

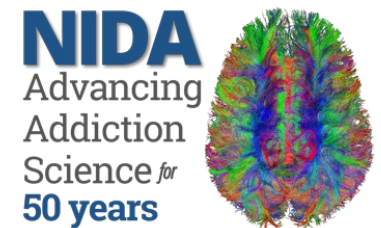
Director's Report to the National Advisory Council on Drug Abuse

Nora D. Volkow, M.D.

Director

National Institute on Drug Abuse

February 6, 2024



NIH Welcomes A New Director!

- Nominated by President Joe Biden on May 15, 2023, confirmed by the Senate on Nov. 7, 2023, [took office on Nov. 9, 2023](#).
- First surgeon and second woman to hold the position.
- Leader in [clinical oncology](#)
- Her research has focused on [genetic drivers of gastrointestinal cancer development and the role of inflammation on cancer growth](#).
- Led translational science initiatives in the NCI-funded Cooperative Groups Program (NCI's National Clinical Trials Network) from 1994-2011.
- Group chair of the Alliance for Clinical Trials in Oncology, a National Clinical Trials Network member organization from 2011–2022.
- Chief of the division of Surgical Oncology for Dana-Farber Brigham Cancer Center from 2007-2018.



*Monica M. Bertagnolli, M.D.,
17th director of NIH*

Guiding Principles Articulated by the NIH Director

- Our work is not finished when we deliver scientific discoveries, **our work is finished when all people are living long and healthy lives.**
- NIH research encompasses the laboratory, the clinic, and the community.
- **Patients are partners in discovery.**
 - NIH aims to bring more members of the public into the research enterprise as partners in discovery.
 - Income, age, race, ethnicity, geographic location, and disability status should not be barriers to participating in research or benefitting from research advances.
- Progress is accelerated when advanced **scientific methods are applied to data that includes everyone**, and when **new discoveries are rapidly and equitably adopted** in clinical care.
- **NIH is committed to harnessing the power of AI/ML** to advance research across diverse fields, diseases, and scientific communities.

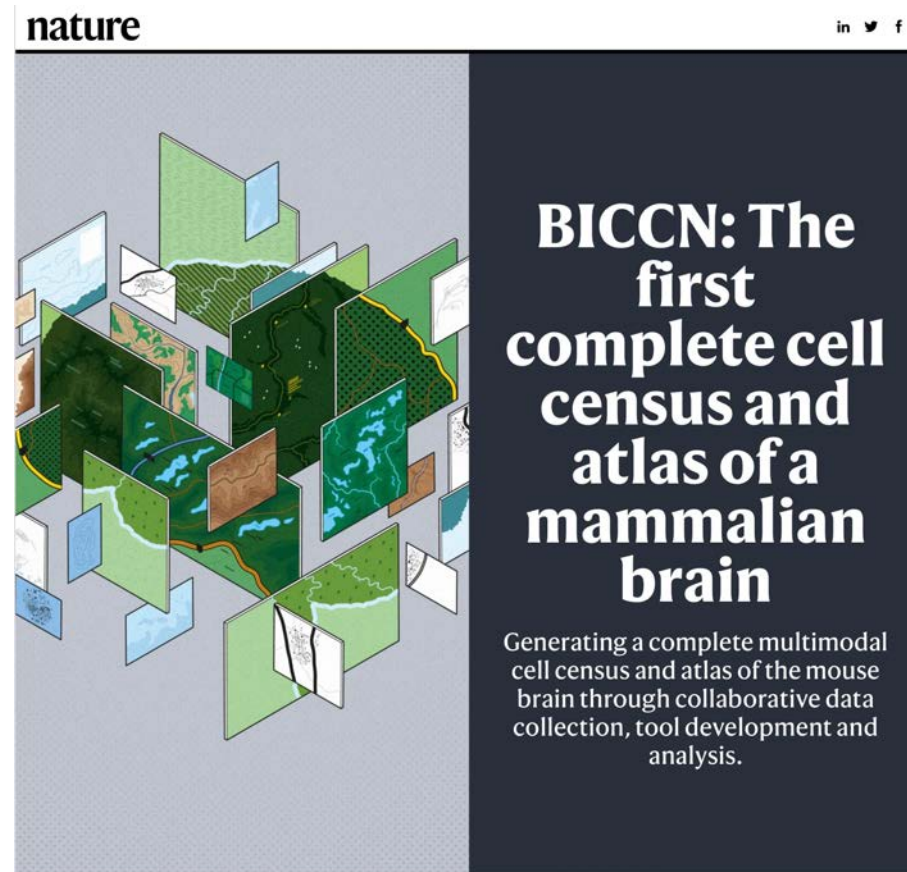
NIH Fellows United

- On December 7, 2023, a majority of the voting NIH Fellows United voted to be represented by the **International Union of United Automobile, Aerospace and Agricultural Implement Workers of America (UAW)**.
- The Federal Labor Relations Authority (FLRA) certified the bargaining unit on December 15, 2023. The **UAW unit covers approximately 5,000 NIH fellows**.
- NIH will partner with the UAW to negotiate a collective bargaining agreement for the parties. Collective bargaining will be ongoing throughout 2024.

Budget

- We remain hopeful that NIH will not be subject to drastic cuts.
- However, even a “flat budget” will have a significant impact:
 - Potential for new discoveries will be slowed down.
 - Concern that we may lose a generation of early career investigators.
 - The Intramural Research Program (IRP) is particularly sensitive to budget cuts as most of the expense is fixed personnel costs and has restricted ability to seek additional funding to compensate.
- **Partnership with all stakeholders is crucial.**

BRAIN INITIATIVE



Brain Initiative Cell Census Network

10th Annual BRAIN Initiative Conference

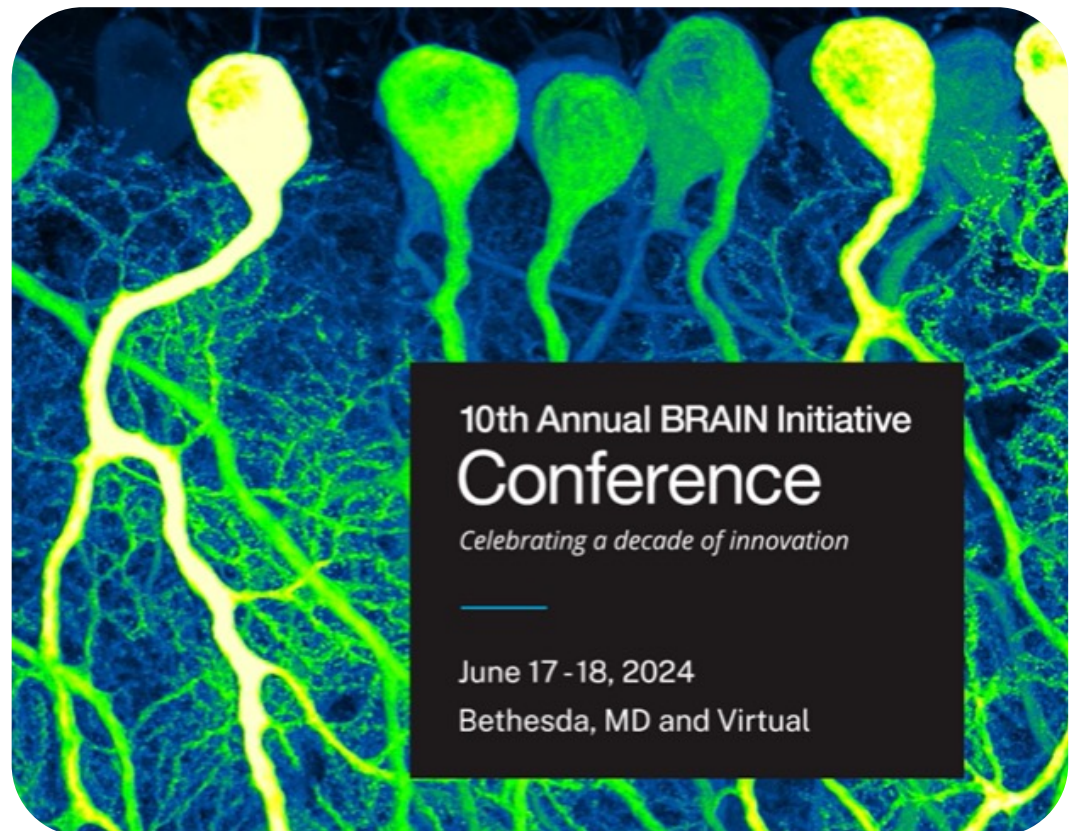
Register Soon!

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

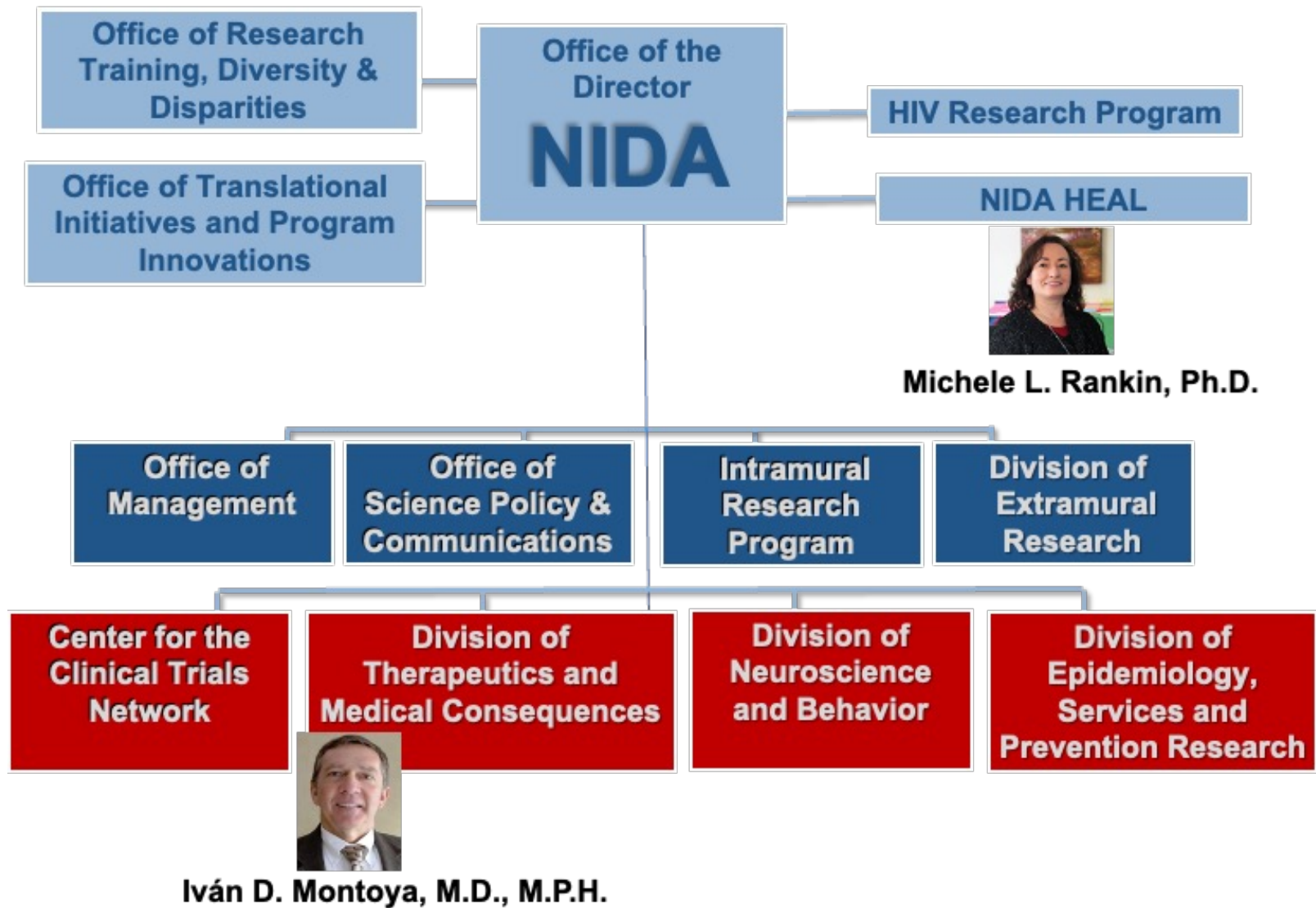


NIDA BUDGET

(all dollars are in \$k)

	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

*NIDA's FY 23 budget includes a 3.8% general increase as well as a \$10m increase for the HEAL program and a \$10m increase for research on pain and pain management.



2023 Monitoring the Future Study Key Findings- Prevalence (2022 to 2023)

	8th	10th	12th		8th	10th	12th
Abstainers				Heroin			
Lifetime		+	+	Lifetime			-
Past Month			+	Past Year			-
LSD				Narcotics o/t Heroin			
Lifetime			-	Lifetime			-
Past Year			-	Past Year			-
Past Month			-	Oxycontin			
MDMA				Past Year		-	-
Lifetime			-	Vicodin			
Past Year			-	Past Year		-	-
Past Month			-	Amphetamines			
Cocaine				Past Year			-
Lifetime			-	Adderall			
Past Year			-	Past Year			-
Past Month			-	Sedatives			
Crack				Past Month			-
Lifetime			-	Tranquilizers			
Past Year			-	Past Year			-
Cocaine o/t Crack				Past Month			-
Lifetime			-				
Past Year		+	-				
Past Month		+	-				

	8th	10th	12th		8th	10th	12th
Alcohol				Vaping, Any			
Lifetime		-	-	Lifetime		-	-
Past Year			-	Past Year		-	-
Past Month			-	Past Month		-	-
Daily			-	Vaping Nicotine			
10+ drinks row/2wks			-	Lifetime			-
Been Drunk				Past Year		-	-
Past Month			-	Past Month		-	-
Beer				Daily		-	
Lifetime	-			Snus			
Flavored Alc				Past Month	-		
Lifetime	-			Any Nicotine			
Alc Bev + Caff				Past Month		-	-
Past Year	+			Nicotine o/t Vaping			
Cigarettes				Past Month			-
Daily			-	Steroids			
1/2+ pack/day			-	Past Month			-
Reg little cigars/Cigarillos				Legal use of non-stim ADHD Rx			
Past Month		-		Current			-
Large Cigars							
Past Month		-					

2023 Monitoring the Future Study

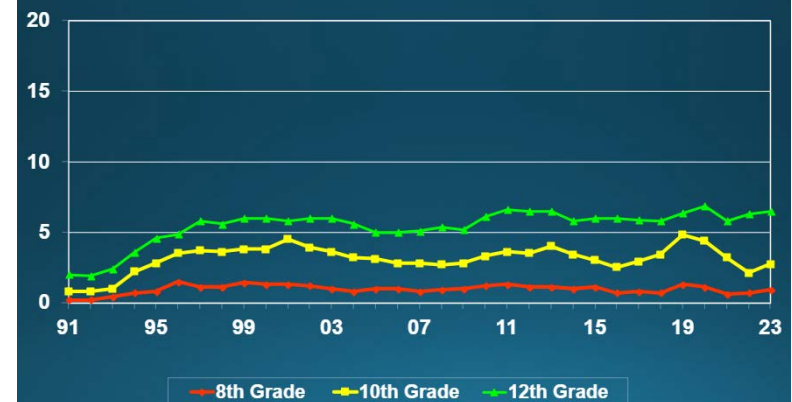
Prevalence of Past Year Drug Use Among 12th graders

Drug	Prev.	Drug	Prev.
Alcohol	45.7	Hookah	2.7
* Vaping, Any	28.8	Cough Medicine*	2.4
Marijuana/Hashish	29.0	Amphetamines*	2.1
Vaping Nicotine	23.2	Inhalants	2.0
Vaping MJ	19.6	Sedative/Tranquilizers*	1.9
Alcohol w/ Caffeine	11.6	Snus	1.8
Delta-8	11.4	Adderall*	1.7
Small Cigars	4.4	LSD	1.2
* Hallucinogens	4.3	Narcotics o/t Heroin*	1.0
Hall other than LSD	4.0	Ketamine	1.0
Nicotine pouches	2.9	MDMA (Ecstasy)	0.7

Percent of Students Reporting Any Illicit Drug Use in Past Year, by Grade

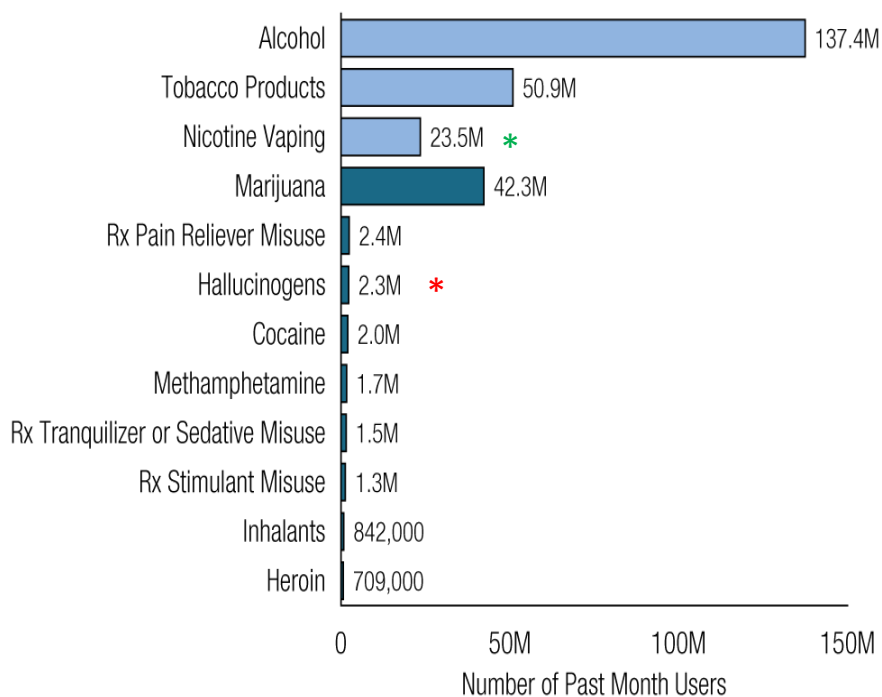


Percent of Students Reporting Daily Use of Marijuana, by Grade

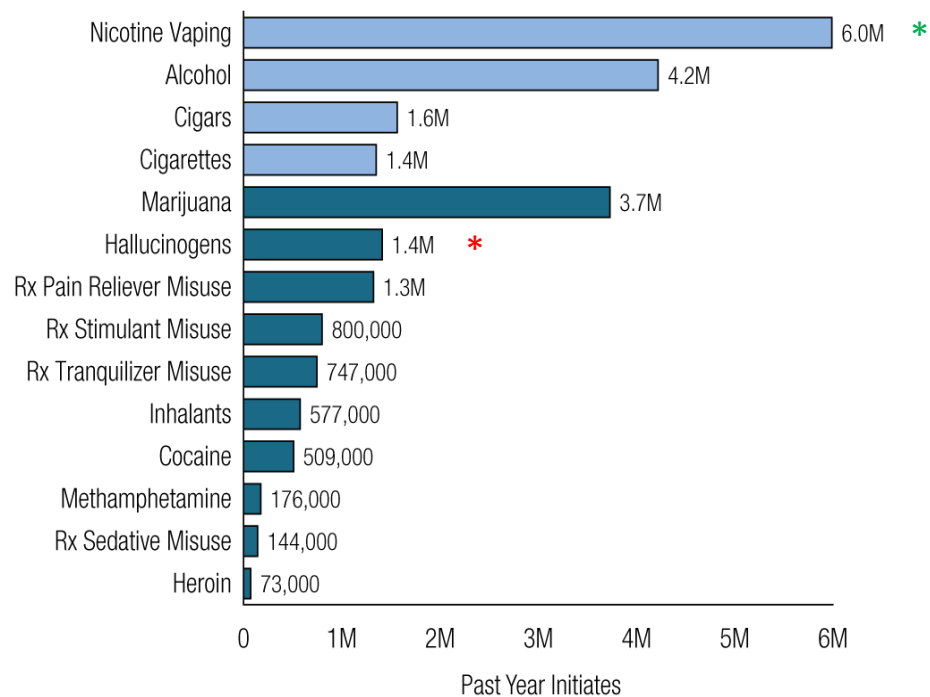


National Survey Drug Use and Health

Past Month Substance Use: People Aged 12 or Older; 2022



Past Year Initiates of Substances: People Aged 12 or Older; 2022



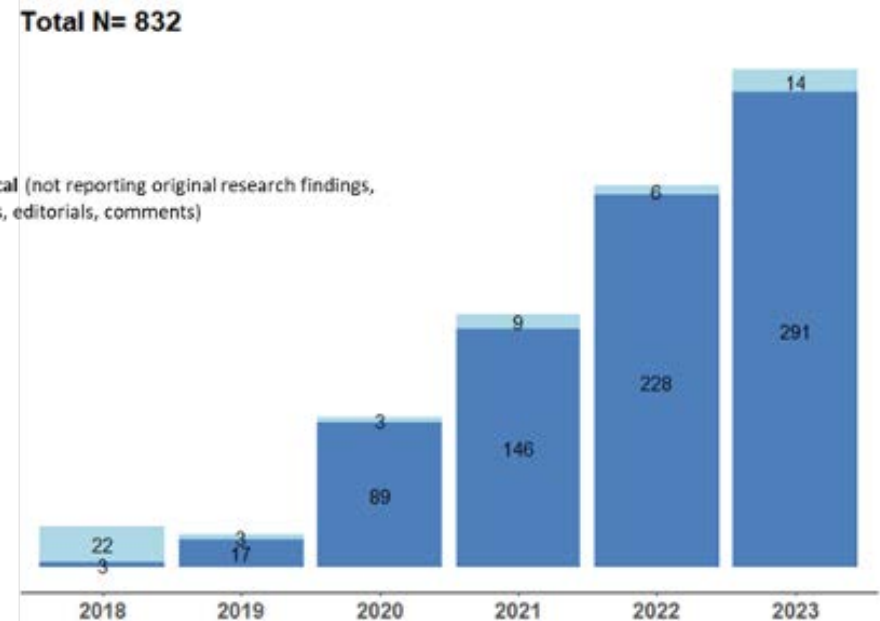
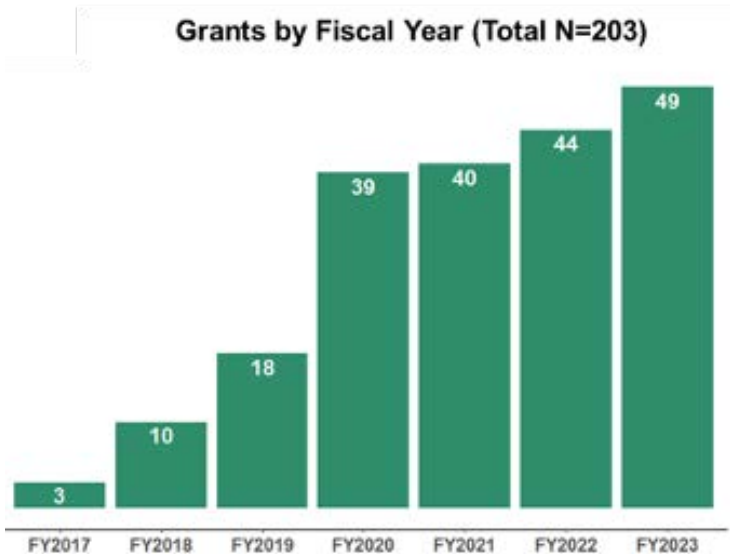
Rx = prescription.

Note: The estimated numbers of past year users of different illicit drugs are not mutually exclusive because people could have used more than one type of illicit drug in the past year.

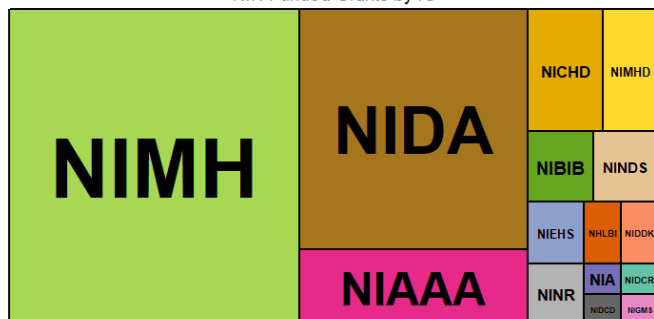
Adolescent Brain Cognitive Development Study

96.3 Percent Retained

Publications



NIH-Funded Grants by IC



AVAILABLE NOW

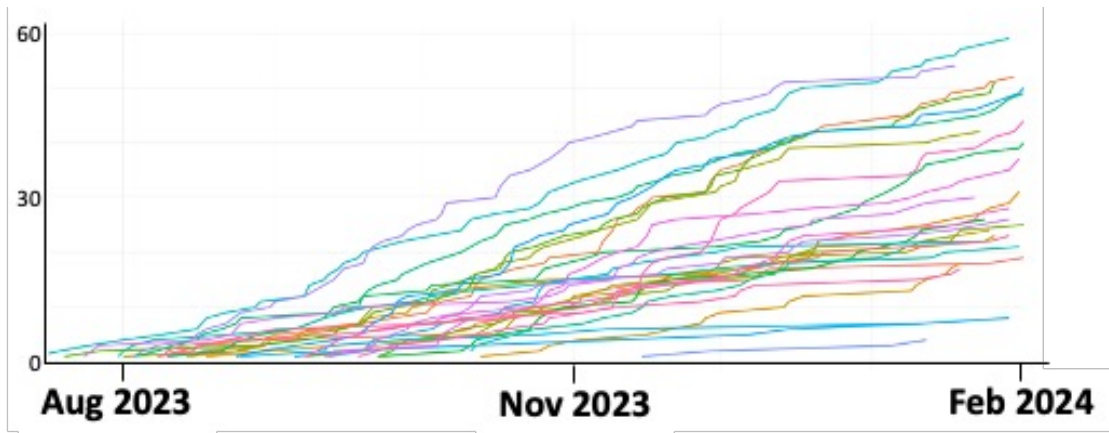
ABCD 5.1 Data Released

through the NIMH Data Archive

- New Data Dictionary Explorer (<https://data-dict.abcdstudy.org/?>)
- New ABCD Wiki Release Notes (<https://wiki.abcdstudy.org/>)

HEALTHY Brain and Child Development Study

Enrollment Across 27 Sites (N=844)

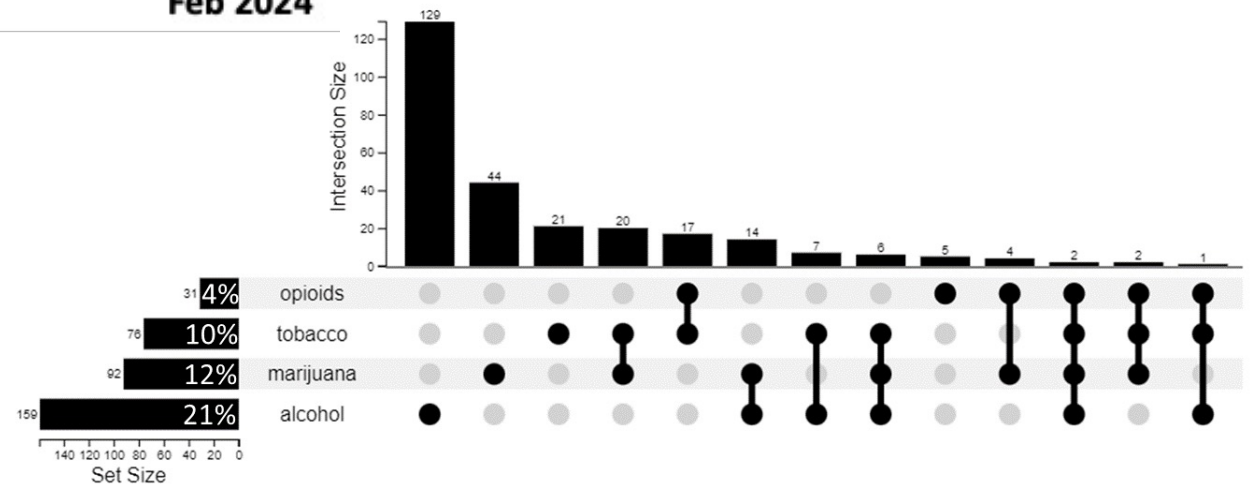


HBCD Study Updates

- **78.2%** of Enrollment Goal (7,500 participants/3yrs)
- **34%** Prenatal Substance Use (Goal of 25%)
- **Piloting** Visit 4 (9-15 months) – Visit 6 (15-48 months)

Data Release Timeline
 Summer 2024 – Freeze data
 Fall 2024 – Beta Release
 End of 2024 – Full Release

Polysubstance Use (286/844 = 34%)



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>

Medications for the Treatment of Opioid Use Disorder: Final Rule

- Eliminates 1-year opioid addiction history requirement and promotes priority treatment for pregnant individuals.
- Incorporates harm reduction principles into treatment.
- Removes requirement for two documented instances of unsuccessful treatment for people under age 18.
- Medication access no longer contingent on counseling.
- Screening can be performed by practitioners outside OTP.
- COVID-19 take-home flexibilities made permanent, including from first week of treatment under certain conditions.
- Allows screening for bup. initiation via audio-only or audio-visual telehealth and for methadone initiation via audio-visual telehealth under certain conditions.
- Interim treatment allowed at any qualifying OTP; time frame expanded from 120 to 180 days.
- Allows NPs and PAs to order MOUD for OTP dispensing

The screenshot shows the official Federal Register page for the final rule. At the top, it features the National Archives logo on the left, the 'FEDERAL REGISTER' title in the center, and the Department of Health and Human Services seal on the right. Below the title, it states 'The Daily Journal of the United States Government'. A blue banner at the top right indicates it is a 'Rule'. The main heading is 'Medications for the Treatment of Opioid Use Disorder', with a sub-heading 'A Rule by the Health and Human Services Department on 02/02/2024'. The page is divided into sections: 'PUBLISHED DOCUMENT' on the left with a navigation menu, and 'DOCUMENT DETAILS' on the right. The main content area includes sections for 'AGENCY:' (Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services), 'ACTION:' (Final rule), and 'SUMMARY:' (This final rule modifies and updates certain provisions of regulations related to Opioid Treatment Program (OTP) accreditation, certification, and standards for the treatment of Opioid Use Disorder (OUD) with Medications for Opioid Use Disorder (MOUD) in OTPs. This includes making flexibilities put forth during the COVID-19 Public Health Emergency (PHE) permanent, as well as expanding access to care and evidence-based treatment for OUD. The final rule also removes all language and rules pertaining to the Drug Addiction and Treatment Act (DATA) Waiver from the regulations pursuant to the "Consolidated Appropriations Act, 2023"). 'DATES:' (The effective date of this final rule is April 2, 2024, and the compliance date is October 2, 2024). The 'DOCUMENT DETAILS' sidebar lists: 'Printed version: PDF', 'Publication Date: 02/02/2024', 'Agencies: Department of Health and Human Services, Office of the Secretary', 'Dates: The effective date of this final rule is April 2, 2024, and the compliance date is October 2, 2024.', 'Effective Date: 04/02/2024', 'Document Type: Rule', 'Document Citation: 89 FR 7528', 'Page: 7528-7563 (36 pages)', 'CFR: 42 CFR 8', 'RIN: 0930-AA39', and 'Document Number: 2024-01693'. A 'Site' button is visible in the bottom right corner.

HHS Overdose Prevention Strategy



Syringe Exchanges and Syringe Services Programs (SSPs)



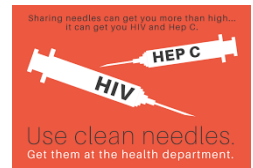
SSPs save lives by lowering the likelihood of deaths from overdoses.



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????

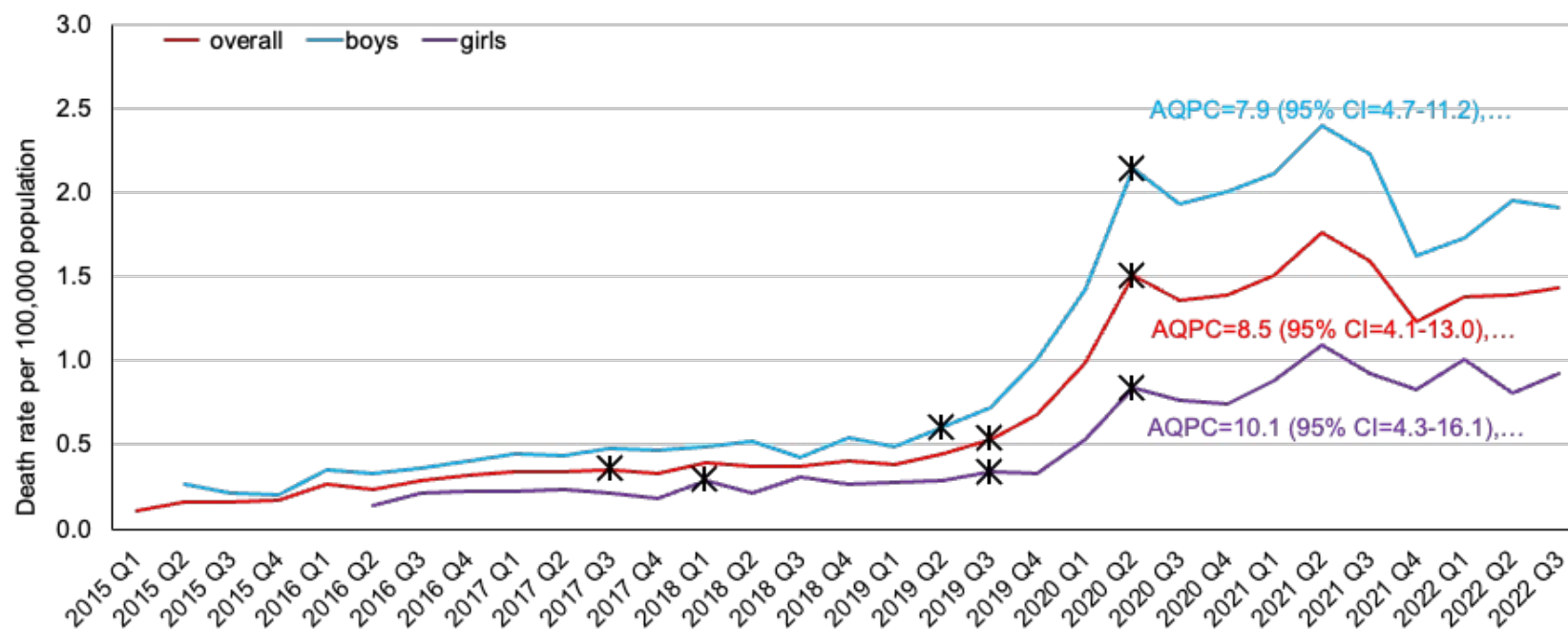
Harm Reduction Research Network

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

Novel harm reduction approaches	Novel settings for and modes of service delivery	Understanding and addressing barriers	Reaching understudied populations	Coordination Center – 4 cores
<ul style="list-style-type: none">• Community drug checking• Overdose prevention centers• Meth sobering center• Contingency management	<ul style="list-style-type: none">• Emergency department• Mobile apps• Hotline• Text messages• Mail delivery• Secondary distribution• Remote lockboxes	<ul style="list-style-type: none">• Limited access• Not using naloxone when it is available• Burnout & trauma from responding to overdose• State-level policy barriers	<ul style="list-style-type: none">• Racial/ethnic minority groups• Women• Rural communities• People who use stimulants	<ul style="list-style-type: none">• Communication and Coordination• Data Harmonization and Methodology• Community and Stakeholder Engagement• Dissemination and Translation

(10 R01s, 1 R24)

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 changes 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.

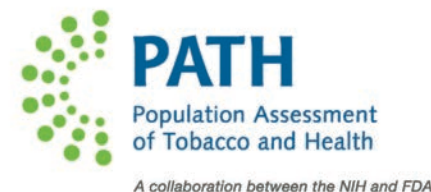
Limited Treatments for Adolescents with SUD

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.

Population Assessment of Tobacco and Health (PATH) Study Continuation



- Nationally representative longitudinal cohort study of tobacco use, its determinants, and impact, U.S. population ages 12+.
- Collecting data since 2013 for 7 completed full waves and 3 special data collections (45,000+ baseline). 800+ publications. Data available to researchers through: <https://doi.org/10.3886/Series606>
- PATH Study has been supported through 2 contracts (5 and 8 years) and on **February 1, 2024 contract awarded to Westat to support 4 additional waves of data collection over 8 years (2024-2032).**
- Administered by NIDA, renewal primarily funded by the FDA Center for Tobacco Products (CTP), with additional funds from NIDA, NCI, NHLBI, NIMHD, NIAAA, NIDDK, OBSSR, NIEHS, ODP, NLM.

Lead ICO Sponsors of NIH Challenges: FY11-23



THANK YOU!

NIDA
Advancing
Addiction
Science *for*
50 years

