DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH

Testimony before the
Senate Caucus on International Narcotics Control

Hearing Title

The Federal Responses to the Drug Overdose Epidemic

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July 20, 2021

Chairman Whitehouse, Co-Chairman Grassley, and members of the Senate Caucus on International Narcotics Control, thank you for inviting the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), to participate in this hearing. Our mission at NIDA is to use science to address addiction in all its complexity, and I am glad for the opportunity to speak to you today about the collision of our nation's addiction and overdose crises with the COVID-19 pandemic.

Impact of the COVID-19 Pandemic on Drug Use and Overdose

The twin addiction and overdose crises have collided with the COVID-19 pandemic, each exacerbating the deleterious effects of the other, resulting in increased rates of substance use and overdose, and increased risk for serious effects of COVID-19 illness. Large increases in many kinds of drug use and overdose have been recorded since March 2020, when a national emergency was declared and our lives radically changed due to lockdown and the closure of businesses and schools. Several reports have revealed increases in the number of positive urine drug screens for fentanyl, cocaine, heroin, and methamphetamine. 1,2,3 There have also been increases in cannabis and alcohol use, especially among people with anxiety and depression and those experiencing COVID-19-related stress.^{4,5,6} Further, state and local data suggest substantial increases in emergency visits for drug overdose, including nonfatal overdose, despite a decline in overall non-COVID emergency department visits.^{7,8,9,10,11,12}

Provisional data from the Centers for Disease Control and Prevention (CDC) show that drug overdose deaths reached an estimated 93,000 deaths in 2020, a nearly 30 percent increase over the previous year and the highest number ever recorded in a 12-month period. Death rates increased by nearly fifty-five percent for fentanyl-category involved overdoses, by forty-six percent for methamphetamine-category involved overdoses, and over twenty-one percent for cocaine-involved overdoses.¹³

Social isolation and pandemic-related stress are likely contributing factors to the rise in substance use and overdose. Social isolation can make people with substance use disorders (SUD) more vulnerable to negative outcomes because it interferes with many of the support systems that can help them to reach

¹ Millennium Health's Signals Report™ COVID-19 Special Edition Reveals Significant Changes in Drug Use During the Pandemic (prnewswire.com)

Analysis of Drug Test Results Before and After the US Declaration of a National Emergency Concerning the COVID-19 Outbreak | Emergency Medicine | JAMA | JAMA Network

³ The Opioid Epidemic Within the COVID-19 Pandemic: Drug Testing in 2020 | Population Health Management (liebertpub.com)

⁴ Alcohol Consumption during the COVID-19 Pandemic: A Cross-Sectional Survey of US Adults (nih.gov)

⁵ Increased alcohol use during the COVID-19 pandemic: The effect of mental health and age in a cross-sectional sample of social media users in the U.S. - ScienceDirect

⁶ Changes in Alcohol Consumption Among College Students Due to COVID-19: Effects of Campus Closure and Residential Change: Journal of Studies on Alcohol and Drugs: Vol 81, No 6 (jsad.com)

⁷ Patterns of alcohol and drug utilization in trauma patients during the COVID-19 pandemic at six trauma centers | Injury Epidemiology | Full Text (biomedcentral.com)

⁸ Patterns of alcohol and drug utilization in trauma patients during the COVID-19 pandemic at six trauma centers | Injury Epidemiology | Full Text (biomedcentral.com)

⁹ Brief Report: The Impact of COVID-19 on Emergency Department Overdose Diagnoses and County Overdose Deaths -Shreffler - - The American Journal on Addictions - Wiley Online Library

¹⁰ Nonfatal Opioid Overdoses at an Urban Emergency Department During the COVID-19 Pandemic | Emergency Medicine | JAMA | JAMA Network

¹¹Nonfatal Opioid Overdoses at an Urban Emergency Department During the COVID-19 Pandemic | Emergency Medicine | JAMA | JAMA Network

¹² Injury Center | CDC

¹³ Products - Vital Statistics Rapid Release - Provisional Drug Overdose Data (cdc.gov)

and sustain recovery. Researchers have long recognized the strong correlation between stress and substance use, particularly in prompting relapse. Although exposure to stress is a common occurrence for many of us, it is also one of the most powerful triggers for relapse to substance use for people with SUD, even after long periods of abstinence. Notably, there are increased reports of mental distress since the COVID-19 pandemic emerged, including among individuals with no history of mental disorders and among younger adults, racial/ethnic minorities, essential workers, and unpaid adult caregivers. 14,15,16,17

SUD and Risk for Serious COVID-19 Illness

SUDs are among the health conditions identified by the CDC as increasing a person's risk for becoming severely ill from COVID-19. Drugs themselves negatively influence human physiology, and data have demonstrated that those who use drugs are more vulnerable to getting infected with SARS-CoV-2, the virus that causes COVID-19 infection, and more vulnerable to worse outcomes; this is especially true for Black people and those with opioid use disorder (OUD). 18,19,20,21

Chronic cardiovascular or respiratory conditions related to substance use may mediate this higher vulnerability. Because it attacks the lungs, the coronavirus that causes COVID-19 could be an especially serious threat to those who smoke tobacco or marijuana or who vape. Smoking or vaping drugs - including tobacco/nicotine, marijuana, heroin, or crack cocaine - has been shown to worsen chronic lung conditions, which can make a person more likely to get severely ill from COVID-19. People with OUD are also vulnerable because opioids act in the brainstem to slow breathing, increasing risk for long-term damage to the lungs, heart, and brain. This may be among the reasons that people with OUD are more susceptible to COVID-19, and their illness may be more severe. In addition, the use of stimulants such as cocaine, methamphetamine, and amphetamine constricts the blood vessels and may increase the risk for stroke, heart attacks, abnormal heart rhythm, seizures, and other conditions that may lead to more severe heart or lung damage in someone with COVID-19.

Importance of Vaccination for People with SUD

Due to the compounding injurious effects of COVID-19 and SUD, it is especially important that people who use or have an addiction to drugs become vaccinated. As individuals with SUD are also more likely to experience homelessness or incarceration than those in the general population, they may face circumstances that pose additional unique challenges regarding COVID-19 transmission. Nevertheless, fears around vaccines and misinformation are preventing many people from taking the potentially lifesaving measure of getting vaccinated. Reasons cited include distrust of the government, wariness about

¹⁴ Mental Health - Household Pulse Survey - COVID-19 (cdc.gov)

¹⁵ Early Release of Selected Mental Health Estimates Based on Data from the January–June 2019 National Health Interview Survey (cdc.gov)

¹⁶ Mental distress during the COVID-19 pandemic among US adults without a pre-existing mental health condition: Findings from American trend panel survey - ScienceDirect

¹⁷ Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic — United States, June 24–30, 2020 | MMWR (cdc.gov)

¹⁸ COVID-19 risk and outcomes in patients with substance use disorders: analyses from electronic health records in the United States | Molecular Psychiatry (nature.com)

^{19 ::} JKMS :: Journal of Korean Medical Science

²⁰ Association of substance use disorders and drug overdose with adverse COVID-19 outcomes in New York City: January—October 2020 (nih.gov)

²¹ The Impact of Substance Use Disorder on COVID-19 Outcomes | Psychiatric Services (psychiatryonline.org)

²² Mechanisms of fatal opioid overdose - PubMed (nih.gov)

²³ Mechanisms of fatal opioid overdose - PubMed (nih.gov)

the rapidity with which vaccines were developed, and skepticism about being at higher risk. ²⁴ Vaccine hesitancy could be a particular problem for people who may have experienced previous mistreatment in healthcare settings due to their drug use. Because people with a history of experiencing stigma from the healthcare system due to an addiction may be hesitant, community leaders, healthcare providers, and others in the community must play a role in encouraging and facilitating vaccination for people who use drugs. As trusted messengers, health professionals are in the best position to help patients understand vaccine safety and the many important benefits of becoming vaccinated. ²⁵

Effects of the COVID-19 Pandemic on SUD Treatment

Treatment Policy Changes

While the COVID-19 pandemic has presented enormous challenges for people with SUD, the altered realities of healthcare have created both barriers to SUD treatment as well as opportunities to reach more people with services and to potentially increase the reach of recovery support systems. There are many anecdotal reports of people with SUDs having to wait longer to obtain treatment as centers had to reduce in-person services in response to social distancing policies. There are reasons to expect that lower-income people and minorities could be especially affected; despite implementing widespread COVID-19 testing, community health centers, which predominantly serve disadvantaged populations, have seen declines in patient visits and have experienced staffing problems.²⁶ The good news is that pandemic-related policy changes facilitating telehealth and expanding access to medications for OUD may help ameliorate these problems. During the COVID-19 public health emergency, people with OUD can now begin treatment with buprenorphine with a telehealth appointment rather than the initial inperson doctor visit that was previously required. In addition, methadone treatment previously mandated daily supervised dosing with tightly controlled take-home options, but patients deemed stable may now obtain 28 days of take-home doses; others may receive 14 days of doses. Changes to Medicare and Medicaid rules are also enabling telemedicine consultations for SUD to be reimbursed more easily. These developments may particularly benefit people who live in rural areas or who otherwise have had trouble accessing treatment in the past.

Racial Inequities

The COVID-19 pandemic has also highlighted the large racial health disparities in the United States. Black Americans have experienced worse outcomes during the pandemic, continue to die at a greater rate than white Americans, and also suffer disproportionately from a wide range of other acute and chronic illnesses. These disparities are particularly stark in the field of addiction, where entrenched punitive approaches have exacerbated stigma and made it hard to implement appropriate medical care. Abundant data show that Black people and other communities of color have been disproportionately harmed by decades of addressing drug use as a crime rather than as a matter of public health. Not only does incarceration fail to address SUD treatment needs, but congregate settings increase risk for COVID-19 transmission and other harms.

²⁴ Trust in a COVID-19 vaccine among people with substance use disorders (nih.gov)

²⁵ Safety of COVID-19 Vaccines | CDC

²⁶ Impact of Coronavirus on Community Health Centers | KFF

²⁷ Racism and Health | Health Equity | CDC

²⁸ Racial Disparities in COVID-19 Testing and Outcomes: Retrospective Cohort Study in an Integrated Health System - PubMed (nih.gov)

²⁹ National Disparities in COVID-19 Outcomes between Black and White Americans - PubMed (nih.gov)

³⁰ Examining Racial Disparities in Drug Arrests: Justice Quarterly: Vol 32, No 2 (tandfonline.com)

³¹ Release from Prison — A High Risk of Death for Former Inmates | NEJM

NIDA Research Addressing SUD and Overdose

For the past nearly five decades, NIDA-supported research has led to the development of effective prevention and treatment interventions for SUD, providing hope for the more than 20 million people in the United States diagnosed with SUD and their loved ones. Although significant strides in establishing-evidence-based practices have been made, there is far more work to be done to develop new prevention and treatment interventions and to implement existing effective interventions with fidelity, for diverse populations, and at scale. In particular, developing strategies to prevent and treat opioid and stimulant use, addiction, and overdose will continue to be key priorities for NIDA.

Prevention

Preventing the initiation of substance use and minimizing the risks of harmful consequences are essential components of addressing SUD. NIDA prevention research aims to understand and intervene upon risk and resilience mechanisms for addiction and common comorbidities. Under the Helping to End Addiction Long TermSM or HEAL InitiativeSM, NIDA leads prevention research aimed at adolescent and young adult populations that are at highest risk for opioid misuse and OUD.³² Goals of the program include preventing individuals with low-severity OUD from developing a more serious OUD; building strategies to keep people in medication treatment for opioid addiction; understanding the role of sleep dysfunction in OUD and recovery; stopping at-risk adolescents from developing OUD; and exploring collaborative care for people with OUD and mental health conditions. Seven pilot studies were completed and are continuing across a variety of prevention strategies including: modifying an existing alcohol and drug prevention intervention designed for American Indian/Alaska Native (AI/AN) youth to be appropriate for opioid prevention in young adults; preventing OUD among homeless adolescents/young adults ages 18-24 years, exploring whether providing housing in addition to opioid and related risk reduction services could improve outcomes; and leveraging technology that is appealing to adolescents and young adults to facilitate delivery of an emergency-department-based intervention via health coaches. Preventing harms related to substance use is another critical priority and includes strategies to prevent overdose and other medical consequences of substance use such as infectious diseases.

Medication Development

Developing effective medications for SUDs is one of our highest priorities and is critical to improving treatment for people with addiction. While effective medications exist for OUD, these medications are underutilized. Suboptimal patient retention in treatment regimens, policy barriers that limit opioid prescribing, and stigma around opioid agonist medications all contribute to their underutilization. More options are needed to help people with OUD achieve long-term recovery. Under the HEAL Initiative, NIDA is supporting research on medications development for OUD and overdose. Since HEAL began, 16 Investigational New Drug applications were filed with the FDA and authorized for human studies. These studies focus on a variety of drug targets, as well as vaccines that could prevent opioids from entering the brain. Others are repurposing existing medications for OUD indications, such as the FDA-approved insomnia medication, suvorexant, based on known overlaps between brain signaling systems involved in sleep and addiction. We are also prioritizing the development of medications to treat stimulant use disorders for which there are currently no FDA-approved medications. Numerous compounds are being tested and approaches span novel biological targets for new medications, to anti-cocaine and anti-meth vaccines, to the repurposing of existing medications. The recently completed Accelerated Development

³² Preventing At-Risk Adolescents from Developing Opioid Use Disorder | NIH HEAL Initiative

of Additive Pharmacology Treatment (ADAPT-2) trial demonstrated that bupropion (used to treat depression) plus naltrexone (used to treat OUD) was effective for reducing methamphetamine use and craving in individuals with moderate to severe methamphetamine use disorder. We continue to place a high priority on medications development for SUD, including new and improved overdose reversal medications, particularly those that are effective for opioid overdoses involving other drugs such as methamphetamine. More coordinated and targeted approaches to incentivize drug development related to addiction are sorely needed. The pharmaceutical industry has historically underinvested in research and development of addiction treatments, due to the biological complexity of this disorder, the stigma that surrounds it, and concerns around the profitability potential of the market for addiction medications.

Translating Research into Practice in Diverse Settings

Effective provision of prevention and treatment services across health care, justice, and community settings is key to addressing SUD and is the most promising way to improve access to treatment. NIDA places a high priority on implementation research in diverse settings, providing major infrastructure through our Clinical Trials Network (CTN) in healthcare settings, Justice Community Opioid Innovation Network (JCOIN) in justice settings, and HEALing Communities Study (HCS) in community settings.

Clinical Trials Network

NIDA's CTN allows medical and specialty treatment providers, treatment researchers, patients, and NIDA to cooperatively develop, validate, refine, and deliver new treatment options to patients. The CTN comprises 16 research nodes across the country in academic medical centers and large health care networks, and more than 240 community-anchored treatment programs. This unique partnership enables the CTN to conduct studies of behavioral, pharmacological, and integrated treatment interventions in multisite clinical trials to determine effectiveness across a broad range of settings and populations, including hard-to-reach rural settings. The CTN is conducting studies to evaluate strategies for integrating OUD screening and treatment into emergency departments, primary care clinics, infectious disease programs and rural and AI/AN communities. It also tests alternative models of care for SUD such as the use of pharmacies for delivering medication for OUD and the integration of telehealth for support of treatment. The CTN also supports research based on data relevant to SUD by taking advantage of electronic health record (EHR) systems. It is currently developing and testing a clinical decision support tool that integrates with EHR systems to help doctors diagnose OUD and provide treatment or refer patients to appropriate care. The primary goal of CTN is to bridge the gap between the science of drug treatment and its practice, through the study of evidence-based interventions in real world settings.

Justice Community Opioid Innovation Network

NIDA's JCOIN, which is part of NIH HEAL initiative, is testing strategies to expand effective OUD treatment and care for people in justice settings in partnership with local and state justice systems and community-based treatment providers.³³ JCOIN includes a national survey of addiction treatment delivery services within the justice system; studies on the effectiveness and adoption of new medications, prevention and treatment interventions, and technologies; and use of existing data sources in novel ways to understand care in justice populations. Together, these studies are generating real-world evidence to address the unique needs of individuals with OUD in justice settings. JCOIN also

³³ Justice Community Opioid Innovation Network | NIH HEAL Initiative

responded in real time to the COVID-19 pandemic with additional research to study COVID testing protocols in justice-involved populations.

HEALing Communities Study

The HEALing Communities Study, also part of the HEAL Initiative, is a multisite implementation research study investigating coordinated approaches for deploying evidence-based strategies to prevent and treat opioid misuse and OUD tailored to the needs of local communities. Research sites are partnering with 67 communities highly affected by the opioid crisis in four states to measure the impact of these efforts. The ambitious goal of the study is to reduce opioid-related overdose deaths by 40 percent over three years. Despite the impacts of COVID-19 on research, the HEALing Communities study was able to launch a key aspect of its program, a diverse communications campaign to increase awareness and demand for evidence-based practices and to reduce stigma against people with OUD and those taking medications for OUD. The study is a multiple of the s

Driving Solutions through Technological Innovation

NIDA leverages the federal government's small business innovation research (SBIR) and small business technology transfer (STTR) programs and other funding mechanisms to help biotech startups develop innovative technologies that translate addiction science into healthcare and consumer products. These tools help provide more timely information about substance use in communities, connect people to care, provide or support treatment, help individuals sustain their recovery from SUDs, and even facilitate overdose prevention. For example, wastewater-based epidemiology is a novel approach being used to study substance exposure at the community level in order to help public health officials better understand and respond to the current opioid crisis in the United States. In the past, researchers seeking to directly measure opioid exposure were often limited by the fact that they only had access to people who had contact with the health care system; this approach excluded people who use these drugs and have no interaction with the health care system. Now researchers are using this robotic technology to sample both substances and SARS-Cov-2 in wastewater from municipal sewers. Other products deliver evidence-based therapies to people with SUDs in novel ways. For example, a smartphone app originally designed to connect patients to open acute care beds has been adapted to facilitate referrals to addiction treatment facilities and is currently being used by several state governments and hospital systems. NIDA has also helped small businesses develop tools that put evidence-based psychosocial treatment for SUDs right in the hands of anyone with a smartphone. For example, reSET and reSET-O are apps that deliver cognitive behavioral therapy (CBT) and contingency management (i.e., reinforcement) to people with non-opioid SUDs (reSET) and OUD (reSET-O), and were the first mobile medical applications, "digital medicines," to receive FDA approval for the treatment of addiction. A NIDA SBIR grant is now being used to make these apps more accessible by converting them into a game. To prevent overdose, another app turns a user's smartphone into a portable respiratory monitor capable of detecting changes in breathing associated with an overdose, sounding an alarm and alerting emergency services. Other apps help doctors and patients monitor and maintain their OUD medication, and connect individuals to behavioral therapies, peer support groups, and community interventions. In addition, NIDA supports the development of entirely novel technologies. One is a hospital bassinet pad that applies gentle vibrations to soothe babies born dependent on opioids, which is currently seeking FDA approval. Another technology uses virtual reality as an alternative form of pain relief to opioids. These

³⁴ <u>HEALing Communities Study | NIH HEAL Initiative</u>

³⁵ Introduction to the special issue on the HEALing Communities Study - PubMed (nih.gov)

and other innovative products demonstrate that pairing sound science with biotechnology entrepreneurship has great potential benefit for our underserved patient population.

NIDA Research on the Intersection of SUD and COVID-19

In March 2020, NIDA responded to the urgent research need posed by the pandemic by issuing a Notice of Special Interest to solicit research at the intersection of COVID-19 and substance use. We've funded more than 100 supplemental research studies under this announcement, which was renewed this year. One of the areas of research NIDA is prioritizing is to understand how changes in healthcare policies implemented due to the pandemic, such as telehealth expansion and changes in the methadone takehome dose policy, have affected addiction treatment access and outcomes. Recognizing that many people with SUDs do not have computers or smartphones, NIDA is also focusing on other innovative methods, such as combining telemedicine with street outreach to help ensure that all people receive the care they need.

Through supplements to the HEALthy Brain and Child Development (HBCD) and Adolescent Brain Cognitive Development (ABCD) studies, we have been able to capitalize on existing infrastructure for longitudinal studies to examine the impact of COVID-19 on child development. HBCD, part of the HEAL Initiative, will add to our understanding of early brain development trajectories from the prenatal period through ages 9-10 by determining how environmental factors, including maternal drug exposure, substance use, and COVID-19 influence early brain development and clinical outcomes such as mental illnesses and addiction. ABCD is following nearly 12,000 children from age 9-10 through the subsequent decade, a period likely to capture the initiation of substance use behaviors. This study will determine how childhood experiences interact to affect brain development and social, behavioral, academic, and health outcomes, including substance use and COVID-19. Together, these studies will lead to a better understanding of typical brain and cognitive development and how they are affected by drugs and other environmental exposures.

NIDA is also pleased to be participating in several of the large trans-NIH COVID-19 initiatives made possible with the generous support of Congress. For example, NIDA is participating in the Rapid Acceleration of Diagnostics Underserved Populations, or RADx-UP, Initiative, which aims to expand COVID-19 testing among underserved and medically and/or socially vulnerable populations; NIDA has ensured that people with SUD are recognized as one such population and are included in this research. We are also leading a program under the RADx-Radical initiative to accelerate methods for detecting SARS-CoV-2 in wastewater as a means of improving community-level surveillance of the virus. This project takes advantage of knowledge and expertise NIDA has developed through research on wastewater surveillance of drug use.

Building Partnerships

Partnerships are critical for NIDA research to make a positive impact on public health. NIDA's commitment to synergistic cooperation takes many different forms, designed to better respond to emergent issues or chronic needs in the public health arena. This includes working with a wide range of partners including state and local governments; sister agencies within the Department of Health and Human Services such as SAMHSA, FDA, and CDC; the Department of Justice; the White House Office on National Drug Control Policy (ONDCP); and with private industry.

Some of the largest projects under the HEAL initiative rely on such collaboration. The HEALing Communities Study is led by NIDA in close partnership with SAMHSA to ensure that this research is best poised to impact service delivery toward ameliorating the opioid crisis in hard hit areas. JCOIN fosters collaboration between investigators, justice, and behavioral health stakeholders in search of creative ways for improving the capacity of the justice system to respond to the opioid crisis. Similarly, our work on medication development aims to de-risk promising compounds so that the pharmaceutical industry can develop them into products and obtain their approval for clinical use.

Along with ongoing collaboration to improve the medication treatment development process, NIDA and FDA work closely together on the Population Assessment of Tobacco and Health (PATH) Study, a nationally representative longitudinal study of tobacco use and health in the United States. By following study participants over time, the PATH Study helps scientists learn how and why people start using tobacco products, quit using them, and start using them again after they've quit, as well as how different tobacco products affect health outcomes, such as cardiovascular and respiratory health, over time. Findings from this study and others inform FDA's regulatory actions. For example, results from NIDA's Monitoring the Future study revealed that a large proportion of teens vaped because they liked the taste which prompted the FDA to finalize their enforcement policy on flavored vaping (e-cigarette) products.³⁶

In addition to these specific research examples, NIDA partners with agencies across HHS to ensure that research findings are effectively communicated to support evidence-based policymaking. Ongoing NIDA projects, along with the existing evidence base, support the development of HHS's coordinated overdose prevention strategy and the development of ONDCP's National Drug Control Strategy.³⁷ These collaborations provide valuable and complementary perspectives and infrastructures that NIDA leverages to maximize potential benefit for the populations we serve.

Conclusion

The COVID-19 pandemic has upended every facet of our society and exacerbated the ongoing public health crisis of drug addiction and overdose. As our nation continues to grapple with the pandemic, we must preserve a laser focus on effective prevention and quality treatment of addiction, and enhanced support of people in recovery. NIDA appreciates the support of Congress for our mission, and NIDA research will continue to pursue scientific solutions to the addiction and overdose crisis as it has evolved due to COVID-19.

³⁶ FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint | FDA

³⁷ ONDCP Releases 2020 National Drug Control Strategy and Rural Toolkit - Capitol Connector (thenationalcouncil.org)