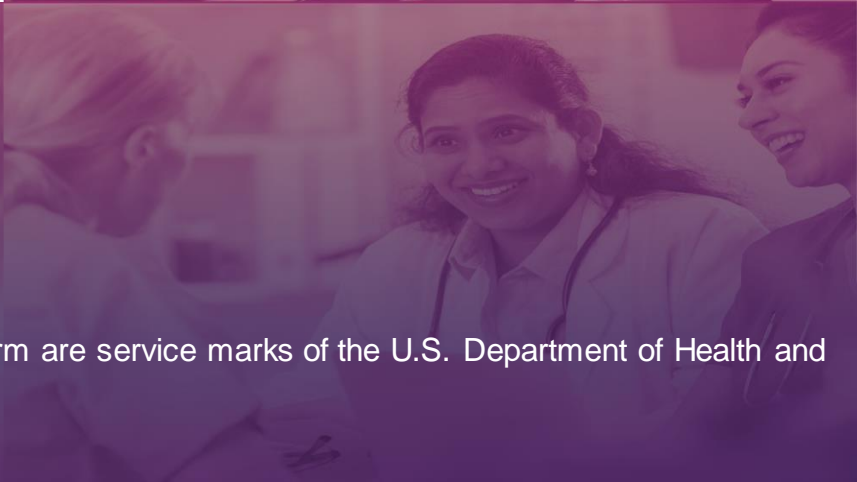
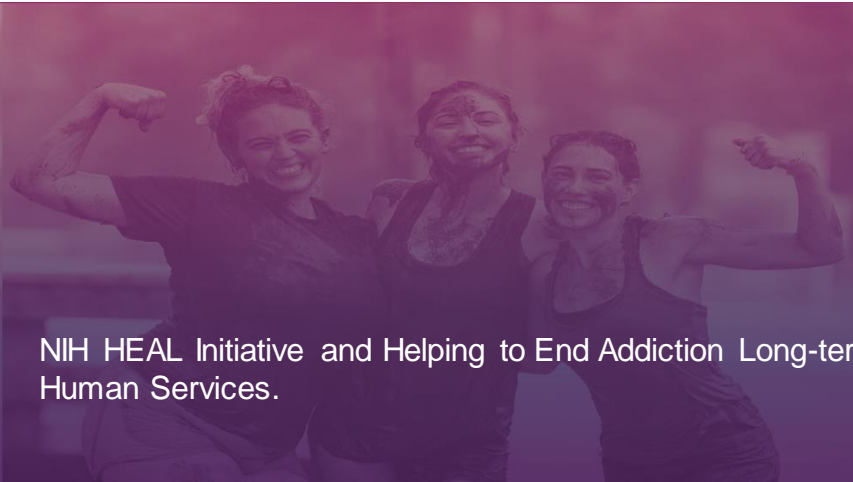




**NIH
HEAL
INITIATIVE**

NIH Tribal Consultation on Research Needed to Address the Opioid Crisis, Including Managing Chronic Pain and Addiction

March 31, 2022



NIH National Institutes of Health
HEAL Initiative

NIH HEAL Initiative and Helping to End Addiction Long-term are service marks of the U.S. Department of Health and Human Services.

RISE IN OPIOID OVERDOSE DEATHS IN AMERICA

NEARLY
500,000
PEOPLE DIED FROM AN
OPIOID OVERDOSE
(1999-2019)

www.cdc.gov

A Multi-Layered Problem in Three Distinct Waves



1990s

mark a rise in prescription
opioid overdose deaths

Rx OPIOIDS

Include natural, semi-synthetic,
and methadone and can be
prescribed by doctors



2010

marks a rise in heroin
overdose deaths

HEROIN

An illegal opioid



2013

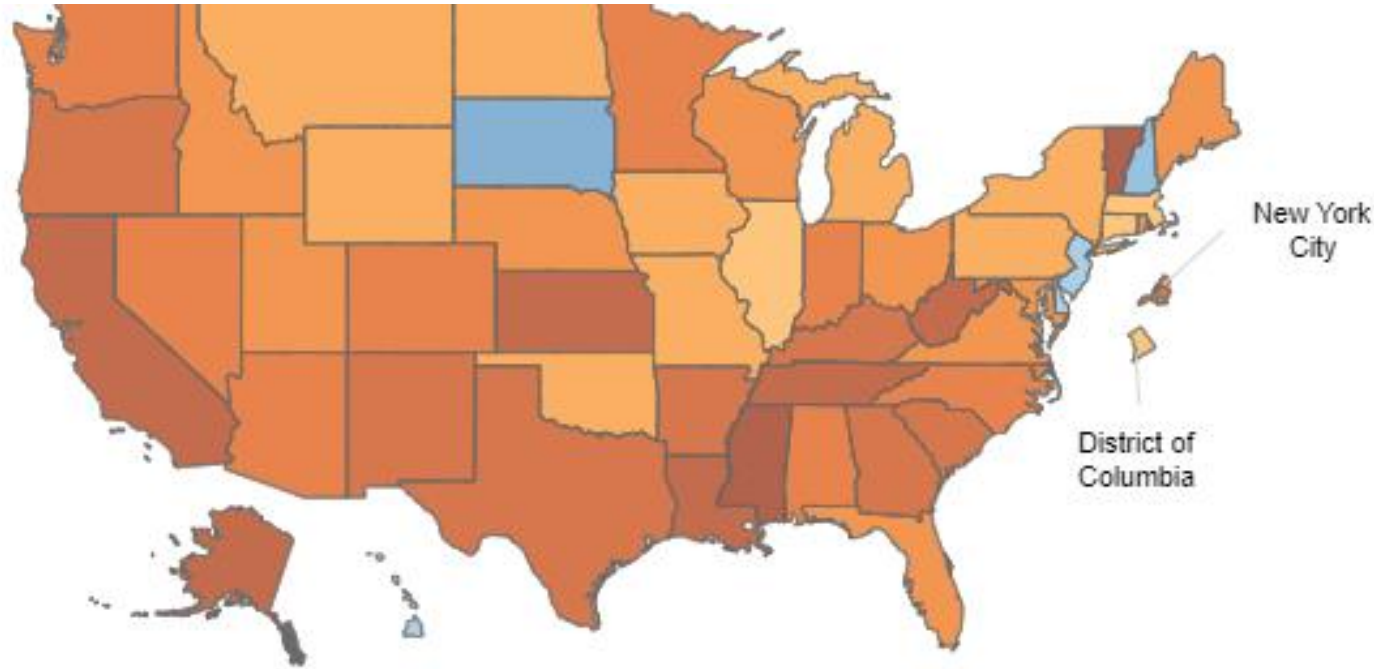
marks a rise in synthetic
opioid overdose deaths

SYNTHETIC OPIOIDS

Include fentanyl and can
be illicitly made

Learn more about the evolving opioid overdose crisis: www.cdc.gov/drugoverdose

Crisis #1: National Overdose Deaths



**Stimulant Overdose
Deaths Increased By
28% from 2018 to 2019**

**23% change in 12-months
on all fatal drug overdoses
ending May 2021**

Legend for Percent Change in Drug Overdose Deaths Between 12-Month Ending Periods



Crisis #2: Chronic Pain in the U.S.

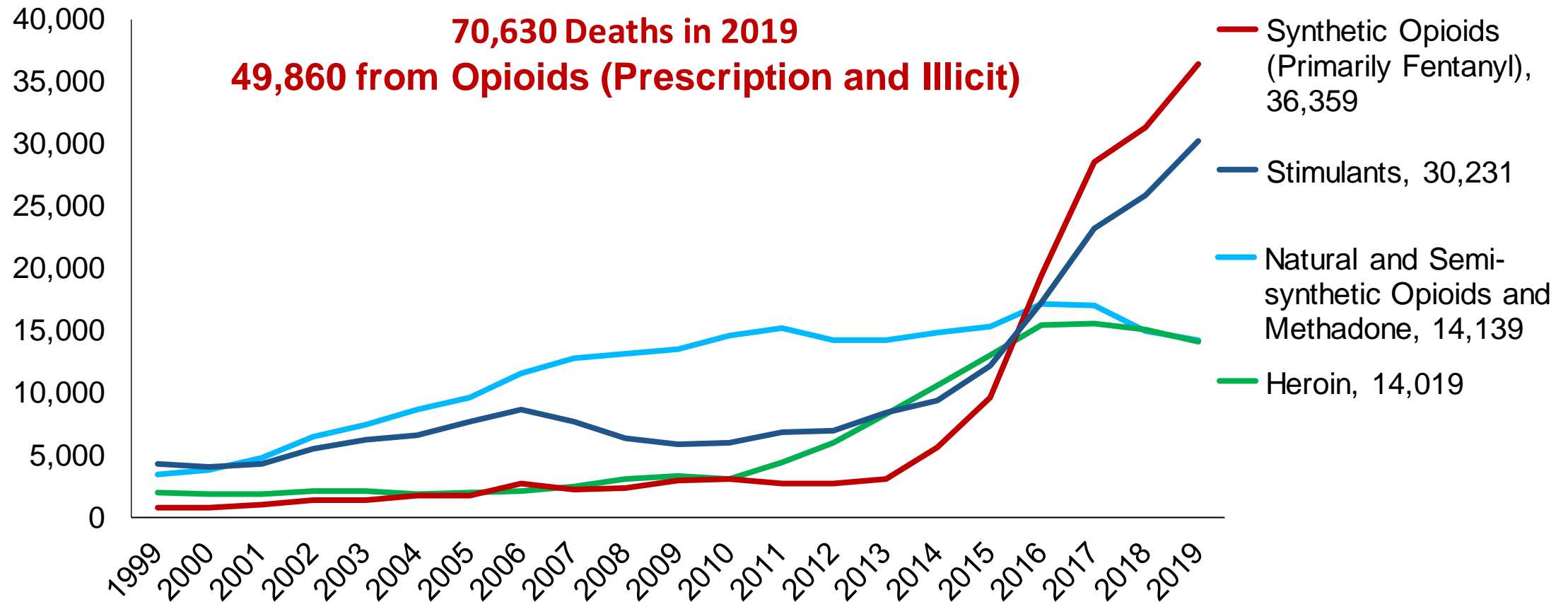
- 50 million adults are affected by chronic pain
- 25 million report severe pain daily
- 20 million have high impact chronic pain



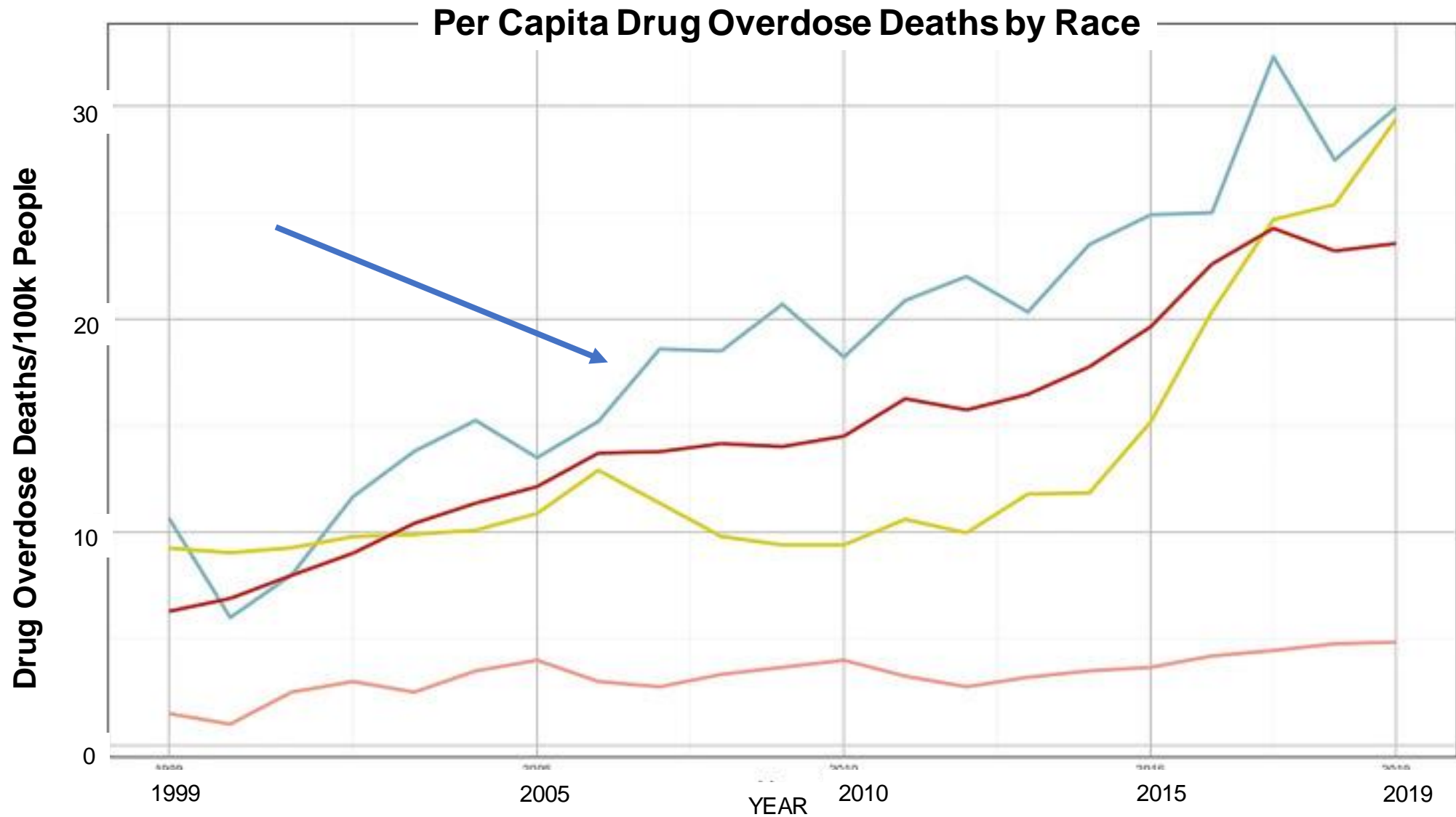
CDC, Morbidity and Mortality Weekly Report, Sept. 2018

Evolution of Drivers of Overdose Deaths, All Ages

Analgesics → Heroin → Fentanyl → Stimulants



Source: The Multiple Cause of Death data are produced by the Division of Vital Statistics, National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), United States Department of Health and Human Services (US DHHS).

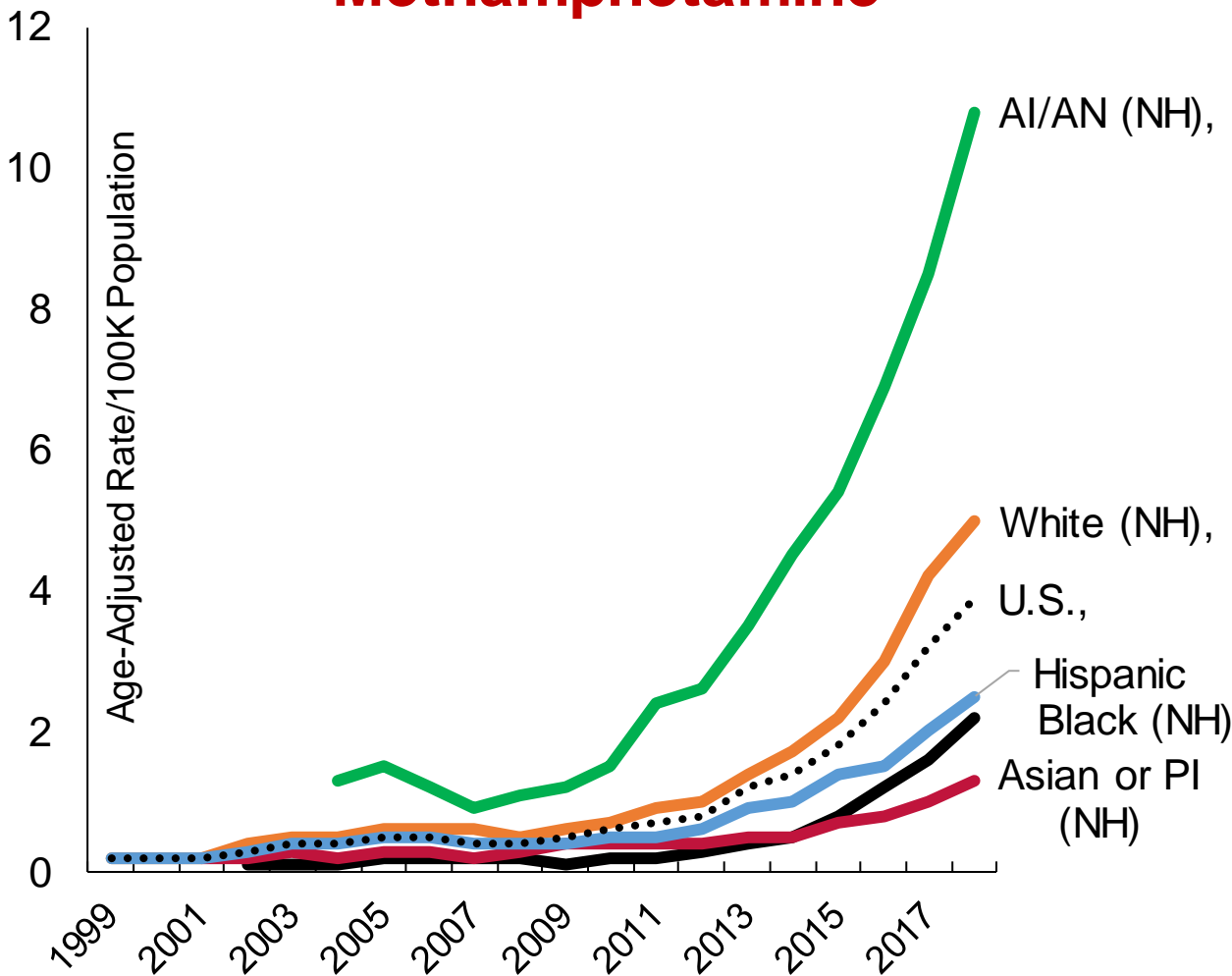


RACE — American Indian or Alaska Native — Asian or Pacific Islander — Black or African American — White

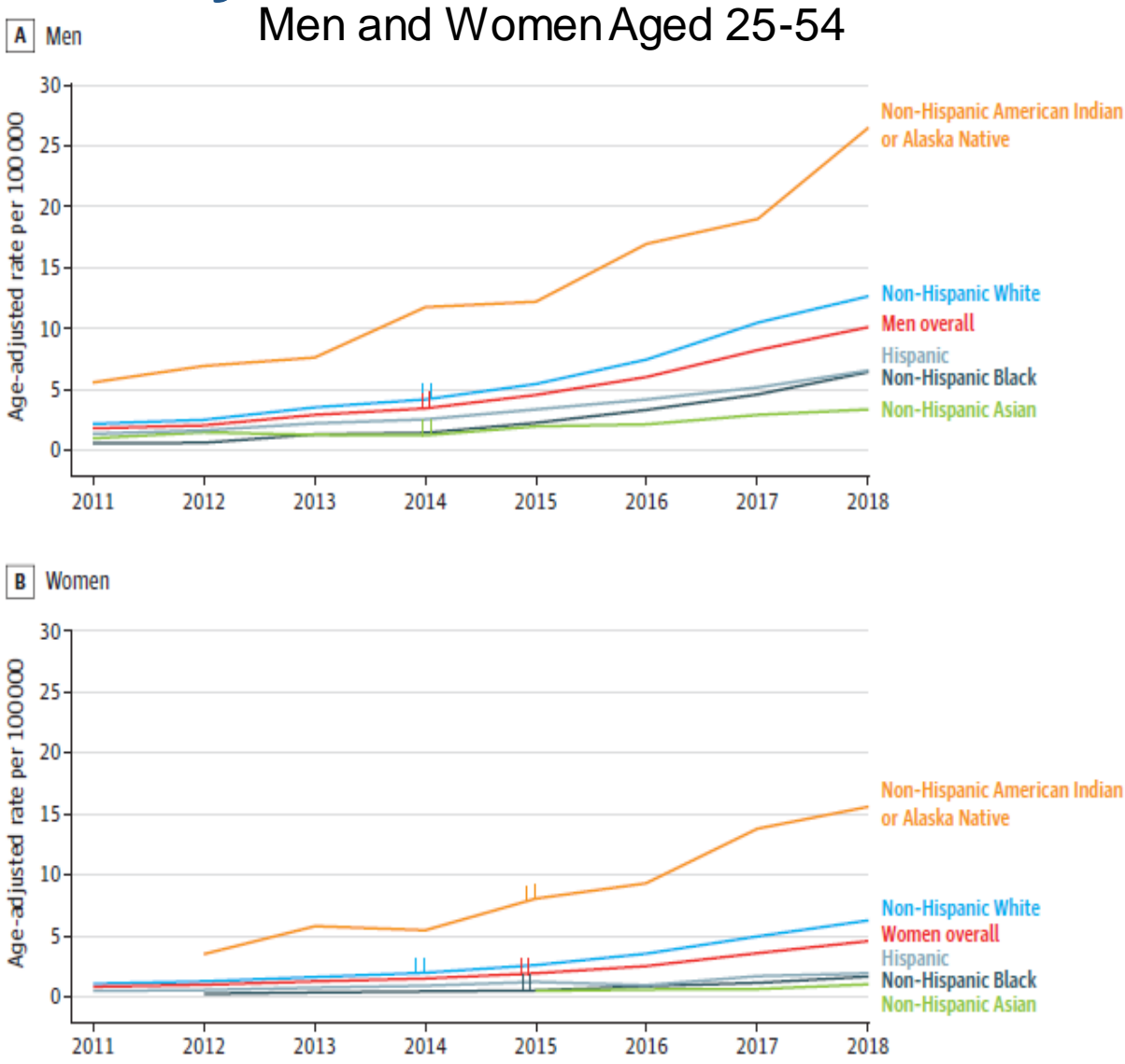
CDC Wonder Online Database (2020) Multiple Cause of Death Files, 1999–2019, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. [[Ref list](#)]

Age-adjusted Rates Of Drug Overdose Deaths Involving Methamphetamine By Race and Ethnicity: US, 2009–2018

Methamphetamine



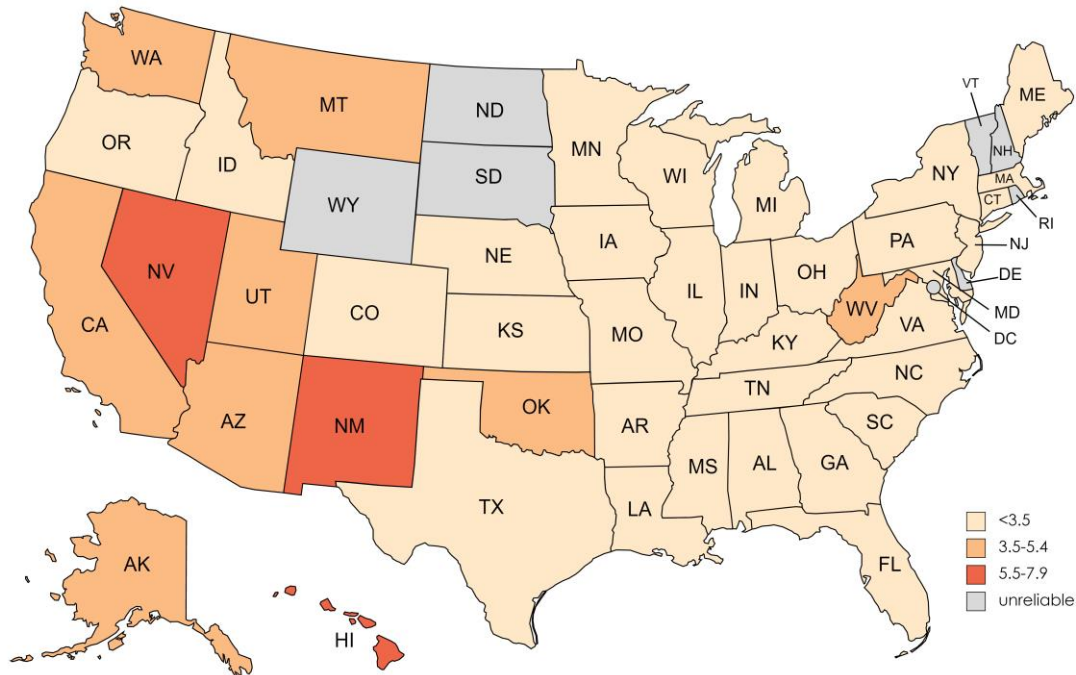
CDC, NCHS Data Brief No. 384, October 2020



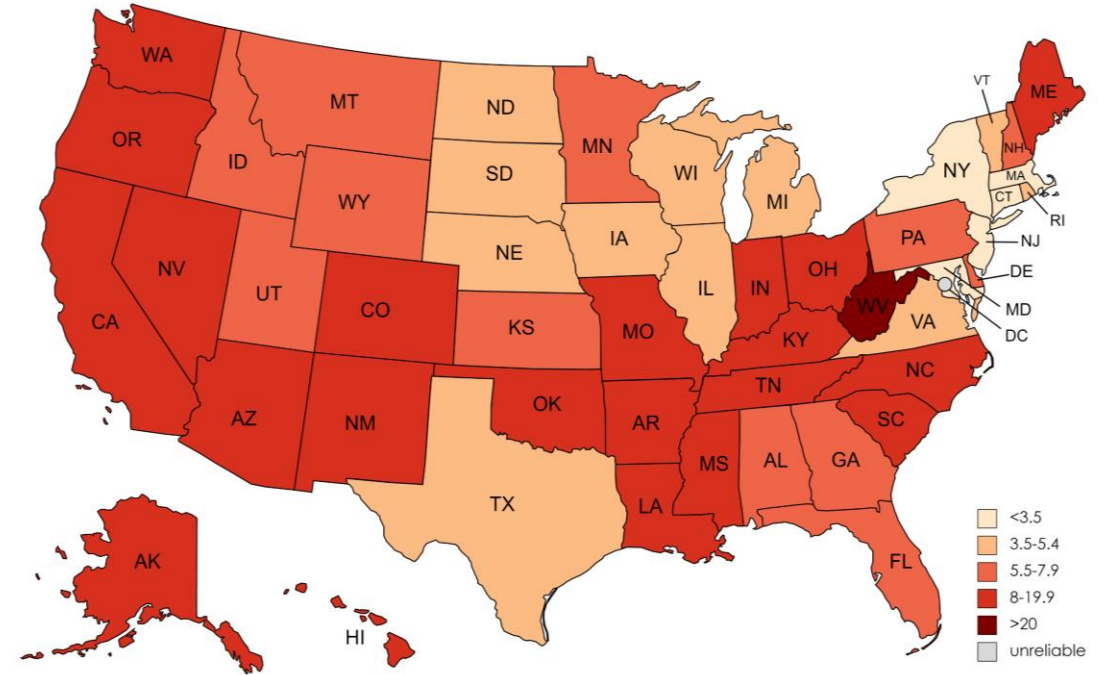
Han B et al., JAMA Psychiatry May 2021 Volume 78, Number 5.

U.S. overdose deaths involving methamphetamine* age-adjusted rates/100k persons

2015



2020



*Psychostimulants With Abuse Potential ICD-10 code (T43.6). This category is dominated by methamphetamine-involved overdose deaths.
Source: CDC, National Center for Health Statistics. Multiple Cause of Death 1999-2020 on CDC WONDER Online Database, released in 2021.

'Opioid overdoses are skyrocketing': as Covid-19 sweeps across US an old epidemic returns

The pandemic is creating the social conditions - no jobs, isolation, despair - that helped enable the opioid crisis to emerge in the first place. Now it's back



'There was nothing to help me': how the pandemic has worsened opioid addiction

US treatment centers have shut down or turned away patients amid as they struggle to adhere to Covid-19 safety protocols



THE WALL STREET JOURNAL.

Opioid Use Hits Construction Industry as Overdoses Soar

Physically challenging work often leads laborers to turn to addictive painkillers, and Covid-19 makes treatment more difficult

I-TEAM

Drug overdose deaths spike amid COVID-19 pandemic

By Chuck Goudie and Barb Markoff, Christine Tressel, Ross Weidner, Jonathan Fagg
Wednesday, February 10, 2021

THE OTHER EMERGENCY

Covid-19 is undoing a decade of progress on the opioid epidemic



U.S.

The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic

Overdose deaths rise as job losses and stress from Covid-19 destabilize people struggling with addiction

A Collision of Public Health Crises: COVID-19 and Opioids/Substance Use for American Indian and Alaska Native Communities

- Intersecting crises resulting in devastating consequences across American Indian and Alaska Native (AI/AN) communities.
 - Reported increases in overdose, relapse, drug substitution, mental health problems, suicide-related behaviors, and violence.
- Community stakeholders reported a general increase in need for services, prompting many communities to prioritize the development of telehealth as substitutes for in-person care.
- ***Despite challenges, AI/AN communities have rallied together, using strength and cohesion to address the intersecting crises (e.g. high vaccination rates).***

The Response: NIH HEAL Initiative

A trans-agency effort to speed scientific solutions to stem the national opioid public health crisis in all communities

- More than 600 research projects across NIH
- 32 research programs
- Projects underway in all 50 States
- Released 50+ funding announcements since inception

From prevention research, basic and translational research, clinical trials, to implementation science

NIH HEAL INITIATIVE RESEARCH OVERVIEW



Cross Cutting Themes

- Advancing Health Equity in Pain Management and Comorbidities
- Diversity
- Partnership with people with lived experience
- Research Dissemination
- Adapting Research Interventions for COVID-19
- *And much more...*

Viewpoint

August 26, 2021



The Helping to End Addiction Long-term (HEAL) Initiative of the National Institutes of Health

Rebecca G. Baker, PhD¹; Walter J. Koroshetz, MD²; Nora D. Volkow, MD³

» [Author Affiliations](#) | [Article Information](#)

JAMA. Published online August 26, 2021. doi:10.1001/jama.2021.13300

The Helping to End Addiction Long-term (HEAL) Initiative was established in 2018 to provide scientific solutions to the opioid crisis. With dedicated support from Congress, the HEAL initiative has funded more than 500 projects nationwide, and plans to expand its efforts to develop more effective therapies for managing pain and effective pain management strategies that limit addiction across a variety of settings.¹ The HEAL initiative joins the public health community in addressing an urgent public health need (see [Table](#) for select

ONLINE FIRST | FREE

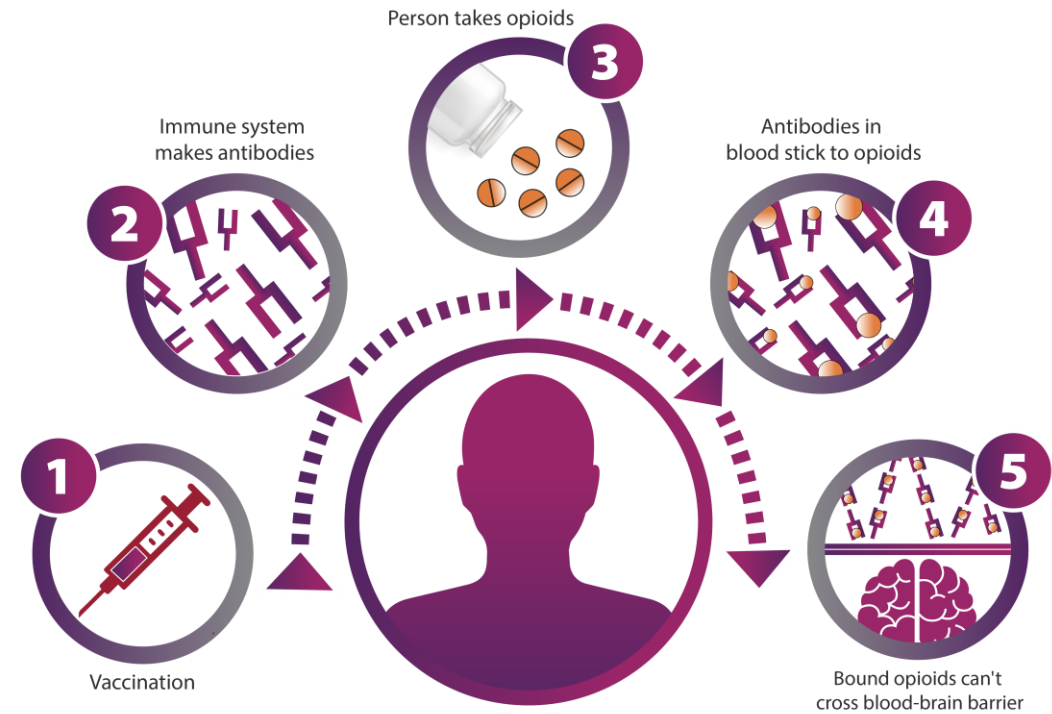


Novel Therapeutic Options for Opioid Use Disorder and Overdose:

Expand treatment options for all aspects of opioid addiction

- Encompasses all aspects of opioid addiction
- Novel immunotherapeutics offer protection from overdose
 - New medication formulations treat progression to chronic use, withdrawal symptoms, craving and overdose

HOW THE OPIOID VACCINE WORKS



Enhanced Outcomes for Infants and Children

Addresses the long-term consequences of early opioid exposure



- **Advancing Clinical Trials in Neonatal Opioid Withdrawal (ACT NOW)** found significant site to site practice variation in treatment of infants with NOW S;
- **HEALthy Brain and Child Development Study (HBCD)** developing neuroimaging measures in infants and young children



New Prevention & Treatment Strategies for Opioid Use Disorder

Supports a wide range of programs to develop new or improved strategies.

- Optimizing care for people with opioid use disorder and mental health conditions, including in primary care settings
- Preventing opioid use disorder in at-risk populations
 - Adolescents transitioning to adulthood, homeless, American Indian/Alaskan native (AI/AN) communities
- Intervening on social determinants of health



Translation of Research into Practice for Effective Treatments for Opioid Use Disorder

Tests the integration of evidence-based interventions in an array of settings.

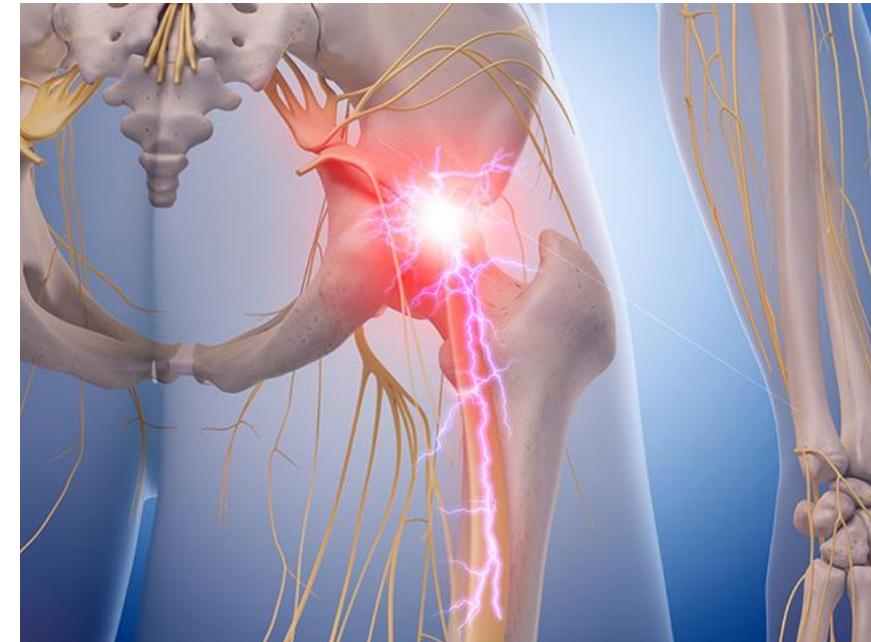
- Justice Community Opioid Innovation Network
- Management of polysubstance use through the NIDA Clinical Trials Network
- Recovery support services research
- HEALing Communities Study
 - Real-time data tools to monitor overdose spikes



Preclinical and Translational Research in Pain Management

Suite of non-addictive therapeutic development programs

- Discovery and validation of novel targets for safe and effective pain treatment
- Screening and testing platforms, tissue chips, and optimization research
- Devices to treat pain
- Studying pain in human genes & cells
- Restoring joint health and function (REJOIN)



Clinical Research in Pain Management

Research to evaluate the safety and efficacy of innovative therapies for pain management

- Early Phase Preclinical Investigation Network (EPPIC Net)
- Back Pain Consortium (BACPAC)
- Hemodialysis Opioid Prescription Effort (HOPE)
- Pain Effectiveness Research Network (Pain ERN)
- Pragmatic and Implementation Studies for Management of Pain to reduce opioid prescribing (PRISM)
- Integrated Management of chronic pain and OUD (IMPOWR)



New Research Directions for HEAL Research

Improve Care through Coordination and Collaboration

- Healthcare Systems
- Research Adoption Partnerships

Health Equity

- Sickle Cell Disease Pain Management
- Social Determinants of Addiction and Behavioral Health
- Pain Management and Comorbidities

Data Driven Research

- Real World Healthcare Data
- Secondary Data Analysis

Harm Reduction

- Policies, Practices and Modes of Delivery

Evidence Based Treatments

- Polysubstance Use
- Medication Development
- Recovery Support Services

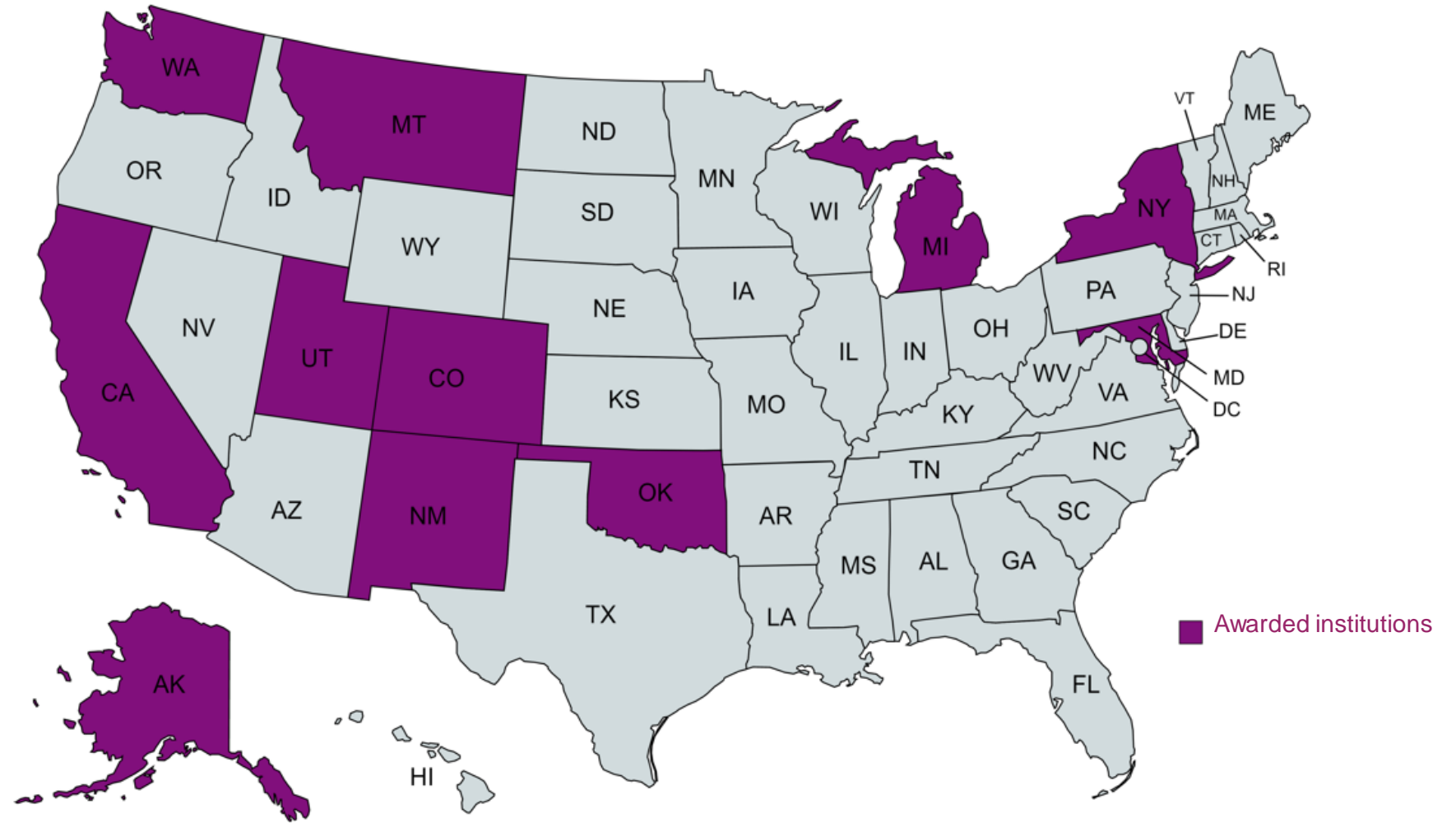
Preventing Overdose Through Pain Management

- Basic and Translational Neuroscience
- Innovation to Treat Pain

Research Underway in AI/AN Communities

- Whole person approach to co-occurring pain and addiction (New Mexico)
 - Focus on quality of life and participation in meaningful activities
 - Draw on cultural strengths through inclusion of traditional practices
- Strategies for prevention and treatment of opioid use disorder (Alaska)
 - Suicide prevention and mental health focus
 - Work through social networks and connectedness
 - Interventions at individual and community-levels
- Addressing barriers to treatment (multiple sites)
 - Stigma associated with therapeutic treatments for opioid use disorder
 - Integrate therapeutic treatments into existing care

HEAL Research in AI/AN Communities



Tribal Consultation on the Helping to End Addiction Long-term® (HEAL) Initiative ***Research Needed to Address the Opioid Crisis Including Managing Chronic Pain and Addiction***

- Understand *research priorities* important to your communities
- How HEAL could engage with AI/AN communities to develop a Tribally focused initiative to speed development of scientific and local solutions to the opioid crisis.
- Continue to build on the input from the 2018 [Consultation](#) and adapt approaches as the overdose crisis continues to change.

Tribal Consultation on the Helping to End Addiction Long-term® (HEAL) Initiative
Research Needed to Address the Opioid Crisis Including Managing Chronic Pain and Addiction

Date: Thursday, March 31, 2022

Time: 2:00-4:00pm ET

- Please send any testimony, comments, and questions to NIHTribalConsultation@nih.gov before May 1, 2022.

Potential Discussion Topics

1. What areas of research do you think are important to aid in addressing the opioid crisis? This may include research on chronic pain, opioid misuse, addiction, and overdose and other targets of research.
2. What research resources are needed to effectively and ethically conduct research with AI/AN communities responding to the opioid crisis?
3. Is there interest in including Traditional healing practices as part of new research approaches? How should it be approached (including studies investigating traditional healing practices for the prevention and treatment of chronic pain, opioid misuse, addiction, and overdose)?
4. If this is a research priority, what resources are needed to support research on Traditional healing practices and non-pharmacological therapies for chronic pain, opioid misuse, addiction, and overdose?
5. How could or should the impact of social, economic, and historical factors be included in research on chronic pain and accompanying conditions? For opioid misuse, addiction, and overdose?
6. Does the lack of availability of data hinder your ability to respond to the opioid crisis? What data would be most helpful?
7. What resources are needed to support research infrastructure for data collection and analysis, and research by Tribes to support programs to improve chronic pain management, reduce opioid misuse, addiction, or overdose?