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

Nora D. Volkow, M.D.
Director
National Institute on Drug Abuse
September 15, 2021
## NIDA BUDGET

<table>
<thead>
<tr>
<th></th>
<th>FY 2020 ($k)</th>
<th>FY 2021 ($k)</th>
<th>FY 2022 PB ($k)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Base</strong></td>
<td>$1,191,362</td>
<td>$1,210,014</td>
<td>$1,447,060</td>
</tr>
<tr>
<td><strong>HEAL</strong></td>
<td>$266,321*</td>
<td>$270,295*</td>
<td>$405,443*</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$1,457,683</td>
<td>$1,480,309</td>
<td>$1,852,503</td>
</tr>
</tbody>
</table>

*NIH's total HEAL funding is split evenly between NIDA and NINDS*
FY 20 Funding Overview

### Non-HEAL Research
- Therapeutics and Medical Consequences, 11%
- Clinical Trials Network, 4%
- Office of the Director, 8%
- Epidemiology, Services & Prevention Research, 32%
- Neuroscience & Behavior, 45%

### HEAL Research*
- Therapeutics and Medical Consequences, 26%
- Clinical Trials Network, 19%
- Epidemiology, Services & Prevention Research, 49%
- Office of the Director, 5%
- Neuroscience & Behavior, 0.1%

*Includes all NIDA HEAL projects regardless of funding source
UPDATE ON COVID-19 INITIATIVES

NIDA is supporting over 100 studies related to COVID-19, including:
• Effects of COVID-19 on people who use drugs
• Effects of COVID-19 on brain development and behavior
• Impact of pandemic-related policy changes on access to SUD treatment
• Understanding and addressing vaccine hesitancy in SUD

NIDA Involvement in Trans-NIH Initiatives
• RADx-Rad: Wastewater Detection of SARS-Cov-2
• RADx-Rad: Multimodal Surveillance Methods for High-Risk Populations
• RADx-UP: Underserved Populations, including SUD
• Social, Behavioral, and Economic Impacts of COVID-19
• Pregnant and Lactating Women and Children
• Post-Acute Sequelae of COVID-19
Drug Use in College Age Adults in 2020 MTF

Marijuana Use
- Past year college: 38%, 39%
- Past year non-college: 44%, 43%
- Daily use college: 4.6%, 11.8%
- Daily use non-college: 8%, 13%

Hallucinogens
- Any hallucinogen: College: 5.3%, 6.0%; Non-college: 3.7%, 4.6%
- LSD: College: 7.9%, 8.6%; Non-college: 3.3%, 5.8%
- Hallucinogen other than LSD: College: 8.6%, 9.8%; Non-college: 7.3%, 6.9%

Marijuana Vaping (past month)
- College: 14%, 17%; Non-college: 12%, 14%

Nicotine Vaping (past month)
- College: 19%, 24%; Non-college: 22%, 18%

Alcohol Use
- Alcohol use in past 30 days: College: 62%, 56%; Non-college: 35%, 49%
- Drunk in past 30 days: College: 49%, 49%; Non-college: 32%, 22%
- Binge drinking in past two weeks: College: 28%, 24%; Non-college: 24%, 24%
<table>
<thead>
<tr>
<th></th>
<th>ALL DRUGS</th>
<th>HEROIN</th>
<th>NAT &amp; SEMI – SYNTHETIC</th>
<th>METHADONE</th>
<th>SYNTHETIC OPIOIDS</th>
<th>COCAINE</th>
<th>OTHER PSYCHO-STIMULANTS (mainly meth)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/2020*</td>
<td>72,757</td>
<td>14,183</td>
<td>12,118</td>
<td>2,793</td>
<td>38,071</td>
<td>16,537</td>
<td>16,888</td>
</tr>
<tr>
<td>7/2020*</td>
<td>86,502</td>
<td>14,640</td>
<td>13,274</td>
<td>3,329</td>
<td>50,703</td>
<td>19,757</td>
<td>21,279</td>
</tr>
<tr>
<td>1/2021*</td>
<td>95,230</td>
<td>13,182</td>
<td>13,699</td>
<td>3,677</td>
<td>59,420</td>
<td>20,076</td>
<td>25,300</td>
</tr>
<tr>
<td>Percent Change</td>
<td><strong>30.9%</strong></td>
<td><strong>-7.1%</strong></td>
<td><strong>13.0%</strong></td>
<td><strong>31.7%</strong></td>
<td><strong>56.1%</strong></td>
<td><strong>21.4%</strong></td>
<td><strong>49.8%</strong></td>
</tr>
</tbody>
</table>

*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](https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm)
High-dose Buprenorphine induction was safe and well tolerated in untreated OUD patients (n=391). No cases of respiratory depression or sedation. 5 cases of precipitated withdrawal were not associated with dose.

Herring AA et al., JAMA Network Open. 2021;4(7):e2117128
**Extended-Release vs Daily Buprenorphine in Adults (n=52) with OUD at Time of Release From Jail**

- XR-Bup was acceptable and had fewer in-jail clinic visits and increased treatment retention when compared with daily Bup treatment.

- These results support wider use and further study of XR-Bup in correctional and reentry OUD treatment.

# Medications Development for OUD and OOD

## UG3 Transitions

<table>
<thead>
<tr>
<th>Project</th>
<th>Accomplishment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gpr 151 agonist to treat opioid use disorder</td>
<td>Gpr151 characterized, lead identified</td>
</tr>
<tr>
<td>Evaluation of Kratom and its derivatives for the treatment of OUD</td>
<td>Kratom characterized. IND studies ongoing</td>
</tr>
<tr>
<td>OLANI: 6-month naltrexone implant for relapse prevention of OUD</td>
<td>IND obtained. Human studies ongoing</td>
</tr>
<tr>
<td>Suvorexant for Sleep Disturbance in medication treated OUD</td>
<td>IND exempt. Significant sleep improvement</td>
</tr>
<tr>
<td>LYN-014: A once-weekly oral methadone for OUD therapy</td>
<td>IND obtained. FDA fast-track designation</td>
</tr>
<tr>
<td>SBS-1000: arylepoxamides: New class of potent, safer analgesics</td>
<td>IND to be submitted 10/2021</td>
</tr>
<tr>
<td>BICX104: 3-month implantable depot pellet of Naltrexone for OUD</td>
<td>IND filed. Human studies ongoing</td>
</tr>
</tbody>
</table>

- **Biologics:** First study in humans of an opioid vaccine
- **Devices:** One IDE to study Deep Brain Stimulation for OUD
Adolescent Brain Cognitive Development\textsuperscript{SM} Study
Unanticipated Focus Areas

Publications

- ABCD investigators
- Non-ABCD investigators

Racism and Discrimination

- Research Letter
- Prevalence of Perceived Racism and Discrimination Among US Children Aged 10 and 11 Years
- The Adolescent Brain Cognitive Development (ABCD) Study

COVID-19

- Journal of Adolescent Health
- Early Adolescent Substance Use Before and During the COVID-19 Pandemic: A Longitudinal Survey in the ABCD Study Cohort

Sleep

- Nature Communications
- Polygenic Risk for Insomnia in Adolescents of Diverse Ancestry
- Associations between frontal lobe structure, parent-reported obstructive sleep disordered breathing and childhood behavior in the ABCD dataset

Pain

- Pain
- Neurobiological antecedents of multisite pain in children

Imaging

- Pediatric Neuroradiology
- Imaging and health metrics in incidental cerebellar tonsillar ectopia: findings from the Adolescent Brain Cognitive Development Study (ABCD)
Enhancing Prevention Research Related to Substance Use and Addiction: Identifying Gaps and Opportunities with ABCD Data

Virtual Meeting on Sep 28, 2021 from 12:00PM to 4:00PM EST

Planning: Carlos Blanco, MD, PhD, Bethany Deeds, PhD, MA, Amy Goldstein, PhD. DESPR
Gaya Dowling, PhD, Elizabeth Hoffman, PhD. ABCD Study, Office Trans-NIH Initiatives

Goal of meeting is to stimulate data analyses that lead to the development of targeted prevention intervention research. First meeting will focus on trauma and self-regulation and their roles in substance use initiation.

https://seiservices.zoom.us/webinar/register/WN_wZqT7vgTQ5-yNxIGBjttauA
Prenatal Exposures Exacerbate Risks For Neurodevelopmental Disorders


### RISK-CONFERRING PRENATAL EXPOSURES

- Individual exposures
  - Birth complications
  - Pregnancy complications
  - Early marijuana
  - Early tobacco
  - Early alcohol
  - Unplanned pregnancy

- Cumulative exposures
  - Four or more vs. zero
  - Three vs. zero
  - Two vs. zero
  - One vs. zero

### Selected infectious / inflammatory
- Urinary tract infections
- Influenza
- IL-6
- ? SARS-CoV-2

### PROTECTIVE PRENATAL EXPOSURES

- Evidence-supported
  - Periconceptional folic acid
  - Choline

- Exploratory / exposome
  - Diet / nutrient intake
  - Exercise
  - Mental well-being
  - Optimal prenatal care

Odds of clinically significant total psychopathology symptoms (CBCL Total ≥60) at age 9-10 in the ABCD cohort, n=7,898

From Roffman et al., PLOS ONE, 2021
HBCD Study

Longitudinal study (n=7500) of individual brain developmental and behavioral trajectories from birth through childhood (ages 9-10) including *in utero* substance exposure and effects of adverse social environments

- OPEN ACCESS so data is accessible and can be analyzed in a timely manner
- Identify actionable items as results emerge pertinent to prevention, public policies and innovative products
- Opportunities for parallel projects to validate more accessible imaging tools such as EEG, NIRs
- COLLABORATIVE to increase comparativeness with results from other cohorts

**Risk and protective factors**

EEG EVP, ERP

Pregnancy History

MRI

Biospecimen

Behavioral, neurocognitive assessments
Matthew Akiyama, M.D., M.Sc.
Albert Einstein College of Medicine and Montefiore Medical Center

Leveraging HCV Phylogenetic Networks to Prevent HIV and Other Blood Borne Infections Among People Who Inject Drugs. Engaging PWID is essential to ending HIV epidemic and eliminating viral hepatitis. Needle and syringe programs and MOUD have been challenging to implement in low- and middle-income countries. Dr. Akiyama’s will characterize HCV phylogenetic networks to identify PWID who are highly central in injection networks and model the impact of targeted approaches to prevent HIV and other blood borne infections in Kenya, East Africa.

Hansel Tookes, M.D., M.P.H.
University of Miami Miller School of Medicine

Tele-Harm Reduction for Rapid Initiation of Antiretrovirals in PWID: RCTI. Tele-Harm Reduction seeks to engage PWID into HIV care by bringing healthcare out of the traditional healthcare system and leveraging syringe services programs as venues to enhance access to ARV, MOUD, and HCV cure.
Mortality from COVID is higher in Individuals with SUD but these disparities are markedly exacerbated among African Americans.

UPDATE ON NIDA Racial Equity Initiative

• REI workgroups for the workplace, workforce, and research gaps finalizing NIDA REI Action Plan
• An RFI on the Proposed REI Action Plan will be published in early October
• Racial Equity Initiative Research funded in FY21:
  • 18 supplements in response to the NOSIs Administrative Supplements to Support Research on Health Equity in NIDA-funded Grant Awards and Administrative Supplements to support engagement of functionally diverse teams to advance ongoing NIDA-funded research
  • 3 supplements to support addiction science and related neuroscience pilots at NIMHD-funded Research Centers at Minority Institutions
  • 14 projects that characterize the impact of racism on drug use outcomes, research to ameliorate disparities in SUD care, and studies on culturally-tailored interventions, along with projects from underrepresented minority scientists
THANK YOU!