



Public Meeting

Strategies to Improve Health Equity Amidst the Opioid Crisis

November 21, 2019

Strategies to Improve Health Equity Amidst the Opioid Crisis

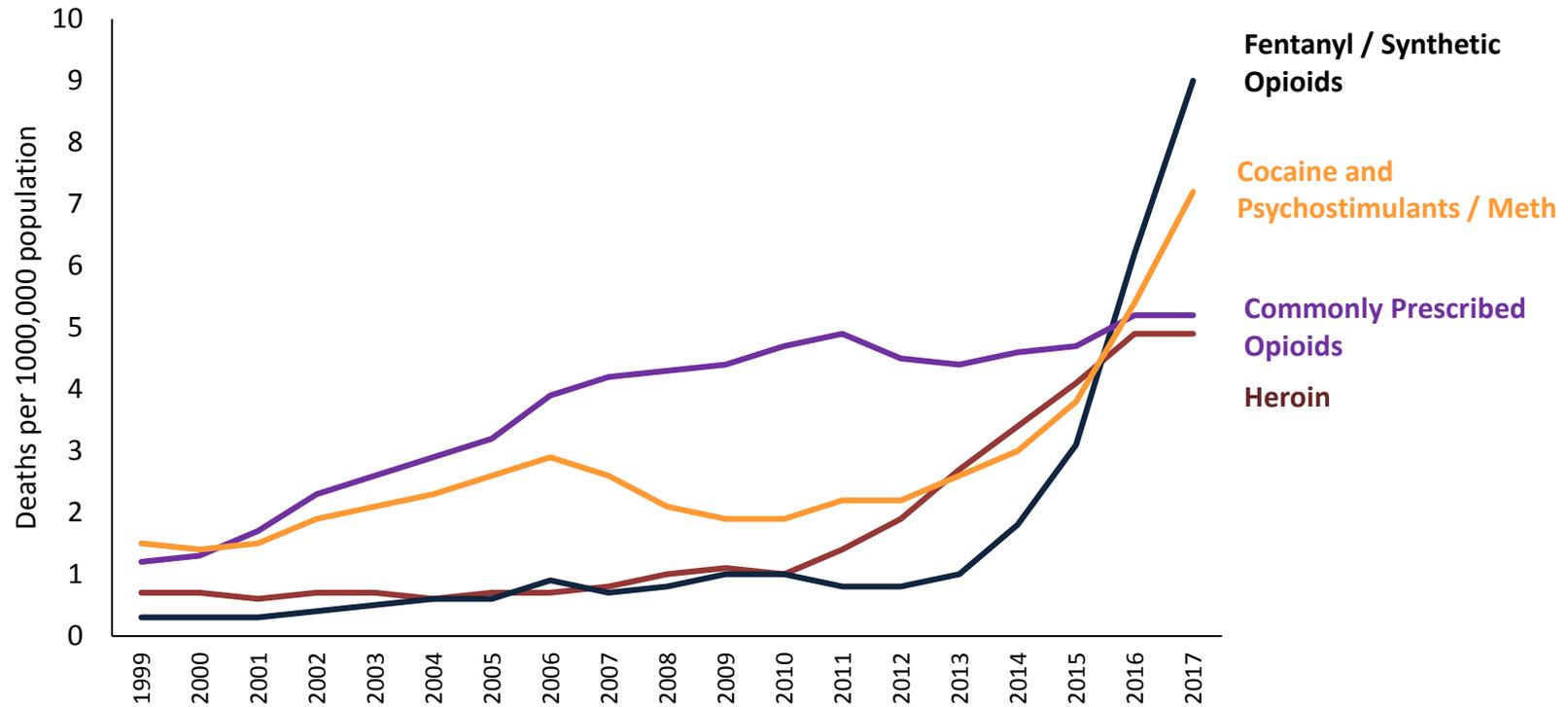
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CDER, FDA

Office of Minority Health and Health Equity
Public Meeting
November 21, 2019



The opinions and information in this presentation
are my own and do not necessarily reflect the
views and policies of the FDA

Deaths Due to Opioid Overdose



Source: Data retrieved on June 6th, 2019 from CDC WONDER



Equally Critical Social and Medical Issue: Pain in America

- From the Functioning and Disability Supplement of the 2012 National Health Interview Survey
 - 25.3 million adults (11.2%) suffering from daily (chronic) pain
 - 23.4 million (10.3%) reporting a lot of pain.

Nahin RL, J.Pain, 2015 Aug;16(8):769-80

Behind These Numbers

- Differential impact of these twin crises on US populations
 - Racial
 - Socio-economic
 - Age
 - Sex/Gender

Disparities for Opioid Overdose Deaths Between 2016 and 2017

- Overdose deaths decreased 13.2% among males aged 15–24 years but increased 10.5% among persons aged ≥ 65 years
- The largest relative change occurred among blacks (increased 25.2%)
- Heroin-associated overdose deaths declined 3.2% among whites. However, heroin-involved overdose death rates among persons aged ≥ 65 years (16.7%) and among blacks (8.9%).

https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w

Disparities for Access to Pain Management

- Regarding pain treatment, a 2015 study conducted from over 6,000 emergency departments across the country found that patients of color were 22 to 30 percent less likely to receive pain relieving medication than their white counterparts

ScienceDaily, 17 November 2015

Central Messages from these Data

- The opioid crisis is not one crisis, but many
- These crises are impacting critical US demographics in different ways
- Addressing the opioid crises requires attention to the many factors driving the epidemic and unique strategies targeted at specific groups

FDA's Priorities & Actions to Address the Opioid Crisis



1. Decreasing Exposure & Prevent New Addiction

-  Appropriate Dose/Duration Labeling
-  Appropriate Packaging, Storage, and Disposal
-  Health Care Provider Education

2. Supporting the Treatment of Those With Opioid Use Disorder

-  Naloxone
-  Medication Assisted Treatment

3. Fostering the Development of Novel Pain Treatment Therapies

-  Partnerships & Meetings
-  Pain Treatment Alternatives
- Abuse Deterrent Formulations (ADFs)

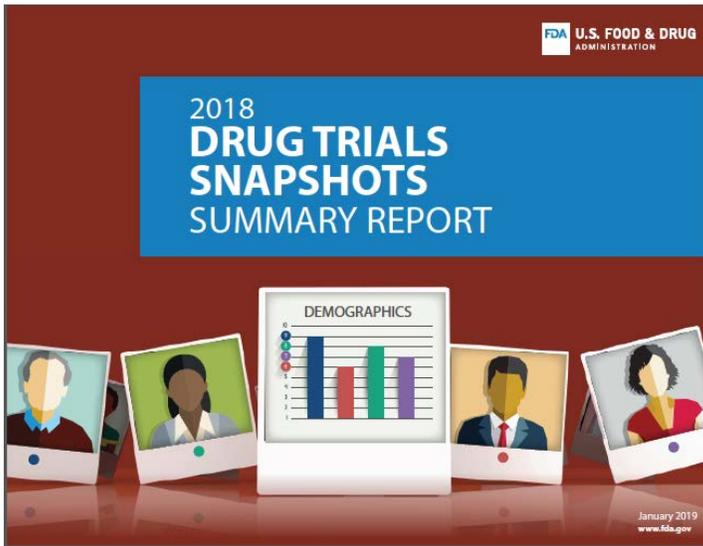
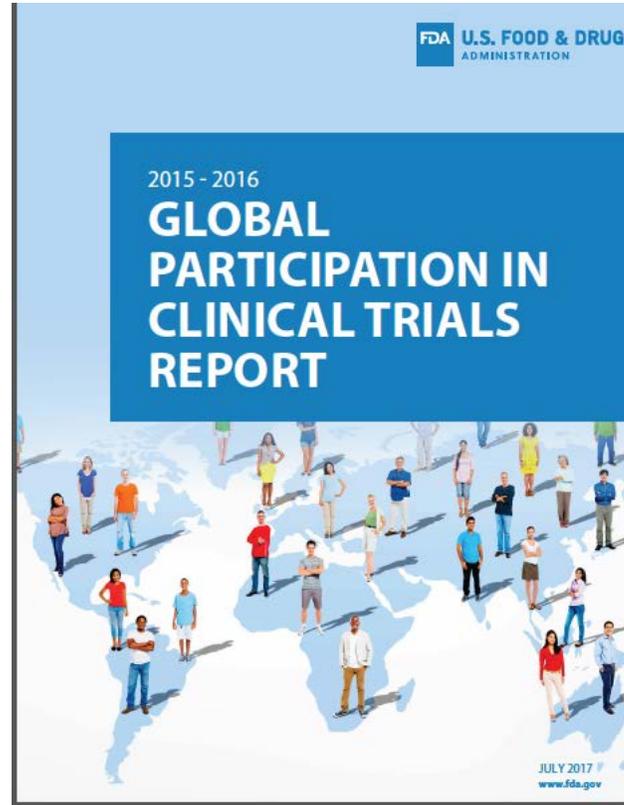
4. Improving Enforcement & Assessing Benefit-Risk

-  Improving Enforcement
-  Assessing Benefit-Risk

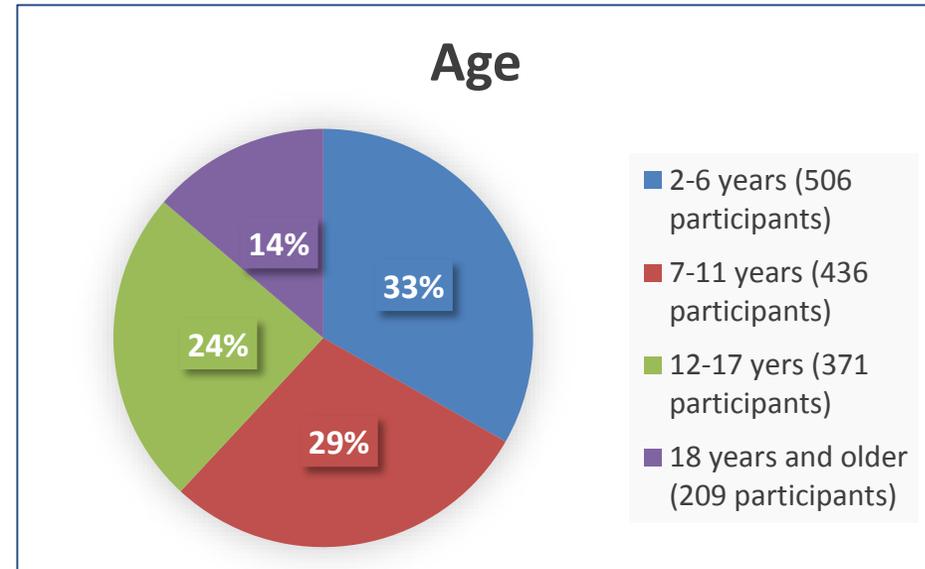
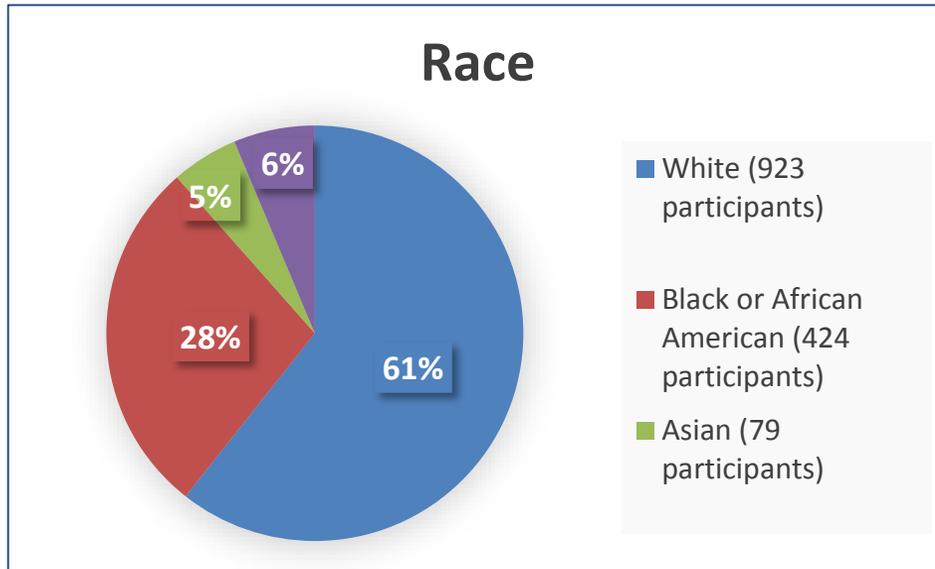
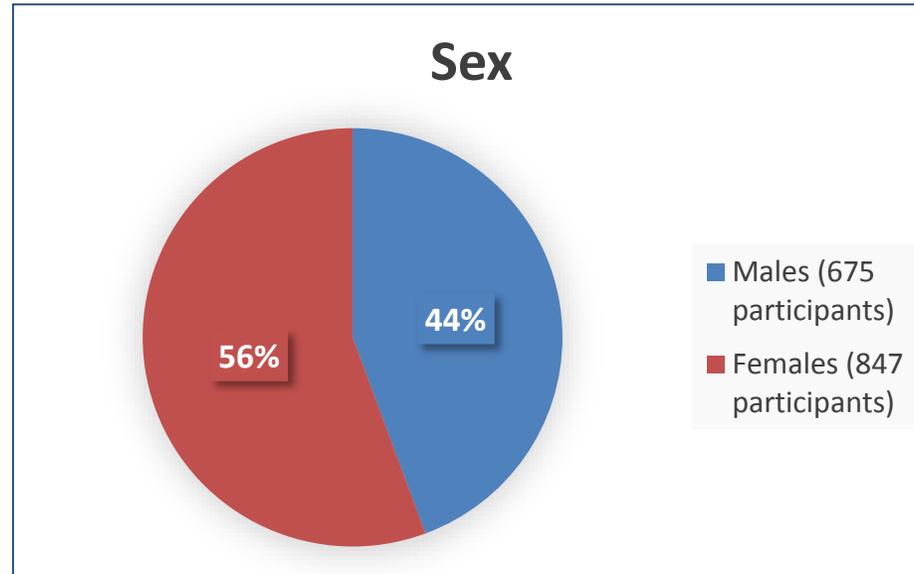
Information-Sharing Focused on Demographic Sub-Groups

Drug Trial Snapshots

Remove the Risk Campaign



Drug Trials Snapshot Example



Remove *the* RISK

Safe Opioid Disposal Campaign



Free digital toolkit includes materials in the following formats.



Video Public Service Announcements (PSAs)



Print PSAs



Radio PSAs



Fact Sheets



Website Badges



Social Media Posts



Social Media Graphics



Drop-in Content

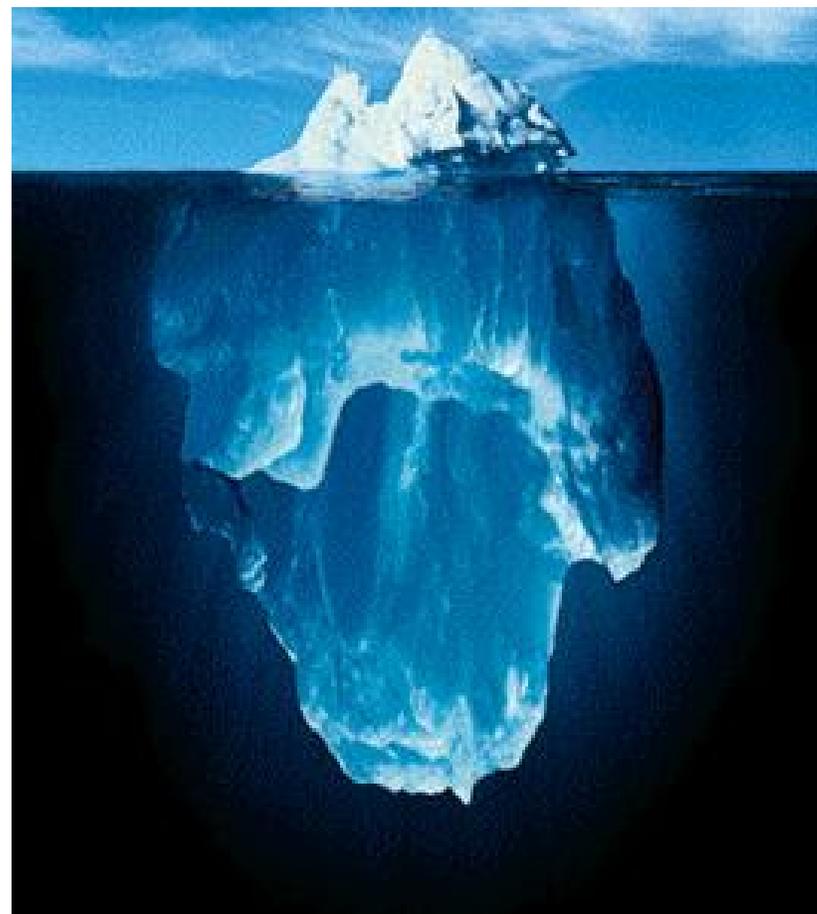
- ✓ Keeping unused opioids in the home creates a serious health risk, especially if teens or children live with or visit you.
- ✓ Remove unused opioids as soon as possible to reduce the chance of accidental or intentional misuse.

Resources are available in English and Spanish.

<https://www.FDA.gov/RemovetheRisk>

Solutions Must Come from Many Sources

- FDA is one of many Federal agencies addressing issues involving opioids
- Many Federal Agencies working together on issue
- Each state has programs to address opioids
- Guidelines and educational programs are available from specialty societies and State Medical Boards
- Healthcare institutions
- Advocacy groups
- Individual providers (n = 800,000+)
- Patients (n = millions)



Conclusions

- FDA's response to issues raised by opioids must reflect the unique challenges of how they are used, misused and abused
 - The opioid crisis, and the crisis of inadequate pain management co-exist
 - Different demographic communities are affected differently by these crises
- Successful response begins by identifying the sources of those differences and by targeting solutions targeted with those populations in mind
- FDA is committed to making a difference in this critical public health area

Thank You



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PRIORITIES OF THE NATION'S DOCTOR



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VADM Jerome Adams, M.D., M.P.H.

Surgeon General of the United States



SURGEON GENERAL'S ADVISORY ON NALOXONE AND OPIOID OVERDOSE

*I, Surgeon General of the United States Public Health Service, VADM Jerome Adams, am emphasizing the importance of the overdose-reversing drug naloxone. For patients currently taking high doses of opioids as prescribed for pain, individuals misusing prescription opioids, individuals using illicit opioids such as heroin or fentanyl, health care practitioners, family and friends of people who have an opioid use disorder, and community members who come into contact with people at risk for opioid overdose, **knowing how to use naloxone and keeping it within reach can save a life.***

BE PREPARED. GET NALOXONE. SAVE A LIFE.



OFFICE OF THE
Surgeon General



SURGEON GENERAL'S DIGITAL POSTCARD ON OPIOID MISUSE

WHAT CAN YOU DO TO PREVENT OPIOID MISUSE?



TALK ABOUT IT.

Opioids can be addictive and dangerous. We all should have a conversation about preventing drug misuse and overdose.



BE SAFE.

Only take opioid medications as prescribed. Always store in a secure place. Dispose of unused medication properly.



UNDERSTAND PAIN.

Treatments other than opioids are effective in managing pain and may have less risk for harm. Talk with your healthcare provider about an individualized plan that is right for your pain.



KNOW ADDICTION.

Addiction is a chronic disease that changes the brain and alters decision-making. With the right treatment and supports, people do recover. There is hope.



BE PREPARED.

Many opioid overdose deaths occur at home. Having naloxone, an opioid overdose reversing drug, could mean saving a life. Know where to get it and how to use it.



For help, resources,
and information:

<https://www.hhs.gov/opioids/>

1-800-662-HELP (4357)



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For Media Requests:

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Link to Invitations Form:

<https://www.hhs.gov/surgeongeneral/about/contact-us/surgeon-general-invitation-form/index.html>



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Session 1

The Voice of the Patient:
Diverse Patient Perspectives on
Opioid Use Disorder

The Voice of the Patient: Opioid Use Disorder and Chronic Pain

Public Meeting on Strategies to Improve
Health Equity Amidst the Opioid Crisis
November 21, 2019

Meghana Chalasani, MHA
FDA Center for Drug Evaluation and Research





The views and opinions expressed in this presentation are those of the individual presenter and should not be attributed to or considered binding on the U.S. Food and Drug Administration (FDA).



Patient-focused drug development (PFDD) is a systematic approach to help ensure that **patients' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated** into drug development and evaluation.



Patient-Focused Drug Development

**FDA Wants
To Hear
From Patients**

FDA

**U.S. FOOD & DRUG
ADMINISTRATION**

FDA's Public Meeting on Patient-Focused Drug Development for Opioid Use Disorder



- April 17, 2018, 10 am – 4pm
- The Voice of the Patient summary report capturing participants' input in their own words was published in November 2018.
- The following is a highlight of select input gathered at the meeting (in-person and webcast) and through the public docket.



> 100 individuals with opioid use disorder or caregivers attended the meeting in person

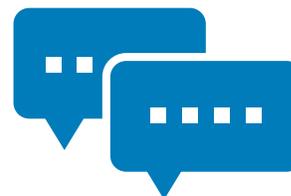
> 85 individuals with opioid use disorder or caregivers provided input through the interactive webcast

> 70 submitted comments through the public docket, majority from individuals with opioid use disorder, caregivers, or advocates.



Participants varied in gender, race, age, history of opioid use, experiences with opioid use disorder, and time to recovery.

Participants varied in their overarching perspectives on substance use and treatment.



Discussion topics focused on experiences and perspectives:

- Health effects and daily impacts of opioid use disorder
- Individuals' and families' perspectives on current approaches to treating opioid use disorder

Public Meeting on Patient-Focused Drug Development for Opioid Use Disorder (OUD): Key Themes



**OUD is a chronic,
neurobiological
disease with
devastating impacts.**

- Participants reiterated both the acute and chronic health effects of OUD, which sometimes last decades into their recovery.
- Participants described “being a prisoner” to opioid withdrawals often accompanied by nausea, vomiting, and uncontrollable muscle spasms.
- Participants also offered insight on opioid “cravings,” or desire to use. They highlighted the relationship between craving and anxiety and stressed that cravings are more than a physical liking for a substance.
- Cravings were described as “the act of doing it, preparing it, consuming it, the immediate relief afterwards.” Participants also stressed that cravings may last well beyond acute withdrawal and can be triggered unpredictably.
- Other long-term effects included scarring due to IV drug use, insomnia, anxiety, and fear.

Public Meeting on Patient-Focused Drug Development for Opioid Use Disorder (OUD): Key Themes



OUD affects all aspects of individuals' lives.

- Participants described significant impact on their work and ability to care for themselves and family.
- Many participants described the devastating loss of meaningful relationships with family and friends due to their OUD.
- Some participants commented that mending relationships with family and friends was often a key motivator for their journey to recovery.
- Participants also expressed their worries of relapse in the future.

Public Meeting on Patient-Focused Drug Development for Opioid Use Disorder (OUD): Key Themes



**Management of OUD
requires a holistic
approach tailored to
the needs of the
individual.**

- Participants expressed varying perspectives on the desired outcomes of treatment, ranging from complete abstinence from opioid use to better managing or controlling use of opioids. The shared focus, however, was to improve their functioning, well-being, and safety.
- Participants also expressed mixed views on the role of medication-assisted treatment (MAT) in their journey.
 - Some said that they accept the need to stay on MAT for the long term.
 - Some hope to “detox off MAT” once they have stabilized in recovery.
 - Some said they do not see a role for the currently available MAT in their recovery.

Public Meeting on Patient-Focused Drug Development for Opioid Use Disorder (OUD): Key Themes



Several challenges and barriers to accessing and sustaining MAT.

- Participants highlighted the impact of stigma on their interactions with healthcare providers and others, particularly when being perceived as “an addict” or when being labeled as “dirty” or “clean.”
- Participants also highlighted challenges in access to MAT, including long wait times, difficulty finding facilities that provide MAT, strict requirements for entry into MAT programs, medication cost, and concerns about safety at the facility.
- They described the added challenges of maintaining recovery due to the intensity of withdrawal and craving, the significant pain or mental health needs, and their own difficulty in coming to terms with their illness.

Public Meeting on Patient-Focused Drug Development for Opioid Use Disorder (OUD): Key Themes



Need for greater awareness of OUD and understanding of their needs as a community.

- Participants offered insights on how to better help individuals with OUD manage their condition, including working toward development of non-opioid treatment options, integrating MAT into primary care, and implementing holistic approaches that integrate mental health, social support, and medical treatment.
- Most importantly, participants stressed the need to reduce the stigma of OUD, help individuals create “situations of stability”, and to not lose sight of their underlying pain, trauma, or mental health needs.

FDA's Public Meeting on Patient-Focused Drug Development for Chronic Pain



- July 9, 2018, 9 am – 5pm
- The Voice of the Patient summary report capturing participants' input in their own words was published in March 2019.
- The following is a highlight of select input gathered at the meeting (in-person and webcast) and through the public docket.



> 120 individuals who experience chronic pain, caregivers or advocates attended the meeting in person

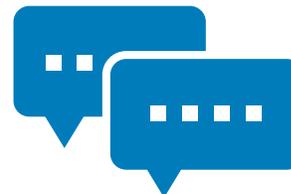
> 300 individuals who experience chronic pain, caregivers or advocates provided input through the interactive webcast

> 2,400 submitted comments through the public docket, majority from individuals who experience chronic pain, caregivers or advocates



Participants varied in gender, race, age, underlying condition, and their current approaches to management.

Participants did represent a certain population with chronic pain who have had successful pain management in the past through opioids, but have experienced a loss of access or reduced access to opioids because recent opioid policies.



Discussion topics focused on experiences and perspectives:

- Impact of chronic pain on daily life
- Current treatment approaches
- Challenges or barriers to accessing treatments



The health effects of chronic pain are pervasive and wide ranging.

- Participants frequently described living with daily unrelenting chronic widespread pain, in addition to persistent fatigue, sleep issues, and other debilitating health effects.
- Many shared fears that their chronic pain would worsen over time.



Chronic pain affects all aspects of individuals' lives.

- Many participants described severe limitations and adaptations needed to perform at work or at school, and to care for themselves and their family.
- Many also described the devastating loss of meaningful relationships with family and friends due to their chronic pain.
- Participants shared the emotional toll of experiencing stigma, social isolation, and financial challenges of treatment, and fears of living with an often-misunderstood condition.

Public Meeting on Patient-Focused Drug Development for Chronic Pain: Key Themes



Management of chronic pain requires a multidisciplinary approach tailored to the needs of the individual.

- Some stressed the need for a holistic approach to treating chronic pain, including lifestyle management, diet and exercise, and psychosocial techniques, in addition to medical treatments.
- They expressed varying perspectives on the desired outcomes of treatment. For most, the shared focus, however, was to improve their daily quality of life.



Several challenges and barriers to accessing treatments to manage their chronic pain.

- They highlighted growing stigma on the use of opioid analgesics and the impact of stigma on their interactions with healthcare providers and others when seeking treatment, particularly being perceived as “an addict.”
- A common experience shared during the meeting is that of an individual living with chronic pain who has had successful pain management in the past using a stable dose of opioid analgesics but who now has severely worsened pain resulting from reduced access to opioids because of a change in their doctor’s practice or willingness to prescribe opioids.

Public Meeting on Patient-Focused Drug Development for Chronic Pain: Key Themes



Need increased awareness and understanding of chronic pain across the medical and policymaking community.

- Participants offered perspectives on how to better help individuals with chronic pain manage their condition, expressing hope for progress in the development of effective non-opioid treatment options.



For the complete summary reports and other meeting materials, please visit:
[CDER Patient-Focused Drug Development Homepage](#)

The Voice of the Patient: Patient Perspectives on Opioid Use Disorders



- Amanda Sabino
- Adrienne Shapiro
- David Urick
- Adrian Williams



#justB HONEST  HEPATITIS B FOUNDATION

“ I was adopted out of South Korea when I was 5 months old.

I remember my parents taking me to the clinic when I was 13 and hearing about this thing called “hepatitis B.” I was in middle school, thinking about dating, doing sports, not about having a chronic illness.

The doctor said, “You can live a long, healthy life”. But nobody helped me talk about the things that mattered to me.

It built up, and during freshman year in high school, I tried to stop all the questions by swallowing a bunch of Tylenol pills. After that, I started therapy, but it focused on my suicide attempt and not on hepatitis B.

In my early 20s, I found opioids. They were an escape from feeling. The silver lining was that my loved ones noticed, and we started talking about it, which led to me talking about hep B for the first time... and things started to change.

I still alternated between not caring, being worried, and wanting to ignore it. I didn’t go to the doctor as often as I should have, and found out my liver wasn’t doing so hot.

I went home afterwards to have dinner with my parents. The spinach from their garden was crisp, the smell of garlic filled the house, we laughed and enjoyed each other’s company. I thought, “I like this moment. I want more of them.” So I decided to take control of my health.

It’s been a wild ride. I’m on medication now. Most days are still tough, but my liver is healthy! The struggles and successes, they’re all linked together. I feel more comfortable in my own skin, I’m learning from my past, and I’m living with hepatitis B. ”

- David

The #justB storytelling campaign is a program of the Hepatitis B Foundation in collaboration with AAPCHO & StoryCenter, sponsored by Arbutus Biopharma, Dynavax Technologies and Gilead Sciences.

David’s Story



The Voice of the Patient: Patient Perspectives on Opioid Use Disorders



- Amanda Sabino
- Adrienne Shapiro
- David Urick
- Adrian Williams



Thank you!



Questions?



BREAK



Session 2

**Impact of Opioids on Diverse Communities:
What does the data show?**

Drug Overdose Epidemic in the United States and CDC's Response

Jan Losby, PhD, MSW

Branch Chief, Health Systems and Research Branch

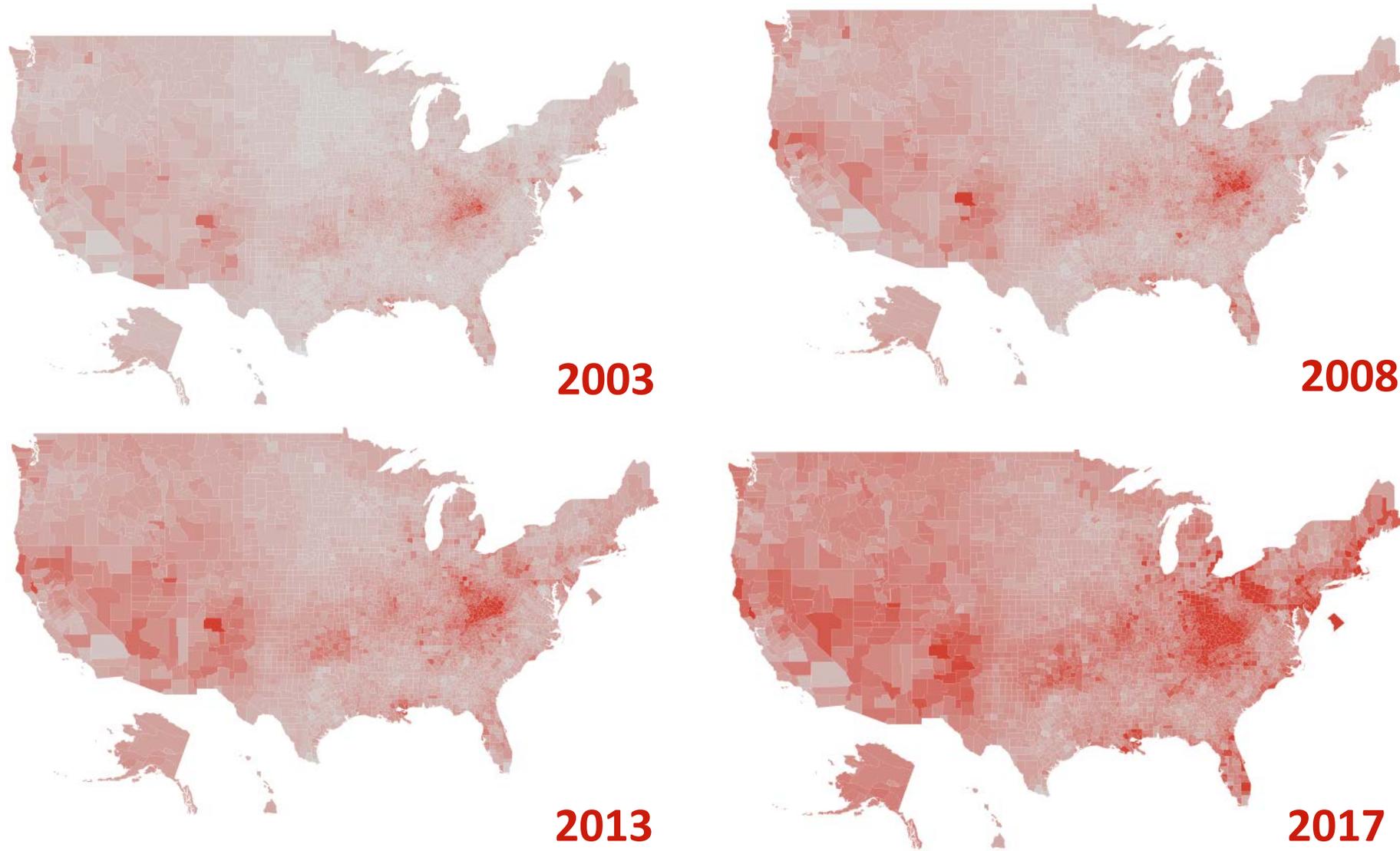
Division of Overdose Prevention

CDC- National Center for Injury Prevention and Control

November 21, 2019



Rapid Increase in Drug Overdose Death Rates by County



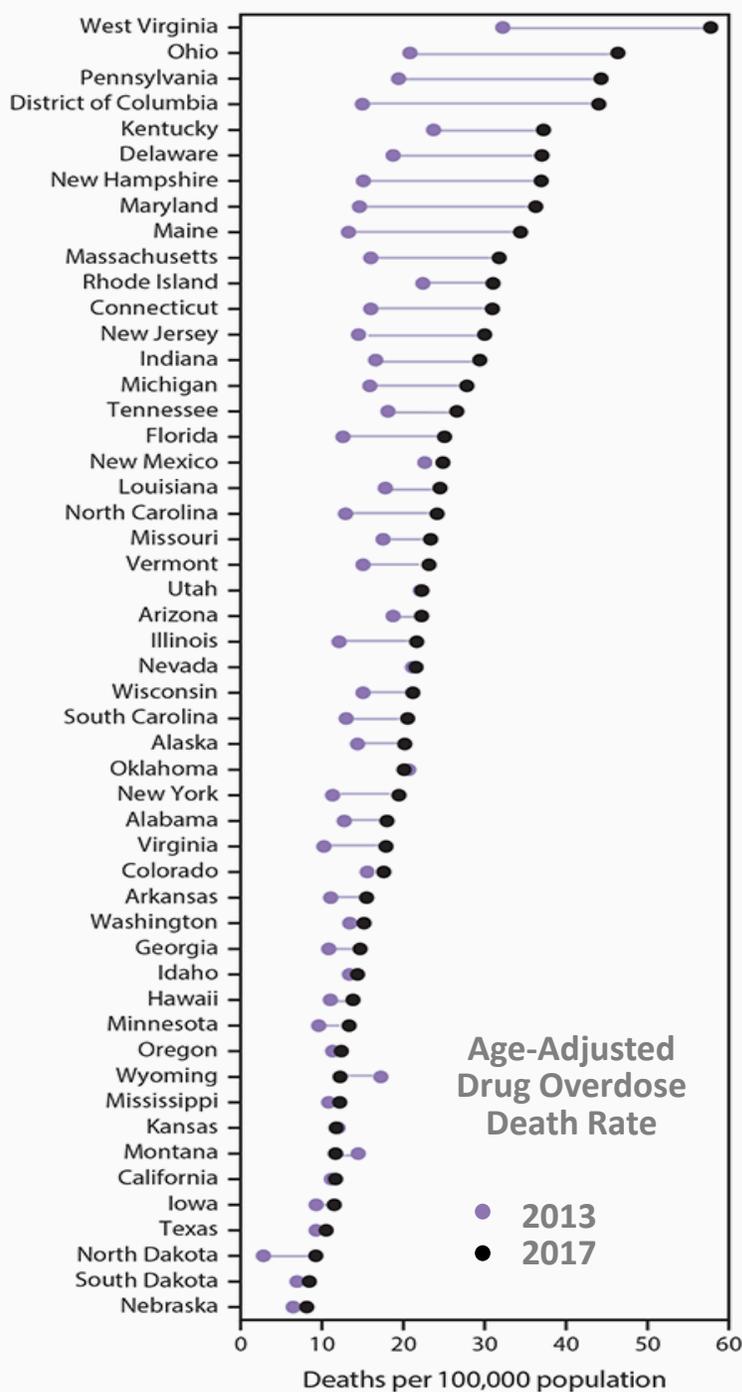
Model-based Death Rate
0.00

40.00

Source: NCHS Data Visualization Gallery

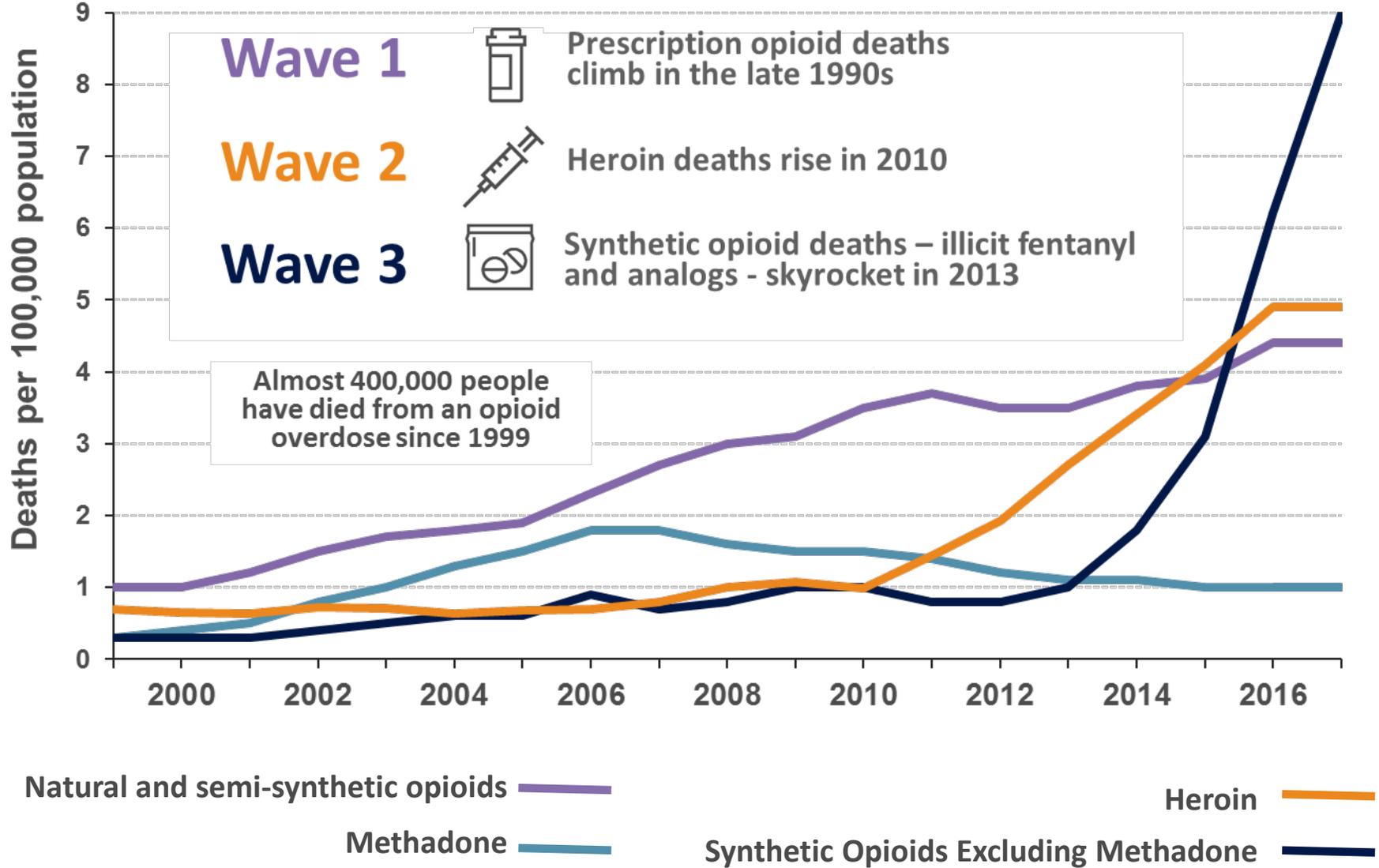
Drug overdose deaths increasing across US from 2013 to 2017

- Number of opioid deaths in the United States almost doubled from 25,052 to 47,600 (For context, there were 8,050 opioid deaths in 1999.)
- 35 states had a statistically significant increase in their drug overdose death rate
- DC, WV, OH, PA, NH, MD and ME had the largest absolute rate increase
- Death rate doubled in ND, DC, ME, MD, NH, PA, OH, NJ, FL, and MA



Source: NCHS Data Brief 329 (2019) and Scholl L, Seth P, Kariisa M, Wilson N, Baldwin G. Drug and Opioid-Involved Overdose Deaths — United States, 2013–2017. MMWR Morb Mortal Wkly Rep 2019;67:1419–1427. DOI: <http://dx.doi.org/10.15585/mmwr.mm675152e1>

Three Waves of the Opioid Overdose Epidemic in the United States



Source: National Vital Statistics System Mortality File

Drug Overdose Deaths Involving Cocaine and Psychostimulants with Abuse Potential in the US

Opioid Deaths Nested in a Broadening Drug Overdose Epidemic. . .

Death Rates Percent Increase from 2010 - 2017

| | |
|--|-----|
| Cocaine Overall | 231 |
| Cocaine <u>without</u> ANY Opioids | 83 |
| Psychostimulant Overall | 433 |
| Psychostimulant <u>without</u> ANY Opioids | 300 |

Deaths Percent of Deaths 2017

| | |
|--|------|
| Cocaine <u>with</u> ANY Opioid | 72.7 |
| Psychostimulant <u>with</u> ANY Opioid | 50.4 |



Number of opioid overdose deaths by opioid type in 25 states from January to June 2018

Opioid deaths with information on involved opioids, Jan–Jun 2018, no. (%)

Characteristic

| | |
|--|---------------------|
| Total opioid overdose deaths | 13,415 (100) |
| Opioid drug class or drug involved in opioid deaths | |
| Any prescription opioid | 3,853 (28.7) |
| Any illicit opioid | 11,124 (82.9) |
| Any suspected IMF | 9,105 (67.9) |
| Any suspected heroin | 5,281 (39.4) |
| Any fentanyl analog | 2,678 (20.0) |
| Any U-series | 63 (0.5) |

Common mutually exclusive combinations of opioids involved in opioid deaths

Opioid combinations co-involving IMF

| | |
|--------------------------------------|--------------|
| IMF with no other illicit opioids | 4,320 (32.2) |
| IMF with heroin | 2,566 (19.1) |
| IMF with fentanyl analogs | 1,172 (8.7) |
| IMF with heroin and fentanyl analogs | 1,008 (7.5) |

Illicit opioid combinations not co-involving IMF

| | |
|---|--------------|
| Heroin with no other illicit opioid | 1,534 (11.4) |
| Fentanyl analogs with no other illicit opioid | 312 (2.3) |
| Prescription opioid with no illicit opioid | 2,291 (17.1) |
| All other combinations of opioids | 212 (1.6) |

Note: IMF is illicitly manufactured fentanyl. Refer to source for other footnotes

Polysubstance epidemic driven by fentanyl



Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

August 30, 2019

Weekly / Vol. 68 / No. 34

Source: Gladden, O'Donnell, Mattson, Seth (2019). DOI: <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6834-H.pdf>

Data = State Unintentional Drug Overdose Reporting System (SUDORS)

Race/Ethnicity

Number of Overdose Deaths Involving All Opioids and Prescription Opioids by Race/Ethnicity: US, 2017

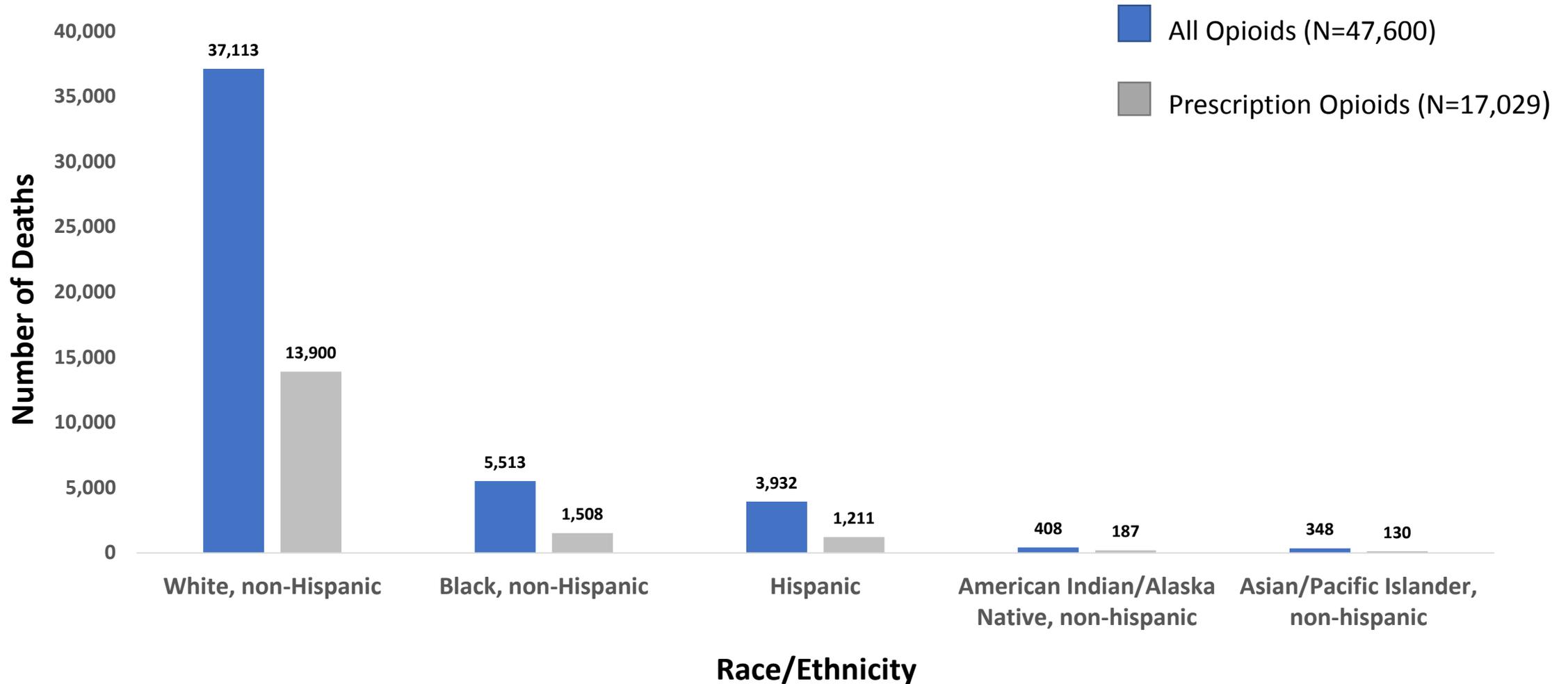


Figure adapted from: Scholl L, Seth P, Kariisa M, Wilson N, Baldwin G. Drug and Opioid-Involved Overdose Deaths — United States, 2013–2017. MMWR Morb Mortal Wkly Rep 2019;67:1419–1427. DOI: <http://dx.doi.org/10.15585/mmwr.mm675152e1>

Number of Overdose Deaths Involving Heroin and Synthetic Opioids Other Than Methadone by Race/Ethnicity: US, 2017

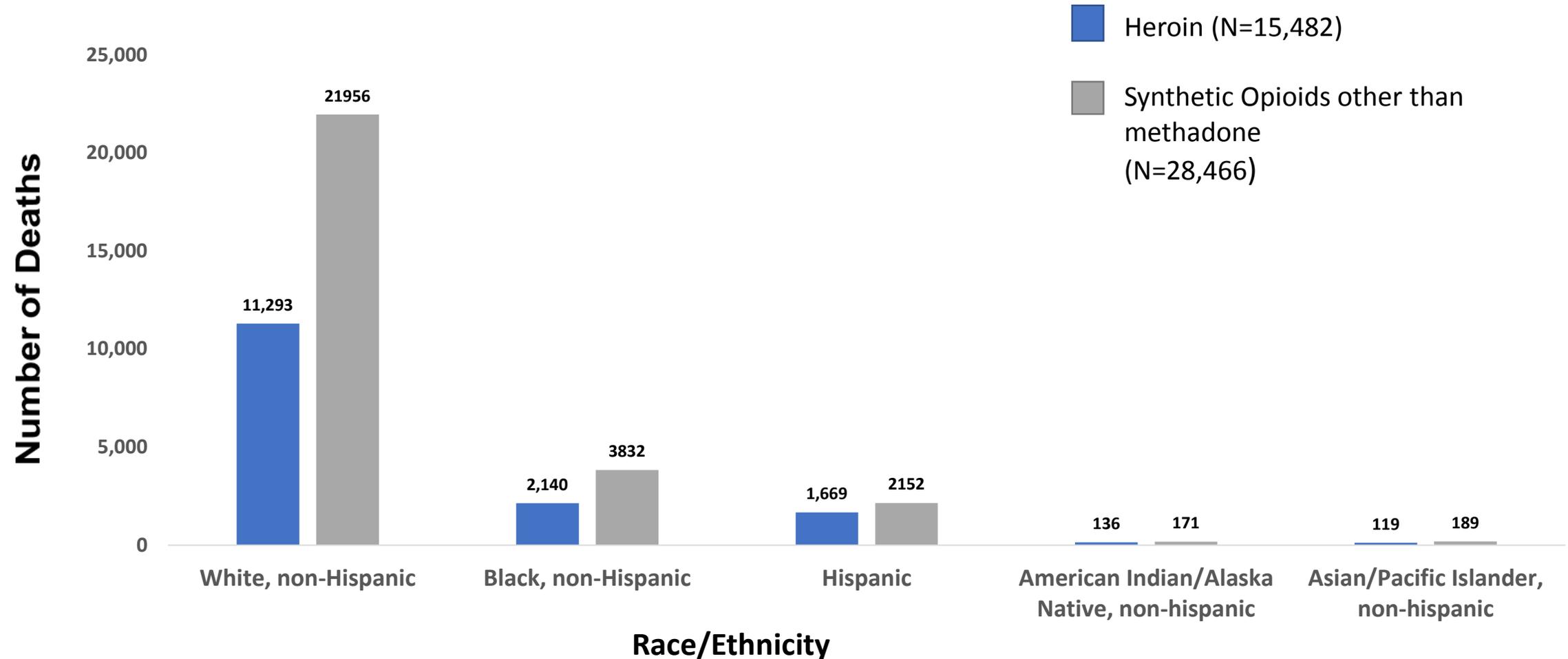


Figure adapted from: Scholl L, Seth P, Kariisa M, Wilson N, Baldwin G. Drug and Opioid-Involved Overdose Deaths — United States, 2013–2017. MMWR Morb Mortal Wkly Rep 2019;67:1419–1427. DOI: <http://dx.doi.org/10.15585/mmwr.mm675152e1>

Number of Overdose Deaths Involving Cocaine and Psychostimulants with Abuse Potential by Race/Ethnicity: US, 2017

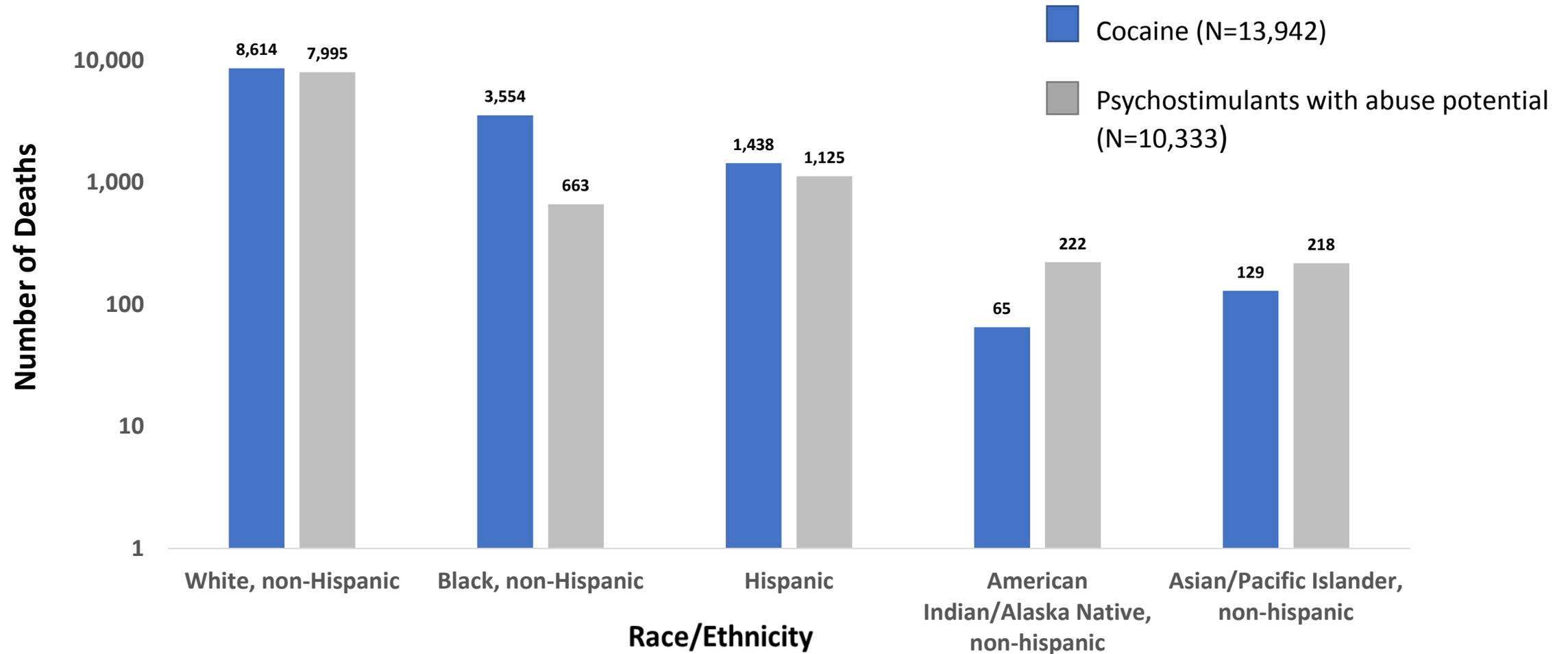


Figure adapted from: Kariisa M, Scholl L, Wilson N, Seth P, Hoots B. Drug Overdose Deaths Involving Cocaine and Psychostimulants with Abuse Potential — United States, 2003–2017. MMWR Morb Mortal Wkly Rep 2019;68:388–395. DOI: <http://dx.doi.org/10.15585/mmwr.mm6817a3>

Number of Deaths Involving Fentanyl and Fentanyl Analogs by Race/Ethnicity: 10 States, 2016

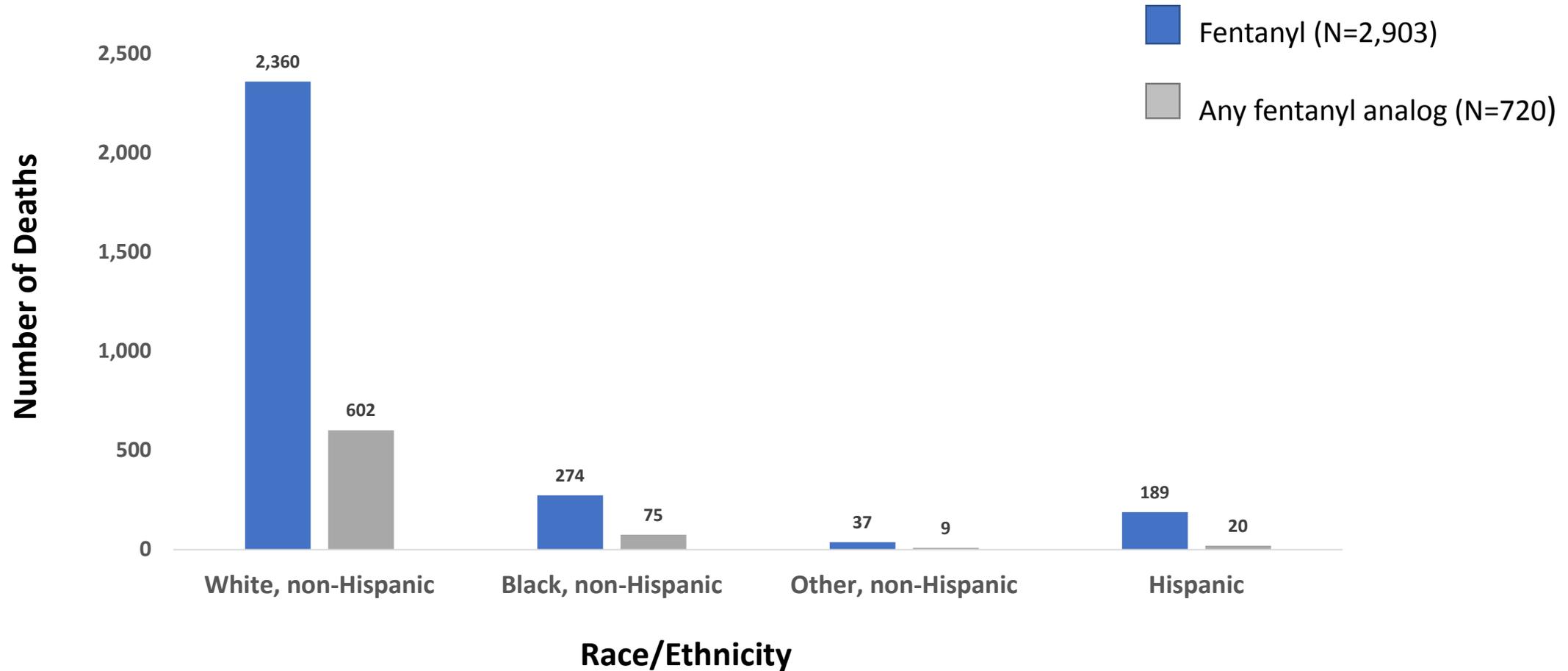


Figure adapted from: O'Donnell JK, Halpin J, Mattson CL, Goldberger BA, Gladden RM. Deaths Involving Fentanyl, Fentanyl Analogs, and U-47700 — 10 States, July–December 2016. MMWR Morb Mortal Wkly Rep 2017;66:1197–1202. DOI: <http://dx.doi.org/10.15585/mmwr.mm6643e1>

Percentage Increases in Opioid Overdose Death Rates involving Any Opioid by Urbanization Level, and Race/Ethnicity, US 2015-2017

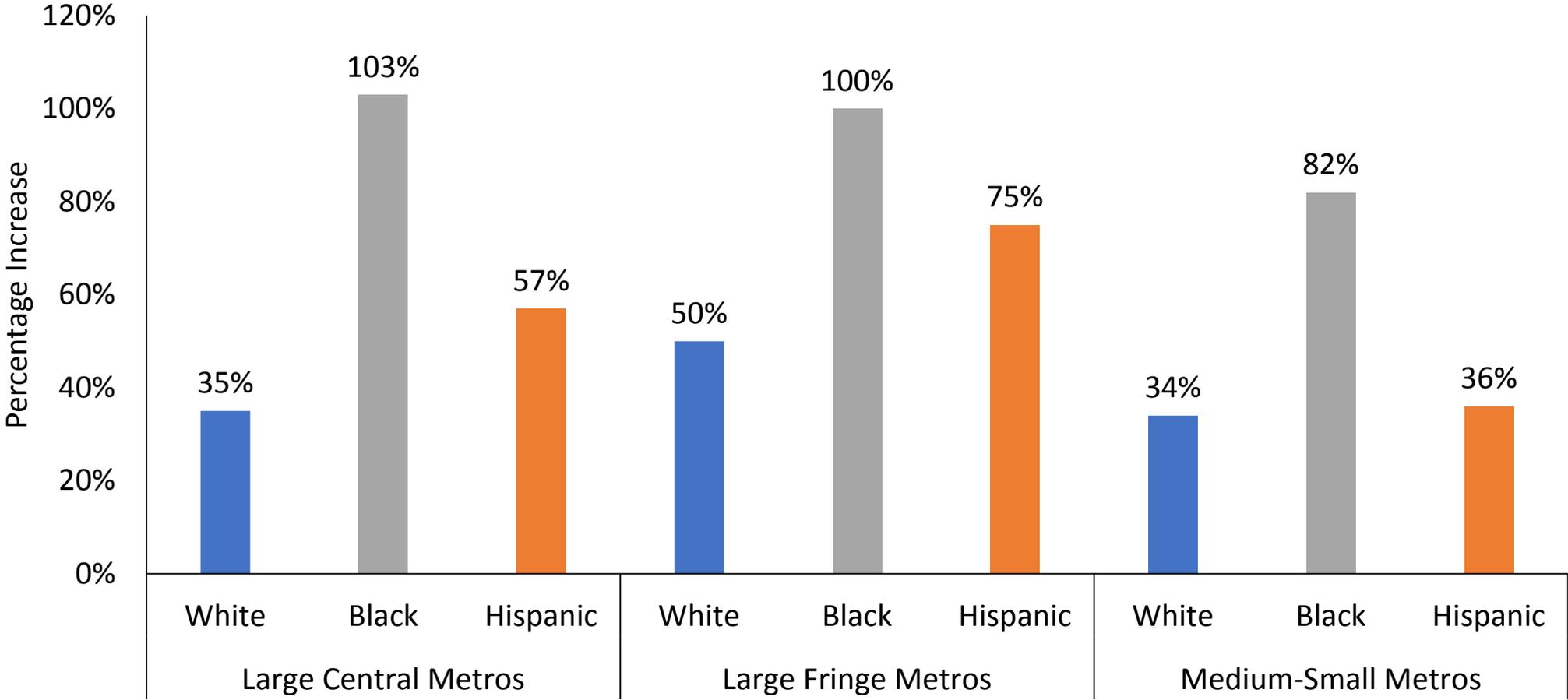


Figure adapted from: Lippold KM, Jones CM, Olsen EO, Giroir BP. Racial/Ethnic and Age Group Differences in Opioid and Synthetic Opioid-Involved Overdose Deaths Among Adults Aged ≥18 Years in Metropolitan Areas — United States, 2015–2017. MMWR Morb Mortal Wkly Rep 2019;68:967–973. DOI: <http://dx.doi.org/10.15585/mmwr.mm6843a3>

Percentage Increases in Opioid Overdose Death Rates involving Synthetic Opioids by Urbanization Level and Race/Ethnicity, US 2015-2017

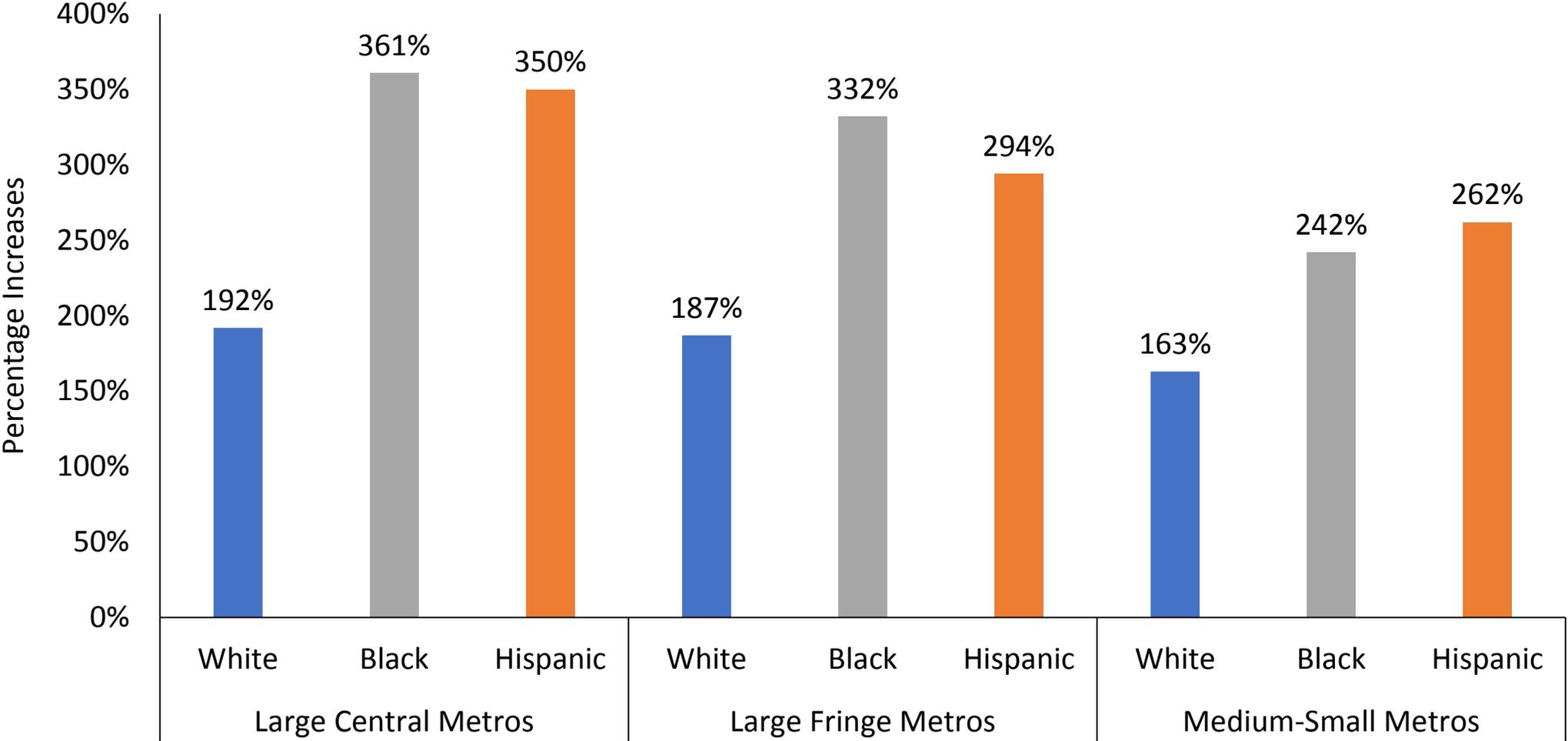


Figure adapted from: Lippold KM, Jones CM, Olsen EO, Giroir BP. Racial/Ethnic and Age Group Differences in Opioid and Synthetic Opioid-Involved Overdose Deaths Among Adults Aged ≥18 Years in Metropolitan Areas — United States, 2015–2017. MMWR Morb Mortal Wkly Rep 2019;68:967–973. DOI: <http://dx.doi.org/10.15585/mmwr.mm6843a3>

Percentage Increases in Synthetic Opioid Involvement in Opioid Overdose Deaths by Urbanization Level and Race/Ethnicity, US 2015-2017

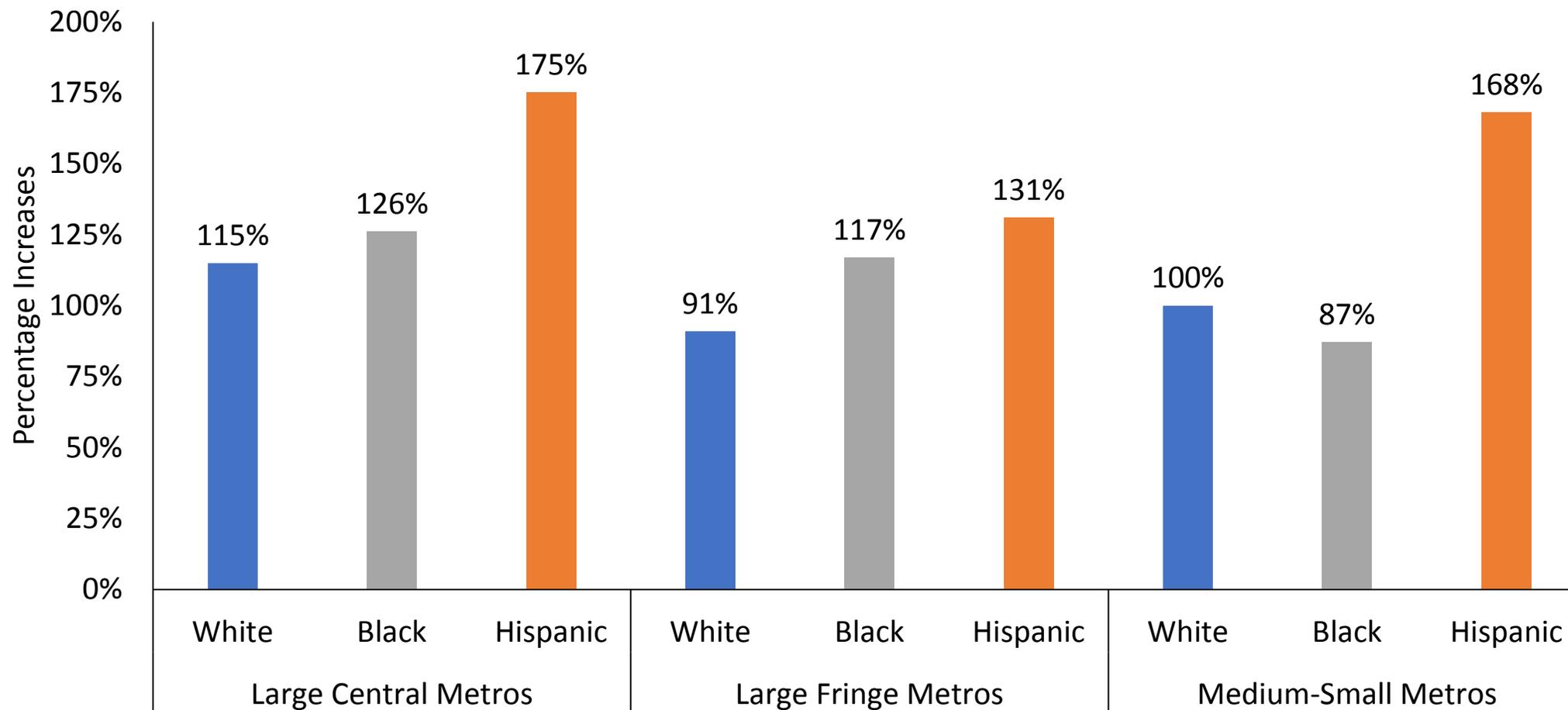
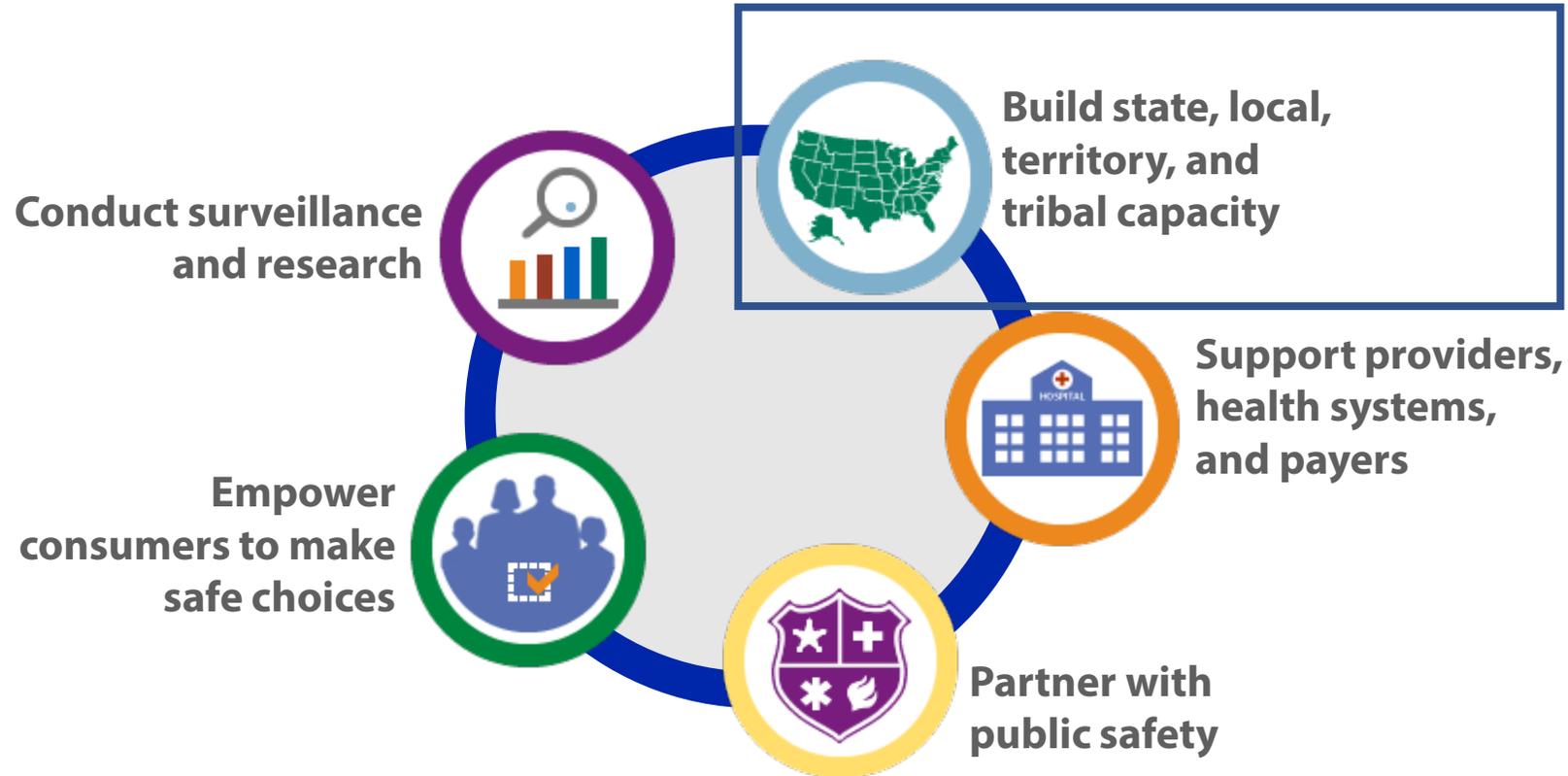


Figure adapted from: Lippold KM, Jones CM, Olsen EO, Giroir BP. Racial/Ethnic and Age Group Differences in Opioid and Synthetic Opioid-Involved Overdose Deaths Among Adults Aged ≥ 18 Years in Metropolitan Areas — United States, 2015–2017. MMWR Morb Mortal Wkly Rep 2019;68:967–973. DOI: <http://dx.doi.org/10.15585/mmwr.mm6843a3>

CDC Response

CDC's Approach to Overdose Prevention





Naloxone is a drug that can reverse the effects of opioid overdose and can be life-saving if administered in time.



Medication-assisted treatment (MAT) for opioid use disorder (OUD) can aid in preventing repeat overdoses. MAT combines the use of medication (methadone, buprenorphine, or naltrexone) with counseling and behavioral therapies.

Connecting Community Infrastructure

Activating and Coordinating Prevention & Response Activities

National Center for Injury Prevention and Control
Division of Overdose Prevention

- Local Emergency Department**
- Offer naloxone and training to patient's family and friends, in case the patient has another overdose.
 - Connect patients with hospital case managers or peer navigators to link them to follow-up treatment and services.
 - Plan for the increasing number of patients with opioid-related conditions, including overdose, injection-related concerns, and withdrawal.

Local Emergency Department



First Responders | Public Safety | Law Enforcement Officers



- Get adequate supply and training for naloxone administration.
- Identify changes in illicit drug supply and work with state and local health departments to respond effectively.
- Collaborate with public health departments and health systems to enhance linkage to treatment and services.

Mental Health and Substance Abuse Treatment Providers



- Increase treatment services, including MAT for OUD.
- Increase and coordinate mental health services for conditions that often occur with OUD.

Coordinated, informed efforts can better prevent opioid overdoses and deaths

Community Members



- Connect with organizations in the community that provide public health services, treatment, counseling, and naloxone distribution.

Community-Based Organizations



- Assist in mobilizing a community response to those most at risk.
- Provide resources to reduce harms that can occur when injecting drugs, including ones that offer screening for HIV and hepatitis B and C, in combination with referral to treatment and naloxone provision.

Local Health Departments



- Alert the community to the rapid increase in opioid overdoses seen in emergency departments and inform strategic plans and timely responses.
- Ensure an adequate naloxone supply.
- Increase availability and access to necessary services.
- Coordinate with key community groups to detect and respond to any changes in illicit drug use.



CDC

**CENTERS FOR DISEASE
CONTROL AND PREVENTION**

**EDWARD R. ROYBAL
CAMPUS**

The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Strategies to Improve Health Equity Amidst the Opioid Crisis Opioid Use, Treatment Access, and Treatment Resources Results from the 2018 National Survey on Drug Use and Health

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U.S. Department of Health and Human Services

November 21st 2019
Rockville, MD



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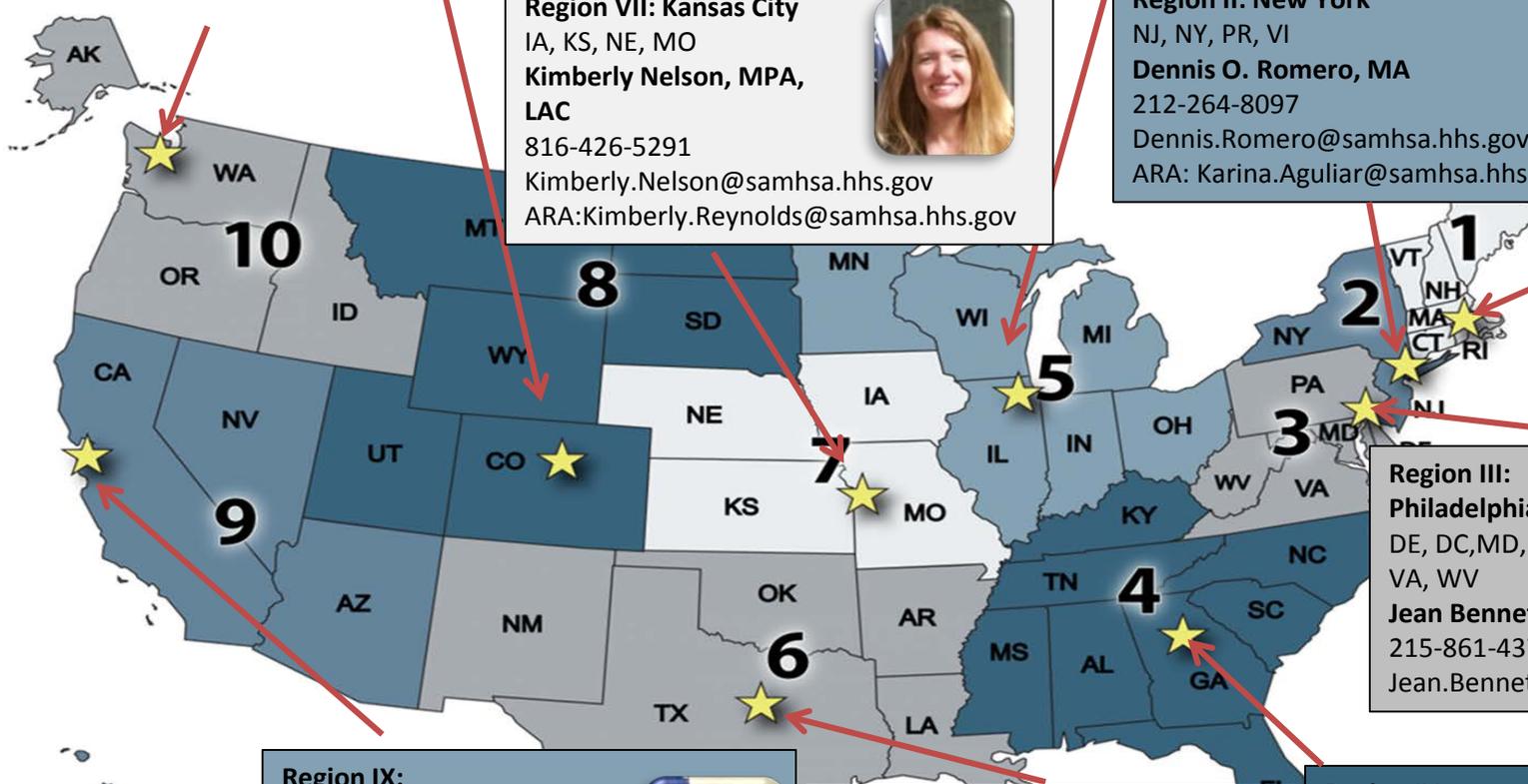
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Valerie Kolick, Special
Assistant



*ARA: Assistant Regional Administrator

SAMHSA Region III: PA, Delaware, Maryland, DC, Virginia, West Virginia



SAMHSA Region 3 Summits and Learning Collaboratives

★ = in-person summit + recurring call or in person

1. ↑ Access to Medication Assisted Treatment ★

2. Suicide Prevention

3. Interprofessional Addiction Education ★

★ Medschools, ★ Schools of Social Work

4. Peer Recovery Specialists ★

5. Harm Reduction ★

6. Naloxone

7. Regional Opioid Task Force ★

**SAMHSA
REGION III**

**801 Market St
Suite 9108
Philadelphia**



National Survey on Drug Use and Health (NSDUH)

Primary source for statistical info on:

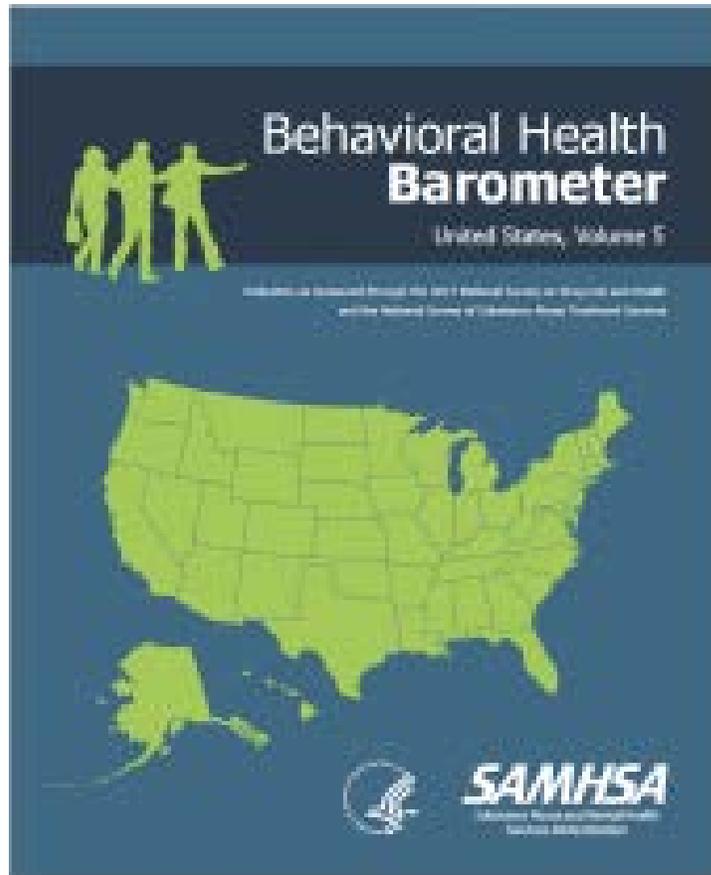
- illicit drug use, alcohol use, substance use disorders (SUDs)
- mental health issues for the civilian, noninstitutionalized population of the United States.

Information on mental health and substance use allows SAMHSA and other policymakers to gauge progress toward improving the health of the nation.

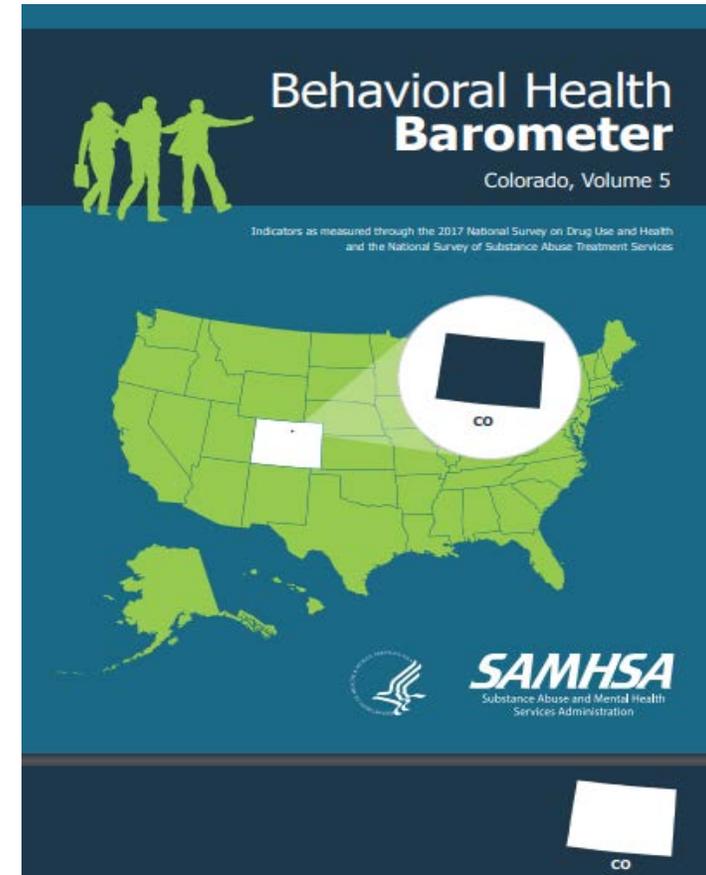
Comprehensive 2018 NSDUH detailed tables are available at

<https://www.samhsa.gov/data/>

Example of Downloadable State Behavioral Health Barometer, Volume 5



- 2018 NSDUH and NSSATS data
- Racial/ethnic breakdowns
- Published June 2019



- Snapshot of SUD & MH State data
- Comparison of State, HHS Region, & National data

Behavioral Health Barometer, United States, Volume 5

Behavioral Health Barometer

United States, Volume 5



Indicators as measured through the 2017 National Survey on Drug Use and Health
and the National Survey of Substance Abuse Treatment Services



SAMHSA
Substance Abuse and Mental Health
Services Administration

- 2018 NSDUH and National Survey of Substance Abuse Treatment Services data
- Racial/ethnic breakdowns
- Snapshot of:
 - Substance use Disorders National Data
 - Mental Health Disorders National Data
- Published June 2019

<https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/National-BH-BarometerVolume5.pdf>

SAMHSA
Substance Abuse and Mental Health
Services Administration

Mental and Substance Use Disorders in America: NSDUH 2017

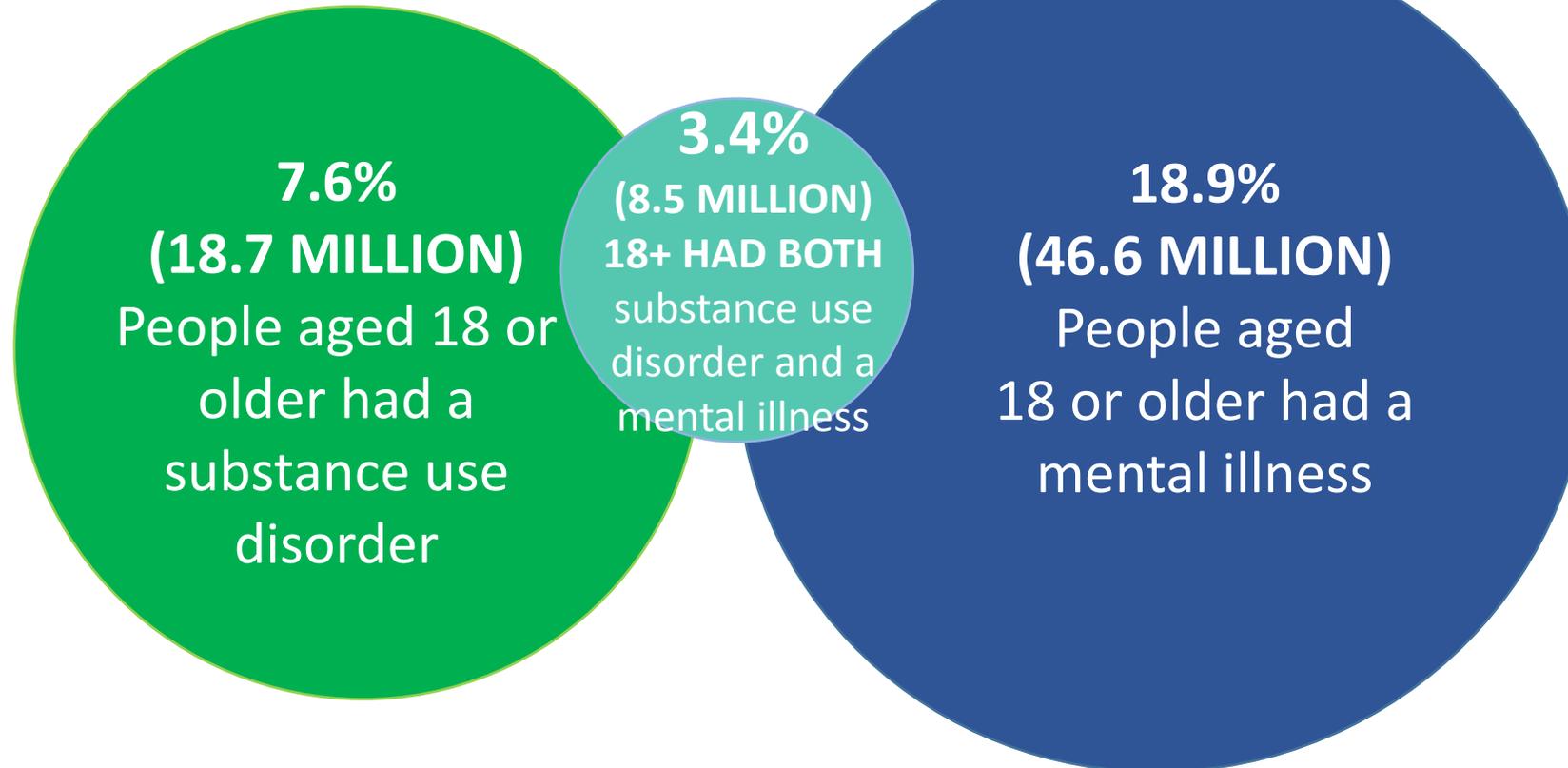
PAST YEAR, 2017, 18+

Among those with a substance use disorder approximately:

- **3 IN 8 (36.4%)** struggled with illicit drugs
- **3 IN 4 (75.2%)** struggled with alcohol use
- **1 IN 9 (11.5%)** struggled with illicit drugs and alcohol

Among those with a mental illness approximately:

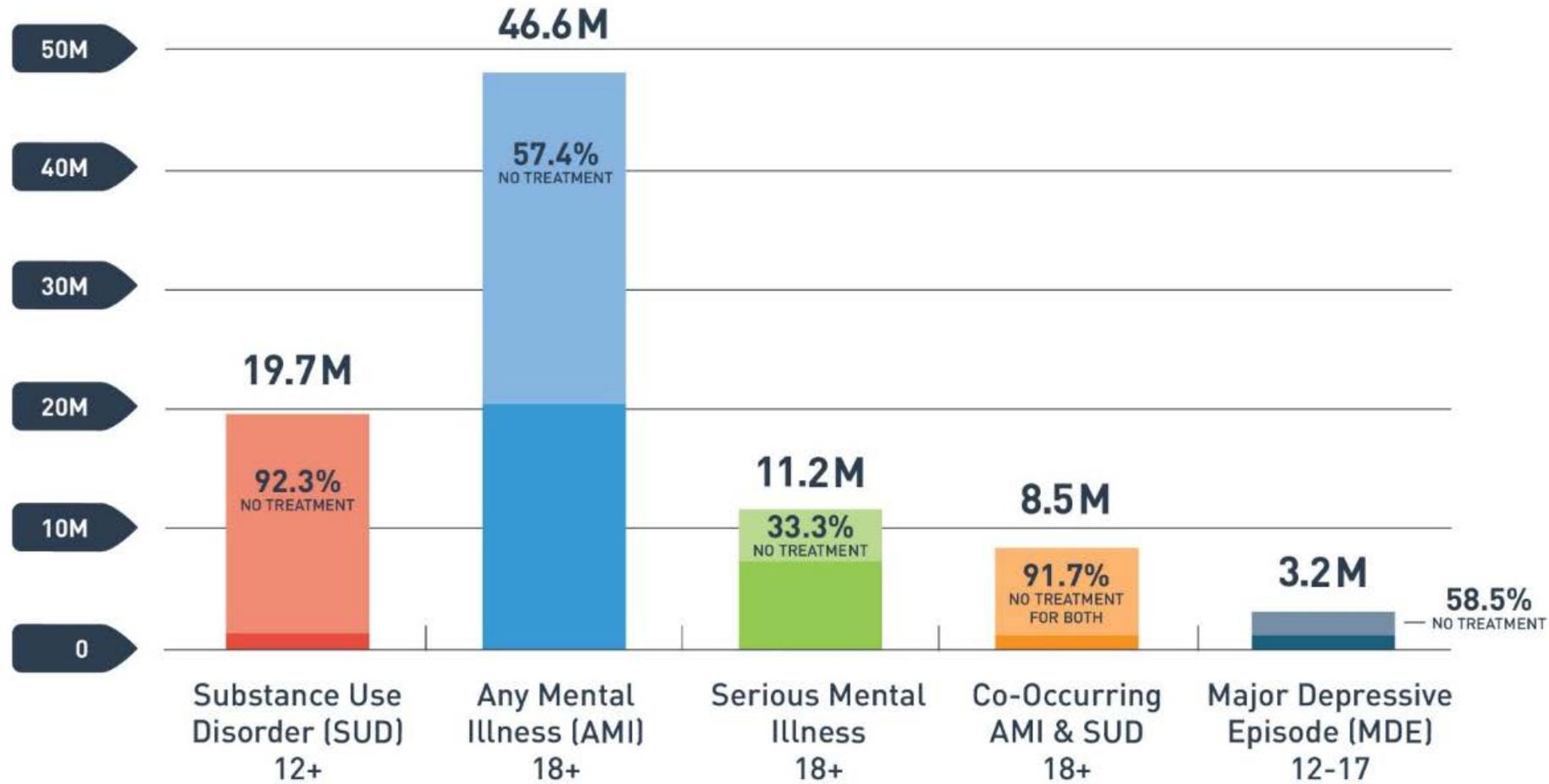
- **1 IN 4 (24.0%)** had a serious mental illness



56.8 million adults are affected either by a mental disorder or substance use disorder.

Despite Great Need Treatment Gaps Remain Vast

PAST YEAR, 2017



Opioids Crisis: A Galvanizing Problem with Solutions that Could be Generalized

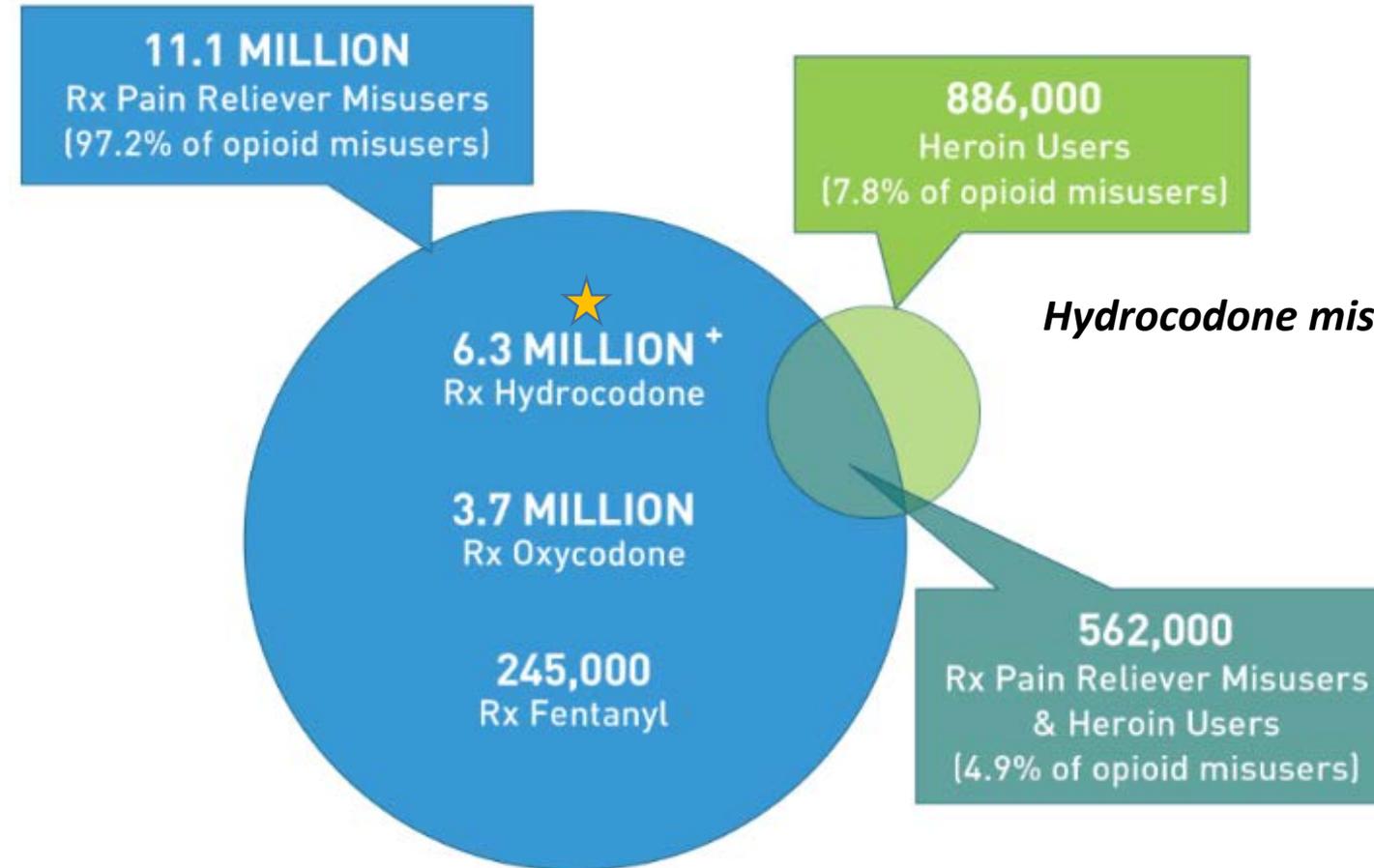
- 11.4 million Americans misusing opioids in 2017
- 2.1 million Americans with Opioid Use Disorder (OUD)
- 55% got treatment for heroin use disorder, 21% got treatment for prescription pain reliever use disorder
- Over 70,000 drug overdose deaths in 2017, 2/3 related to heroin and synthetic opioids (e.g.: fentanyl)
- First: How did we get here?

Opioids Grip: Millions Continue Misuse

PAST YEAR, 2017, 12+

★
Significant decrease
from 12.7 M misusers
in 2015

11.4 MILLION PEOPLE WITH OPIOID MISUSE (4.2% OF TOTAL POPULATION)



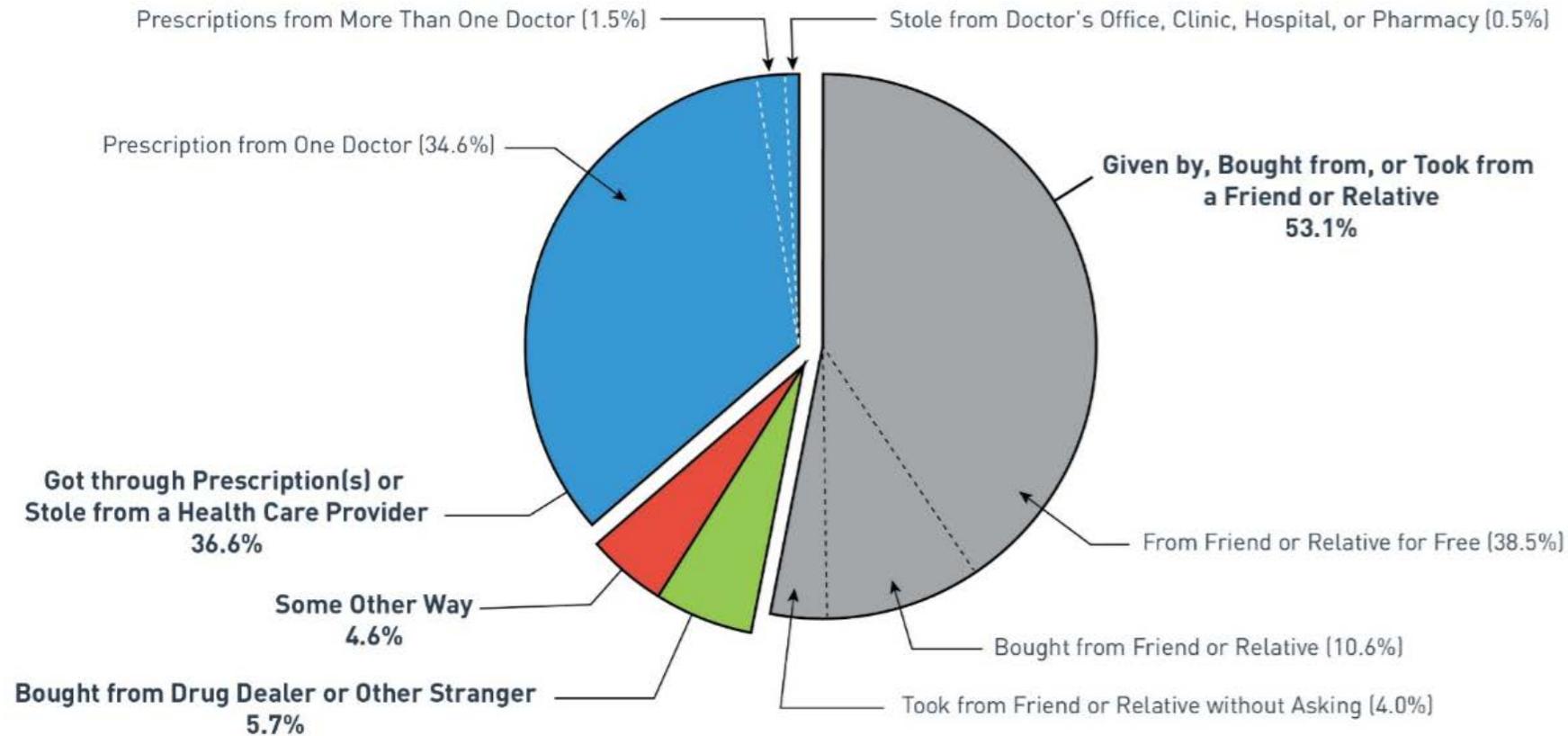
Hydrocodone misuse down from 6.9M in 2016

+ Difference between this estimate and the 2016 estimate is statistically significant at the .05 level.

Note: Opioid misuse is defined as heroin use or prescription pain reliever misuse.
Note: The percentages do not add to 100 percent due to rounding.

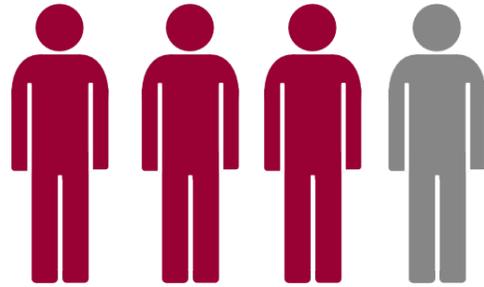
Sources Where Pain Relievers Were Obtained for Most Recent Misuse Among People Who Misused Prescription Pain Relievers

PAST YEAR, 2017, 12+

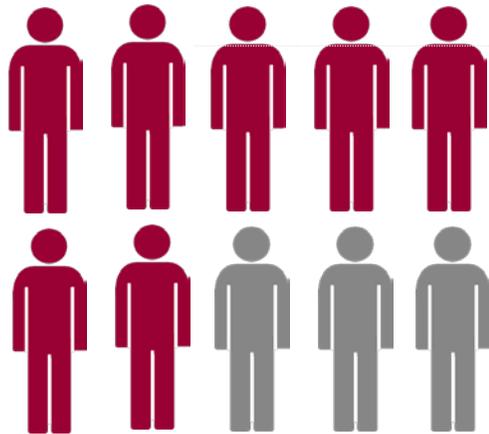


11.1 Million People Aged 12 or Older Who Misused Prescription Pain Relievers in the Past Year

Nonmedical use of Prescription Opioids Significant Risk Factor for Heroin Use



3 out of 4 people who used heroin in the past year misused prescription opioids first



7 out of 10 people who used heroin in the past year also misused prescription opioids in the past year

2017: 2.1 million with opioid use disorder

Synthetic Opioid Deaths Closely Linked to Illicit Fentanyl Supply

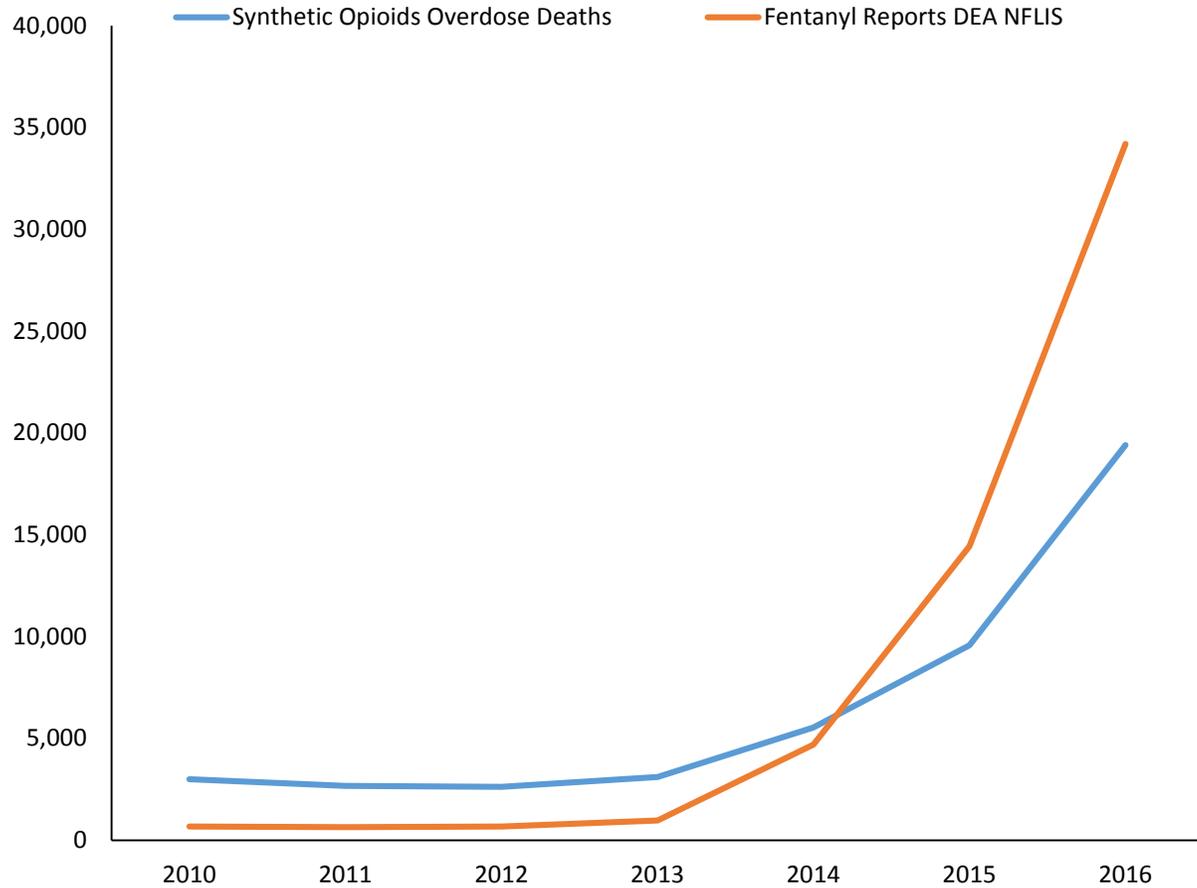
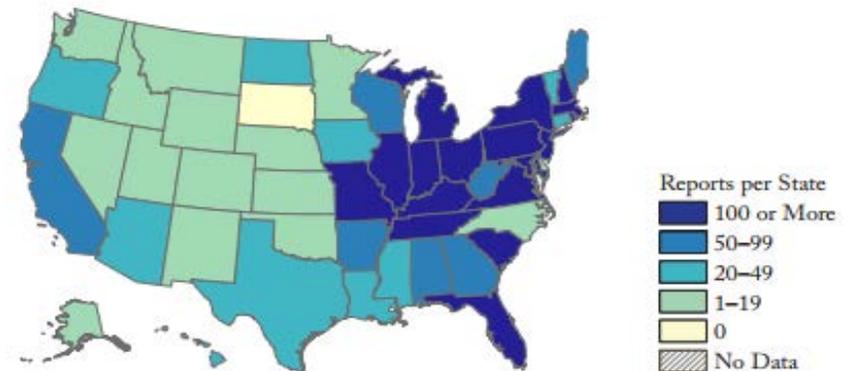


Figure 3 Fentanyl reports in NFLIS, by State, 2001



Figure 4 Fentanyl reports in NFLIS, by State, 2015



Known or suspected exposure to fentanyl in past year (n = 121)

| Behavior or experience | APR | 95% CI | p |
|---------------------------|-------------|------------------|--------------|
| Regular heroin use | 4.07 | 1.24-13.3 | 0.020 |

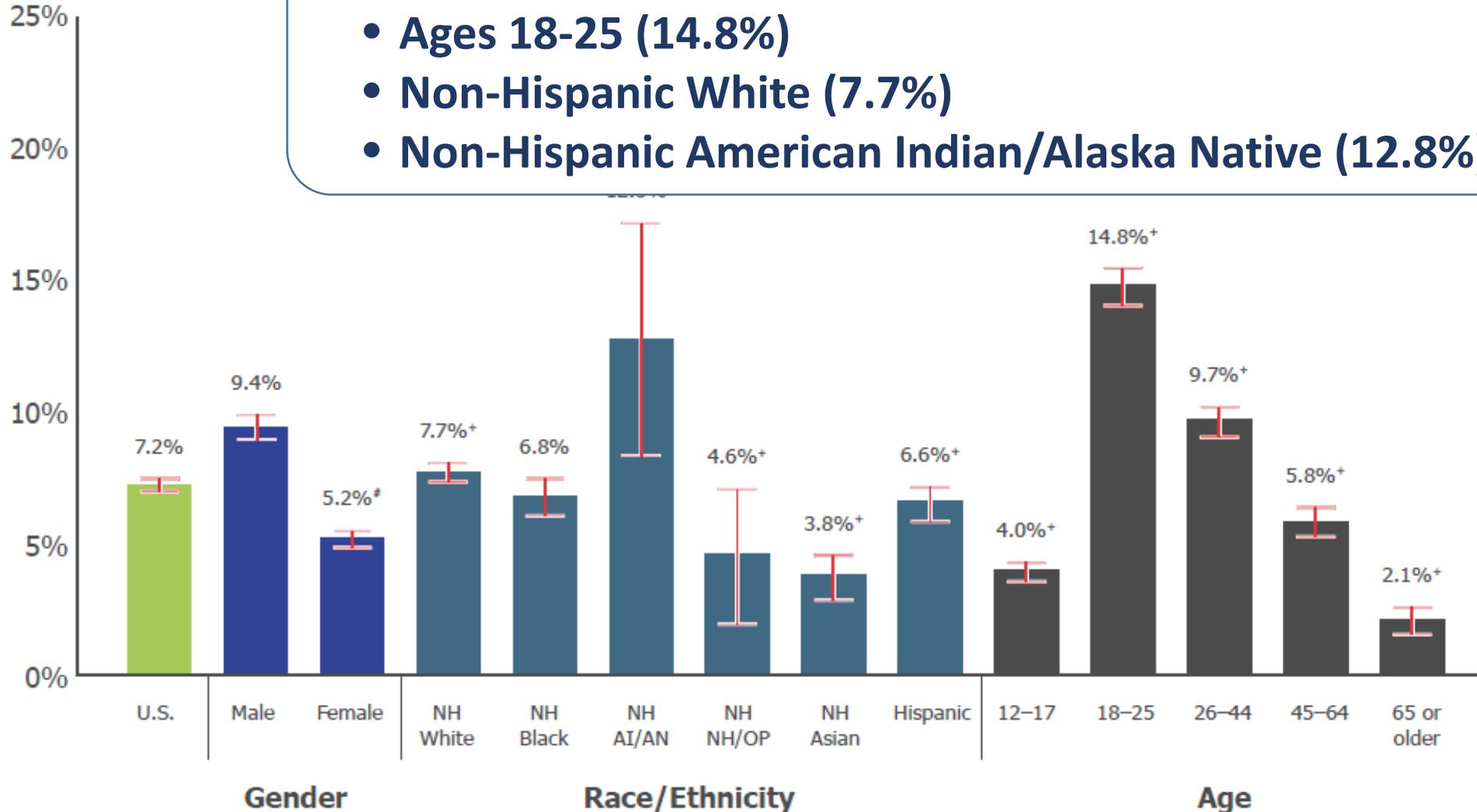
Source: Carroll et al, Int. J. Drug Policy, 2017 and CDC Epi-Aid 2015-2016 OH and MA

Substance Use Disorder Rate for Age 12 and Above

PAST YEAR, 2017, 12+

Higher rate than national average:

- Ages 18-25 (14.8%)
- Non-Hispanic White (7.7%)
- Non-Hispanic American Indian/Alaska Native (12.8%)

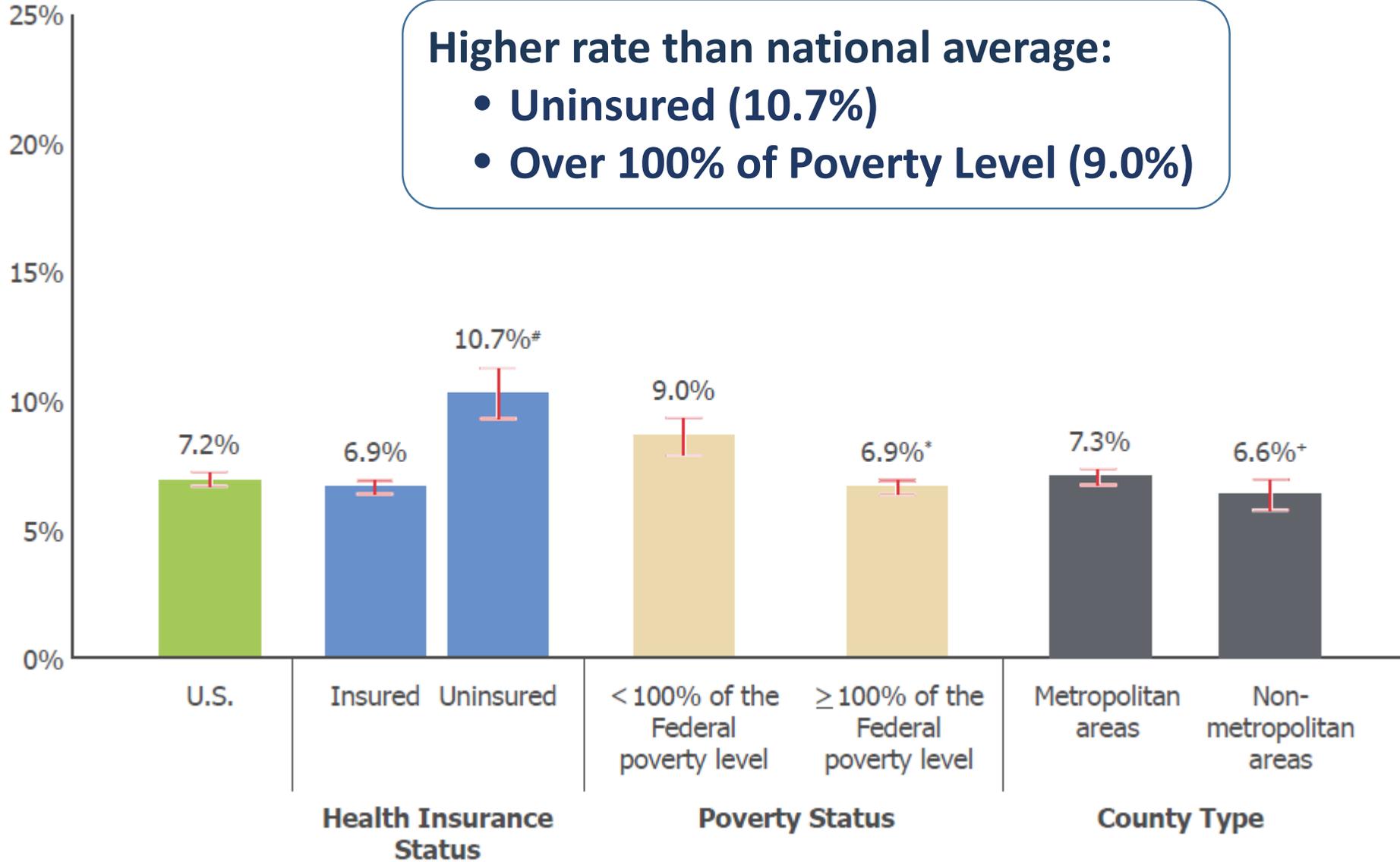


National Average



Substance Use Disorder Rate Higher for the Uninsured and Poor

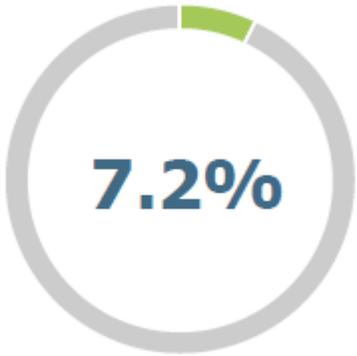
PAST YEAR, 2017, 12+



Higher rate than national average:

- Uninsured (10.7%)
- Over 100% of Poverty Level (9.0%)

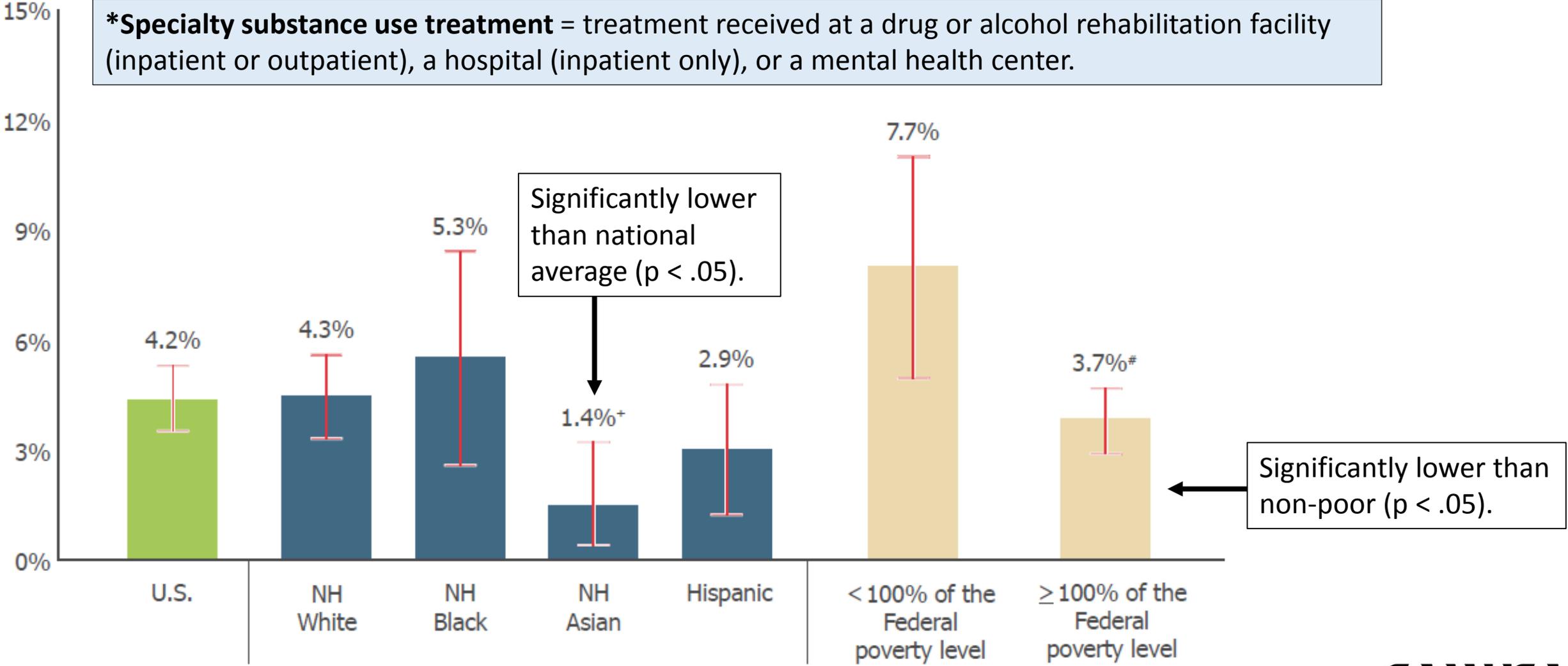
National Average



Past Year Receipt of Specialty Treatment for Alcohol Use Disorder for Age 12 and older with Race/Ethnicity Categories & Poverty Status

PAST YEAR, 2017, 12+

***Specialty substance use treatment** = treatment received at a drug or alcohol rehabilitation facility (inpatient or outpatient), a hospital (inpatient only), or a mental health center.



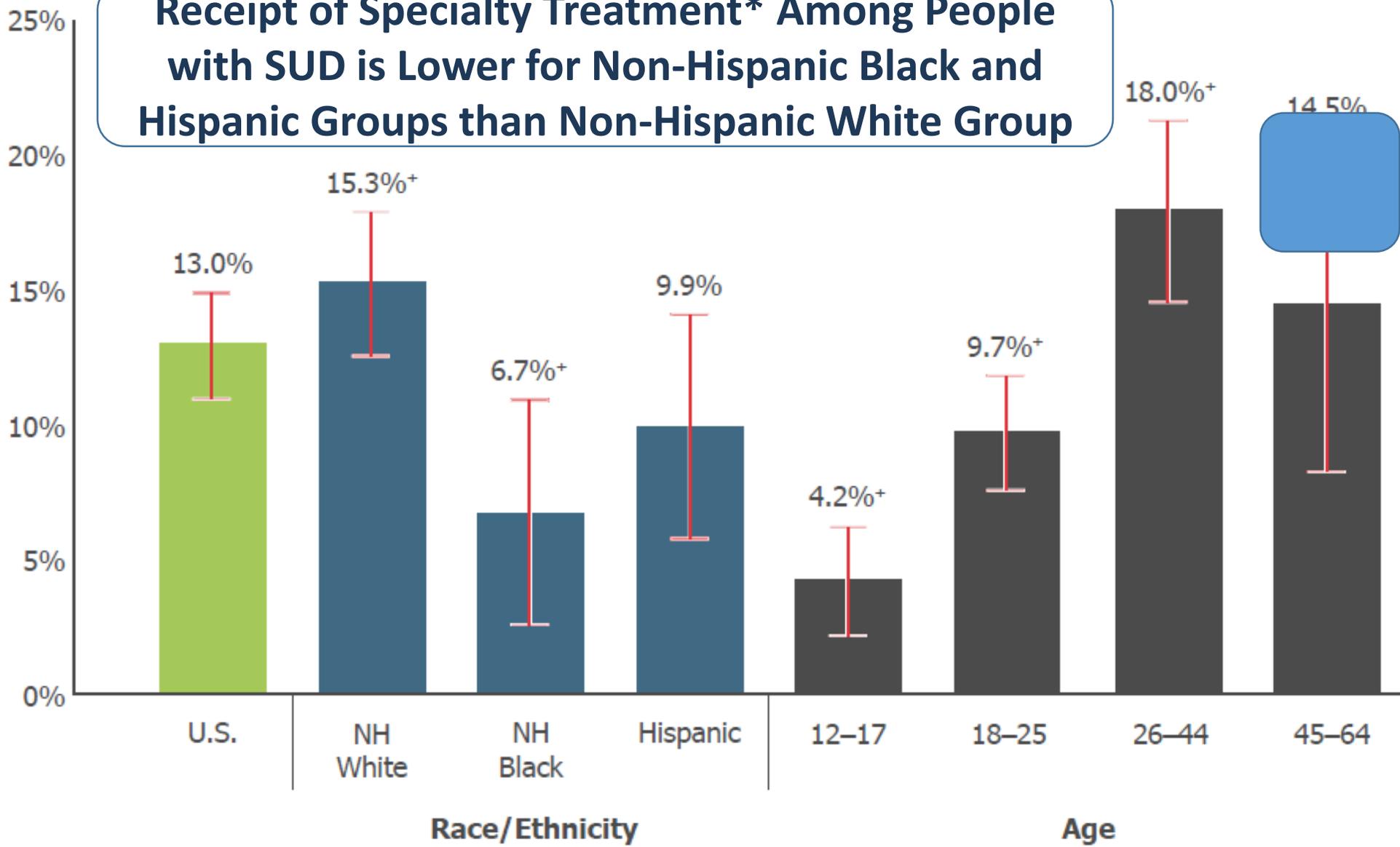
Race/Ethnicity

Poverty Status

Past Yr. Receipt of Specialty Treatment for Illicit Drug Use Among People Age 12 or older with An ****Illicit Drug Use Disorder**

PAST YEAR, 2017, 12+

Receipt of Specialty Treatment* Among People with SUD is Lower for Non-Hispanic Black and Hispanic Groups than Non-Hispanic White Group



***Specialty substance use treatment** = treatment received at a drug or alcohol rehabilitation facility (inpatient or outpatient), a hospital (inpatient only), or a mental health center.

****Illicit Drug Use**= Misuse of Prescription Psychotherapeutics for the use of Marijuana, Cocaine including Crack, Hallucinoens, Inhalant or Methamphetamine

SAMHSA's Behavioral Health Treatment Services Locator

The launch of [FindTreatment.gov](https://www.findtreatment.gov) is a critical example of systems improvement happening at the national level. A modernization of SAMHSA's Behavioral Health Treatment Services Locator, this effort is designed to increase access to care for addiction treatment. The new locator also allows searches of programs based on payment option, age, languages spoken, and access to medication-assisted treatment for an opioid use disorder.

Behavioral Health Treatment Services Locator

[FindTreatment.gov](https://www.findtreatment.gov)

[FindTreatment.gov](https://www.findtreatment.gov)



Millions of Americans have a substance use disorder. Help is available.

The Substance Abuse and Mental Health Services Administration (SAMHSA) collects information on thousands of state-licensed providers who specialize in treating substance use disorders, addiction, and mental illness.

[Find treatment](#)

[Learn more](#)



Find a treatment facility near you

City or zip code

[Search](#)

Thank You

SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities.

Jean.Bennett@samhsa.hhs.gov

Nina.Cross@samhsa.hhs.gov

Free Publications Information: <https://store.samhsa.gov/>

Grant Information: <https://www.samhsa.gov/grants>

www.samhsa.gov

1-877-SAMHSA-7 (1-877-726-4727) • 1-800-487-4889 (TDD)



Let's continue the conversation

Jean Bennett, PhD, MSM, MSN, BSN, RN
Regional Administrator, Region III (DC, DE, MD, PA, VA, WV)

https://www.youtube.com/watch?v=L8_iTKf4iGk

Substance Abuse and Mental Health Services Administration (SAMHSA)
U.S. Department of Health and Human Services (HHS)
801 Market Street, Suite 9108, Philadelphia, PA 19106
Phone: 202-446-4710 E-mail: Jean.Bennett@samhsa.hhs.gov
Website: www.samhsa.gov / 1-877-726-4727

*Behavioral Health is Essential To Health • Prevention Works
Treatment is Effective • People Recover*



SAMHSA
Substance Abuse and Mental Health
Services Administration



AGENCY FOR HEALTHCARE RESEARCH AND QUALITY



AHRQ initiatives to address the opioid crisis

Elisabeth Kato, MD, MRP
Center for Evidence and Practice Improvement
AHRQ

AHRQ's Mission

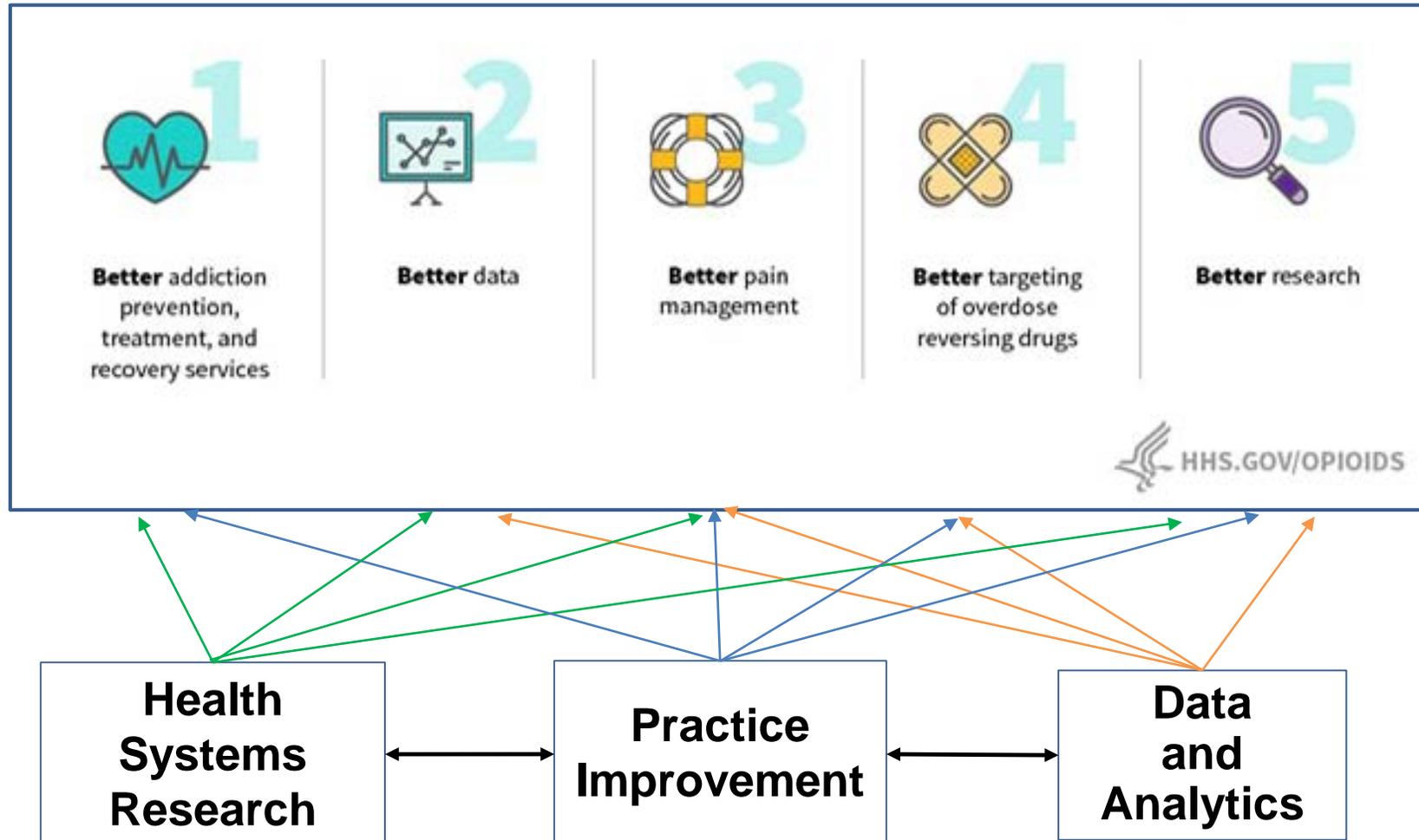


www.ahrq.gov

To produce evidence to make health care safer, higher quality, more accessible, equitable and affordable

To work with HHS and other partners to make sure that the evidence is understood and used

AHRQ core competencies support the HHS 5-point strategy



Health Systems Research to Address the Opioids Crisis



Increasing Access to Medication-Assisted Treatment (MAT) of Opioid Abuse in Rural Primary Care Practices

(cooperative grant initiative)

- \$12 million over 3 years to learn more about effective strategies that help implement MAT for OUD in rural primary care practices
- Targets rural counties in five states (CO, NC, PA, OK, and NM) with high rates of OUD and few or no MAT providers
- Tests innovative means to activate and support patients and clinicians, including virtual consultations and community engagement

Data and Analytics to Address the Opioid Crisis



- **Healthcare Cost and Utilization Project (HCUP)**

<https://www.hcup-us.ahrq.gov/>

- **Medical Expenditure Panel Survey (MEPS)**

<https://meps.ahrq.gov/mepsweb/>

- New opioid measures added to the **National Healthcare Quality and Disparities Report (QDR)**

<https://nhqrnet.ahrq.gov/inhqrdr/reports/qdr>

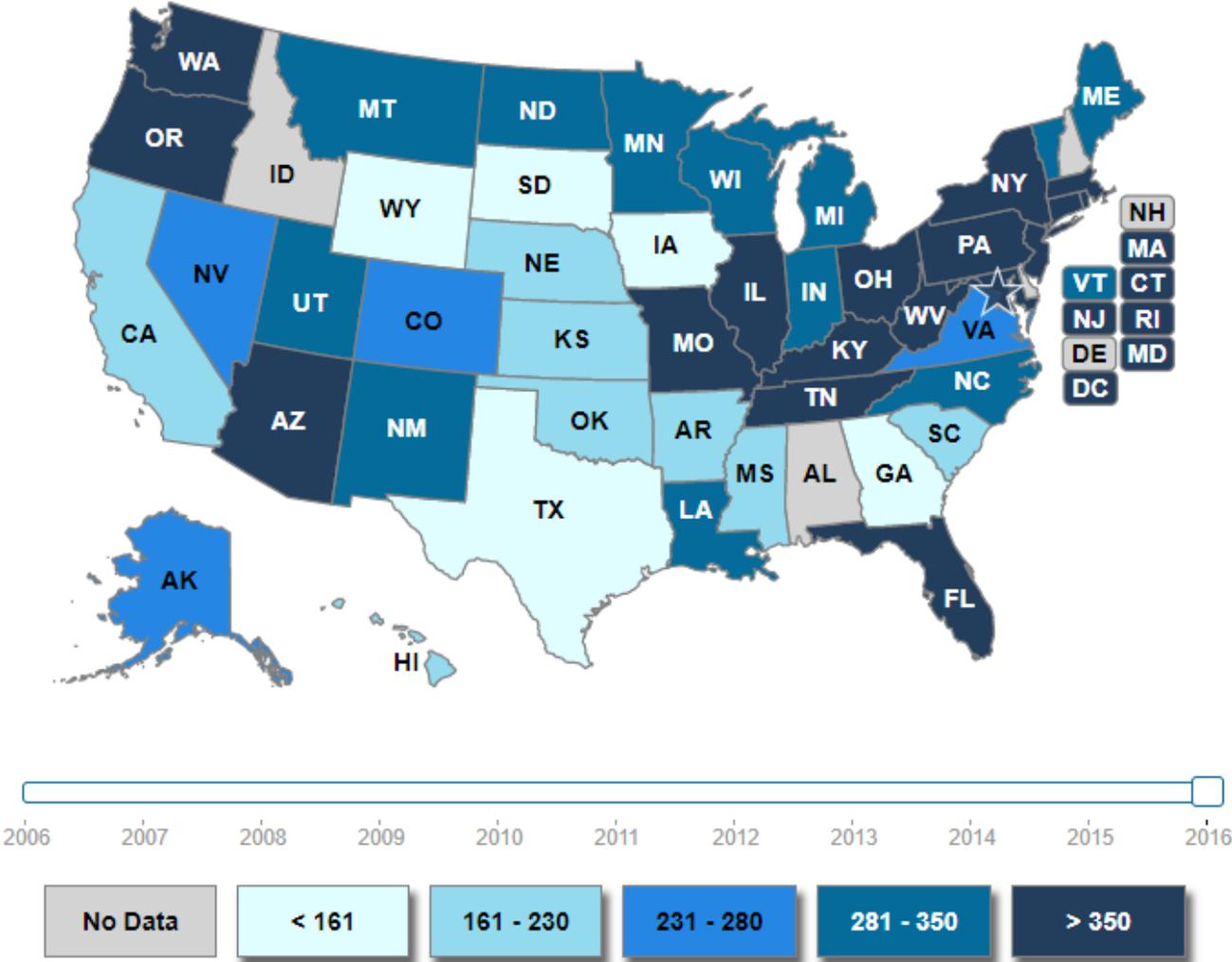
Healthcare Cost and Utilization Project (HCUP)



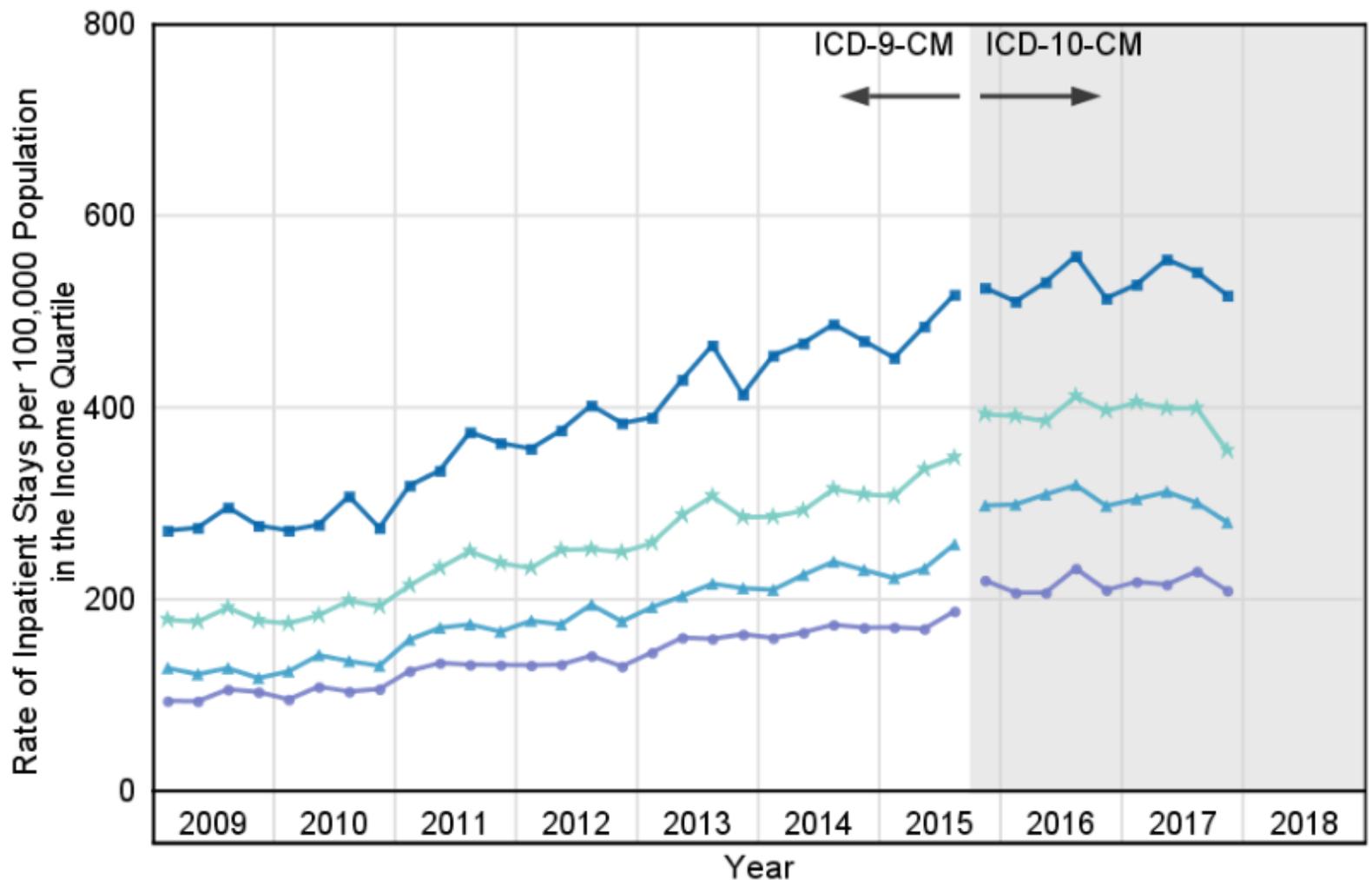
- The largest collection of longitudinal hospital care data in the United States.
- HCUP databases are derived from administrative data and contain encounter-level, clinical and nonclinical information
- Interactive web tools allow exploration of national and state trends for inpatient stays and ED visits by geography, age, sex, community income, and payer
- Dedicated trackers available for **opioid related hospitalizations** and **neonatal abstinence syndrome**
- Statistical briefs present simple, descriptive statistics on a variety of topics including opioids and substance use disorders

Rate of Opioid-Related Inpatient Stays per 100,000 Population

2016 National rate: 296.9



Pennsylvania: Opioid-Related Hospital Use by Community-Level Income Rate of Inpatient Stays



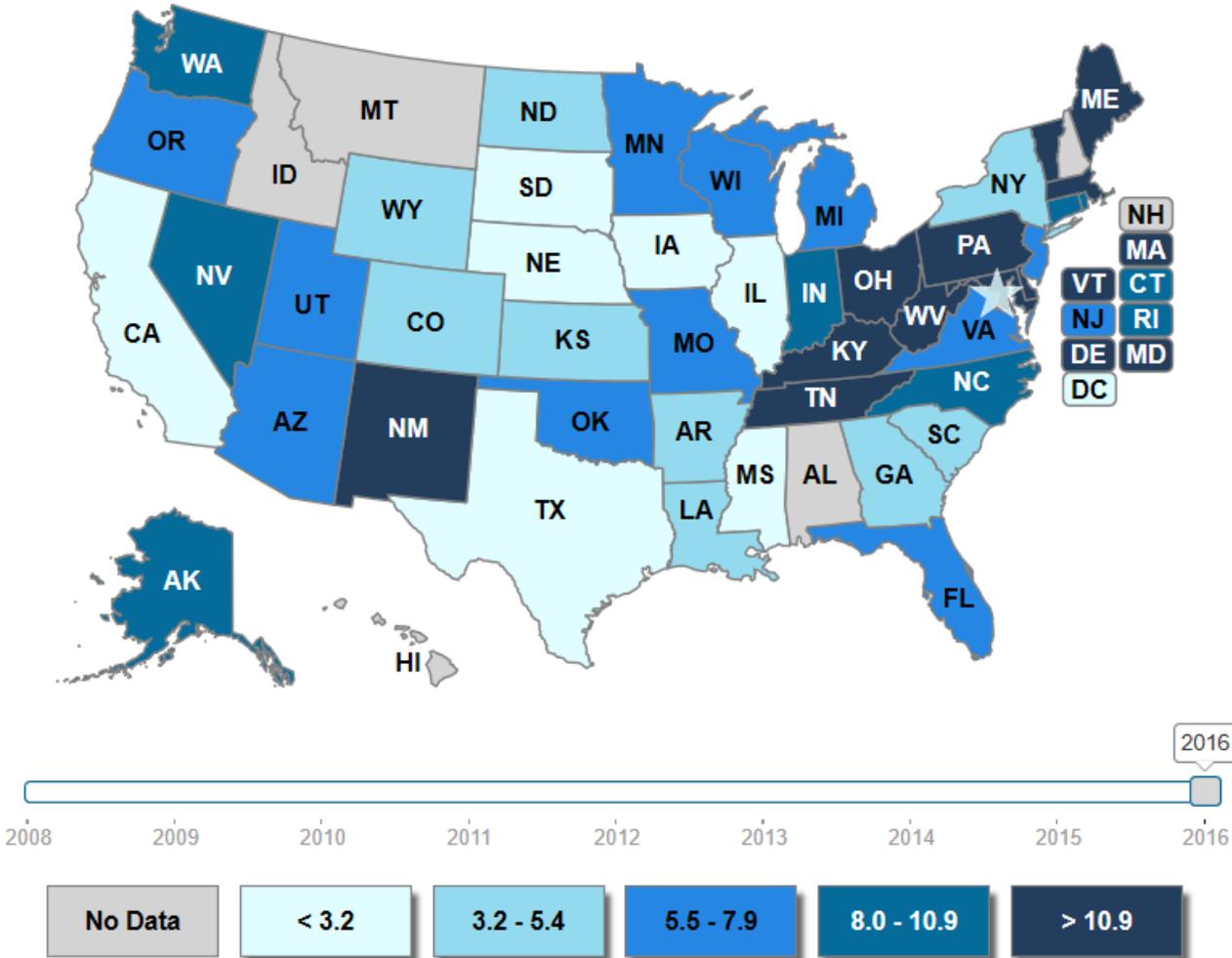
- Income quartile 1 (lowest)
- ★ Income quartile 2 (2nd lowest)
- ▲ Income quartile 3 (2nd highest)
- Income quartile 4 (highest)

Source: Agency for Healthcare Research and Quality (AHRQ), Healthcare Cost and Utilization Project (HCUP), State Inpatient Databases (SID) 2009-2017 (all available data as of 03/22/2019). Inpatient stays include those admitted through the emergency department.

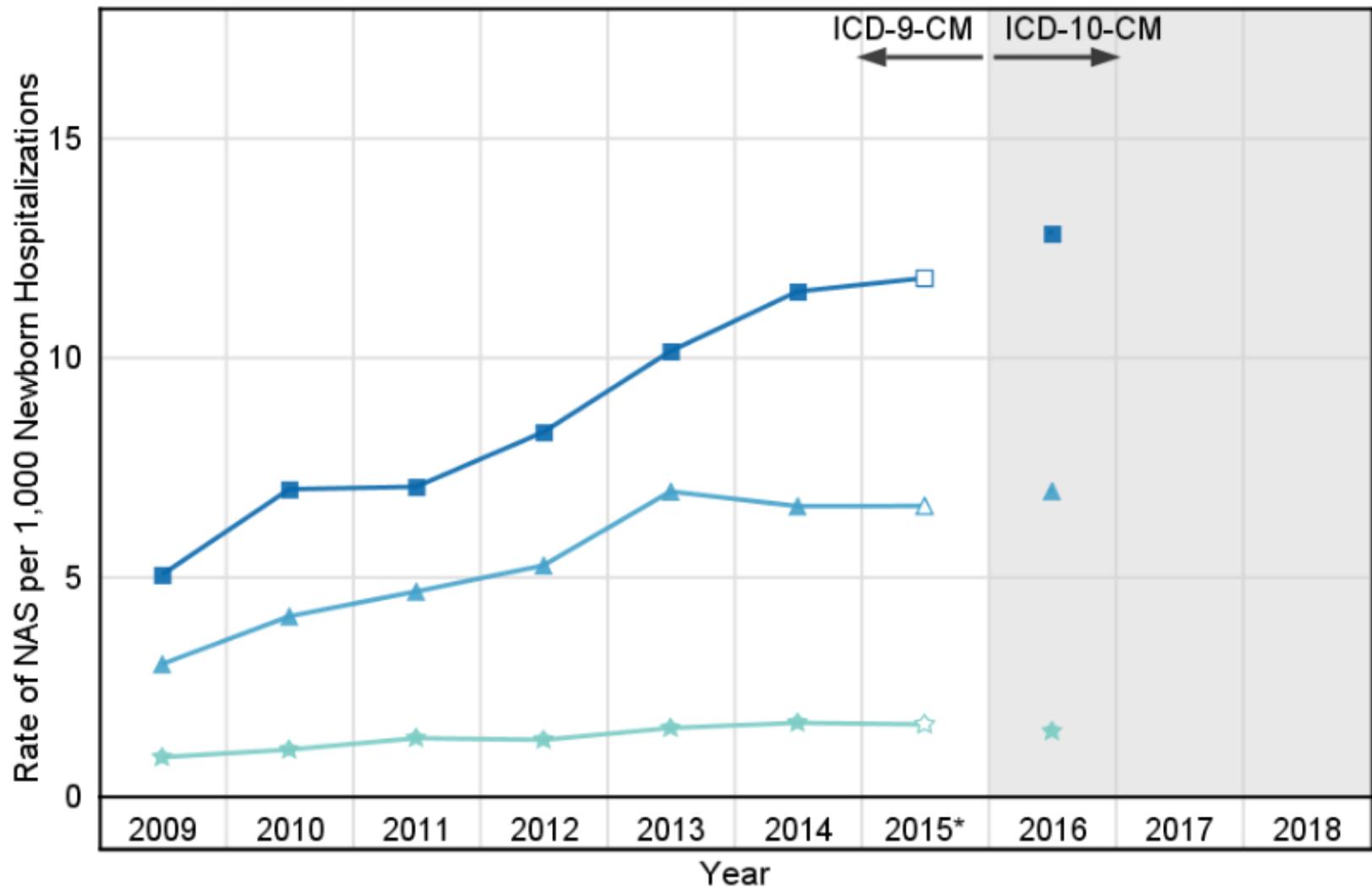


Rate of NAS per 1,000 Newborn Hospitalizations

2016 National rate: 7.0



U.S. National: NAS Among Newborn Hospitalizations Rate per 1,000 Newborn Hospitalizations by Expected Payer



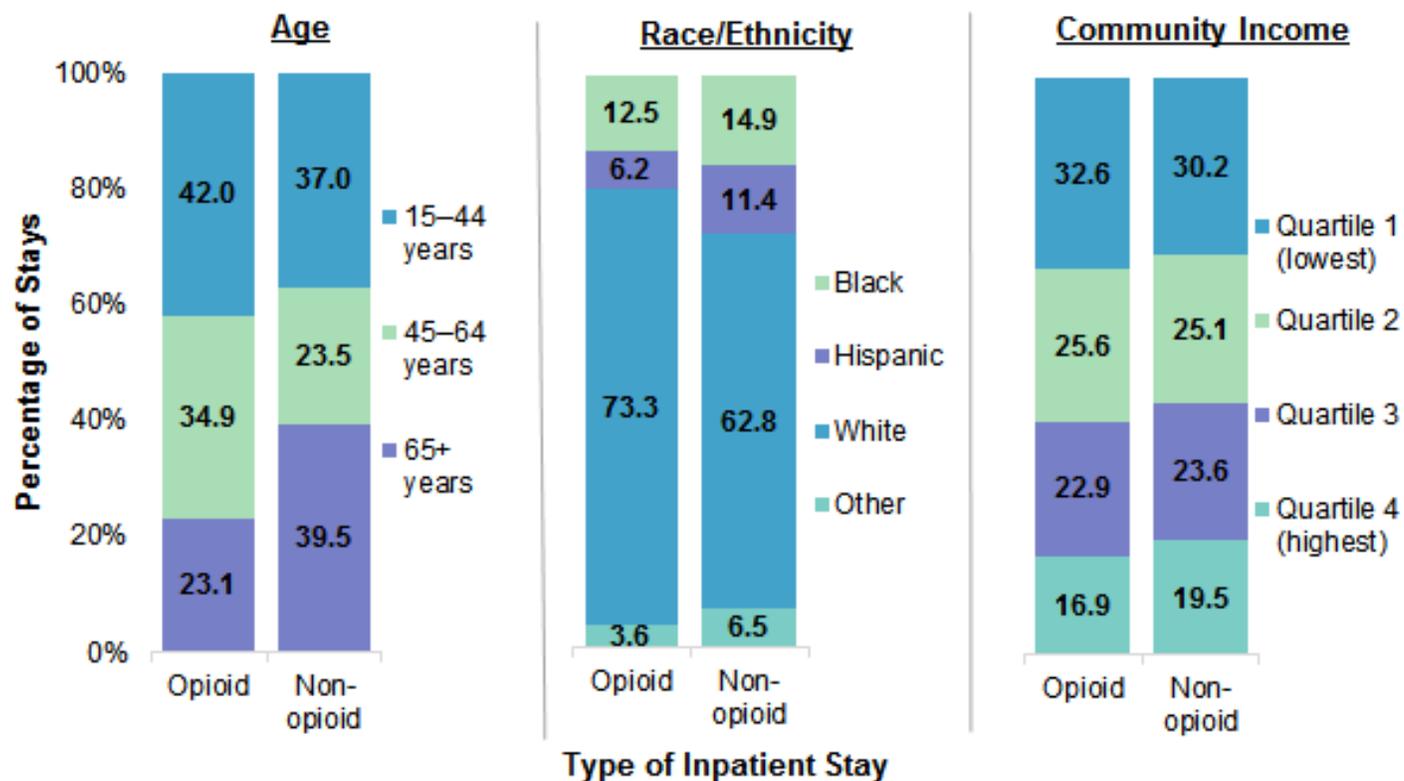
H·CUP
HEALTHCARE COST AND UTILIZATION PROJECT

■ Medicaid ◆ Private insurance
▲ Self-pay/No charge**

Source: Agency for Healthcare Research and Quality (AHRQ), Healthcare Cost and Utilization Project (HCUP), National (Nationwide) Inpatient Sample (NIS), 2009-2016 (all available data as of 08/15/2019). Abbreviation: NAS, neonatal abstinence syndrome.

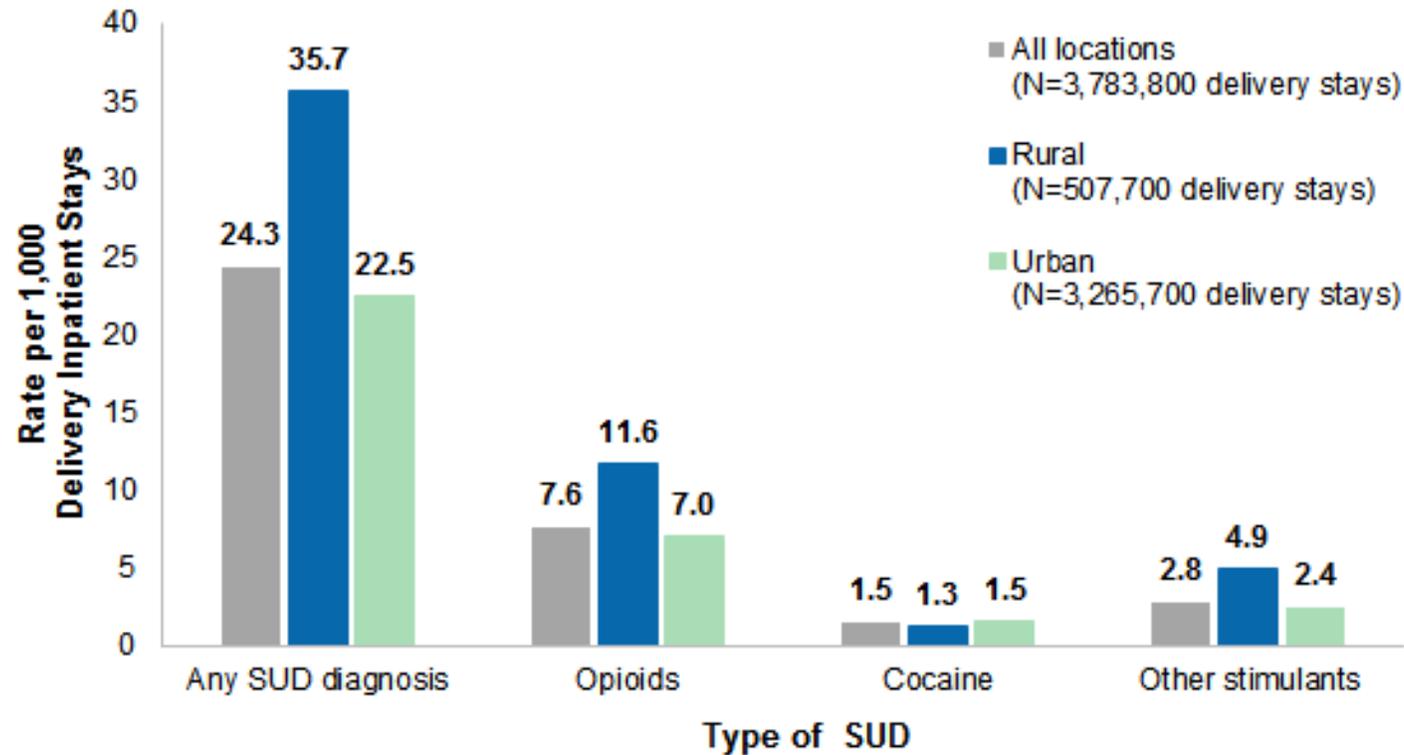
Opioid-Related Hospital Stays Among Women, 2016 (Stat Brief #247)

Characteristics of opioid-related versus non-opioid-related inpatient stays among women, 2016



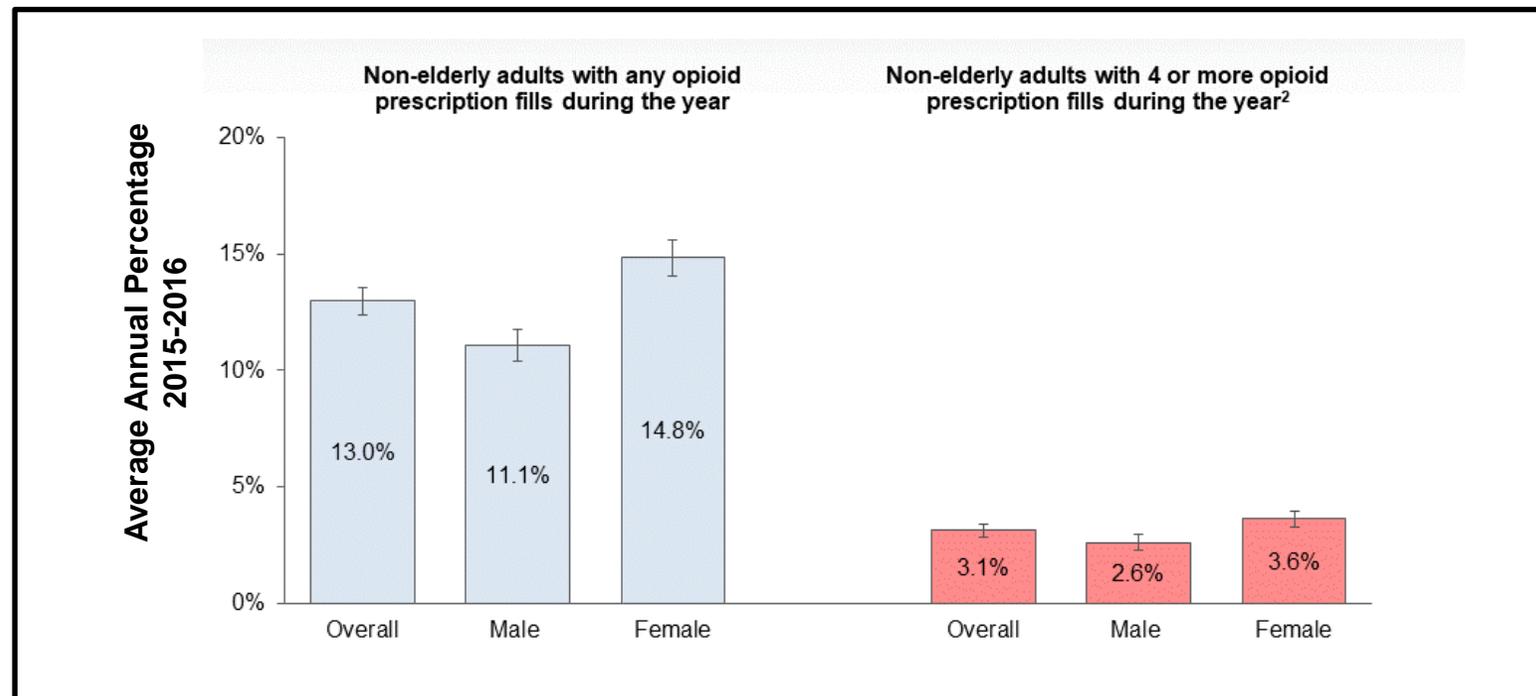
Obstetric Delivery Inpatient Stays Involving SUDs and Related Clinical Outcomes, 2016 (Stat Brief #254)

Rates of delivery stays involving SUDs among patients residing in rural versus urban counties, overall and for select types of SUD diagnoses, 2016



The Medical Expenditure Panel Survey (MEPS)

- a set of large-scale surveys of families and individuals, their medical providers, and employers across the United States
- the most complete source of data on the cost and use of health care and health insurance coverage



https://meps.ahrq.gov/data_files/publications/st516/stat516.shtml

The National Healthcare Quality and Disparities Report (QDR)



U.S. Department of Health & Human Services

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AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

Search

National Healthcare Quality and Disparities Reports

Your source for the Reports, State Snapshots, and QR/DRnet

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National summary across quality measures
- State View**
State-level summaries and snapshots across measures
- Data Query**
Search data across specific measures
- Opioids**
Search for opioids measures in the report
- Resources**
Resources to improve quality performance

2018 National Healthcare Quality and Disparities Report

For the 16th year in a row, AHRQ is reporting on healthcare quality and disparities. The annual National Healthcare Quality and Disparities Report is mandated by Congress to provide a comprehensive overview of the quality of healthcare received by the general U.S. population and disparities in care experienced by different racial and socioeconomic groups. The report is produced with the help of an Interagency Work Group led by AHRQ.

Introduction

The National Healthcare Quality and Disparities Report assesses the performance of our healthcare system and identifies areas of strengths and weaknesses, as well as disparities, for access to healthcare and quality of healthcare. Quality is described in terms of six priorities: patient safety, person-centered care, care coordination, effective treatment, healthy living, and care affordability. The report is based on more than 250 measures of quality and disparities covering a broad array of healthcare services and settings.

Report Files

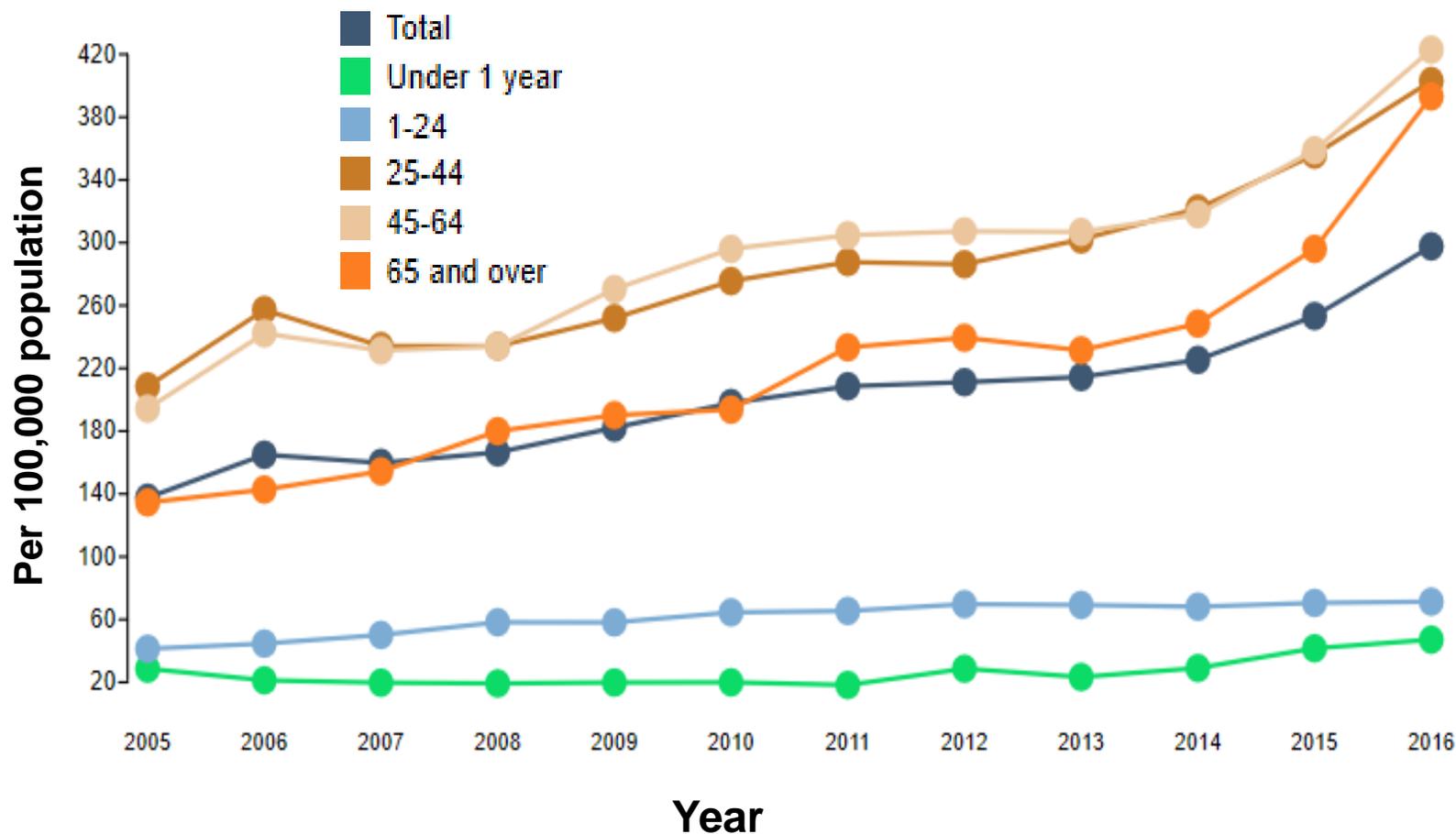
AHRQ no longer offers print copies of the report, but the files are set up for two-sided color printing and may be downloaded free of charge. If you have questions about printing or copying, contact Doreen Bonnett at 301-427-1899 or doreen.bonnett@ahrq.hhs.gov.

- [Introduction and Methods \(PDF, 1.3 MB\)](#)
- [Report and Appendixes B and C \(Accessible PDF, 5 MB\)](#)

<https://nhqrnet.ahrq.gov/inhqrdr/reports/qdr>

Another Face of the Opioids Crisis: Older Americans

Hospital inpatient stays related to opioid use per 100,000 population



AHRQ Opioids and Older Adults Initiative



- Prevention, Diagnosis, and Management of Opioids, Opioids Misuse, and Opioid Use Disorder in Older Adults *Technical Brief, draft to be posted for comment next month*
- Identifying and Testing Strategies for Management of Opioid Use and Misuse in Older Adults in Primary Care Practices *Quality Improvement project, 2019-2022*
- Improving the management of opioids and opioid use disorder in older adults *Notice of Intent for an RFA posted last month*

www.ahrq.gov/opioids

Thank you!

Severe Adverse Event Rates among Minority Veterans

*FDA Public Meeting on Strategies to Improve Health Equity Amidst the
Opioid Crisis*

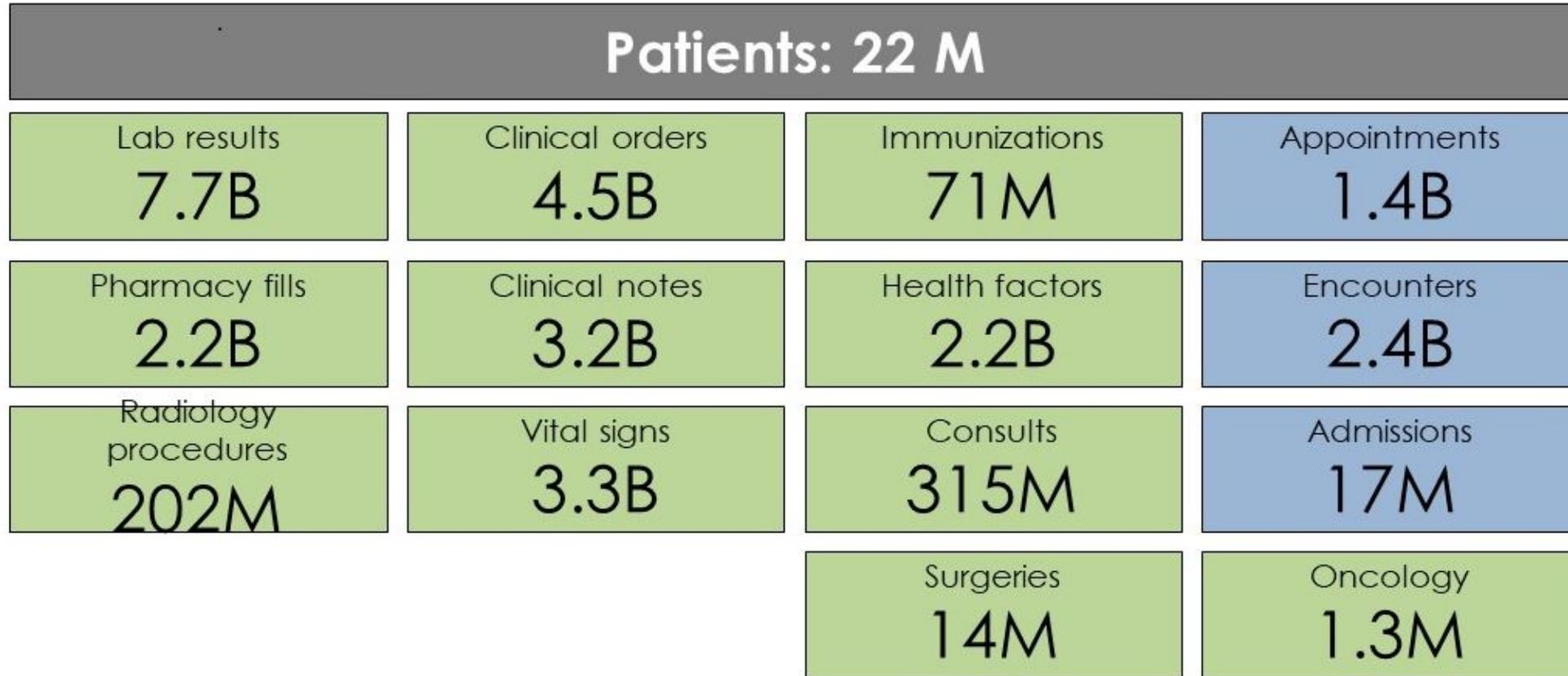
Suzanne Tamang, PHD

Program Evaluation Resource Center | Department of Veterans Affairs

Department of Biomedical Data Science, Center for Population Health Science | Stanford

November 21, 2019

VHA's Treasure Trove of Data



Source: Slide by Jack Bates

Serious Adverse Event Trends among Minority Veterans 2016-2018

PERC-OMHSP Cohort

The VA serves a patient population with higher risk of overdose-related events

- The prevalence of opioid abuse is almost 7 times higher among VA patients compared to commercial health plan patients
- VA treats vets with low socioeconomic status or a service connected-disability.

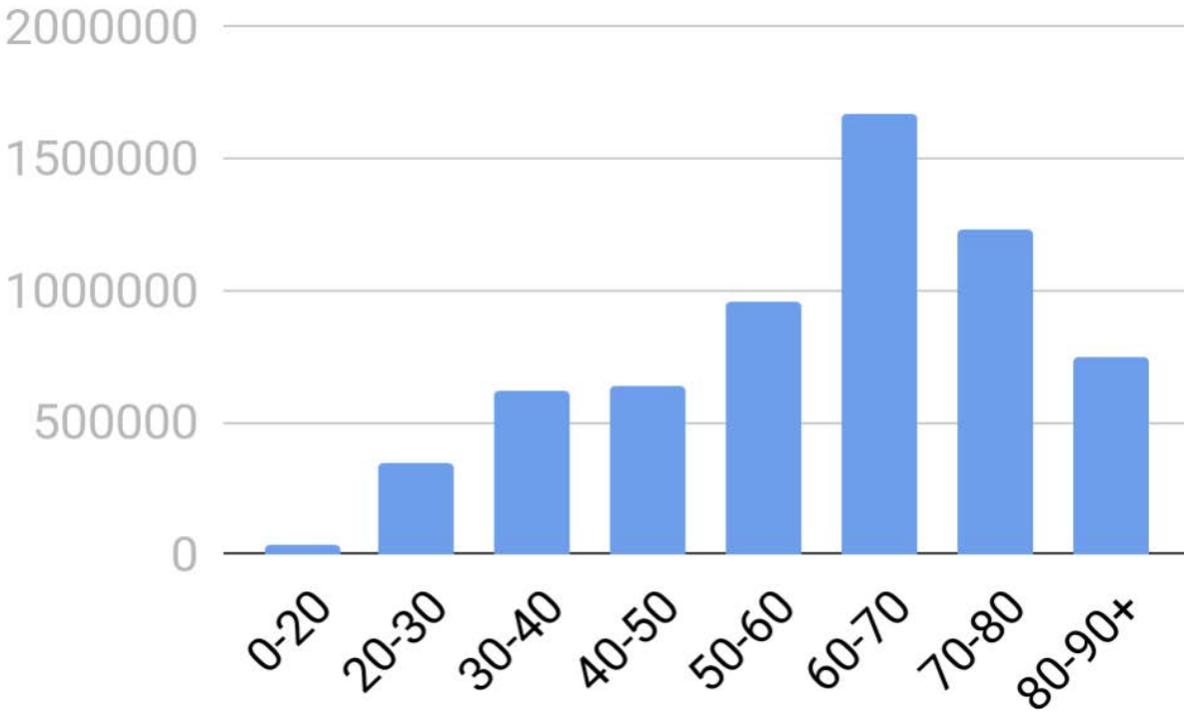
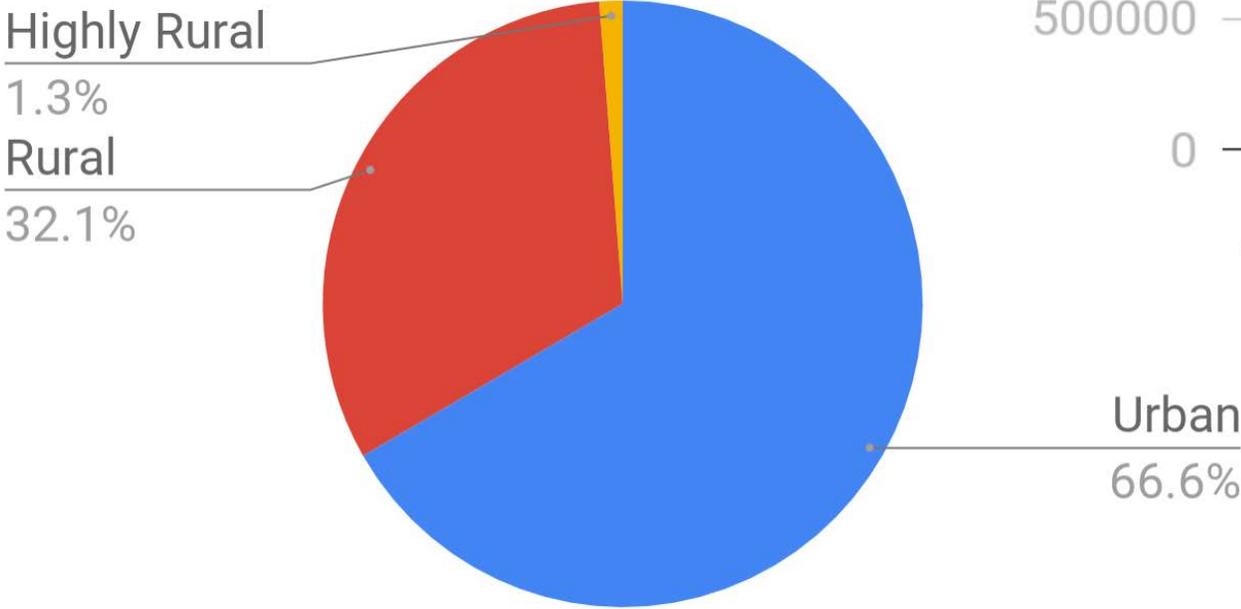
| Fiscal Year | Veterans | Non-White | Female |
|--------------------|-----------------|------------------|---------------|
| 2016 | 5,873,655 | 27.3% | 7.8% |
| 2017 | 5,920,608 | 27.6% | 8.2% |
| 2018 | 5,965,299 | 27.9% | 8.5% |

VHA Cohort, Gender and Race, 2018

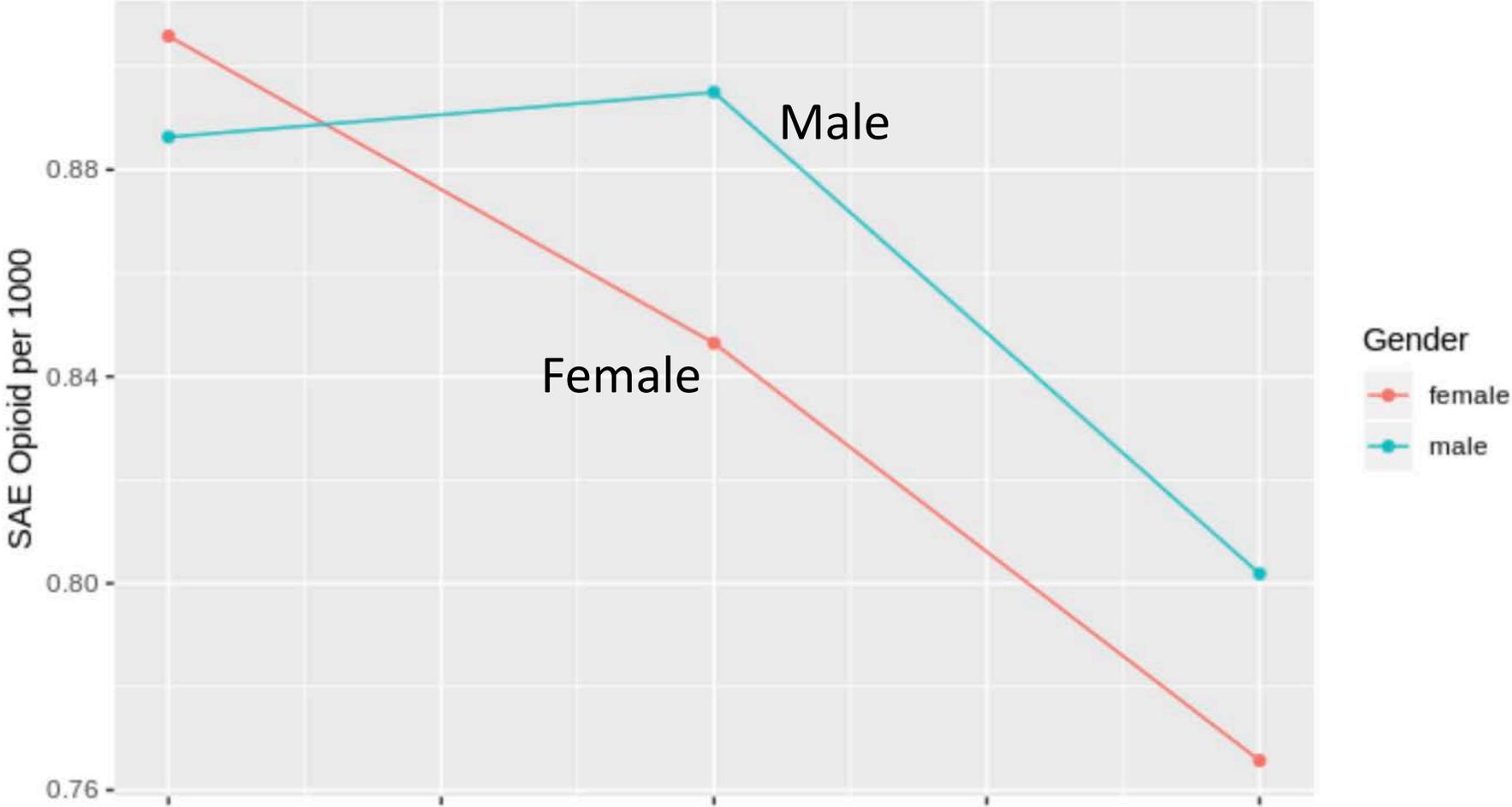
| Gender | Proportion | Count |
|---------------|-------------------|--------------|
| Male | 91.5% | 5,461,177 |
| Female | 8.5% | 504,097 |

| Race | Proportion | Count |
|-----------------|-------------------|--------------|
| White | 72.1% | 4,300,029 |
| Black | 16.8% | 1,002,786 |
| Asian | 1.9% | 115,190 |
| Native American | 0.7% | 44,122 |

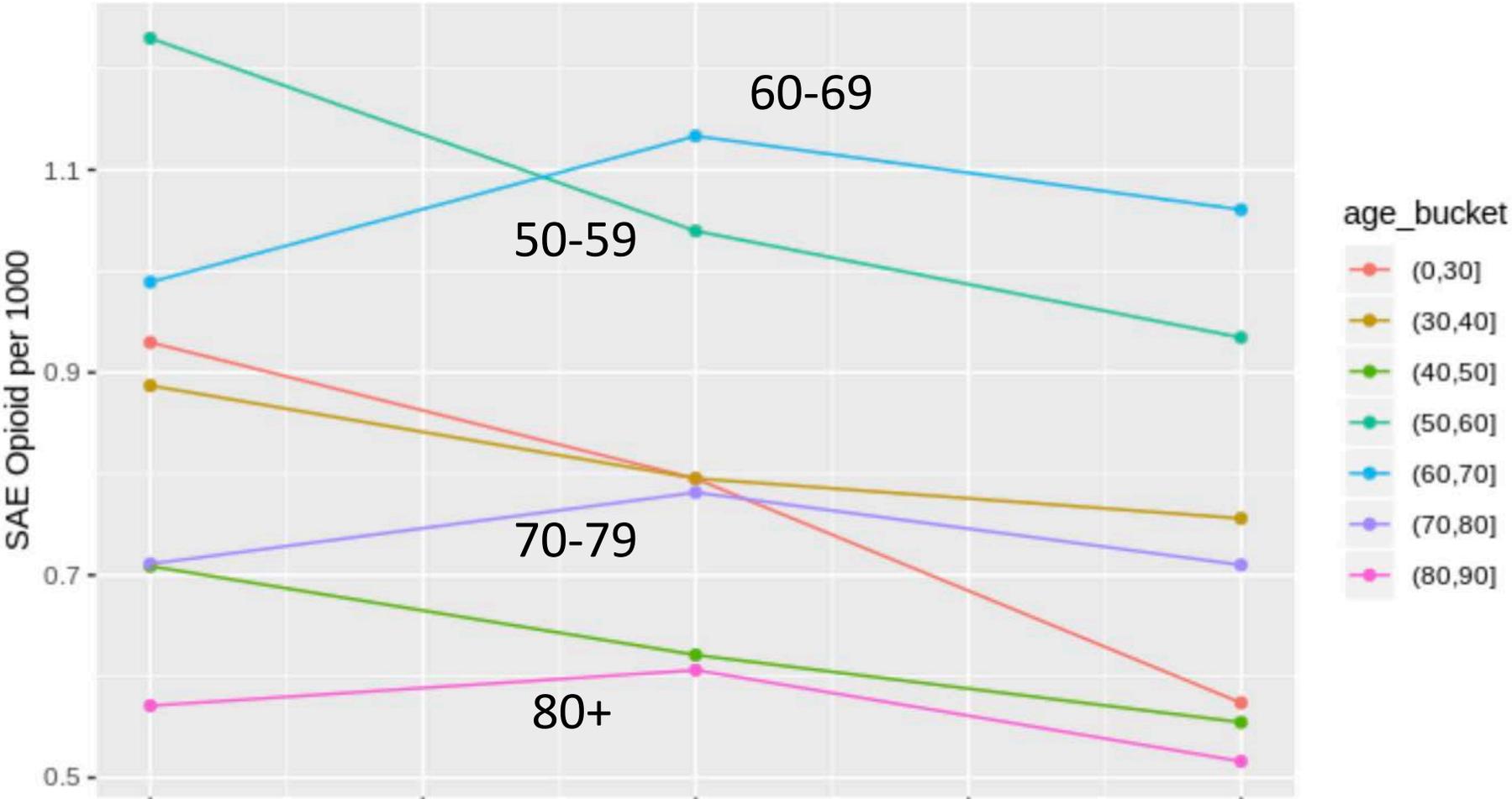
VHA Cohort, Age and Urban/Rural, 2018



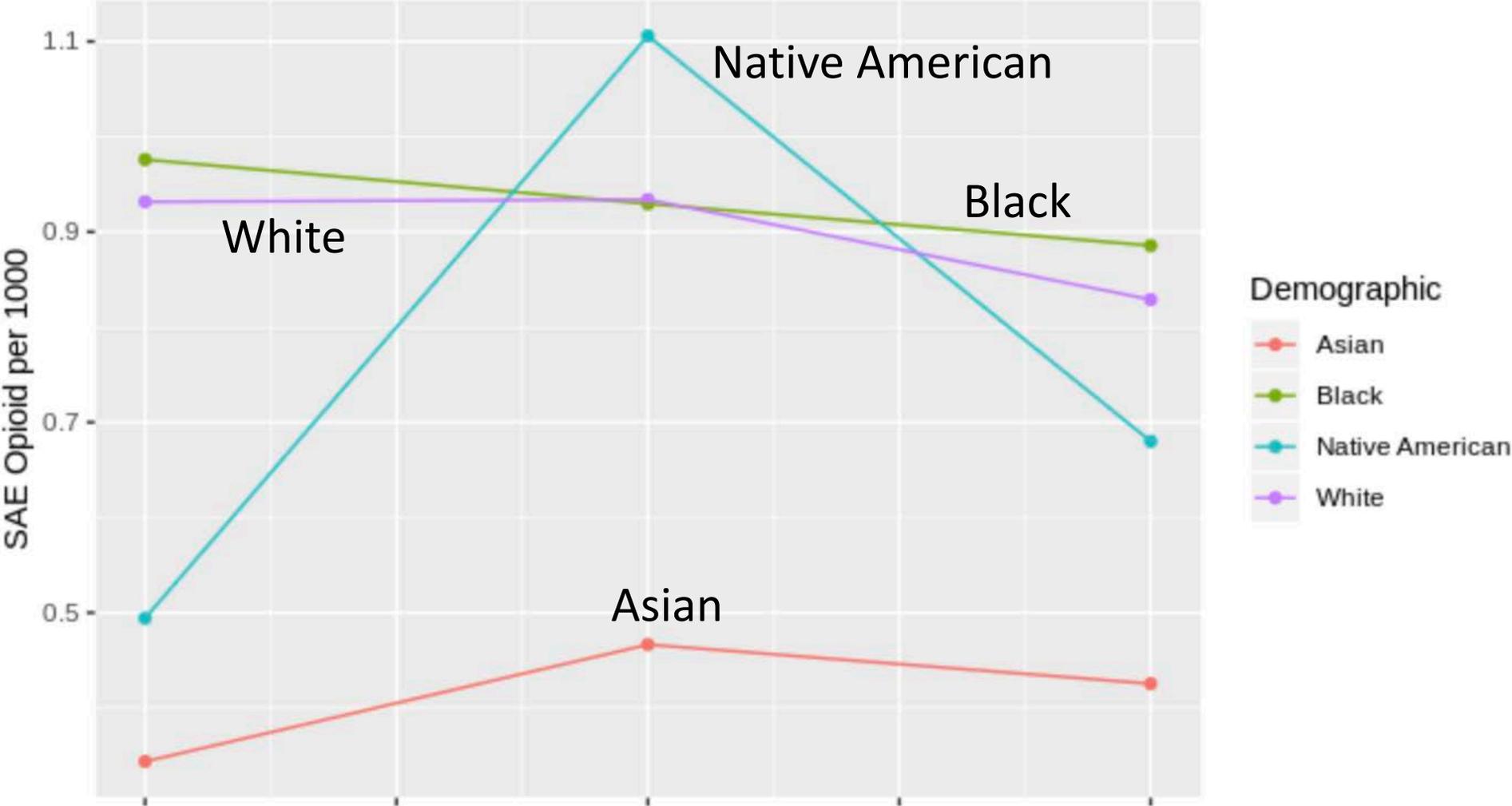
Rate of receipt of health care encounters for opioid overdose by GENDER, 2016-18



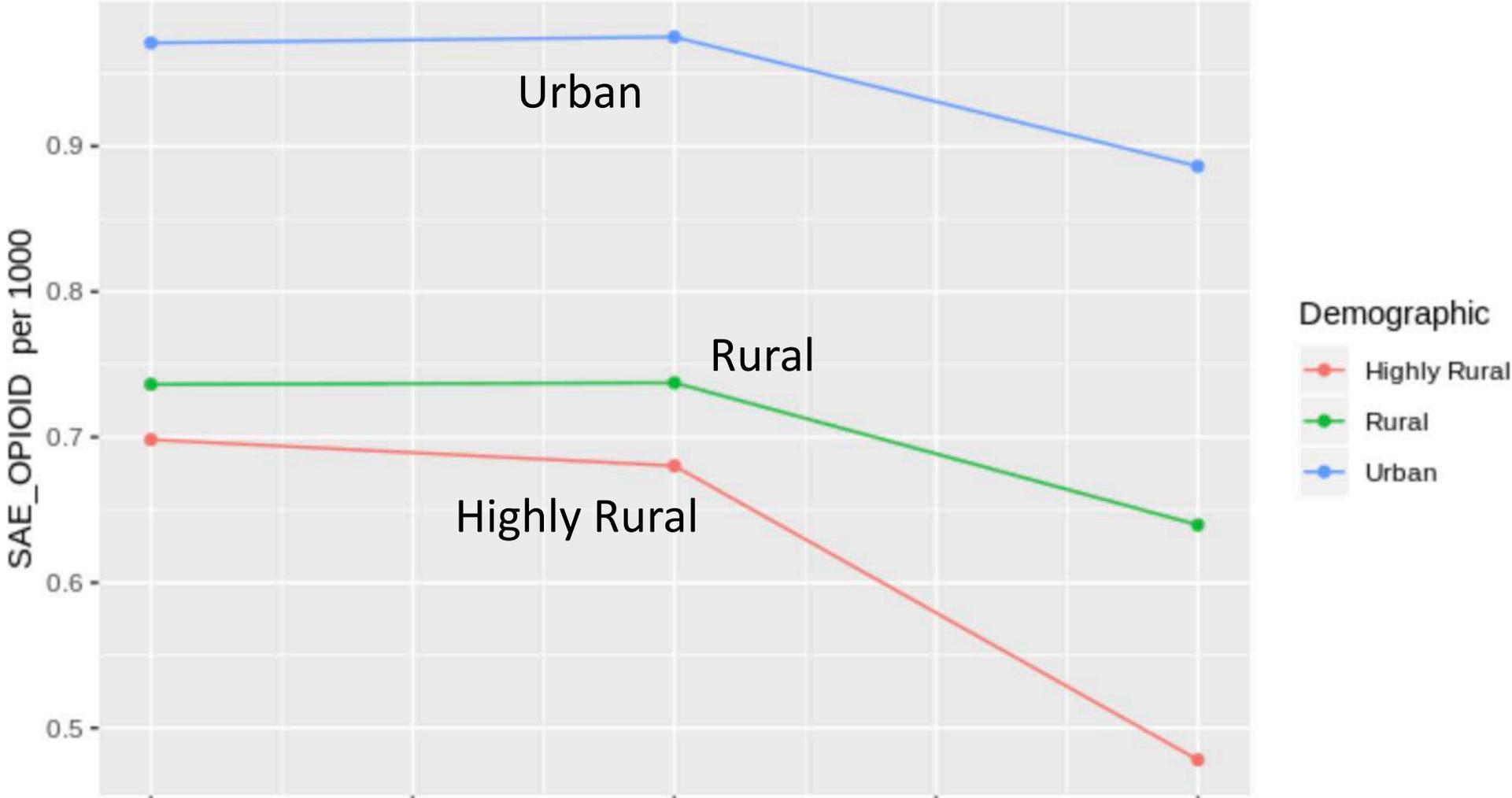
Rate of receipt of health care encounters for opioid overdose by AGE, 2016-18



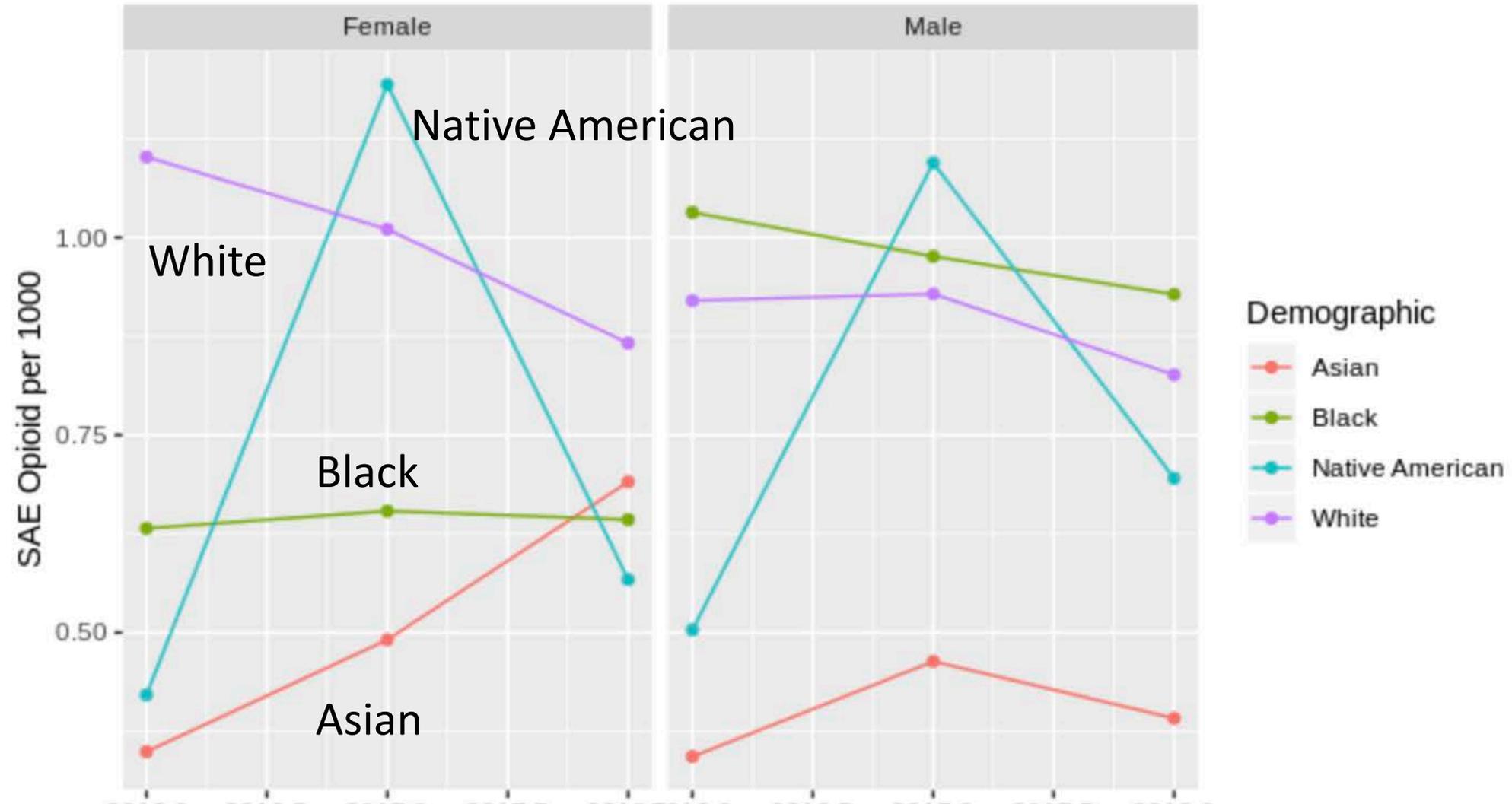
Rate of receipt of health care encounters for opioid overdose by RACE, 2016-18



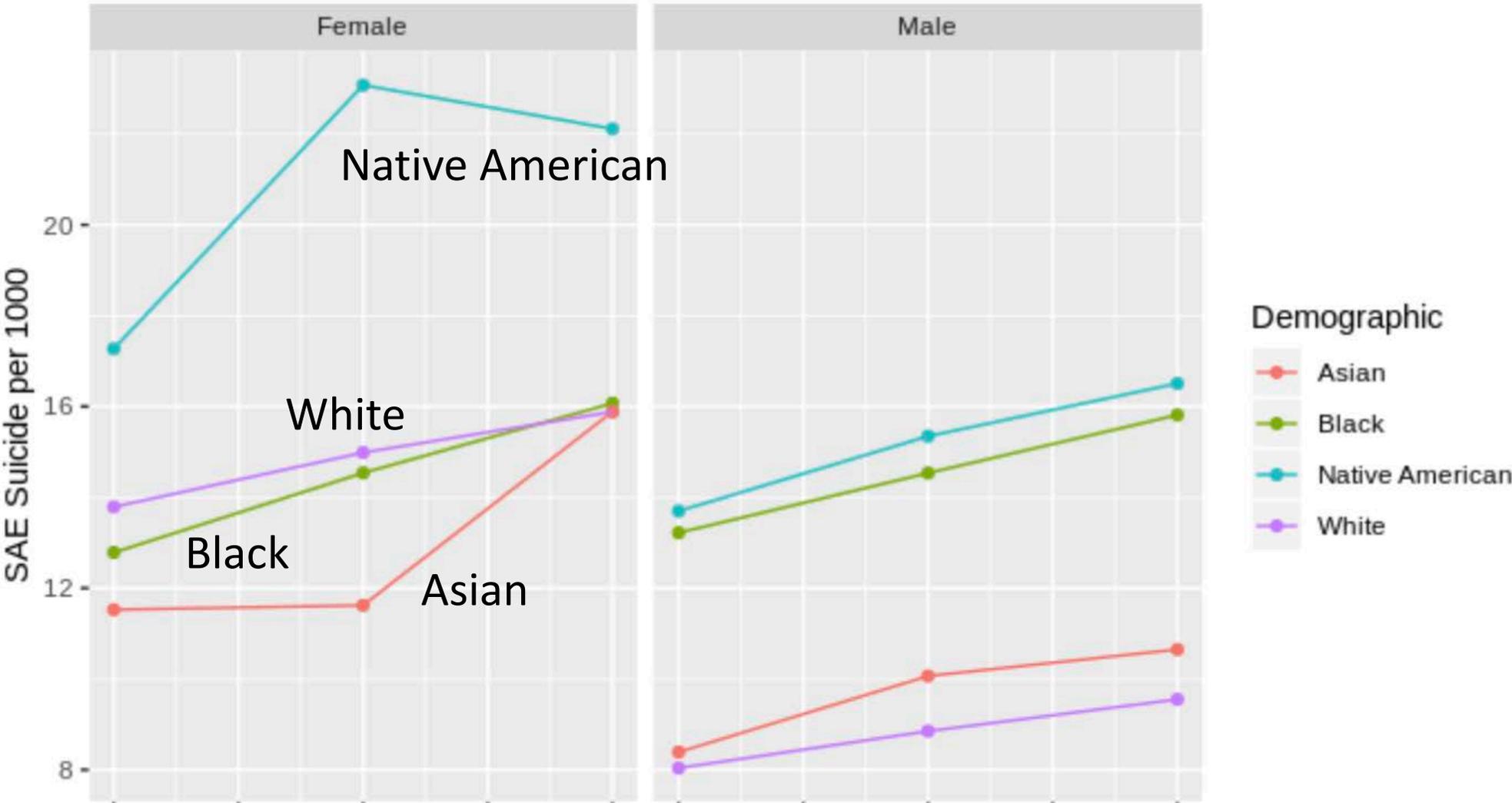
Rate of receipt of health care encounters for opioid overdose by URBAN/RURAL, 2016-18



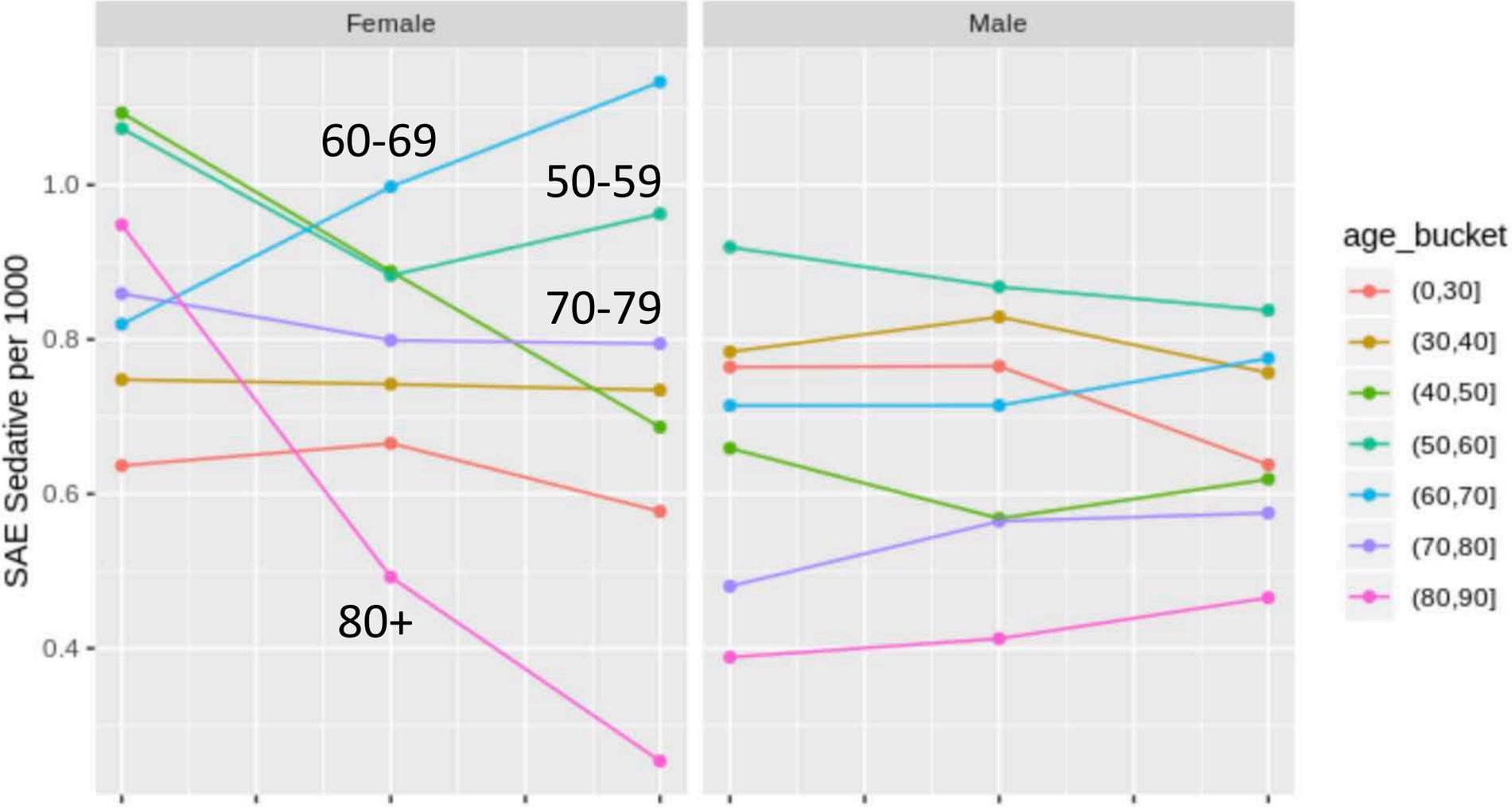
Rate of receipt of health care encounters for opioid overdose by Gender & Race, 2016-18



Rates of health care encounters for suicide ideation or attempt: Gender & Race, 2016-18



Rates of health care encounters for sedative poisoning by Gender & Age, 2016-18



Ongoing Work

Examining facility variation in serious adverse event health care encounter trends

- Template matching (McHugh, *et alia*)

Bias analysis of population-based risk stratification tools

- R software package for visualizing model bias: VA-FDA-Stanford DSSG

PR, McHugh MD, et al. Comparison of the Value of Nursing Work Environments in Hospitals Across Different Levels of Patient Risk. *JAMA Surg.* 2016;151(6):527–536. doi: <https://doi.org/10.1001/jamasurg.2015.4908>

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- Food and Drug Administration: Christine Lee, Christine Miranda
- Stanford Center for Population Health Sciences: Mark Cullen, Isabella Chu, Lesley Park, Valerie Meausone, Joshua Lev Kravitz
- Stanford Aging and Ethnographic Geriatric Research: VJ Periyakoil



Thank You!

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Questions?



LUNCH



Session 3

Innovative Initiatives and Research to
Address the Opioid Crisis
(Part I)

Addressing the Opioid Crisis With Innovative Studies

Mitra Ahadpour, MD, DABAM

Principal Deputy Director

Office of Translational Sciences

U.S. Food and Drug Administration

November 21, 2019



Disclaimers

- I have no conflicts of interest to report.
- The opinions in this presentation are my own.
- The mention of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of any specific product or manufacturer.

On an Average Day in the United States



1

- More than **463,000 opioid prescriptions** are dispensed.¹

2

- **5,205 people** initiate nonmedical use of prescription opioids.²

3

- **320 people** initiate heroin use.²

4

- **130 people** die from an opioid-related overdose.³

Note: *Opioid-related overdose include those involving prescription opioids and illicit opioids such as heroin.

Sources: ¹ IQVIA, National Prescription Audit and static data 2006-2011. January 2006-December 2018(*Immediate-Release formulations include oral solids, oral liquids, rectal, nasal, and transmucosal); ² 2018 National Survey on Drug Use and Health (NSDUH) – 12 or older ; ³ Scholl L et al. Drug and Opioid-Involved Overdose Deaths — United States, 2013–2017. Morb Mortal Wkly Rep 2019;67:1419–1427.

The Faces of the Crisis

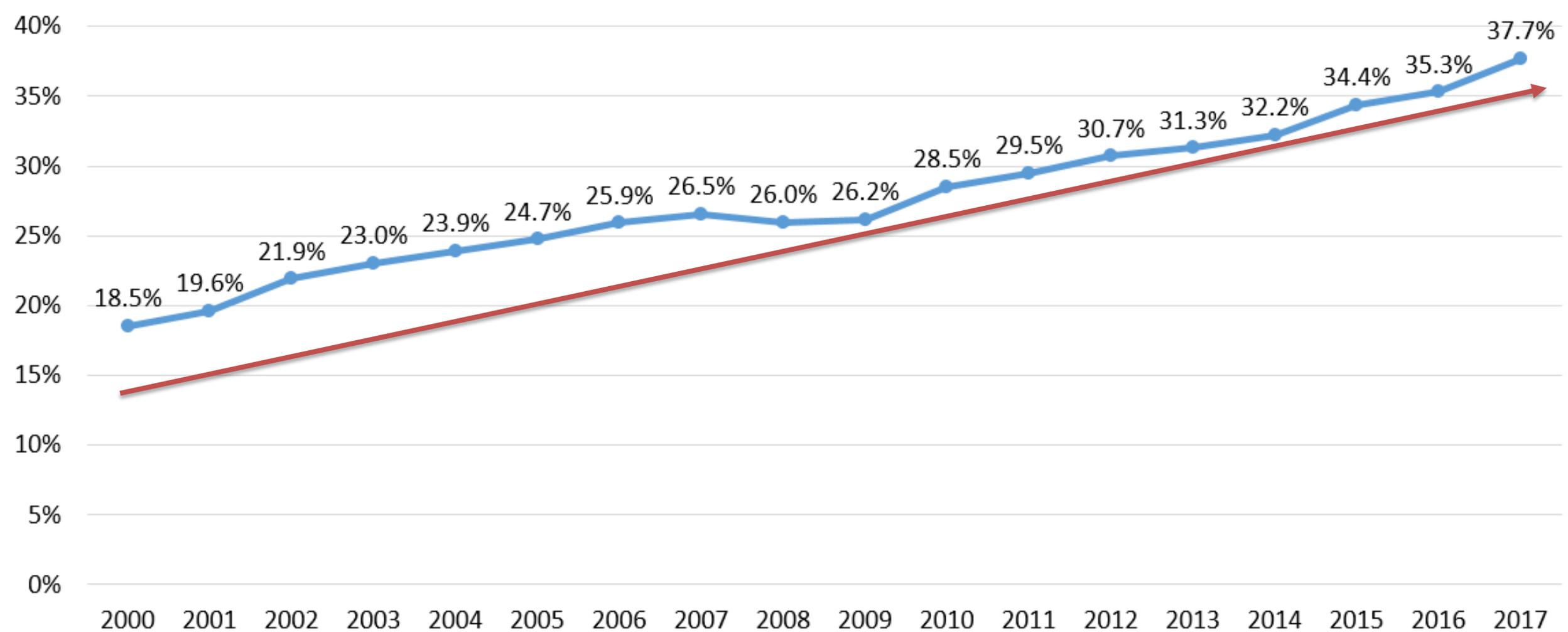


Photo Credit: Truth Pharm

Young Victims of the Crisis



Parental Alcohol or Other Drug Use as a Contributing Factor for Child Removal in the US, 2000 to 2017



Note: Estimates based on all children in out of home care at some point during Fiscal Year

Source: AFCARS Data, 2000-2017

Children With a Parent Who Has Substance Use Disorder



- At risk of experiencing parental abuse or neglect
- Increased difficulties in academic and social settings

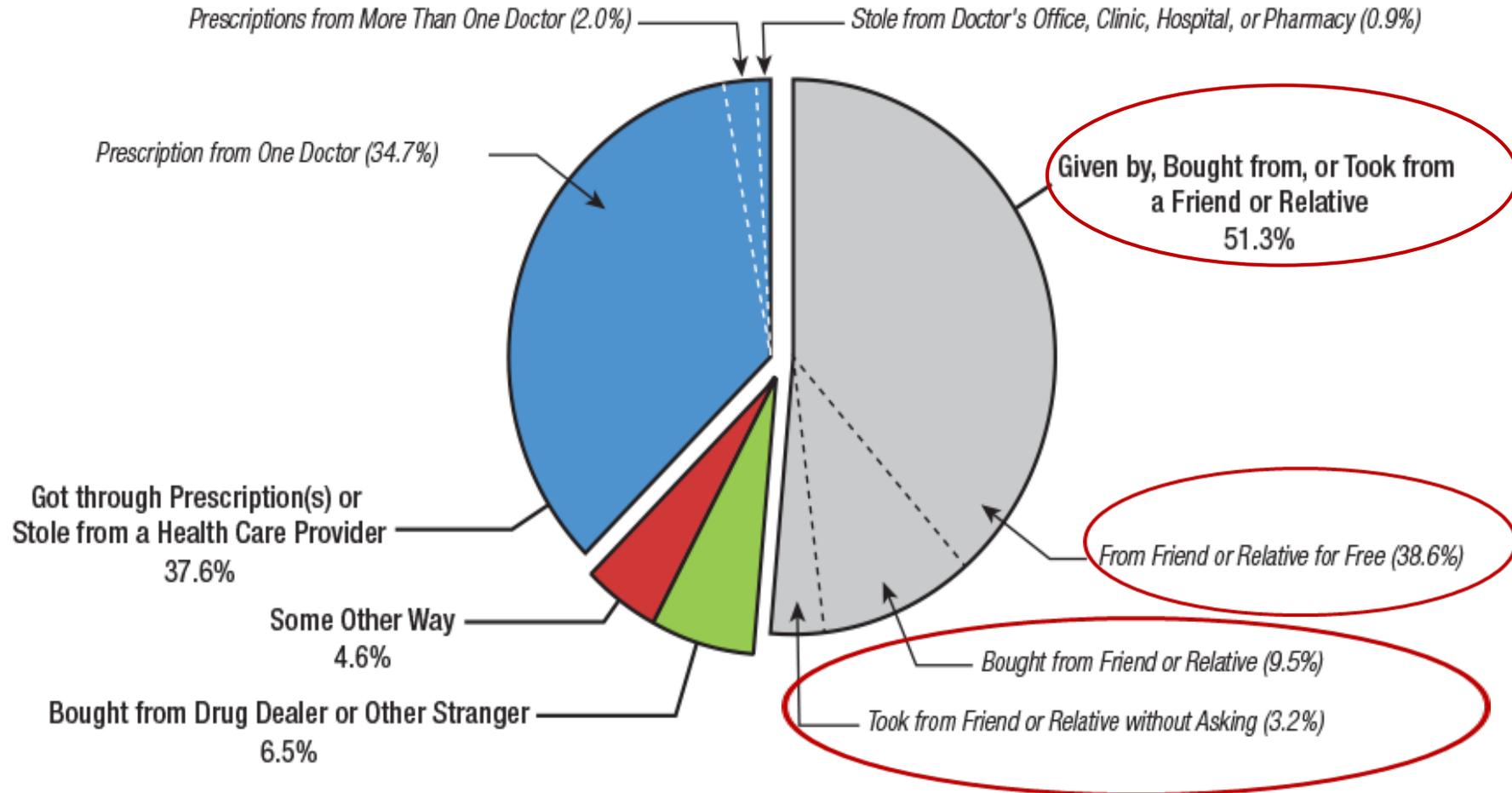


Animal Patients

- 73% of respondents indicated their veterinary medical school training on opioid misuse was fair, poor or absent.¹
- Prescribed veterinary opioids can increase chance of unused pills for misuse.²



Sources for Most Recent Prescription Opioid Misuse



9.9 Million People Aged 12 or Older Who Misused Pain Relievers in the Past Year

Patient Variation and Healthcare Factors



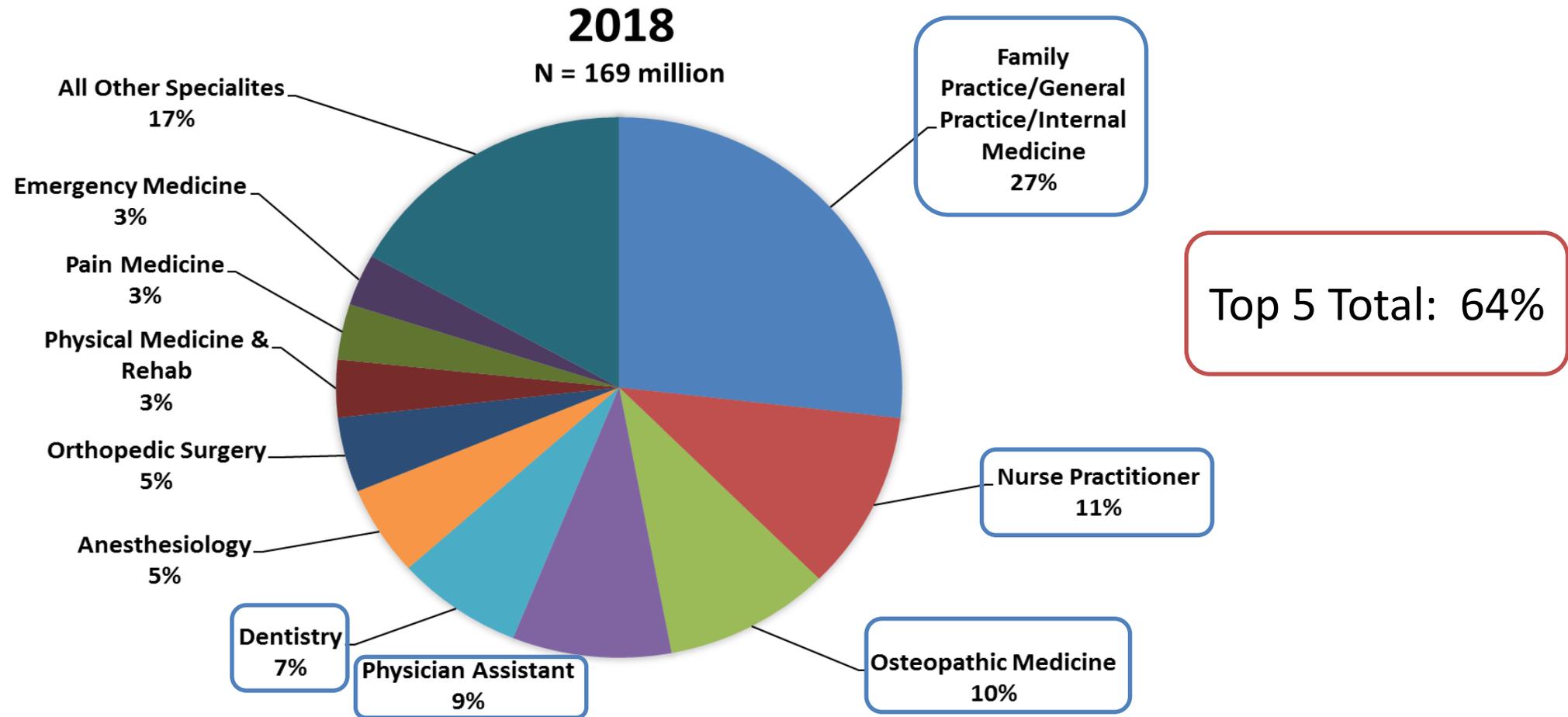
Evidence-based condition-specific prescribing amounts need to allow for prescribing flexibility as factors other than the condition/procedure may drive prescribing decisions.

Variations in patient pain experience

Socio-cultural differences in acceptance of opioid analgesic treatment

Considerations of social support and access to care (e.g., rural settings, insurance)

Opioid Analgesic Prescriptions: Top Prescriber Specialists



Source: IQVIA, National Prescription Audit (NPA). Year 2018. Data Extracted October 2019.
FDA/CDER/OSE

Opioid Analgesic Needs Vary by Condition/Procedure



| Procedure | Mean/(Range) Tablets Filled | Mean/Median Tablets Consumed | ~Days Used | ~Leftover Tablets |
|-------------------------------------|-----------------------------|------------------------------|------------|-------------------|
| Laparoscopic Inguinal Hernia Repair | 33 (15-70) | 9 | 1-2 | 24 |
| Outpatient Shoulder Surgery | 60 (n.d.)* | 37 (n.d.)* | 9-10 | 23 |
| Open Inguinal Hernia Repair | 30 (15-120) | 9 | 1-2 | 21 |
| Cesarean Delivery | 40 (5-80)* | 20* | 4-5 | 20 |
| Laparoscopic Cholecystectomy | 30 (0-100) | 10-12 | 2-3 | 20 |
| Laparoscopic Appendectomy | 30 (n.d.)* | 12* | 2-3 | 18 |
| Partial Mastectomy | 21 (0-50) | 3 | 1 | 18 |
| Partial Mastectomy with Node Biopsy | 23 (0-60) | 6 | 1-2 | 17 |
| Tooth Extraction | 28 (n.d.) | 13 | 2-3 | 15 |
| Upper Extremity Surgery | 30 (n.d.) | 14 (Bone); 9 (Soft Tissue) | 2-3 | 15 |
| Dermatologic Surgery | 9 (3-20) | 4 | 1 | 5 |

Hill, et al., *Ann Surg*, 2017; 2. Bateman, et al., *Obstet Gyn*, 2017; 3. Maughan, et al., *Drug Alc Dep*, 2016; 4. Harris, et al., *JAMA Dermatol.* 2013; 5. Bockman, et al. *J Pain*, 2017 (Abstract); 6. Kumar, et al. *AJSM*, 2017. N.D. is no data on the range. The asterisks are the medians rather than the means.

Table Source: Dr. Tamra Meyer (FDA/CDER/OSE)

Real-World Data to Assess Variation in Opioid Prescribing and Use for Acute Pain



1550 Patients from diverse populations



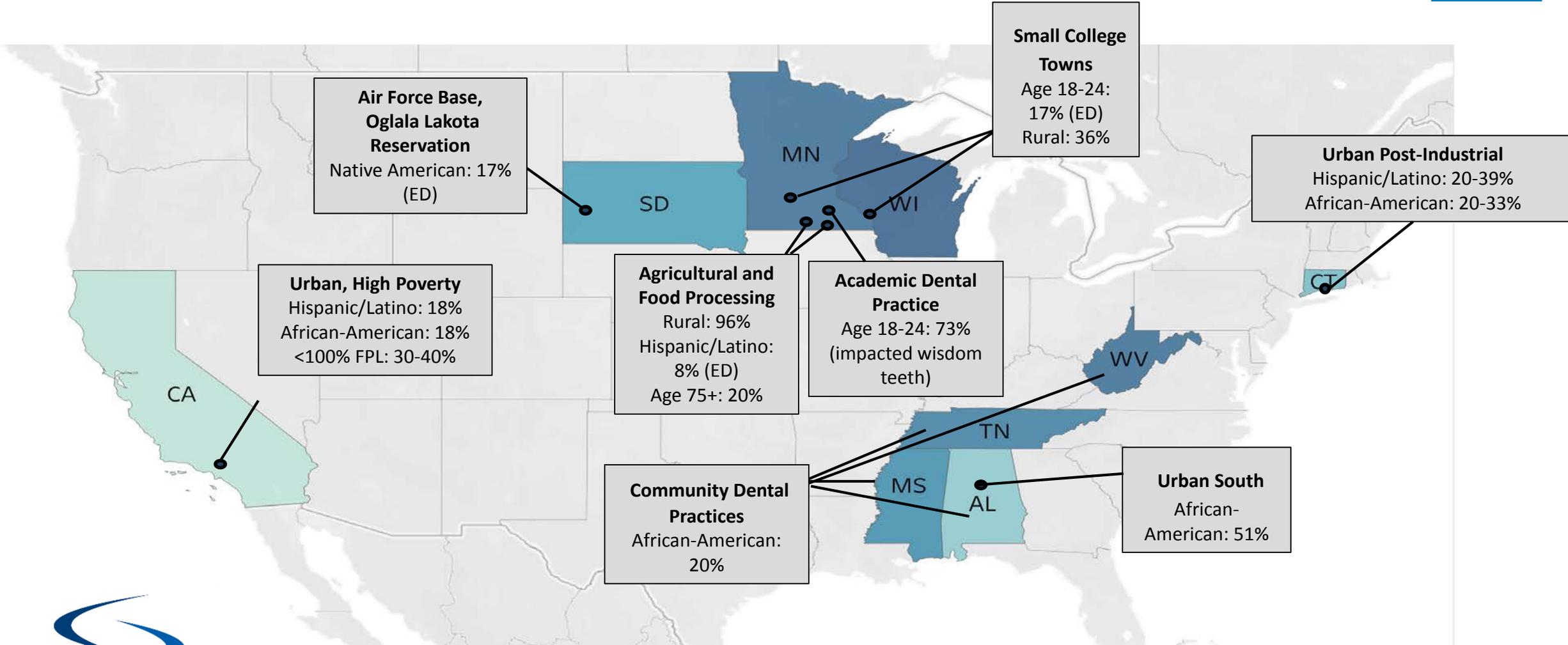
Collecting Data

Primary/Urgent Care
ED
Dental



Information on location, severity and daily consequences of pain; initial opioid prescription and later fills; management of pain; mood; and health outcomes.

Diverse Settings and Populations in 9 States



The Team

FDA Collaborators

Mitra Ahadpour- FDA/CDER/OTS
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Christopher StClair - FDA/CDER/OND
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FDA's Centers of Excellence in Regulatory Science and Innovation Collaborators

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Dentistry
Erik Hess - University of Alabama at Birmingham
Molly Jeffery - Mayo Clinic
Teryl Nuckols - Cedars Sinai Medical Center
Jessica Ritchie – Yale
Joseph Ross - Yale
Nilay Shah - Mayo Clinic
Stephen Tamang - Rapid City Regional Health



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Thank you!

Data and Analytics News from VA

Jonathan R. Nebeker MS MD

Acting CMIO Veterans Health Affairs

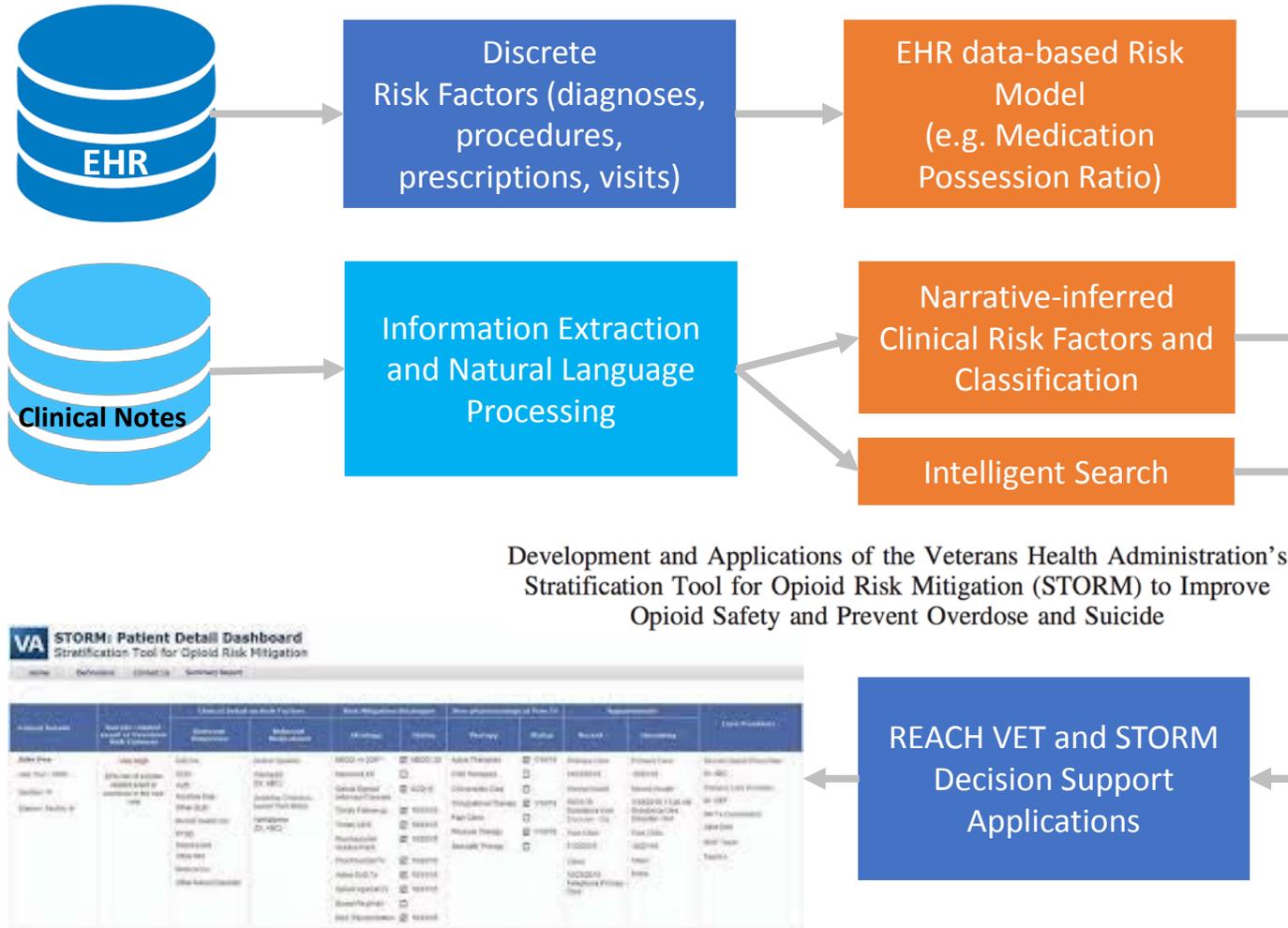
Professor of Medicine, University of Utah

What is VICTOR?

- Long-term commitment between VA (operations and research) for modernization of data and analytics platforms and for new advanced analytics products.
- DoD is joining VICTOR for the purposes of enhancing risk stratification models for suicide, opioid abuse, and traumatic brain injury.
- Provides access to
 - High performance computing environment
 - Engineers for data and analytics capabilities
 - Data scientists for machine learning and artificial intelligence

Predictive Analytics and Decision Support

Scaling and development of the new models for fast and comprehensive methods in support of suicide prevention, recovery, and opioid risk mitigation.



Impact to VA

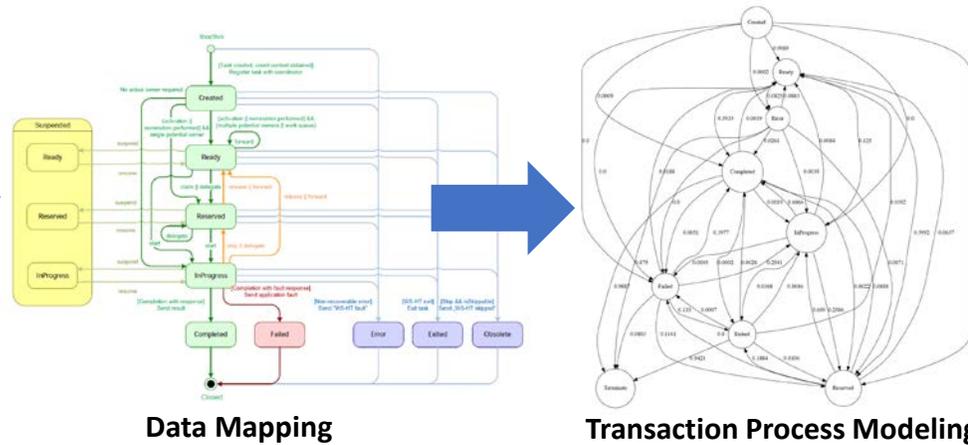
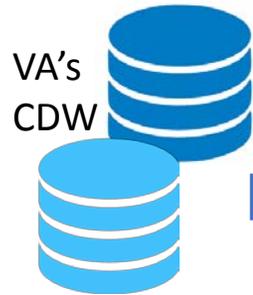
- Saves Lives
- Reduce time to act. Scale, and improve performance of the REACH VET and STORM predictive models.
- Improve coverage of the risk and reach models of the population at risk or needing assistance.
- Enables processing of the data that is currently not processable by VA (3.5B notes)
- Expansion of the current risk models to include risk factors in clinical narratives and other factors.

FDA Relevance: Predictive Modeling

- FDA can use the data from VA and select DoD models to get enriched data about actual use of drugs and devices. FDA does not need to do all of its own risk modeling.
- FDA can use the high-performance computing environment and modern surveillance software to run faster and more reliable algorithms on data.
- Speed: 14 days to 14 hours to 14 minutes to few minutes
- Reliability: discreet service runs independently of other algorithms.

Hazard Detection in Electronic and Human Processes

Towards an automated, near real-time hazard detection tool that reveals safety concerns and presents opportunities to improve HIT and safety



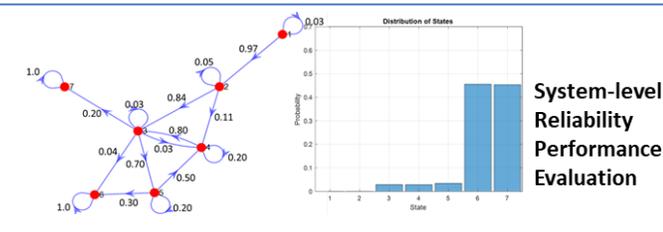
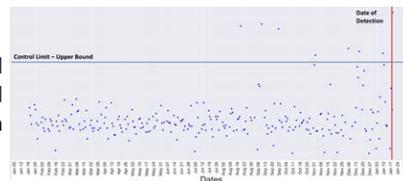
Impact to VA

- Scalable platform for hazard detection
- Reduced mean time to detect and mitigate Hazards
- Automated tool for improving patient safety
- Proactive approach for safe use of HIT



Automated Surveillance Tool for HIT

Event-based Hazard Detection

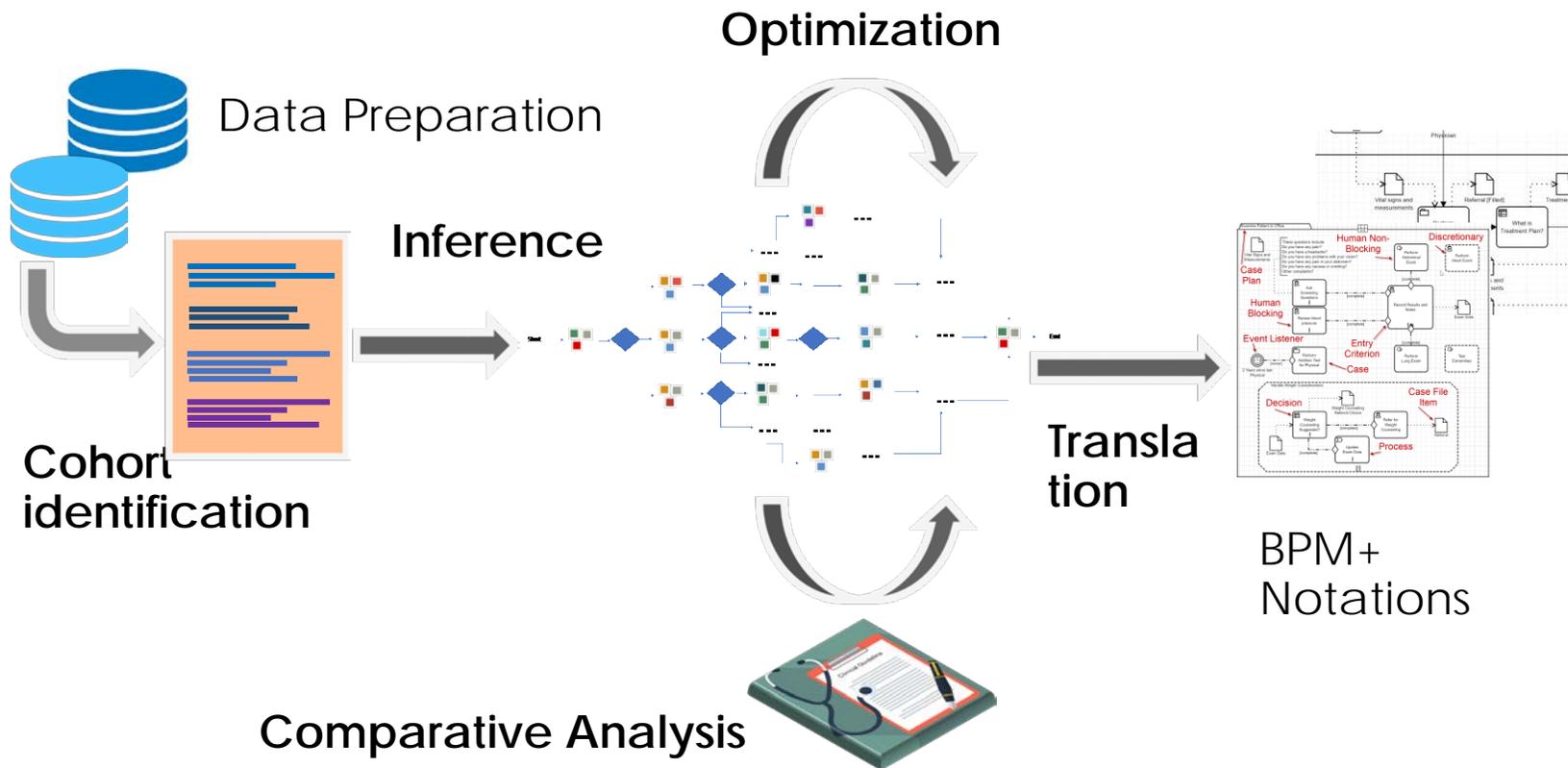


FDA Relevance: Hazard Detection/Process analysis

- The same analytical tools used for EHR task analysis can be applied to intelligent medical devices with data from audit trails.
- The methods are based on standards for tasks and should be generalizable to many different types of devices or could inform standards-based design of future devices.
- Recently, VA discovered over 15,000 radiology orders over two years that the EHR cancelled without provider knowledge. The detailed modeling and analysis helped diagnose 15 different causes.
- Now monitoring consult and laboratory orders

Clinical Pathway Analysis

Towards an automated, near real-time identification and characterization of critical clinical pathways for improve patients safety



Impact to VA

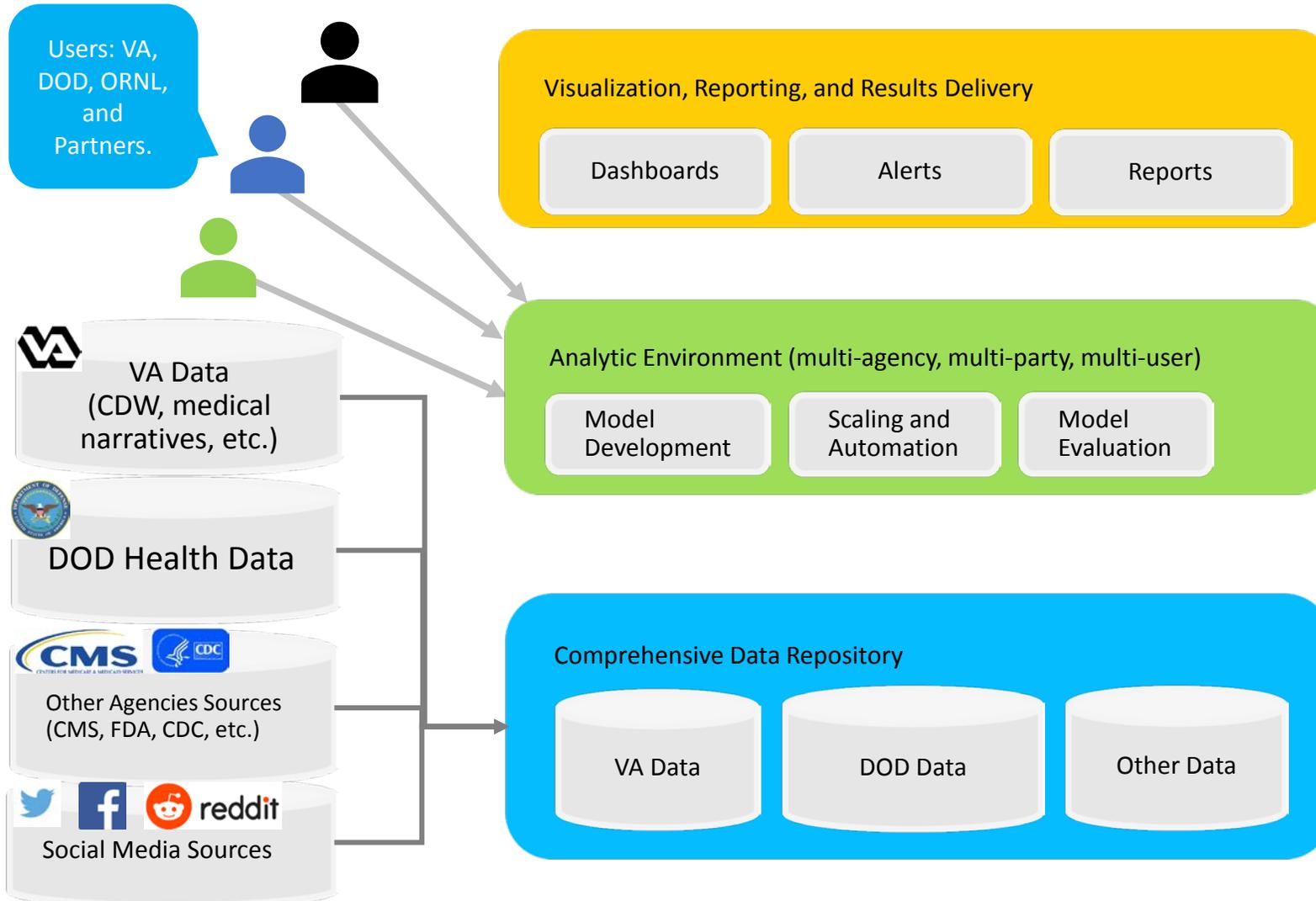
- Improvement of Quality of Personalized Care
- Cost Effective and Evidence-based Care Management
- Standardization of Care Procedure
- Reusable Analytics Framework for Various Diseases

FDA Relevance: Clinical Pathway Analysis

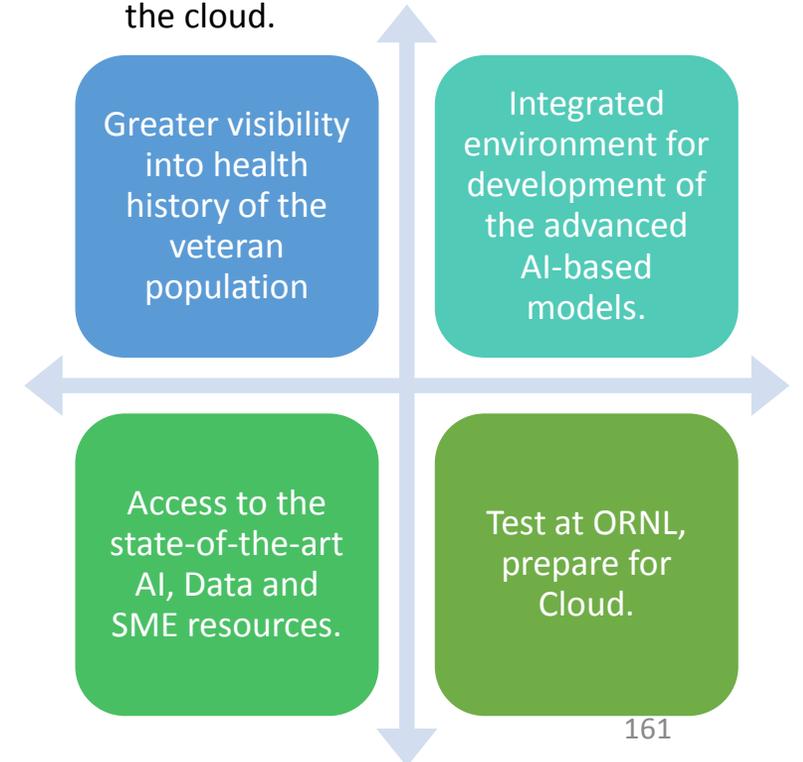
- FDA targets would include post-marketing surveillance.
- This pathway analysis looks at all pathways that patients take, not just the ideal pathway.
- The pathway analysis has not yet incorporated adverse or beneficial outcomes. This is the next step for the project.
- When outcomes are added, we can then look for positive and negative deviance from idealized pathways and protocols in post marketing trials to better understand actual use of drugs and real benefits and risks.

JIF – Joint Investment Funds: DOD-VA Partnership with ORNL

An integrated environment for the hosting, testing/evaluation and development of the advanced models over VA and DOD data, focused on high-priority use cases (e.g. REACH VET/STORM, etc.)



- Develop data and AI infrastructure
- Integrate DOD, VA and other data
- Test, develop and scale high-priority models
- Hosted co-development
- Prototype on ORNL's AI/HPC infrastructure
- Inform the architecture and prepare for the cloud.



FDA Relevance: VA-DoD collaboration

- Provides an example of how other agencies can benefit from a collaboration with VA and DoE.
 - Better data
 - Better analytics
 - Better workflows
- VA and DoD data
 - VA data updated daily, DoD data to be updated monthly (now) to daily (later).
 - Inpatient and outpatient structured clinical data
 - VA clinical notes (3 billion)
 - VA and DoD inpatient pharmacy dispenses. VA outpatient dispense data.
 - Some benefits and hospital data
 - ICU and anesthesia device data (future from VA)
 - Data from other federal agencies (monthly to quarterly) CMS, SSA, CDC

Data and Analytics Product Line

- Consolidates projects and technologies into one IT group.
 - Warehouses
 - Analytical systems
 - Discovery systems
- Modernizes by transitioning capabilities to new data and analytics platform (ORNL model)
 - Backlog management
 - Lifecycle management
- Partnership among CDO, CTO, CMIO



CMS QUALITY IMPROVEMENT NETWORKS: OPIOIDS AND HEALTH DISPARITIES

Jade Perdue, MPA

Director, Division of Quality Improvement Innovation
Models Testing

Quality Improvement Innovation Group
Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services



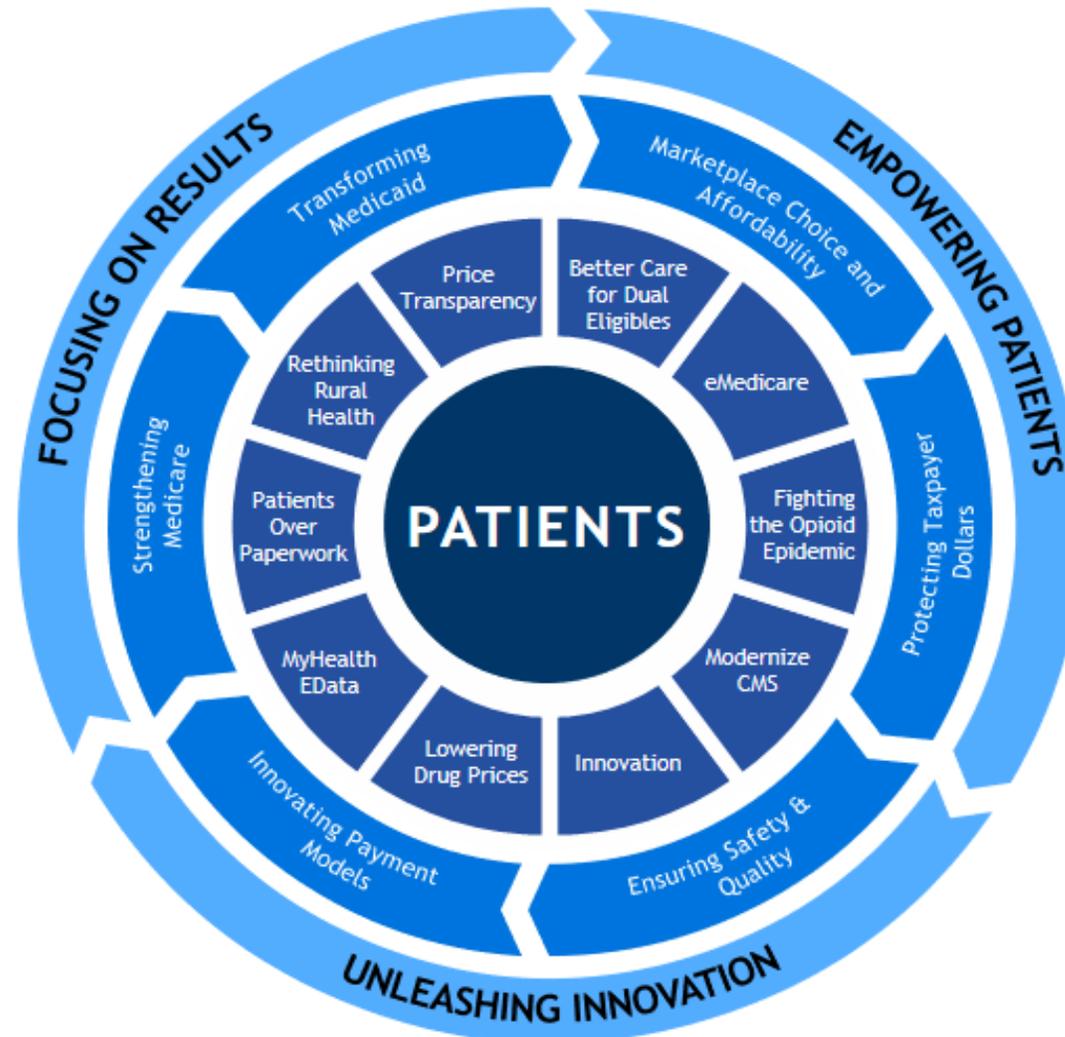
CMS STRATEGIC PRIORITIES 2019

The 2019 CMS strategy is built on one main goal:

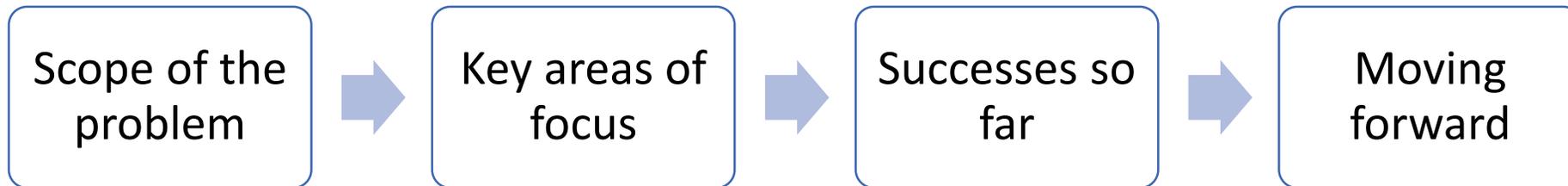
PUT PATIENTS FIRST



CMS STRATEGIC PRIORITIES



CMS ROADMAP FIGHTING THE OPIOID CRISIS—OVERVIEW



To view the entire CMS Opioids Roadmap, go to

[CMS.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf](https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf)



KEY AREAS OF CMS FOCUS

As one of the largest payers of healthcare services, CMS has a vital role in addressing the opioid epidemic and is focused on three key areas:



PREVENTION

Manage pain using a safe and effective range of treatment options that rely less on prescription opioids



TREATMENT

Expand access to treatment for opioid use disorder



DATA

Use data to target prevention and treatment efforts and to identify fraud and abuse



Moving Forward

PREVENTION



Significant progress has been made in identifying inappropriate prescribing patterns

TREATMENT



Medicare, Medicaid, and private health plans provide some coverage for pain and opioid use disorder treatments

DATA



Data provides insight into doctor, pharmacy, and patient use of prescription opioids and effectiveness of treatment

CMS CAN BUILD ON THESE EFFORTS TO FURTHER:

1. **Identify** and stop inappropriate prescribing of opioids
2. **Enhance** diagnosis of OUD to get people the support they need earlier
3. **Promote** effective, non-opioid pain treatments

1. **Ensure** access to treatment across CMS programs and geography
2. **Give** patients options for a broader range of treatments
3. **Support** innovation through new models and best practices

1. **Understand** opioid use patterns across populations
- Promote** sharing of actionable data across continuum of care
- Monitor** trends to assess impact of prevention and treatment efforts

IMPLEMENTING THE SUPPORT ACT

The SUPPORT for Patients and Communities Act was enacted on October 24, 2018. CMS is implementing a number of new initiatives under that law that aim to increase options for treating beneficiaries with opioid use disorder, ensure prescriber accountability and improved safety for patients across CMS programs, and illuminate Medicaid prescribing data.



CMS UTILIZES ALL LEVERS TO IMPROVE QUALITY AND LOWER COSTS

1. **Paying for value** in FFS and through Innovation Center models
2. **Health and safety regulations**, which hold providers accountable for outcomes
3. **Enforcement of regulations** with a focus on consistency and standardization
4. **Quality Measurement** as a foundational component of an outcomes-focused value driven system
5. **Quality Improvement networks** to spread best practices and help health systems transform how they deliver care



CMS QUALITY IMPROVEMENT CONTRACTORS AND OPIOID DISPARITIES



CMS HAS ESTABLISHED A NETWORK OF ACTION-FOCUSED CONTRACTORS TO SUPPORT STATE AND LOCAL QUALITY IMPROVEMENT AND TO GENERATE RESULTS FOR PATIENTS

Hospital Quality Contractors

- 4,042 Hospitals



Clinical Practices Initiative

- 140,000+ Clinicians



End Stage Renal Disease Networks

- 7,000+ Dialysis Facilities



Beneficiary and Family Centered Care (BFCC) Quality Improvement Organizations

- ~800,000 Reviews Performed



Quality Innovation Networks – Quality Improvement Organizations

- 400 Communities
- 12,000+ Nursing Homes
- 3,800 Home Health Organizations
- 300 Hospice
- 1,700 Pharmacies
- 350,000+ Clinicians



MACRA and Quality Payment Program - Small, Underserved, Rural Support (SURS)

- Up to 200,000 Clinicians



12TH SOW- 5 AIMS

- Improve behavioral health outcomes, focusing on decreased opioid misuse
- Increase patient safety
- Prevention & management of chronic disease
- Increase quality of care transitions
- Improve quality & patient safety in long-term care settings



HOSPITAL QUALITY HEALTH EQUITY EFFORTS:

Disparities Impact Statements (DIS) serve to:



- Use data to identify vulnerable populations and differences between populations (outcomes, prevalence, etc.)
- Engage stakeholders/communities
- Set SMART aims and develop action plans, with targeted interventions, that close identified disparate gaps between populations
- Monitor and PDSA interventions and outcomes



DISPARITIES IMPACT STATEMENTS HIGHLIGHTING OPIOIDS

- Developed interactive hospital performance dashboards that allows hospitals to stratify opioid related data (i.e. opioid daily average dose) by race, ethnicity, age, payor and other socioeconomic factors.
- Identify areas with lack of access to Medication Assisted Therapy (MAT) providers (MAT deserts) and increasing provider training and use of MAT with ECHO Model hubs.
- Utilize the Area of Deprivation Index (ADI) to identify and then target interventions at hospitals where the majority of the opioid incidences are occurring (i.e. 80% of opioid events happen at 20 hospital in the state).
- Examine racial-ethnic disparities with opioid prescriptions given in ED vs. opioid prescriptions given at discharge for both non-definitive conditions (i.e. tooth ache, abdominal pain, back pain) and definitive conditions (i.e. long bone fractures, kidney stones).



HOSPITAL SUCCESSES IN RURAL AMERICA

IOWA HEALTHCARE COLLABORATIVE – 10.7% IMPROVEMENT IN ADE

- Background
 - Approximately 80% of the contractor's 152 hospitals are rural critical access
- Interventions
 - Compass Data Portal
 - Reduces hospital burden around data collection and reporting
 - Hospitals can report self-report data, as well as view run charts, reports, and dashboards
 - If hospitals report into the State Inpatient Dataset or NHSN monthly, these data are populated into the portal's database for real-time report access
 - Opioid Guardianship Project
 - Provides clinicians with evidence-based practices
 - Developed and disseminated tools around comfort and pain management
 - Oct. to Dec. 2017: Educated over 1,000 community dwelling adults in over 15 communities on the opioid epidemic
 - Project has engaged 33 CAHs and 9 rural hospitals



THANK YOU

- For the hard work you are doing to improve and transform our nation's healthcare system.
- For your leadership and teaming with Patients, Providers, Quality Improvement Organizations, CMS and one another.
- For your commitment and actions to improve the care of the patients we serve.



Indian Health Service

Response to the Opioid Crisis

IHS National Committee on Heroin, Opioids, and Pain Efforts (HOPE Committee)

CAPT CYNTHIA GUNDERSON

CHAIR, IHS HOPE COMMITTEE

PUBLIC MEETING ON STRATEGIES TO IMPROVE HEALTH
EQUITY AMIDST THE OPIOID CRISIS

NOVEMBER 21, 2019



Opioid Overdose Death Rates

CDC data indicates that American Indians and Alaska Natives (AI/AN) had the second highest overdose death from rates from all opioids in 2017 (15.7 deaths/100,000 population) among racial/ethnic groups in the US

AI/AN had the highest overdose death rate for prescription opioids (7.2)

AI/AN had the second highest overdose death rates from heroin (5.2)

AI/AN had the third highest from synthetic opioids (6.5)

The overall rate of overdose deaths for AI/AN has increased by **13%** between 2015-2017

Scholl L, et. al., Drug and opioid involved overdose deaths- United States, 2013-2017, *MMWR*, Vol 67 (51 & 52) Jan. 4, 2019, pp 1419-1427.



Opioid Misuse

Self-reported prevalence of illicit drug use and prescription misuse, 18-25 years old (2018)

| | AI/AN | All Young Adults |
|-----------------------------|-------|------------------|
| Prescription opioid (18-25) | 7.4% | 5.5 % |
| Methamphetamine (18-25) | 2.5% | 0.8 % |
| Methamphetamine (26 +) | 2.6% | 0.7% |

SAMHSA 2018 National Survey on Drug Use and Health—Office of Applied Studies





Reducing Barriers to Recovery

- IHS is committed to expanding access to Medication Assisted Treatment services
 - SGM on MAT
 - IHM Chapter 38- Internet Eligible Controlled Substance Provider Designation
 - Maternal & Child Health Initiatives
 - Workforce Training Program



Addressing Safe Prescribing Practices

- IHS Opioid Stewardship
 - Policy: Chapter 30 & 32
 - IHS Acute Dental Pain Prescribing Guideline
 - Workforce Development
 - Essential Training in Pain and Addictions
 - Increased access to non-pharmacologic approaches for pain management – Auricular Acupuncture





Assuring Access to Naloxone

- First Responder Toolkit
- Co-prescribing initiatives
- Harm Reduction Initiatives







Innovative Initiatives to Address the Opioid Crisis

Health Resources and Services Administration

**Public Meeting on Strategies to Improve Health Equity Amidst
the Opioid Crisis**

Food and Drug Administration

Office of Minority Health and Health Equity

November 21, 2019

Vision: Healthy Communities, Healthy People



Substance Use Disorder and Mental Illness in the United States

- An estimated **21.2 million** Americans aged 12 or older need substance use disorder treatment
- Approximately **9.2 million** American adults have both a substance use disorder and a mental illness – about **4.5 million** of these adults do not receive treatment for either issue



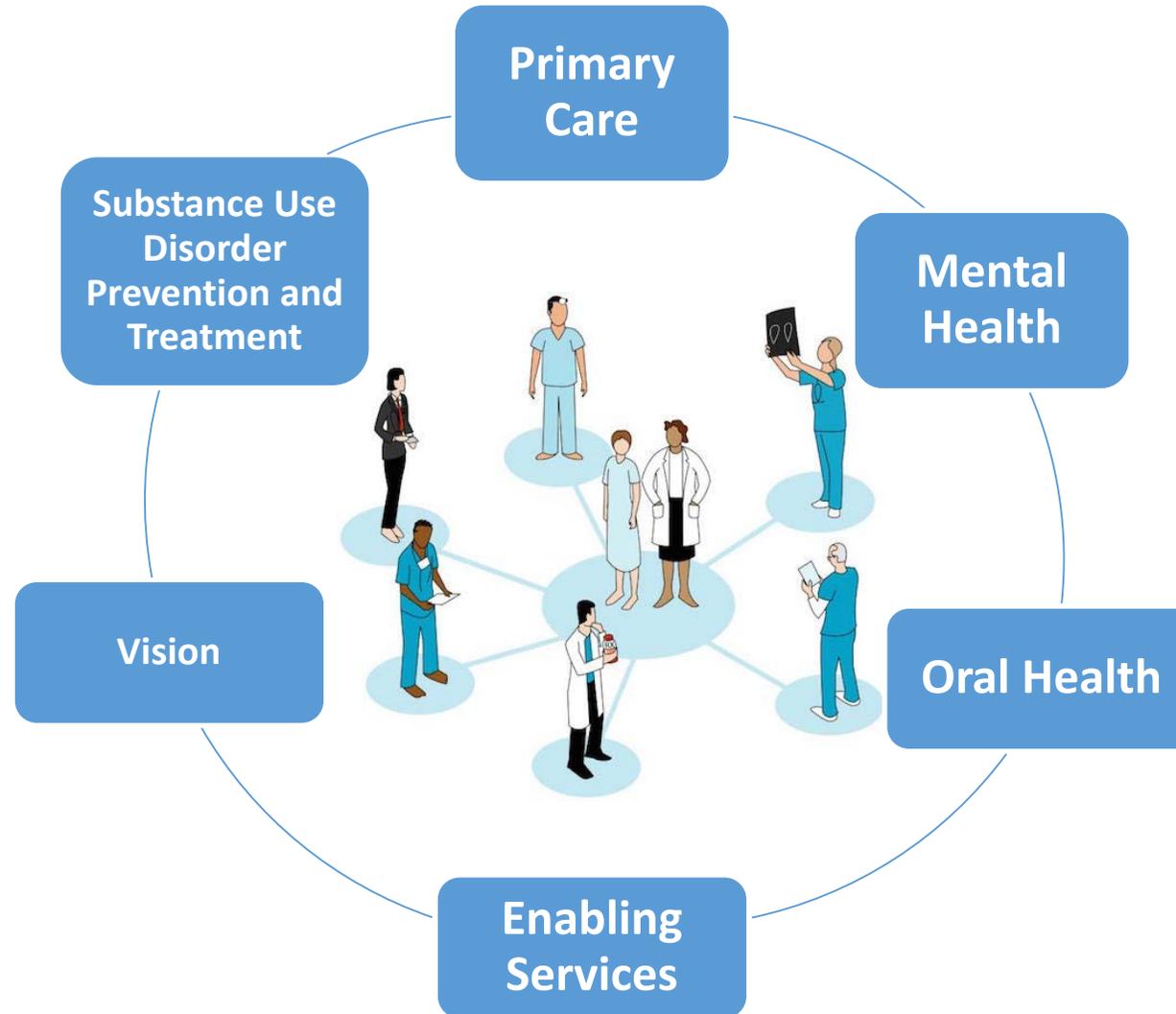
2019 National Survey on Drug Use and Health (NSDUH), SAMHSA (2018 Data)

HRSA
Health Resources & Services Administration

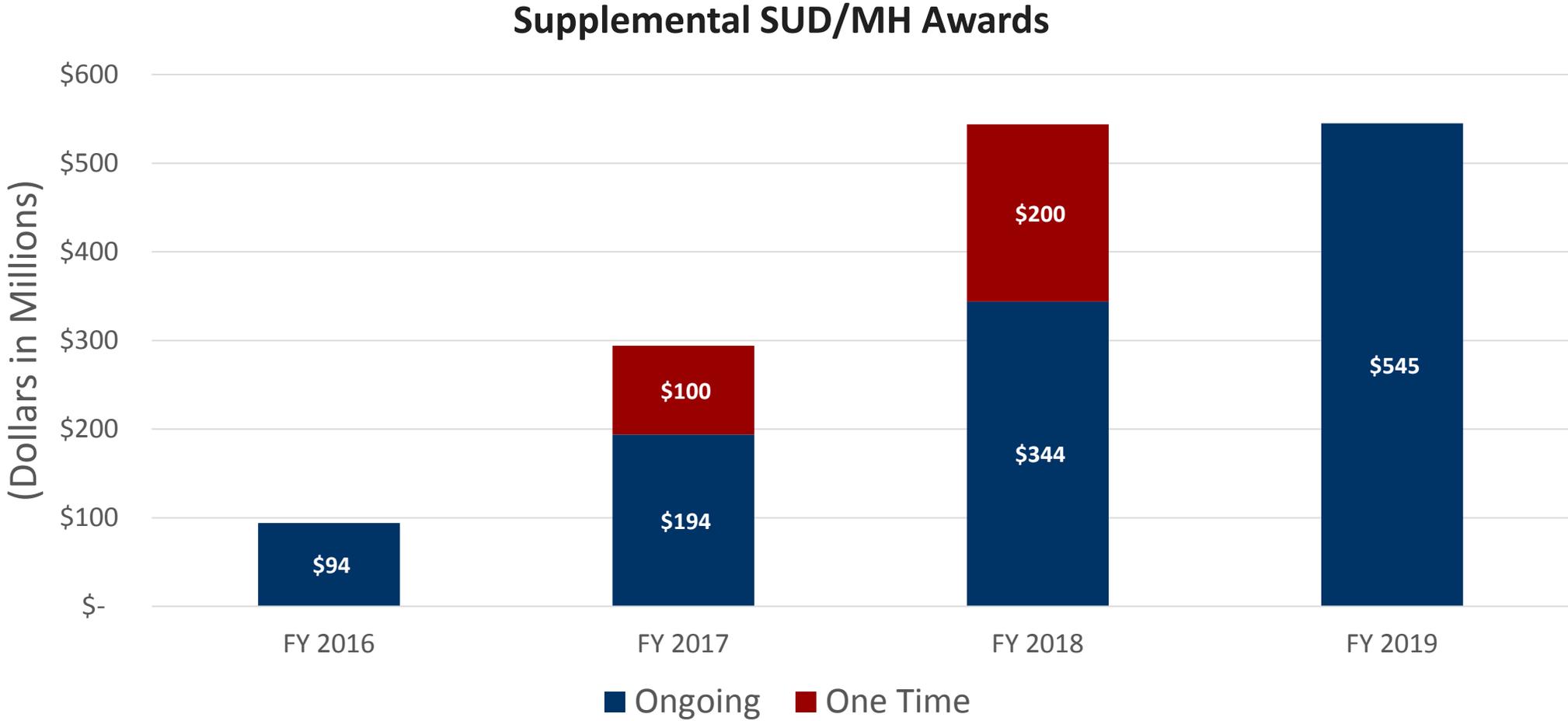
HRSA's Approach to Addressing Substance Use Disorder

- Expanding access through health centers and other primary care settings
- Enhancing substance abuse prevention and treatment in rural communities
- Expanding and training the workforce to better prevent and treat opioid addiction
- Supporting key national, state, and local infrastructure to accelerate change in MCH

Care Model at HRSA-Funded Health Centers



HRSA Investments in Behavioral Health Services



Growth in HRSA Health Center Program Services

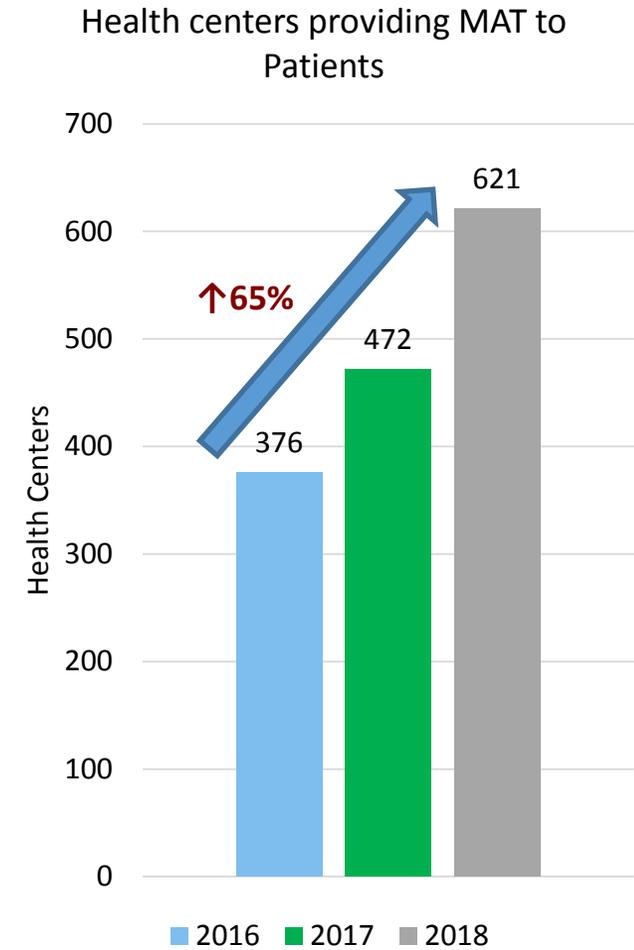
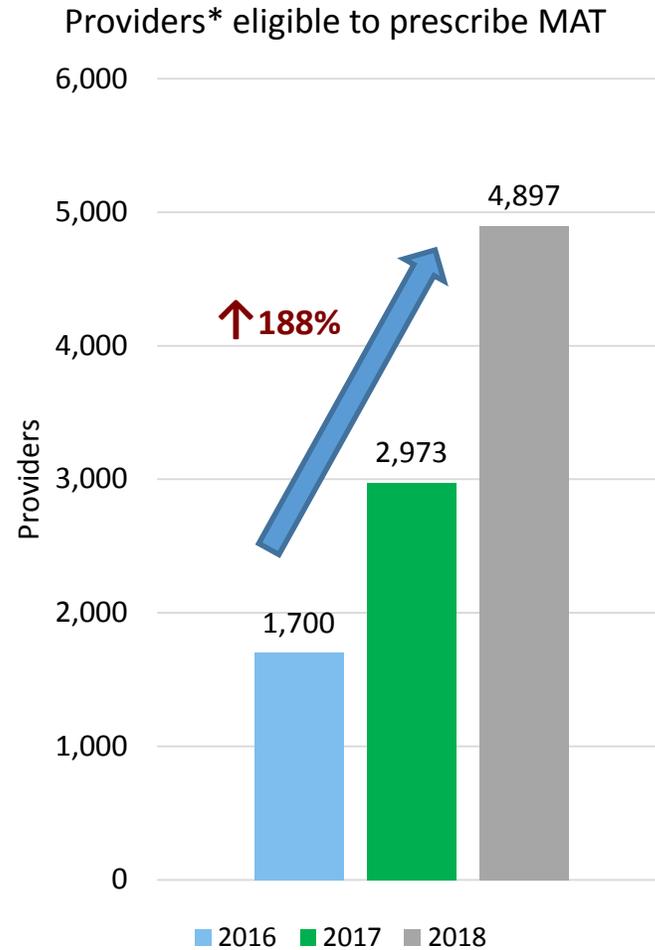
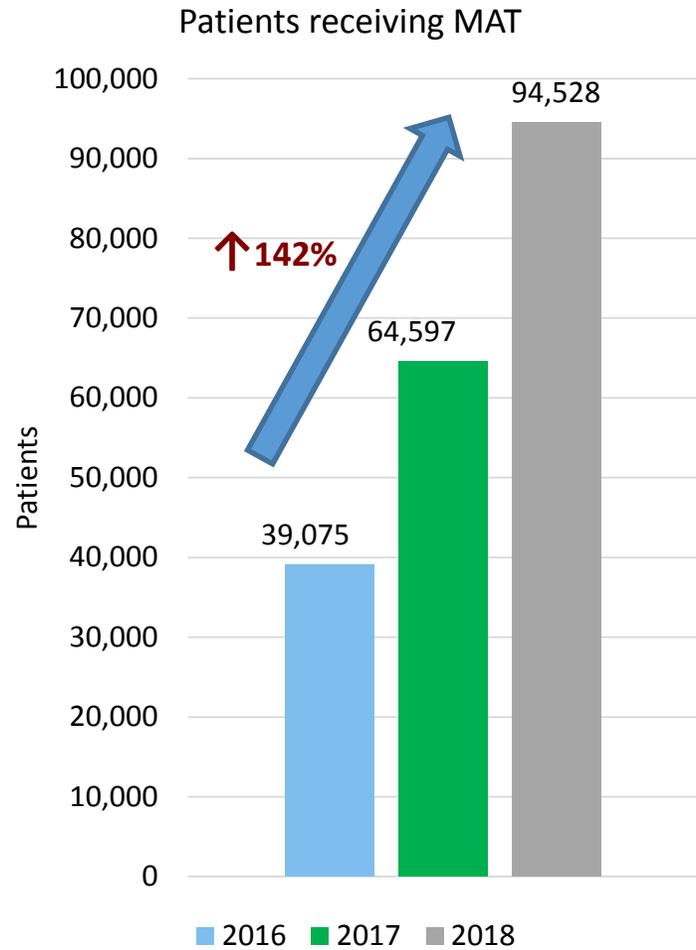
| | 2016 | 2017 | 2018 | Δ 2016 -2018 | % Δ 2016-2018 |
|---------------------------------------|-----------|-----------|------------|--------------|---------------|
| Total Patients | 25.9M | 27.2M | 28.4M | 2,519,384 | ↑ 9.74% |
| Total Visits | 104.1M | 110.4M | 115.8M | 11,699,981 | ↑ 11.24% |
| Mental Health (MH) Patients | 1,788,577 | 2,049,194 | 2,249,876 | 461,299 | ↑ 25.79% |
| Total MH Visits | 8,508,031 | 9,876,669 | 10,804,170 | 2,296,139 | ↑ 26.99% |
| Substance Use Disorder (SUD) Patients | 141,569 | 168,508 | 223,390 | 81,821 | ↑ 57.80% |
| SUD Visits | 1,135,218 | 1,227,629 | 1,483,827 | 348,609 | ↑ 30.71% |
| Depression Screening and Follow-Up | 60.34% | 66.15% | 70.57% | 4.42% | ↑ 10.23% |



Source: Uniform Data System, 2016-2018



Medication Assisted Treatment (MAT)



*Definition of MAT providers expanded to include physician assistants & certified nurse practitioners, in 2017.



Rural Communities Opioid Response Program (RCORP)

- Multi-year initiative developed in FY 2018 with \$100 million appropriation; additional \$120 million appropriation in FY 2019
- Provides funding and technical assistance directly to rural communities to strengthen their capacity to address the opioid epidemic
- Website: hrsa.gov/rural-health/rcorp

The screenshot shows the HRSA website page for the Rural Communities Opioid Response Program. The page features a navigation bar with links for FORHP Home, Funding Opportunities, Resources, and About Us. A search bar is located in the top right corner. The main content area includes a breadcrumb trail, the program title, and a 'Recent Awards' section with four bullet points. A 'Contact Us' sidebar is on the right, and a 'RCORP Initiatives' sidebar is at the bottom right. The main text describes the program's purpose and funding details.

HRSA
Health Resources & Services Administration

FORHP Home | Funding Opportunities | Resources | About Us

Home > Federal Office of Rural Health Policy > Rural Communities Opioid Response Program

Rural Communities Opioid Response Program

Recent Awards

- [RCORP-Implementation Awards](#)
\$1 million each to 80 rural consortia
- [RCORP-Medication-Assisted Treatment \(MAT\) Expansion Awards](#)
Up to \$725,000 each to 12 recipients
- [RCORP-Centers Of Excellence On Substance Use Disorders \(CoEs\) Awards](#)
\$6.6 million each to three recipients
- [RCORP-Evaluation Award](#)
\$3 million to one recipient

The Rural Communities Opioid Response Program (RCORP) is a multi-year initiative supported by the Health Resources and Services Administration (HRSA) to address barriers to access in rural communities related to substance use disorder (SUD), including opioid use disorder (OUD).

RCORP funds multi-sector consortia to enhance their ability to implement and sustain SUD/OUD prevention, treatment, and recovery services in underserved rural areas.

The [National Health Service Corps](#) is a collaborator on this initiative to address SUD provider shortages in rural communities.

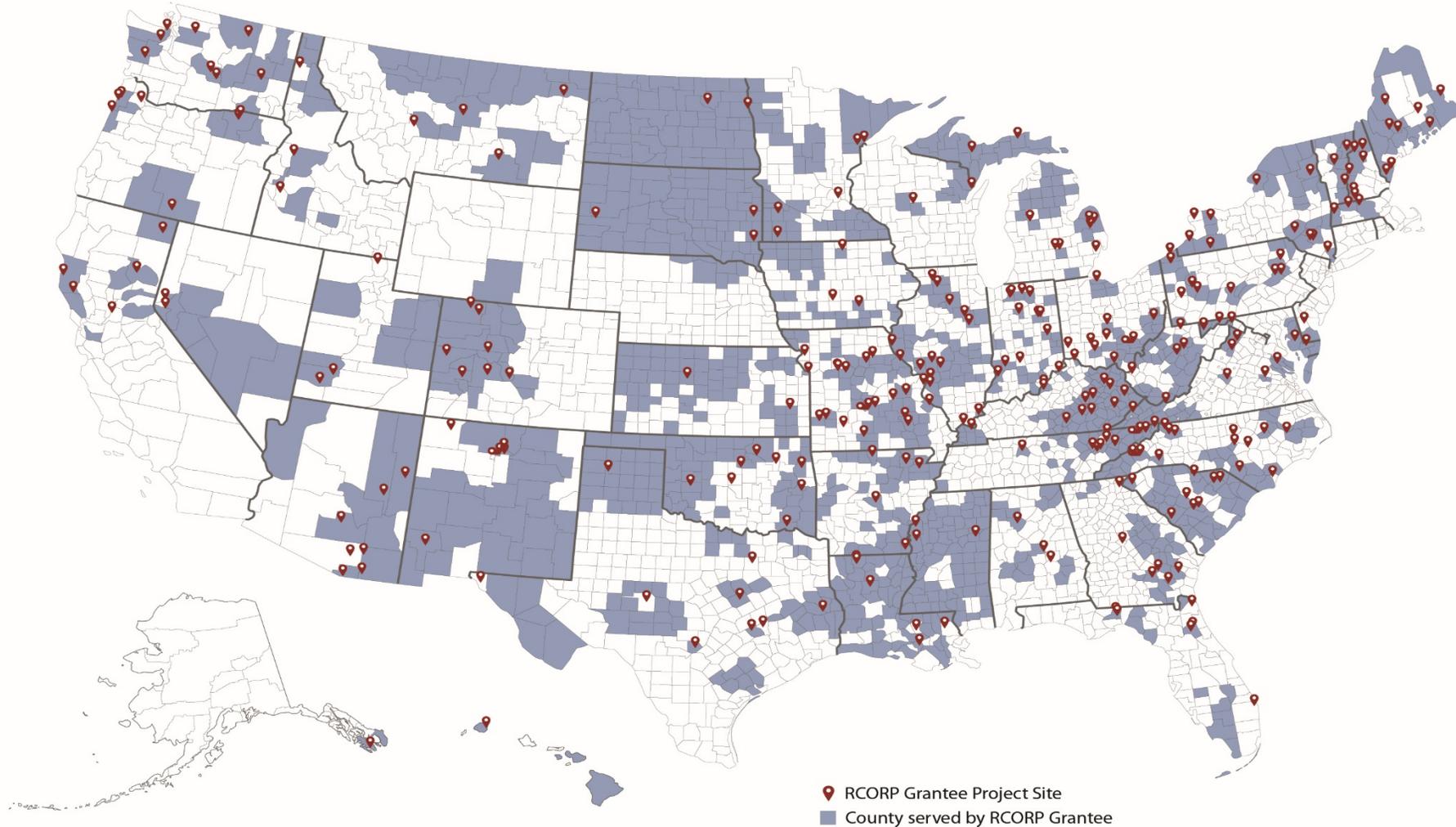
Visit [HRSA's Opioid Crisis page](#) for information about HRSA's comprehensive response to the opioid crisis.

Contact Us
Questions about HRSA's efforts to combat the opioid epidemic in rural communities? [Email us.](#)

RCORP Initiatives
Learn more about our RCORP initiatives.
[RCORP Overview](#)
[Planning](#)
[Implementation](#)
[MAT Expansion](#)
[Centers of Excellence](#)
[Technical Assistance](#)
[Evaluation](#)

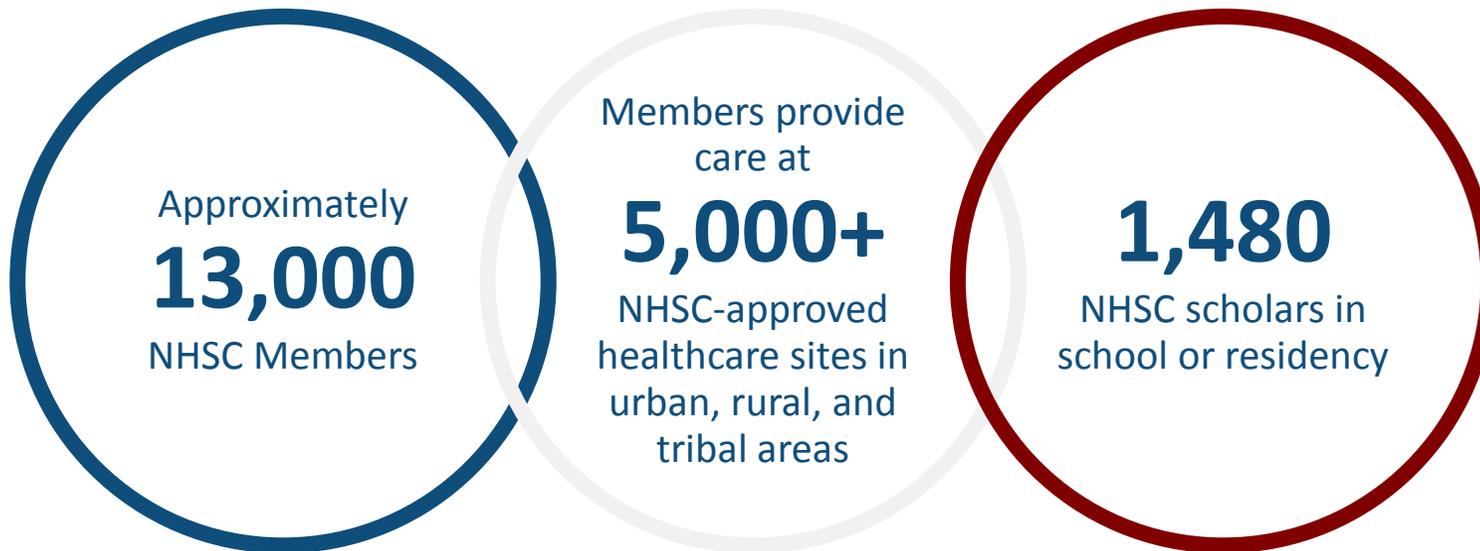


Current RCORP Grantee Sites



Improving Workforce Distribution through NHSC

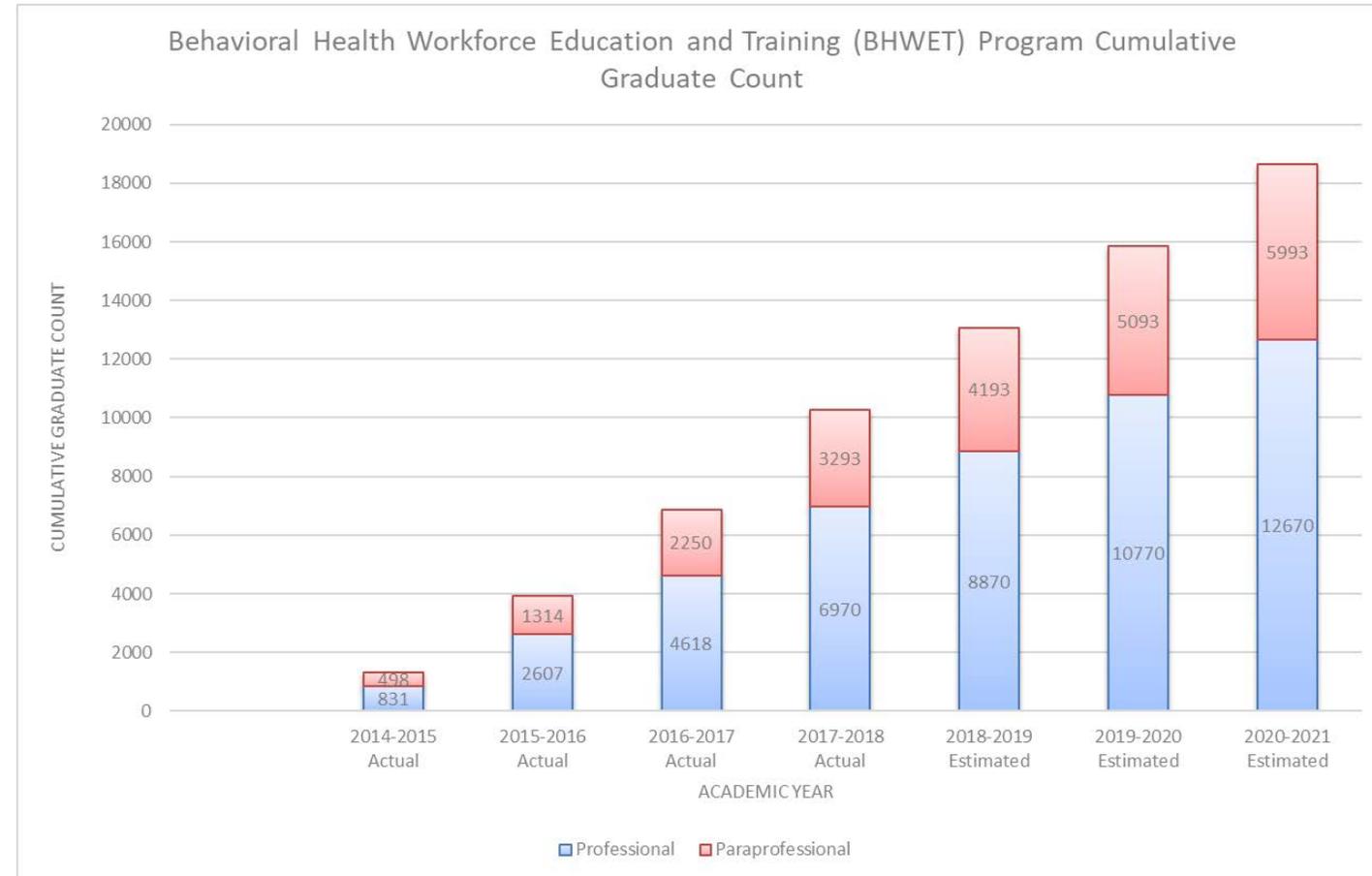
- Behavioral health has grown to 31% of the total NHSC Field Strength, and represents the largest discipline of all NHSC providers.
- In fiscal year 2018, 4,074 NHSC clinicians provided behavioral health services including almost 1,250 new substance use disorder providers.



- NHSC clinicians care for 13.7 million Americans
- Over 60% NHSC clinicians serve in HRSA-funded health centers
- Over 30% of NHSC clinicians serve in rural communities

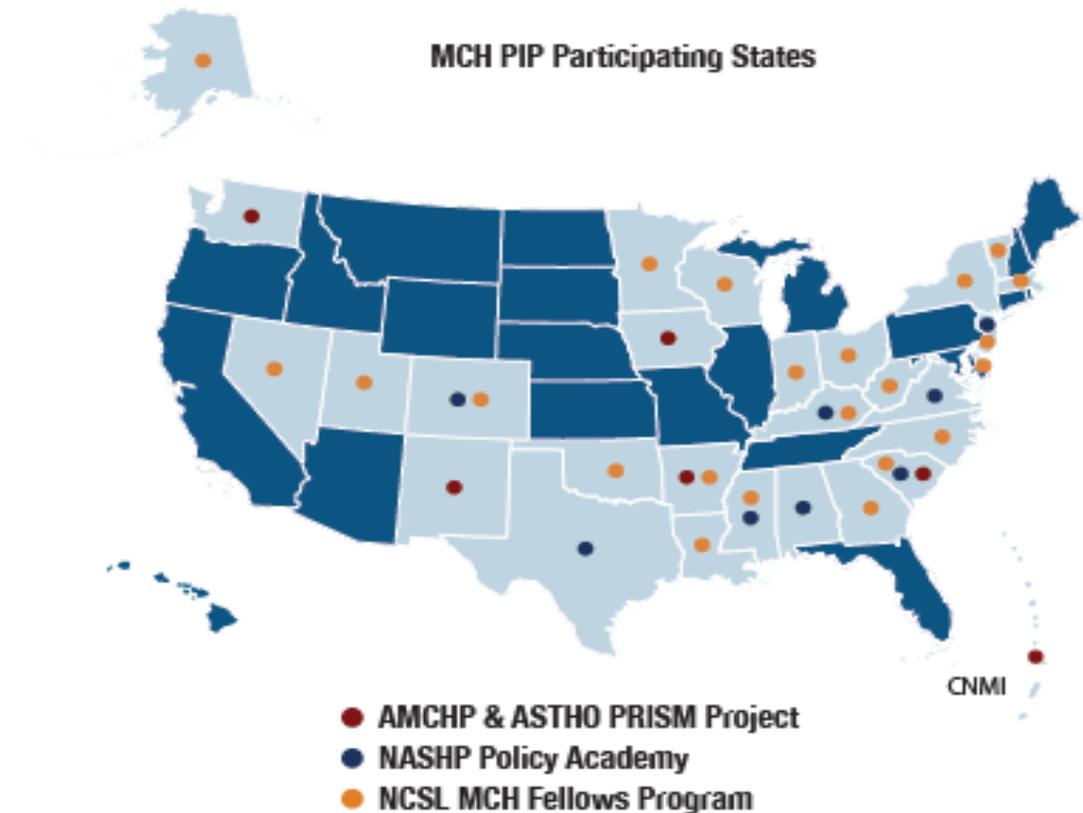
The Behavioral Health Workforce Education and Training Grant Program (BWHET)

- \$50 million investment.
- Trains master's-level behavioral health students, psychology doctoral interns and students in community and technical colleges (paraprofessionals) to expand the behavioral health workforce.
 - 136 awards made
- \$8 million FY18 supplement supports training for additional students to serve in HRSA-supported Health Centers.
 - 21 awards made
- 3 million cumulative hours of service in medically underserved communities



Maternal and Child Health

- **Supporting State Maternal and Child Health Policy Innovations Program (MCH PIP)**
 - Support for state policy initiatives that improve access to quality health care for the MCH population



HRSA Funded Telehealth Resource Centers

TelehealthResourceCenters.org



TRC's have a mission to serve as a focal point for advancing the effective use of telehealth and support access to telehealth services in rural and underserved communities.



TRC Services

- Provide technical assistance, individual consultation, training, and support for healthcare providers and entities planning or providing telehealth services
- Disseminate information or research findings related to telehealth services
- Online web presence – www.telehealthresourcecenters.org
- Monthly National Webinars
- Support effective collaboration among other TRCs
- Conduct evaluations to determine the best utilization of telehealth technologies
- Conduct organizational telehealth assessments
- Understand telehealth regulations, reimbursement models, and parity laws in states



Promising Practices From The Field

1. Integrate psychotherapy (both individual and group) with medical interventions
 - E.g., Schedule a patients' group therapy on same days they meet with their prescriber
2. Invest in multi-disciplinary care teams that include both clinicians and enabling services staff (e.g., community health workers)
3. Convene an interdisciplinary team to review and improve its controlled substance prescribing and dosing
4. Develop a network of trusted community partners and organizations
5. Provide substance use disorder and mental health evaluation, assessment, and treatment services in the field
 - E.g., Mobile health vans and community outreach teams

LESSONS
LEARNED





Connect with HRSA

To learn more about our agency, visit

www.HRSA.gov

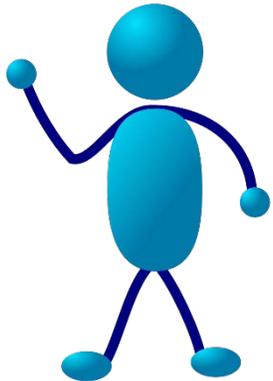


Sign up for the HRSA *eNews*

FOLLOW US:



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Health Resources and Services Administration

U.S. Department of Health and Human Services

Aross@hrsa.gov



Questions?



BREAK



Session 3

Innovative Initiatives and Research to
Address the Opioid Crisis
(Part II)

FDA Innovation Challenge: Devices to Prevent and Treat Opioid Use Disorder

Kimberly Brown Smith, M.D., Ph.D.
Lead Medical Officer
Clinical and Scientific Policy Staff
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Disclosure

I have no financial conflicts.

The Opioid Crisis: FDA's Priorities & Strategies



1. Decreasing Exposure & Prevent New Addiction



Appropriate Dose/Duration Labeling



Appropriate Packaging, Storage, and Disposal



Health Care Provider Education

2. Supporting the Treatment of Those With Opioid Use Disorder



Naloxone



Medication Assisted Treatment (MAT)

3. Fostering the Development of Novel Pain Treatment Therapies



Partnerships & Meetings



Abuse Deterrent Formulations (ADFs)



Pain Treatment Alternatives

4. Improving Enforcement & Assessing Benefit-Risk



Improving Enforcement



Assessing Benefit-Risk

FDA's Efforts to Combat The Opioid Crisis

- In the past few years, FDA has cleared, granted, or approved more than 200 devices related to the treatment or management of pain
- Examples include:
 - 10 devices with new or novel technologies, such as brain and spinal cord stimulators to relieve pain and reduce the need for opioid drugs to patients suffering from either acute or chronic pain
 - A new indication for an electric stimulation device for use in helping to reduce the symptoms of opioid withdrawal
 - A medical app intended to help those with opioid use disorder stay in recovery programs

Overview of the Innovation Challenge

June 1-September 30, 2018



Challenge Goals:

- Innovative and creative approaches to the use of medical devices in combatting the U.S. opioid crisis
- Development of non-opioid treatments for acute and chronic pain
- Expedited development and review of innovative, safe and effective medical devices to help prevent and treat opioid use disorder



Overview of the Innovation Challenge

Eligibility

- Any medical device that prevents or treats opioid use disorder, including:
 - Diagnostic Devices
 - Therapeutic Devices
 - Digital Health Technologies (e.g., mobile medical apps)
 - Combination Products: primary mode of action is by the device
- Medical devices at any stage of development were eligible
- U.S.-based and foreign applicants were eligible to apply
- Per federal law, foreign firms needed a U.S. representative to market a device in the U.S.

Factors Considered in Selecting Submissions



- Intended use
- Novelty of the medical device/concept
- Development plan for the medical device
- Development team
- Anticipated benefit of the device
- Impact on public health as compared to other available alternatives



Applicants Selected for the Challenge

| Company | Product Name | Category |
|--------------------|--|-----------------------------|
| Algomet Rx, Inc. | Rapid Drug Screen | Monitoring |
| Avanos | Withheld Per Company Request | Other |
| Brainsway, Ltd | Brainsway Deep Transcranial Magnetic Stimulation (DTMS) Device | Opioid Use Disorder Therapy |
| CognifiSense, Inc. | Virtual Reality Neuropsychological Therapy (VRNT) | Pain Therapy |
| iPill Dispenser | iPill Dispenser | Medication Dispensing |
| Masimo Corporation | Withheld Per Company Request | Overdose Therapy |
| Milliman | Opioid Prediction Service | Diagnostic |
| ThermoTek, Inc. | NanoTherm™ and VascuTherm™ Systems | Pain Therapy |



Breakthrough Device Program Features

- Breakthrough Device Sprint Discussions
- Data Development Plan Coordination
- Clinical Protocol Agreement
- Other Pre-submission for Designated Breakthrough Device
- Regular Status Updates

Technology Innovation to Combat Opioids Group FDA Participation

1

Evaluation of
next
generation
opioid
overdose
treatments

2

Development
of wearable
diagnostics
and detectors
for treatment
and
intervention

3

Evaluation of
personal
exposure
diagnostic
technologies



Resources

- Devices to Prevent and Treat Opioid Use Disorder Innovation Challenge Webpage
<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/ucm609082.htm>
- Device Advice: Comprehensive Regulatory Assistance
<https://www.fda.gov/medicaldevices/deviceregulationandguidance/>
- Breakthrough Devices Webpage
<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm441467.htm>



Acknowledgements

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CBRN Division, Biomedical Advanced Research and Development Authority

Daniel Dodgen, Ph.D.

Senior Advisor, Office of the Assistant Secretary for Preparedness and Response (ASPR), Office of Strategy, Policy, Planning and Requirements (SPPR)

Questions?

About the Innovation Challenge:

- CDRH-Innovation-Opioid@fda.hhs.gov
- <http://www.fda.gov/cdrhwebinar> (July 25, 2018 webinar)

About Medical Device Regulation:

- Division of Industry and Consumer Education
DICE@fda.hhs.gov



FDA Actions to Address the Opioid Crisis: Interagency Programs, Guidance for Industry, Advisory Committee Meetings

November 21, 2019

Judith A. Racoosin, MD, MPH
Deputy Director for Safety

Division of Anesthesiology, Addiction Medicine, and Pain Medicine
Office of New Drugs, CDER



FDA Disclaimer

- This presentation reflects the views of the author and should not be construed to represent the views or policies of the U.S. Food and Drug Administration.

Outline

- Interagency Programs
- Guidance for Industry
- Advisory Committee Meetings

Interagency Programs

- Interagency Pain Research Coordinating Committee (IPRCC)
- Pain Management Best Practices Inter-Agency Task Force
- NIH HEAL Initiative
- Public-private-partnerships to develop better study designs, endpoints for clinical trials

Interagency Pain Research Coordinating Committee (IPRCC)



- Federal advisory committee created by the Department of Health and Human Services that coordinates all pain research efforts within HHS and other Federal Agencies
 - Encompasses Federal and non-Federal members (scientific, medical, public, and stakeholder groups)
- Goals: advancing the fundamental understanding of pain and improving pain-related treatment strategies by creating the National Pain Strategy
- National Pain Strategy included a focus on disparities with the intent of improving the quality of pain care and reduce barriers for all vulnerable, stigmatized, and underserved populations at risk of pain and pain care disparities by
 - Reducing bias (implicit, conscious, and unconscious) and its impact on pain treatment by improving understand of its effects and supporting strategies to overcome it
 - Facilitating communication among patient and health professionals and
 - Improving the quality and availability of data to assess the impact of pain and under or overtreatment for vulnerable populations, and the costs of disparities in pain care
- https://www.iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf

Pain Management Best Practices

Inter-Agency Task Force



- Authorized by section 101 of the Comprehensive Addiction and Recovery Act of 2016
- 29 members – including special government employees, organization representative members, and regular federal members
- The Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations: <https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf>
 - Emphasis on individualized patient-centered care in the diagnosis and treatment of acute and chronic pain
 - Multimodal and multidisciplinary care
 - Needs of special populations
 - Improved education
 - Access to care
 - Further research
- Among the special populations there is a focus on health disparities in racial and ethnic populations
 - Includes disparities in prevalence, treatment, progression, and outcomes of pain related conditions
 - Suboptimal pain management maybe be related to such factors as barriers to accessing health care, lack of insurance, discrimination, lack of a primary care physician, lack of child care, a lower likelihood to be screened or receive pain treatment, and environmental barriers that impede effective self-management.
 - Strategies to address these issues need to be targeted to the specific needs of these communities

NIH Helping to End Addiction Long-term (HEAL) Initiative

- Improving Prevention and Treatment for Opioid Misuse and Addiction:
 - Novel Medication Options for Opioid Use Disorder and Overdose
 - Enhanced Outcomes for Infants and Children Exposed to Opioids
 - New Strategies to Prevent and Treat Opioid Addiction
 - Translation of Research to Practice for the Treatment of Opioid Addiction
- Enhancing Pain Management:
 - Preclinical and Translational Research in Pain Management
 - Clinical Research in Pain Management

Public-Private-Partnerships

- Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION)
 - identify, prioritize, sponsor, coordinate, and promote innovative activities that will expedite the discovery and development of improved analgesic, anesthetic, addiction, and peripheral neuropathy treatments for the benefit of the public health
- SmartTots
 - coordinate and fund research with the goal of ensuring safe surgery for infants and young children who undergo anesthesia



Guidance for Industry

- Opioid Use Disorder: Developing Depot Buprenorphine Products for Treatment, Guidance for Industry (final)
- Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs for Medication-Assisted Treatment (draft)
- Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework (draft)
- More to come

Advisory Committee Meetings

- Naloxone – Co-prescribing: December 2018
- Opioid Dose – Clinical Utility and Safety: June 2019

Naloxone Co-prescribing

December 2018

- Naloxone co-prescription
 - Targeted approach may be helpful, but hard to define risk-based cut-offs
 - Misses overdose deaths involving illicit opioids
 - Poor allocation of resources—costly without evidence of benefit
- Community-based programs are very effective but lack resources
 - Well-represented at the open public hearing
 - Avoid unintended consequence of diverting resources from these programs
- Outcome
 - Prioritize over-the-counter access and generics and support community-based programs

Opioid Dose – Clinical Utility and Safety: June 2019



- Higher dosing range
 - Clinical need exists including end of life, hospice or palliative care, debilitating illnesses such as cancer and complex neurological and musculoskeletal conditions
 - For some, may reduce pain and improve mobility and quality of life
 - These patients should be managed in settings with pain management expertise and access to expertise in addiction diagnosis and treatment
- Higher dosage strength products
 - May reduce the risk of diversion (i.e., fewer pills at home, easier to keep track)
 - Smaller pill burden for patients, especially those with difficulty swallowing
- Risks of higher dosing range and higher dosage strengths
 - Overdose, especially accidental overdose and death in household contacts
 - Possible greater risk for addiction

Thank You





Presentation

Strategies to Improve Health Equity Amidst the Opioid Crisis

Addiction Policy Forum

Jay Ruais
Chief of Staff
Addiction Policy Forum
November 21, 2019

Vision

Our Why.

Vision

Our vision is to eliminate addiction as a major health problem.

Mission

We lead the fight against the deadly consequences of addiction and help patients, families, and communities affected by the disease.

Who We Are

The Addiction Policy Forum is a nationwide nonprofit organization dedicated to eliminating addiction as a major health problem. Our national headquarters are located in Washington, DC with resources and services in every state.

Strategic Goals

1

Help Families and Patients in Crisis

Provide new, effective resources and support for patients and families in crisis.

2

Integrate Treatment

Develop resources, protocols and tools for physicians, healthcare systems and the workforce to integrate treatment of substance use disorders into healthcare.

3

Raise Awareness

Educate, translate and communicate information about the disease of addiction to key stakeholders and audiences.

4

Prevent Addiction

Helping communities and families take steps to prevent addiction or find it at its earliest, most treatable stage.

5

Advocate and Educate

Intensify the urgency around addiction and mobilize bold action through advocacy and engagement.

Services for Patients and Families



Helpline



Database



Telehealth App



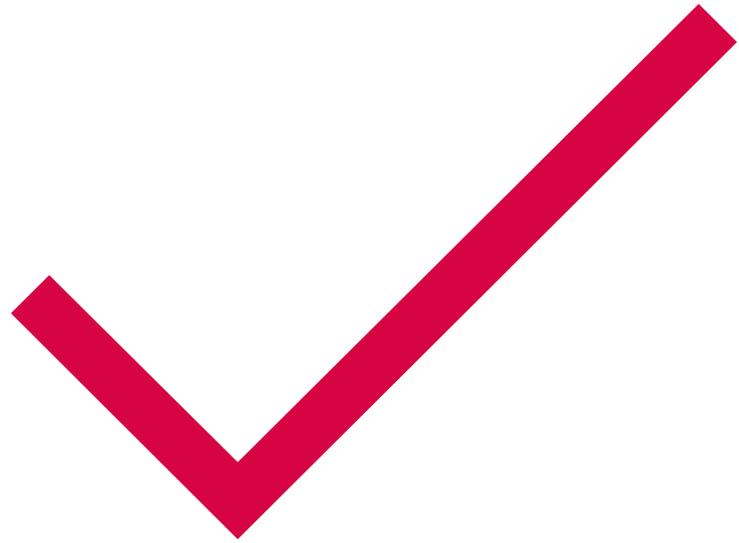
Translation of Science



Clinical Trails

102
BIRTHDAY





Thank You!

Jay Ruais

Chief of Staff

Addiction Policy Forum

jruais@addictionpolicy.org

603.475.0332

Opioid Use Disorder and the Americans with Disabilities Act: Eliminating Discriminatory Barriers to Treatment and Recovery



Disability Rights Section
Civil Rights Division
U.S. Department of Justice
November 21, 2019

DOJ's Response to the Opioid Epidemic

Prevention

Enforcement

Treatment



ADA: Overview

Prohibits discrimination on basis of disability in:

Employment

**State & local
Government**

**Public
accommodations**



ADA: Overview

Definition of “Disability”

- a **physical or mental impairment** that substantially limits one or more **major life activities**;
- a **record** (or past history) of such impairment; or
- being **regarded as** having a disability



ADA: Overview

Definition of “Disability” (cont.)

- **Impairment** – OUDs are impairments under the ADA. Individuals with OUDs that substantially limit one or more of their major life activities are generally considered “disabled” under the ADA.



ADA: Application to OUD

ADA Exclusion

“Individual with a disability” does not include an individual who is currently engaging in the illegal use of drugs, when the covered entity acts on the basis of such use.



ADA: Application to OUD

Currently engaging in the illegal use of drugs
means illegal use that **has occurred**
recently enough to indicate that the
individual **is actively engaged in such**
contact.



ADA: Application to OUD

Does “illegal use of drugs” cover *all* opioid use? Does it cover MAT?

No. “Illegal use of drugs” does not encompass the use of a legally prescribed drug taken under the supervision of a licensed health care professional, or other uses authorized by the Controlled Substances Act or other Federal laws.



ADA: Application to OUD

Obligations of Health Care Providers to People who are Currently Illegally Using Opioids

Health care providers may not deny health or drug rehabilitation services to individuals because of their current illegal use of drugs if they are otherwise entitled to such services.

**However a drug rehabilitation or treatment program may deny participation to individuals who engage in illegal use of drugs while they are in the program.*



ADA TITLE I: EMPLOYMENT



ADA TITLE I: EMPLOYMENT

What Might Illegal Discrimination Look Like? (cont.)

EEOC v. Volvo Group North America, No. 1:17-cv-02889 (D. Md.)
Consent Decree

- Applicant alleged Volvo made a conditional job offer for a laborer position.
- During his post-offer physical examination, the applicant alleged that he explained that he was taking medically-prescribed Suboxone.
- Upon reporting for his first day of work, Volvo informed him that it could not hire him because of his Suboxone use.



ADA TITLE I: EMPLOYMENT

What Might Illegal Discrimination Look Like? (cont.)

EEOC v. SoftPro., No. 5:18-cv-00463 (E.D. N.C.) Lawsuit filed in September 2018 alleging that:

- Employee with OUD took leave to attend an in-patient treatment facility to eliminate his need for MAT.
- Employer questioned the employee about the purpose of his leave; employee disclosed the reason.
- Five days later, the employer terminated the employee.



ADA TITLE II: STATE & LOCAL GOVERNMENTS



ADA TITLE II: STATE AND LOCAL GOVERNMENTS

➤ ***United States v City of Baltimore:***

DOJ successfully challenged discriminatory zoning rules that subjected residential substantial use disorder programs to a burdensome approval process to which similar entities were not subjected

➤ ***DOJ Settlement with the City of Ansonia:***

To remedy discriminatory barriers that barred operation of a Connecticut treatment facility for individuals with substance use disorders



ADA TITLE II: STATE AND LOCAL GOVERNMENTS

What Might Illegal Discrimination Look Like? (cont.)

- A supervised release program prohibits people who are currently on MAT from participating—even if they are not currently illegally using drugs.
- William would benefit from this program, but since it requires individuals to have completely ceased MAT before participating, he is excluded.



ADA TITLE II: STATE AND LOCAL GOVERNMENTS

What Might Illegal Discrimination Look Like? (cont.)

- A parole board prohibits inmates with a record of drug addiction from consideration for parole.
- Jim, an inmate, has a record of drug addiction but is not currently illegally using drugs.



ADA TITLE III: PUBLIC ACCOMMODATIONS



ADA TITLE III: PUBLIC ACCOMMODATIONS

What Might Illegal Discrimination Look Like?

DOJ Settlement with Selma Medical Associates, Inc.

- Medical facility that provides primary and specialty care allegedly refused to accept a prospective patient for an appointment due to the patient's use of Suboxone
- Facility allegedly regularly turned away prospective patients who lawfully took controlled substances to treat their medical conditions.



ADA TITLE III: PUBLIC ACCOMMODATIONS

What Might Illegal Discrimination Look Like?

DOJ Settlement with Charlwell Operating, LLC

- Skilled nursing facility allegedly denied admission to a patient with OUD due to the patient's use of Suboxone
- Allegedly did not admit any patients that had physician-prescribed medication for OUD.



Filing an ADA Complaint/ ADA Resources

File a Complaint at:

ADA ■ gov

Call the ADA Information Line:

800-514-0301 (voice) or 800-514-0383 (TTY)



Contact Information

David Knight
david.knight@usdoj.gov
202-616-2110

Disability Rights Section
Civil Rights Division
U.S. Department of Justice

www.ada.gov

800-514-0301 (voice)

800-514-0383 (TTY)





Questions?



Plenary Presentation

Helping to End Addiction Long Term
(HEAL) Initiative



**NIH
HEAL
INITIATIVE**

November 22, 2019

Using Research to Help End the Opioid Crisis

Rebecca G. Baker, Ph.D.
Director, NIH HEAL Initiative

Jack B. Stein, Ph.D.
Chief of Staff, National Institute on Drug Abuse



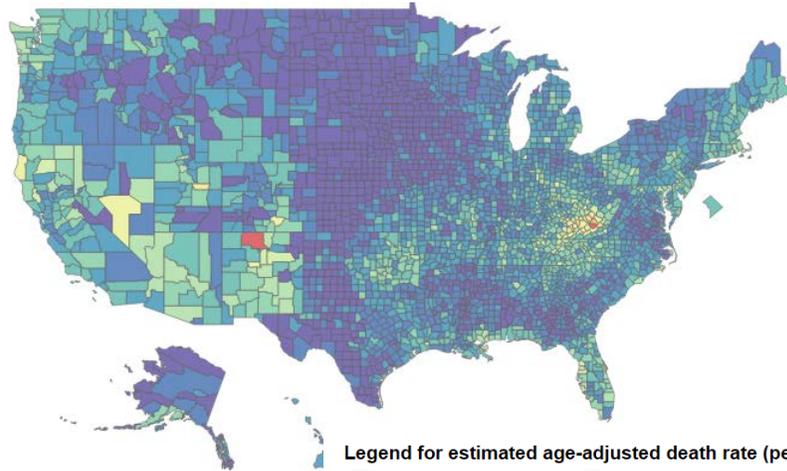
National Institutes of Health
HEAL Initiative

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

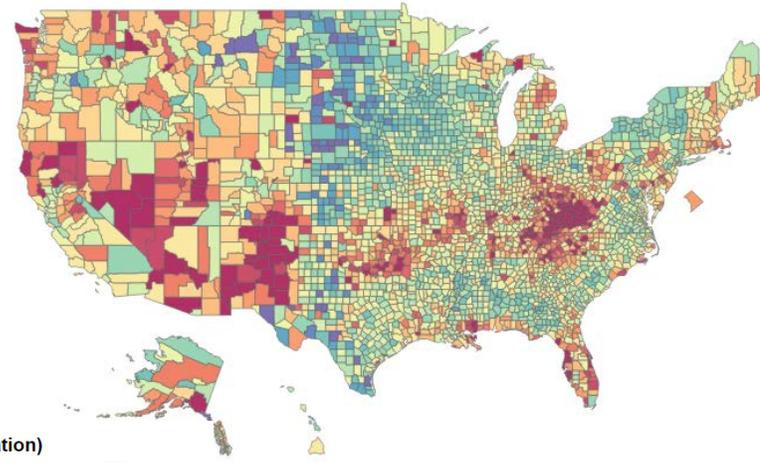
Crisis #1: National Overdose Death Rates

In 2017, there were 70,237 overdose deaths (9.6% higher than 2016)

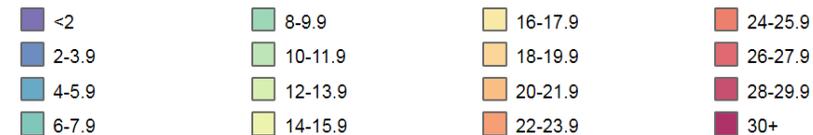
1999



2016



Legend for estimated age-adjusted death rate (per 100,000 population)

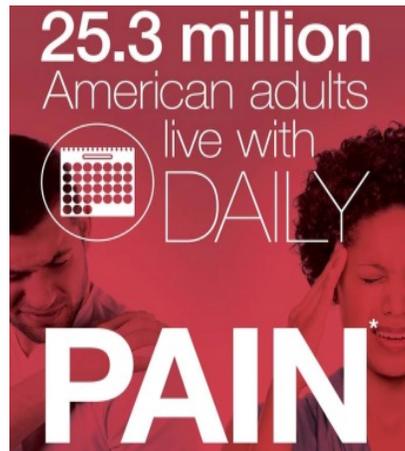


Source: <https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality/index.htm>

- Public Health Emergency Declared in 2017

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

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



[CDC](#), Morbidity and Mortality Weekly Report, Sept. 2018

The Response: NIH HEAL Initiative

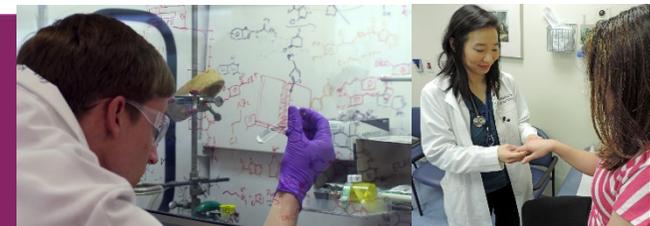
- Mission: scientific solutions to the opioid crisis
- \$500M/year Trans-NIH effort
 - Over \$945M obligated in FY2019
- 12 NIH Institute and Centers currently leading 26 HEAL research projects
 - Over 20 collaborating Institutes, Centers and Offices
 - From prevention, basic and translational research, clinical trials, to implementation science
 - 400+ awards through over 40 funding announcements

HEAL Initiative Research Overview



Improving Prevention and Treatment Strategies for Opioid Addiction

- Novel medication options for opioid addiction and overdose
- Enhanced Outcomes for Affected Newborns
 - Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome: ACT NOW
 - Understanding the long-term consequences of early opioid exposure: HEALthy BCD Study



FDA-Approved Medications for Opioid Addiction and Overdose

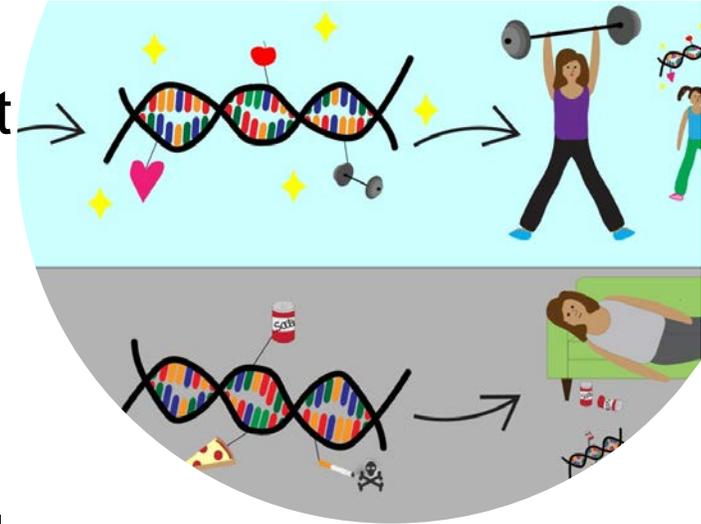


- Methadone
- Buprenorphine
 - Sublingual
 - Monthly injection
 - Six month implant
- Naltrexone
 - Oral
 - Monthly
- Lofexidine
- Naloxone
 - Parenteral
 - Nasal
- Expand options in close collaboration with FDA



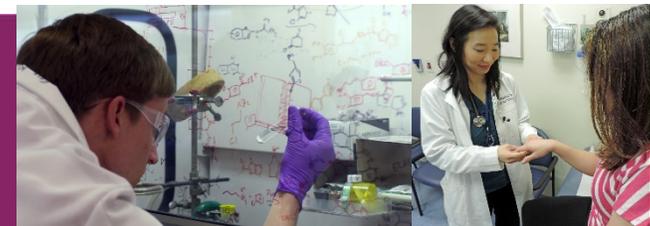
HEALthy BCD Research Objectives

- Establish a cohort of 7,500 pregnant women and follow children for 10 years
- Characterize developmental trajectories (e.g., brain, cognitive, behavioral, social, emotional, academic)
- Evaluate the impact of pre/postnatal exposure to opioids or other substances on developmental trajectories
- Delineate the roles of sex, genetic, epigenetic, social and other environmental factors on risk/resilience



New Prevention & Treatment Strategies for OUD

- Preventing OUD among at risk adolescents
- Understanding the role of sleep dysfunction
- Managing opioid misuse and low severity OUD
- Determining the optimal length of medication treatment
- Optimizing collaborative care for people with OUD and common mental disorders

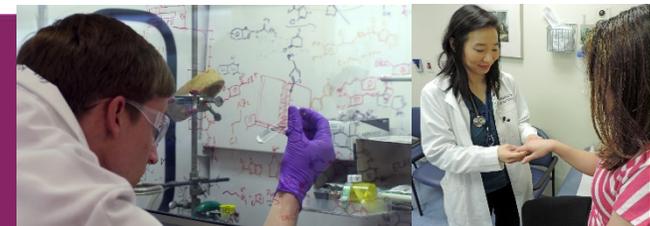


Preventing Opioid Use Disorder in Older Adolescents and Young Adults

- Establish evidence-based interventions to prevent initiation of opioid misuse and OUD in at-risk older adolescents and young adults (ages 16-30)
- Develop:
 - Strategies to identify, reach and engage individuals and populations at high risk
 - Efficacious and/or effective interventions to reduce opioid misuse and OUD
 - Strategies/models and innovative delivery platforms for successful implementation and sustainability

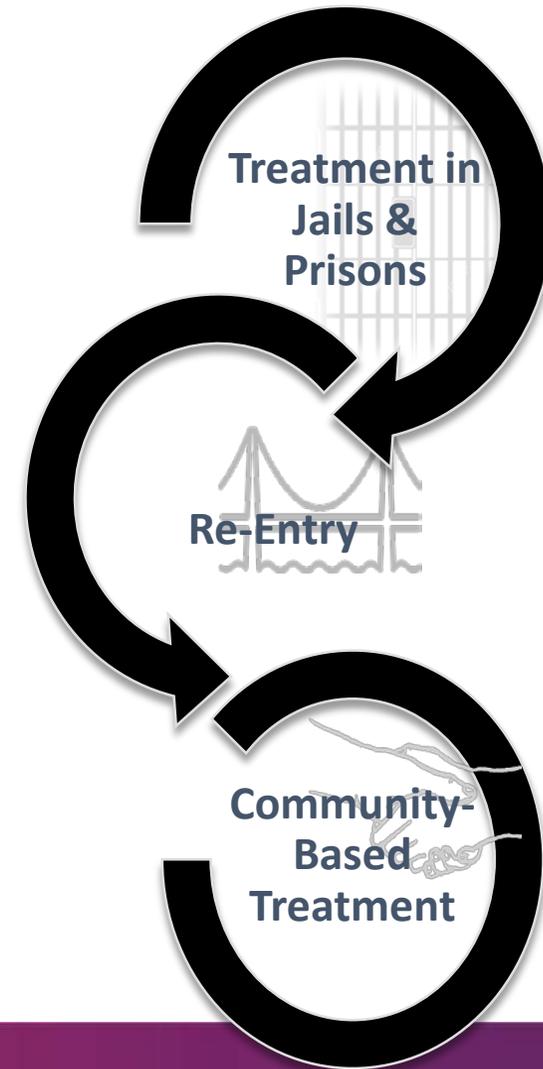
Integrate Research into Practice for Effective Treatments for OUD

- Enhancing the NIDA Clinical Trials Network to address opioids
- Promoting innovation in the criminal justice system
- Understanding the role of behavioral health interventions
- Integrating multiple evidence based interventions in communities: HEALing Communities Study



Justice Community Opioid Innovation Network (JCOIN)

- Multi-year research network to study quality care in justice populations
- Create partnerships between justice system and community-based treatment providers
- 10 research institutions and 2 support centers based in 15 states and Puerto Rico
- Studies conducted include:
 - A national survey of addiction treatment delivery services within the justice system
 - Effectiveness and adoption of new medications, prevention and treatment interventions, and technologies

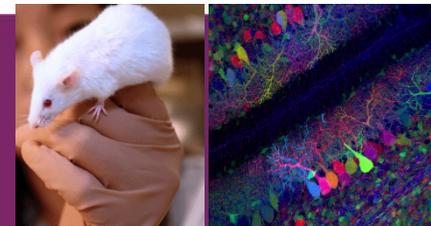


The HEALing Communities Study

- Multi-year study in partnership with SAMHSA
- Reduce opioid overdose deaths by 40% over the course of three years
- Test effectiveness of coordinated systems of care to:
 - increase the number of individuals receiving medication to treat OUD
 - increase the distribution of naloxone
 - reduce high-risk opioid prescribing
- 67 towns and communities in 4 states with high rates of opioid overdose
- Inclusion of rural communities

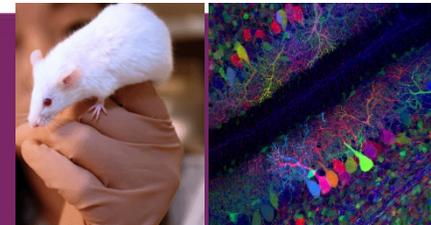
Pre-Clinical and Translational Research in Pain Management

- Discovery and validation of novel targets for safe and effective pain treatment
- Biomarkers, signatures and endpoints for pain
- Translating discoveries into effective devices for pain treatment
- Engineering preclinical screening platforms + novel drug development



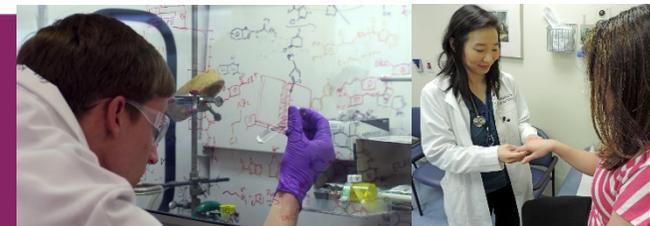
Clinical Research in Pain Management

- Test novel treatments in a new clinical trials network: (EPPIC Net)
- Back Pain Research Consortium
- Pain Management Effectiveness Research Network
- Integrated approach to pain and opioid use in hemodialysis patients
- Pragmatic and Implementation Studies for the Management of Pain



Early Phase Pain Investigation Clinical Network (EPPIC-Net) Mission and Goals

- Accelerate the early phase testing of promising non-addictive therapeutics and devices to relieve pain
 - Develop infrastructure for the rigorous early phase testing of promising pain treatments (small molecules, biologics, devices) from academia and industry
 - Leverage pain expertise in both academia and industry
 - Train new clinical investigators
 - Design and test innovative clinical trial paradigms
- Incorporate biomarkers of target engagement or proof-of-principle into clinical trial design for new non-addictive pain treatments





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Questions?



Closing Remarks

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