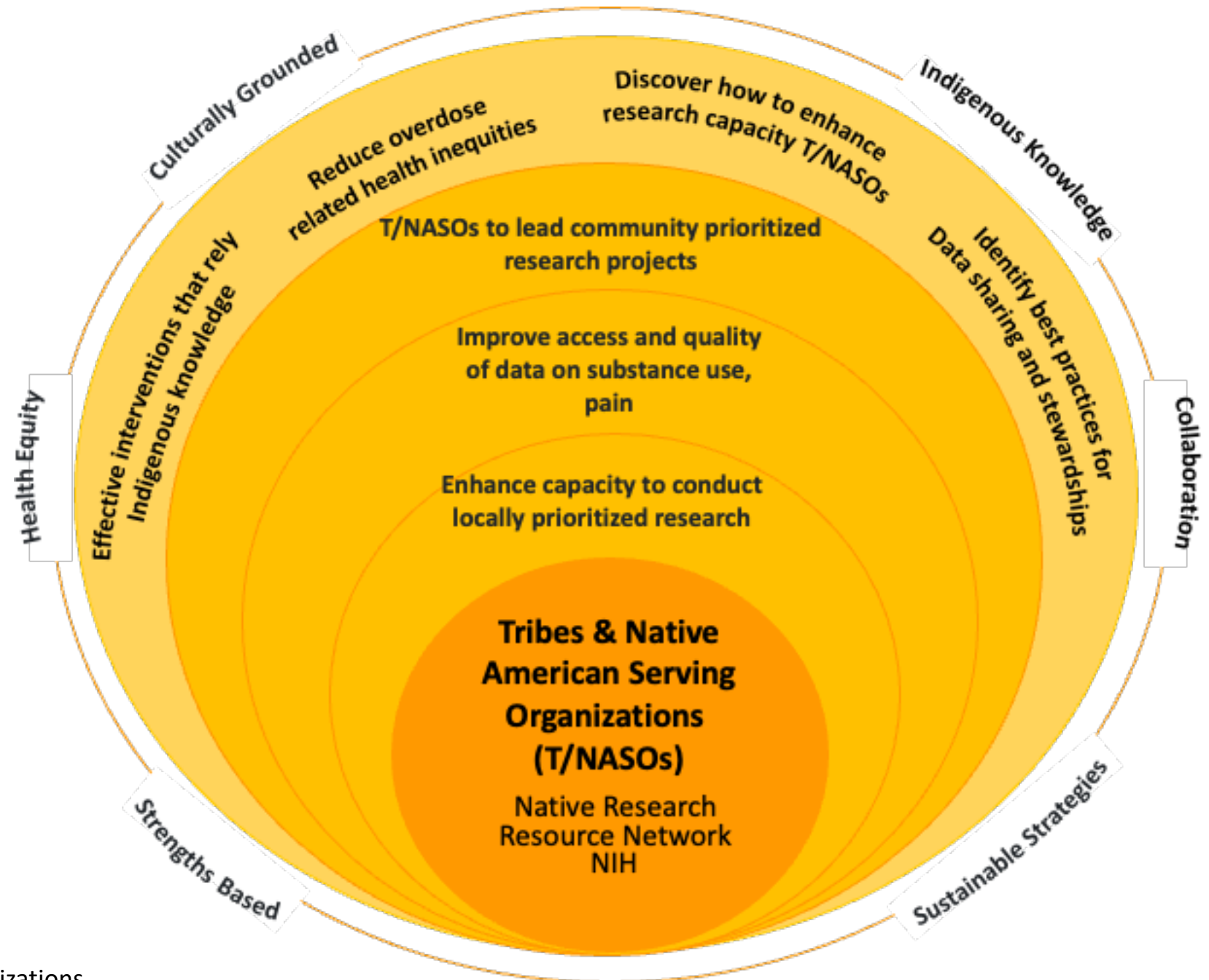
FY24-25 \$~25 million

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

Phase II will build on Phase I

FY26-30 \$~240 million

Contact: NCREW@NIH.GOV



T/NASOs: Tribes and Native American Serving Organizations

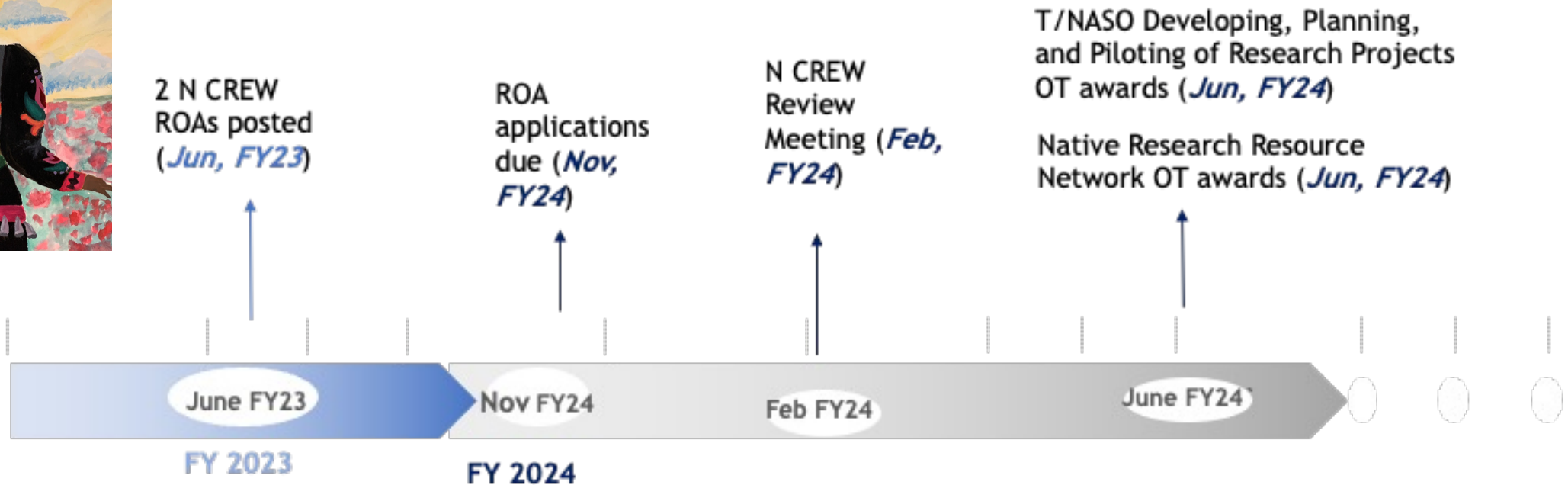


Native Collective Research Effort to Enhance Wellness (N CREW)

Addressing Overdose, Substance Use & Pain



Timeline: OT Components



Therapeutics For Polysubstances

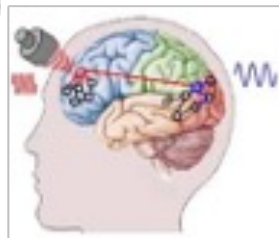
- Overdose reversal agents from polysubstance use
- Pharmacological and biological agents for polysubstance use
- Device-based therapeutics for polysubstance use

Non Invasive Neuromodulation Techniques

Transcranial
Magnetic
Stimulation
(TMS)

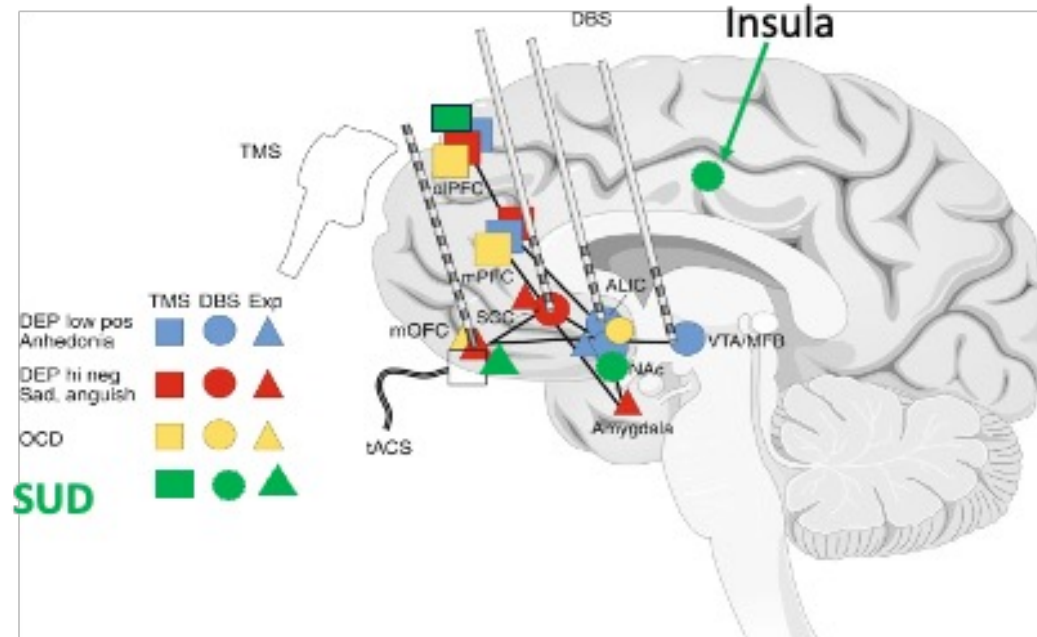


Transcranial Direct
Current Stimulation
(tDCS)



Low Intensity Ultrasound

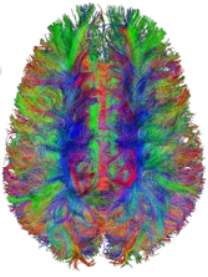
Typical Neuromodulation Targets in OCD, depression, SUD



Challenges to Current Overdose Epidemic

- Consequences of Fentanyl and Polysubstance misuse
 - Treatment (initiation and retention)
 - Overdoses
 - Long term Outcomes
- Addressing hard-to-reach and underserved populations
 - American Indians/Alaskan Natives
 - Black Americans
 - Rural
 - Homeless
 - Pregnant Women
- Addressing challenges associated with pain and psychiatric co-morbidities
- Novel harm reduction approaches
- Monitoring changing Drug landscapes
 - Xylazine
- Prevention across the lifespan
- SDOH

NIDA
Advancing
Addiction
Science for
50 years



College on Problems of Drug Dependence Friends of the National Institute on Drug Abuse Senator Tim Kaine (VA)

50th Anniversary *of the* National Institute on Drug Abuse

Tuesday, May 14, 2024

4:00-6:00 pm

Kennedy Caucus Room

325 Russell Senate Office Building



Nora Volkow, MD
Director
National Institute on Drug Abuse



Jeremy M. Byard
CARE@Arthur Street Hotel



Sandra Comer, PhD
Columbia University Medical Center



Gail D'Onofrio, MD, MS
Yale School of Medicine



Hansel Tookes, MD, MPH
University of Miami Miller School of
Medicine

Retiring Council Members



Anna Rose Childress, Ph.D.
University of Pennsylvania



Dennis Deer, Ph.D.
Cook County Government, IL



Shelley Greenfield,
M.D.
Harvard Medical
School



Andrey Ostrovsky, M.D.
Social Innovation Ventures



Travis Rieder, Ph.D.
Johns Hopkins
University



Rajita Sinha, Ph.D.
Yale University



Melissa Walls, Ph.D.
Johns Hopkins
University

Incoming Council Members



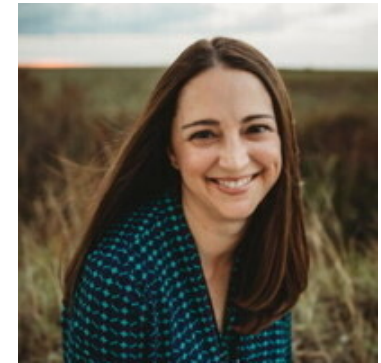
Deborah Chassler M.S.
Boston University



Cristiane Duarte,
Ph.D.
Columbia University



Regina LaBelle, J.D.
Georgetown
University



Angela Laird, Ph.D.
Florida
International
University

Thank you!