

American Indian and Alaska Native Opioid Research

Research Needs and Opportunities



Kathy Etz, Ph.D.

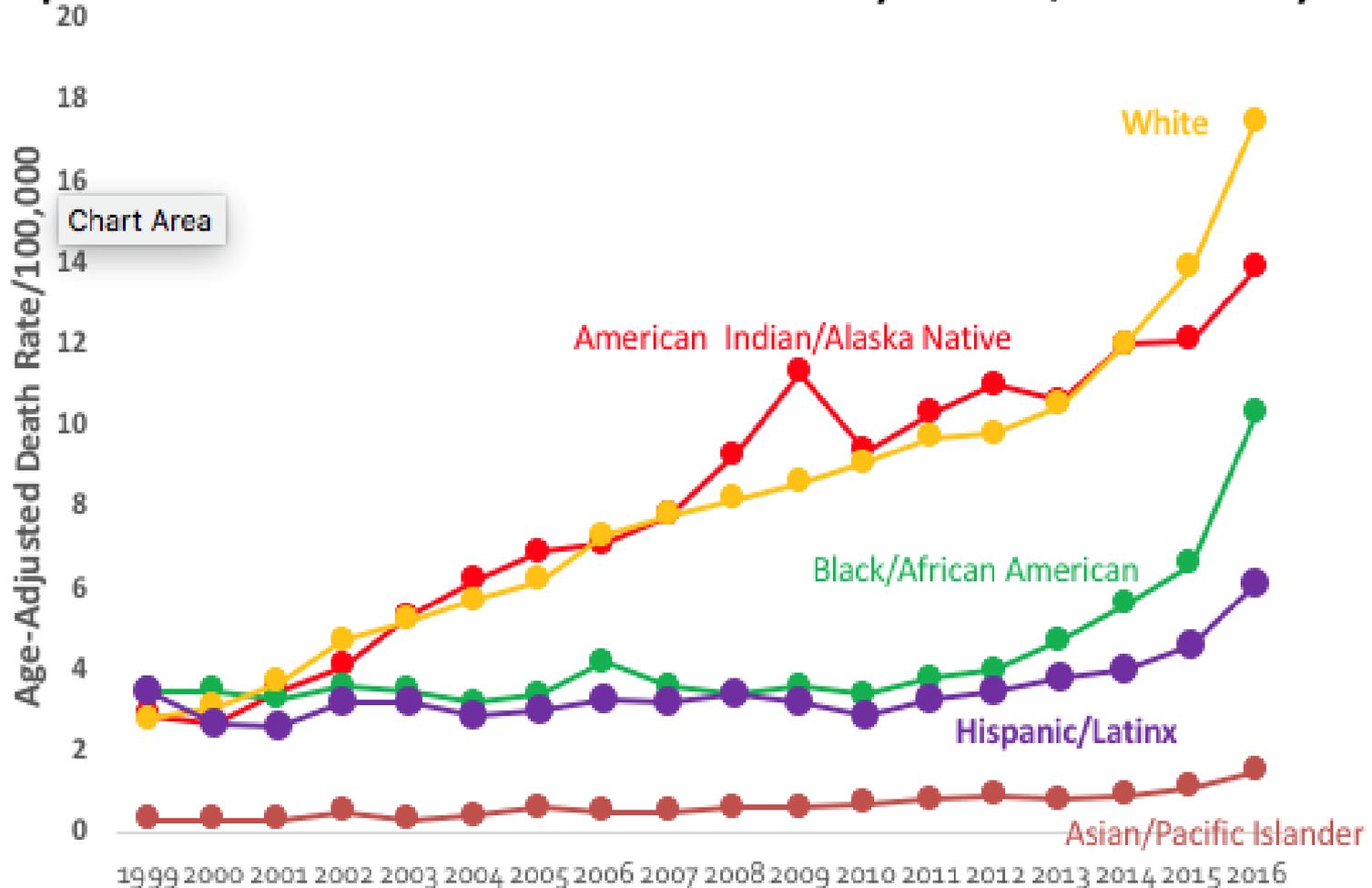
Director, Native American Program

National Institute on Drug Abuse

University of Washington, July 2018, Seattle, WA

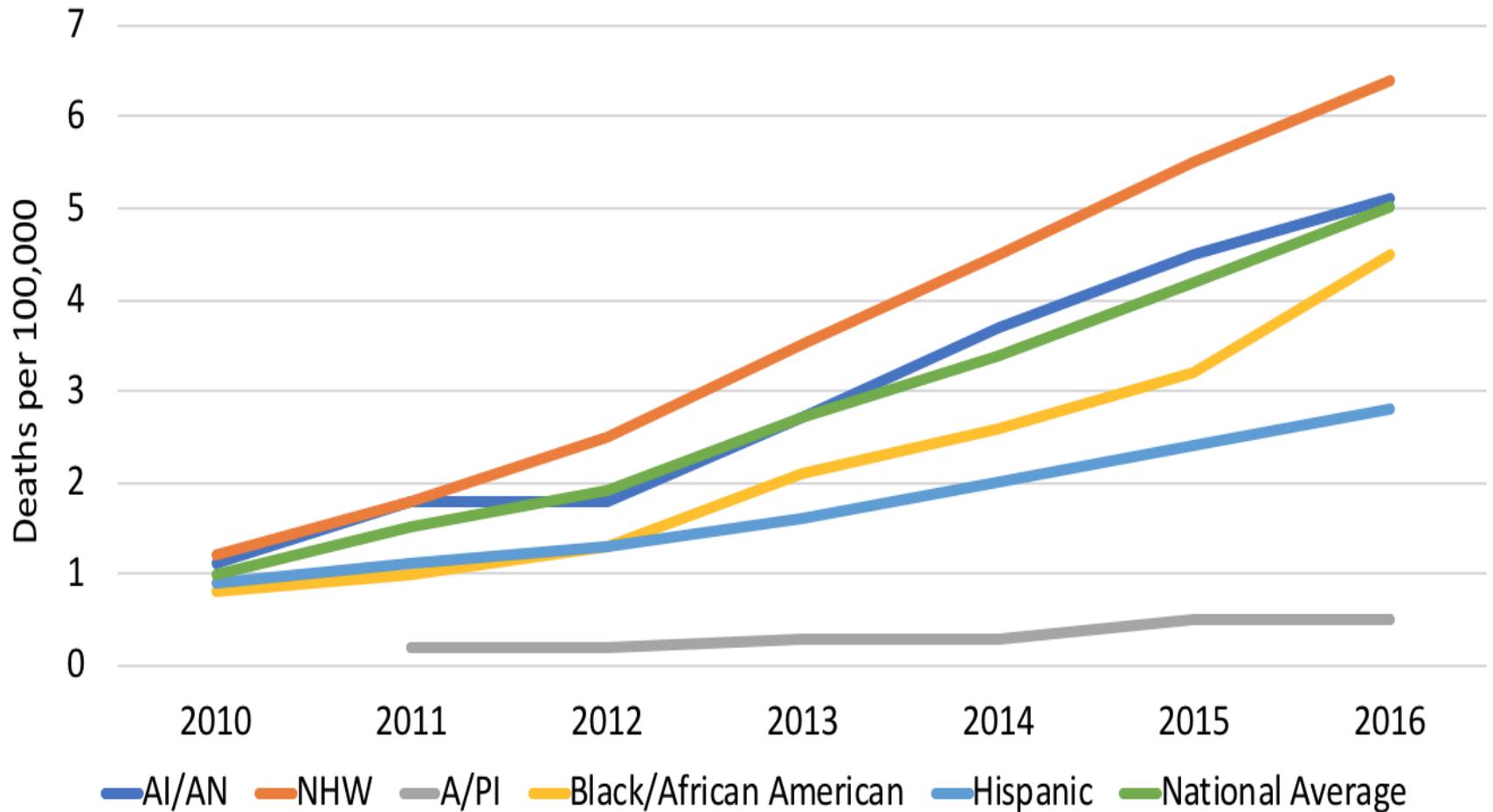
1999-2016 Any Opioid

Opioid Overdose Death Rates by Race/Ethnicity

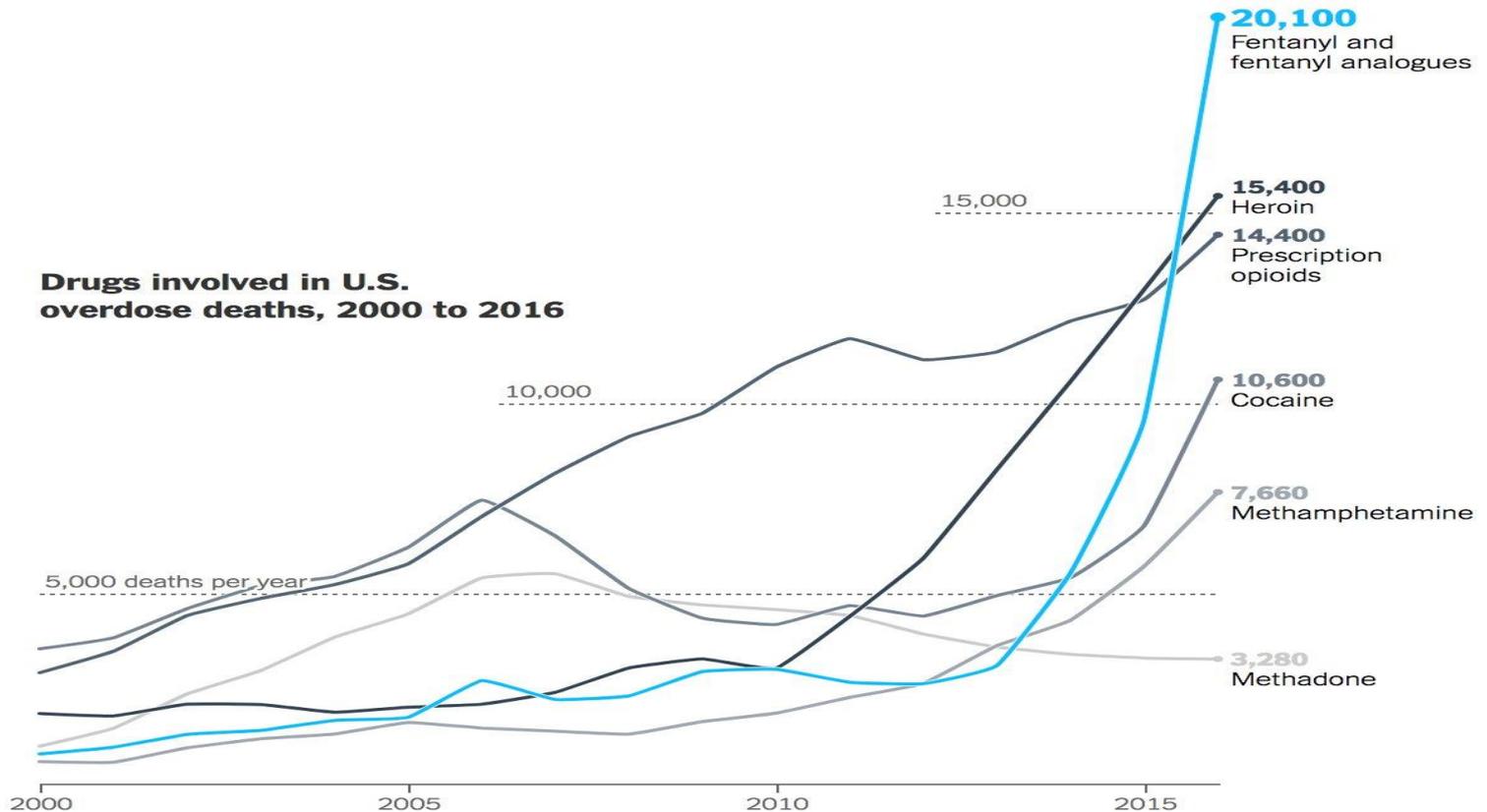


Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2016 on CDC WONDER Online Database, released December, 2017. Data are from the Multiple Cause of Death Files, 1999-2016, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at <http://wonder.cdc.gov/mcd-icd10.html>

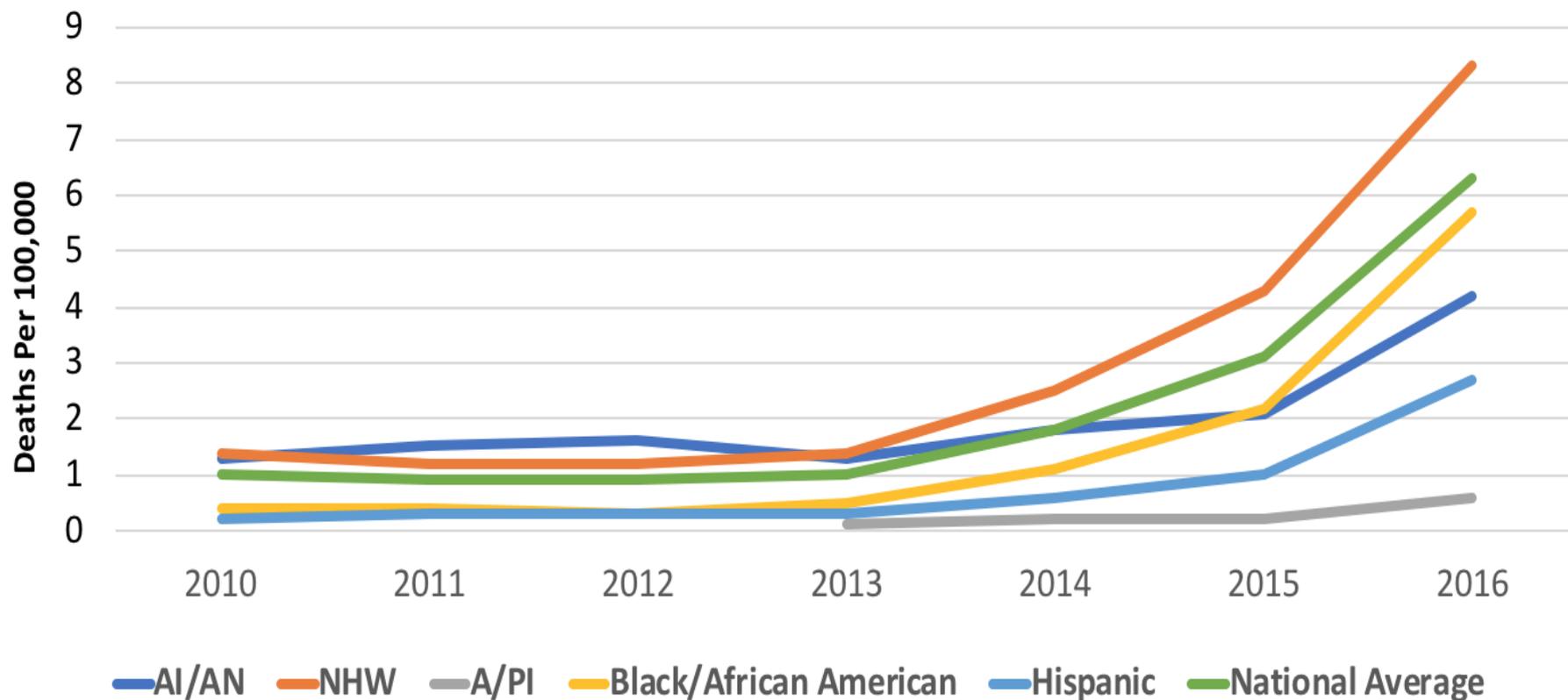
Overdose Deaths Involving Heroin, by Race, United States, 2010-2016



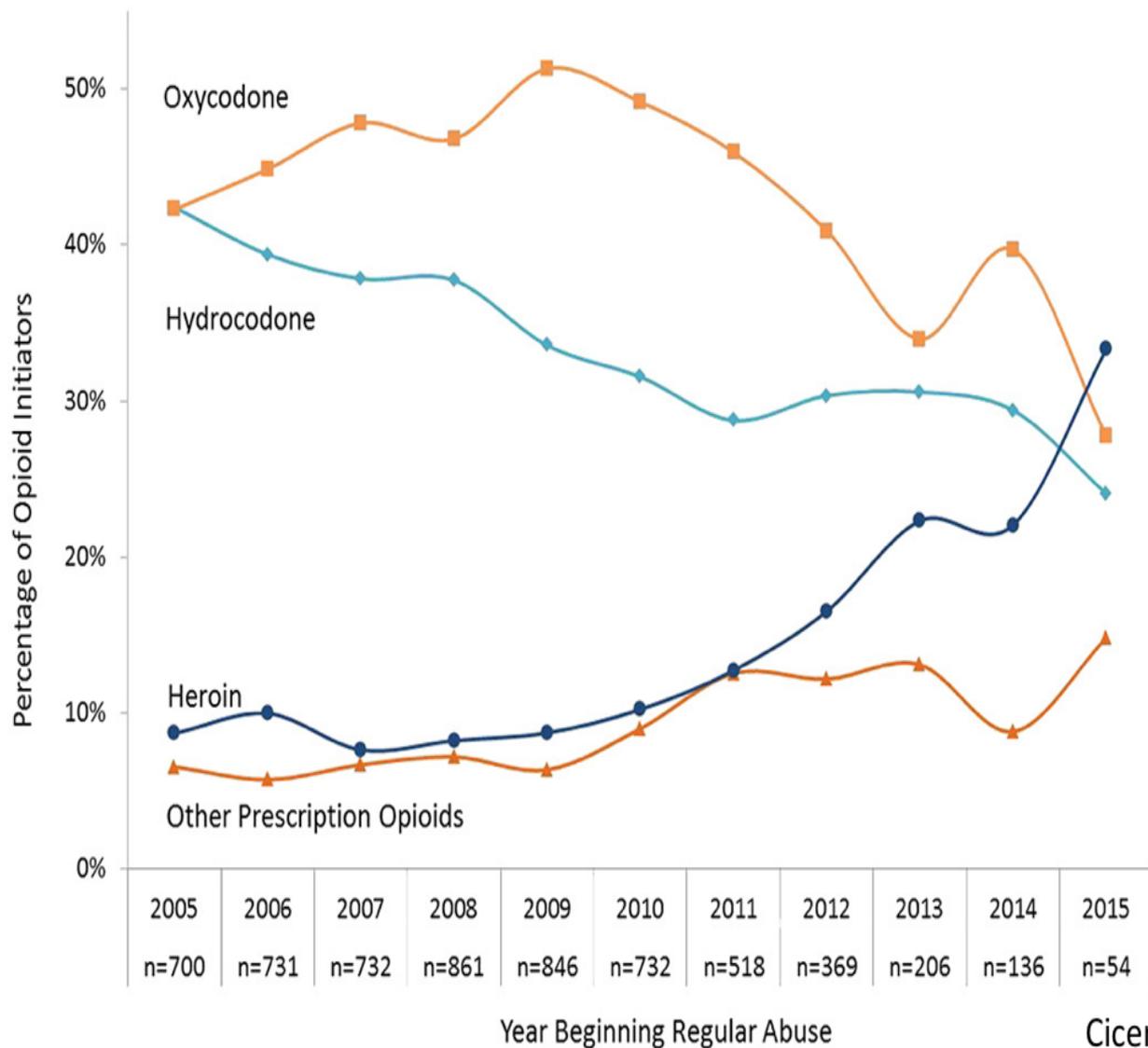
Fentanyl-Related Deaths Surpassed Heroin or Rx Opioids in 2016



Overdose Deaths Involving Other Synthetics, by Race, United States, 2010-2016

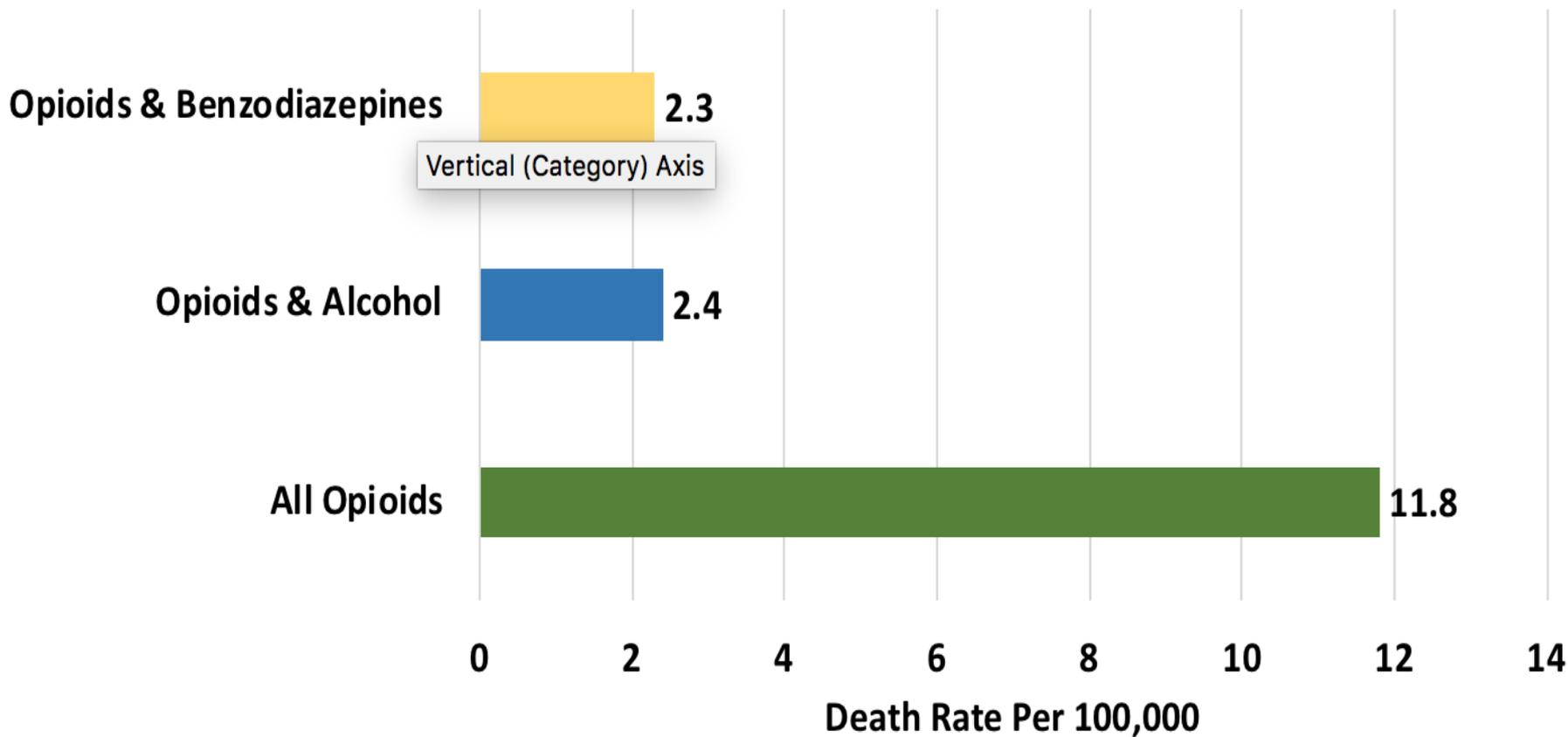


Rising Number of People Initiating with Heroin

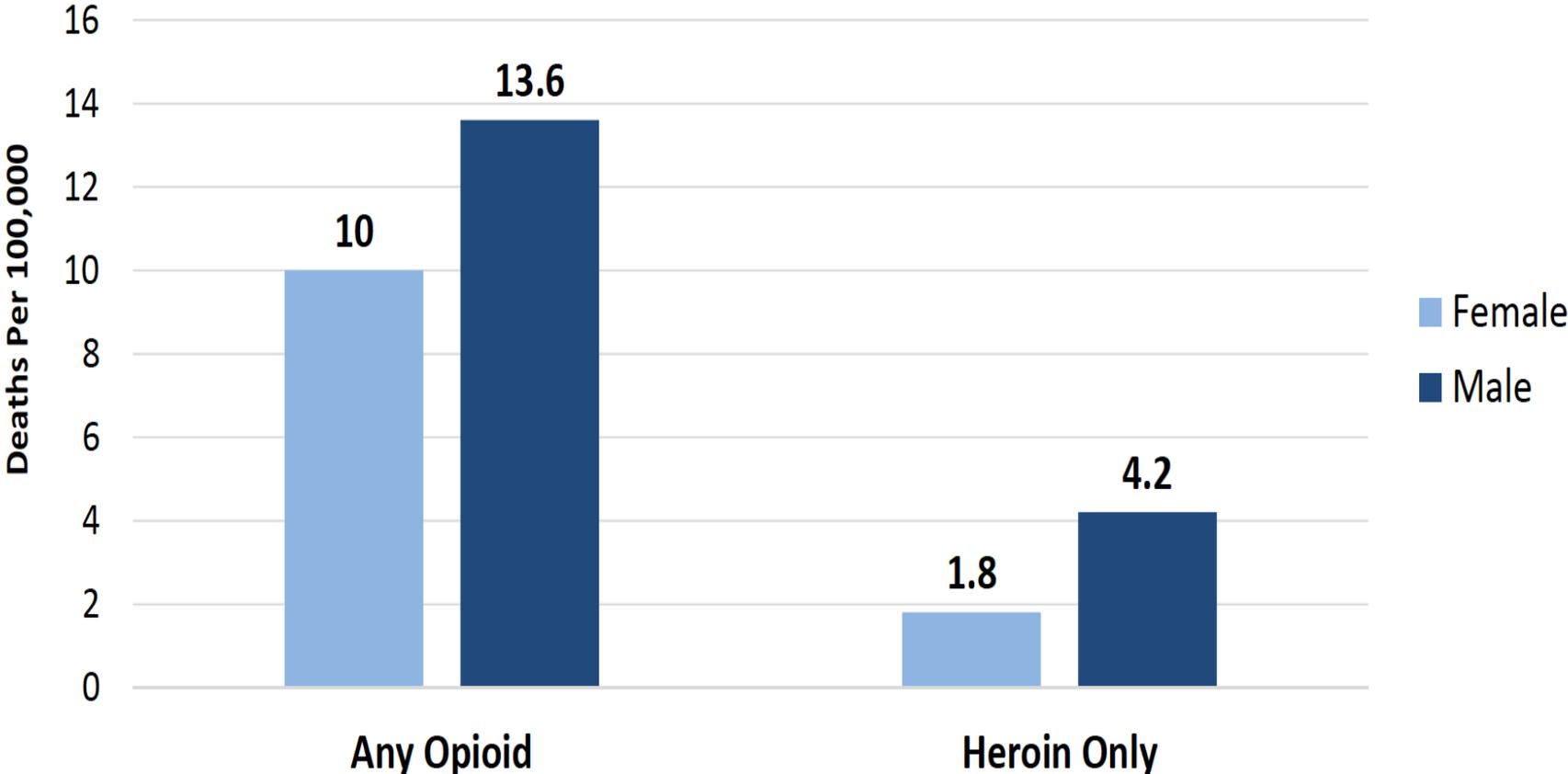


Cicero et al., 2017

Opioid Overdose Deaths, Non-Hispanic AI/AN by Co-Use with Alcohol & Benzodiazepines, U.S., 2010-2016

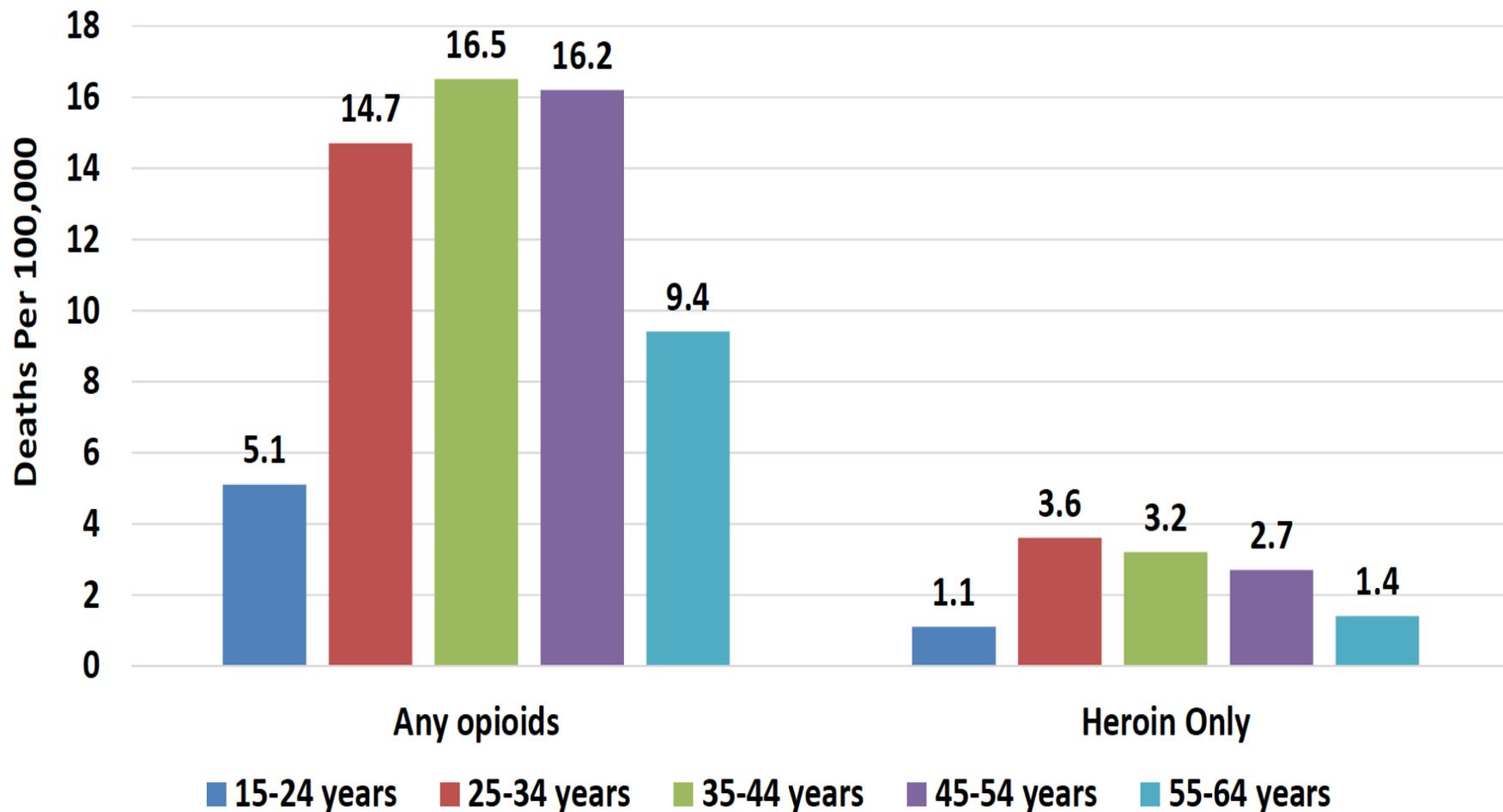


Overdose Deaths By Sex, Non-Hispanic AI/AN, United States, 2010-2016

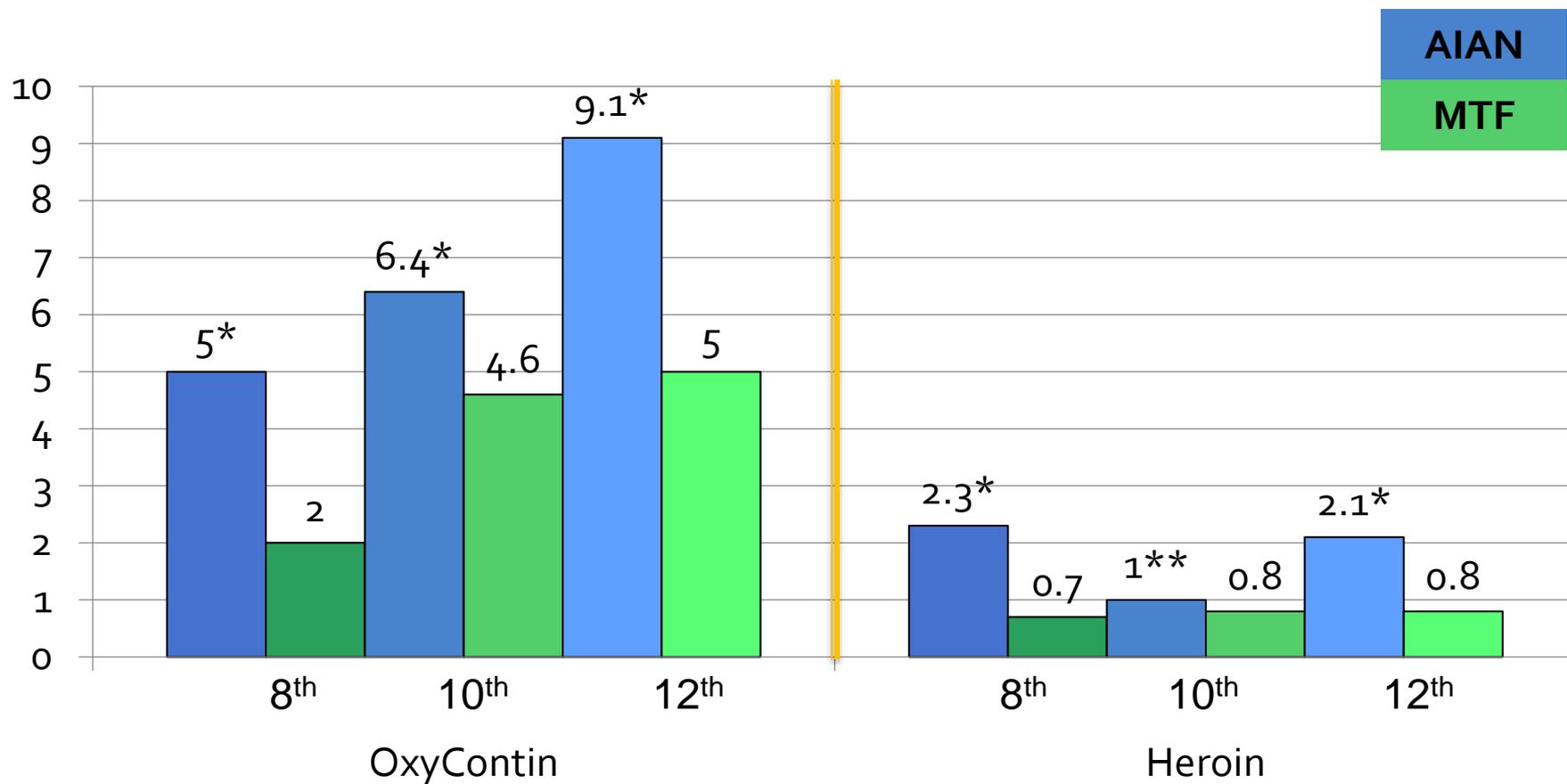


SOURCE: CDC/NCHS National Vital Statistics System, Mortality

Overdose Deaths, Non-Hispanic AI/AN by Age Group, United States, 2010-2016

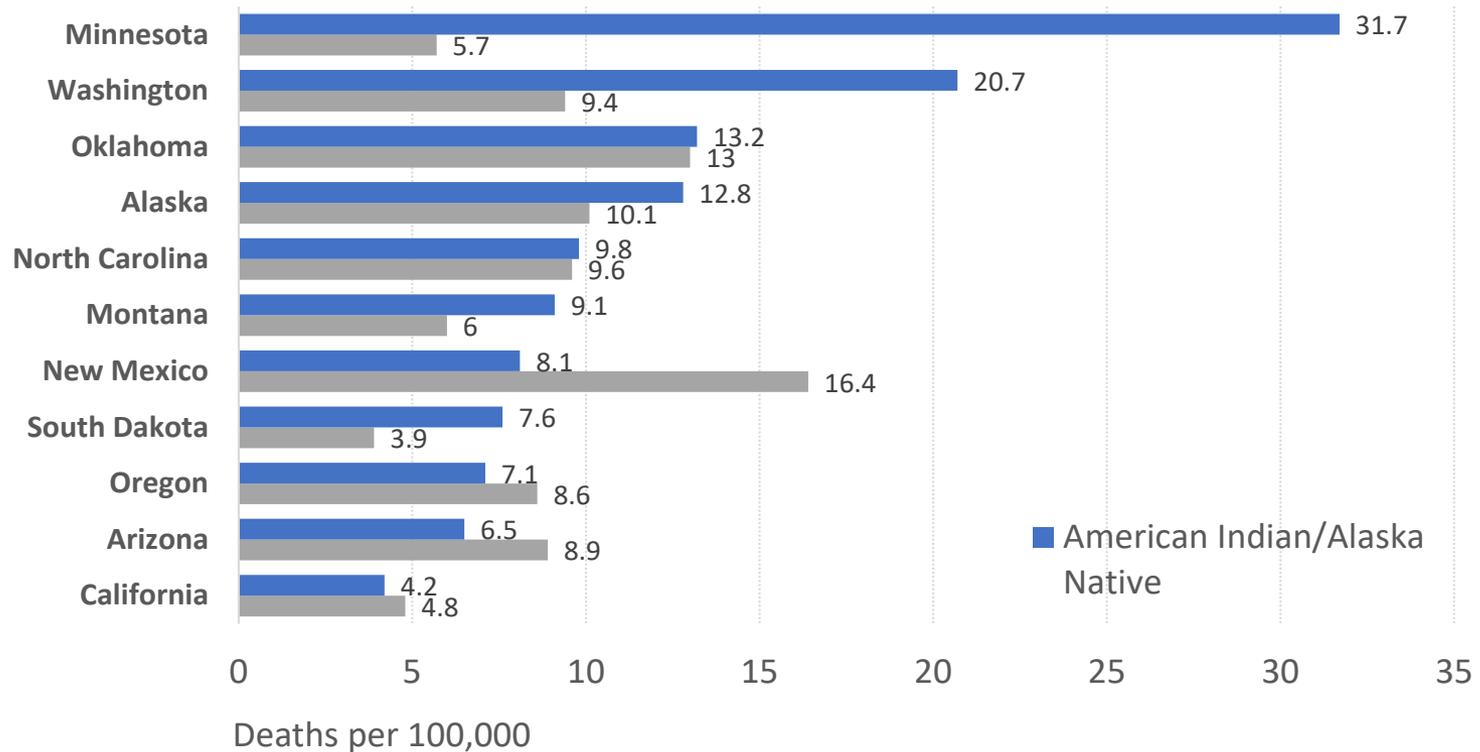


AI Youth on or Near Reservation: Annual OxyContin Use and Heroin Use (2012)



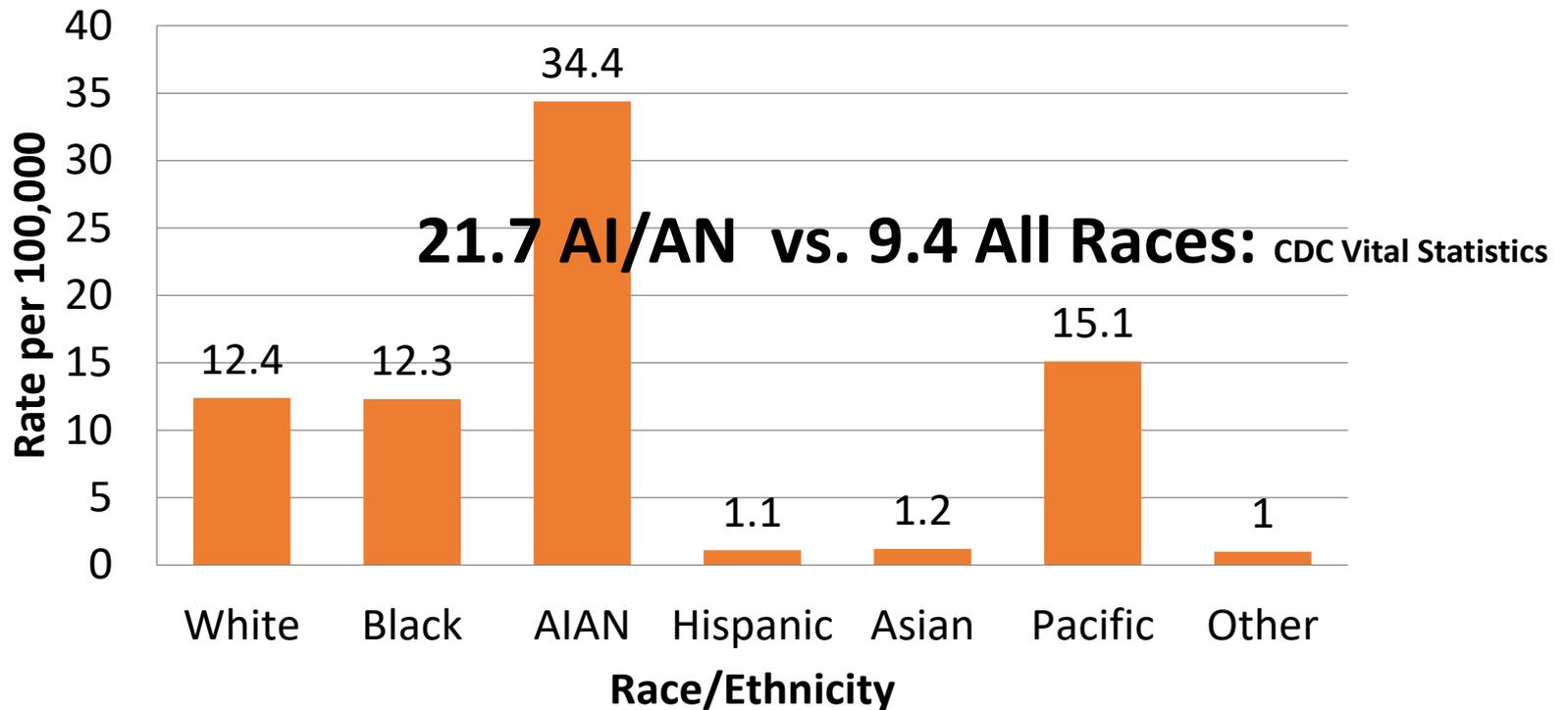
* = .01, ** = .05

Overdose Deaths Involving Opioids, American Indians By State, 2011-2015



Source: CDC/NCHS National Vital Statistics System, Mortality

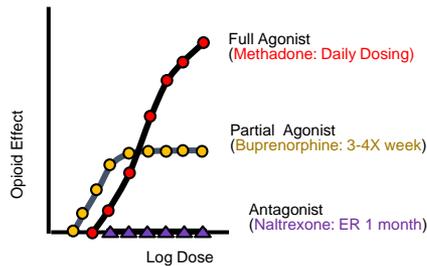
Rates of Opioid Overdose Deaths by Race/Ethnicity, WA State 2011-2015



Source: WA DOH Death Certificates

Includes all intent of drug-related deaths with the additional ICD-10 codes of T40.0, T40.1, T40.2, T40.3 or T40.4

Medication Assisted Treatment (MAT)



DECREASES:

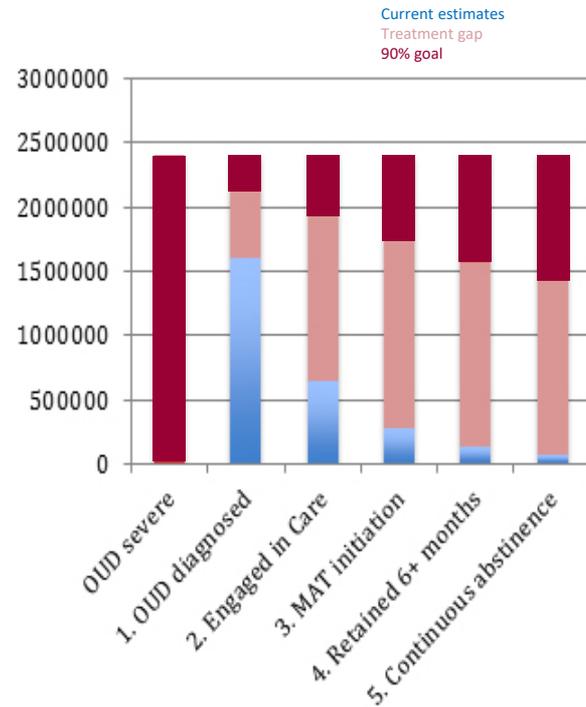
- Opioid use
- Opioid-related overdose deaths
- Criminal activity
- Infectious disease transmission

INCREASES

- Social functioning
- Retention in treatment

But MAT is highly underutilized!
Relapse rates are very high!

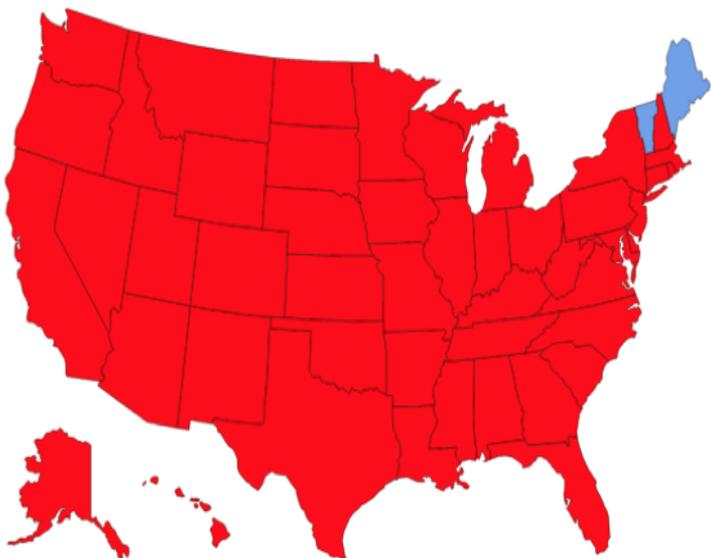
OUD Cascade of Care in USA



Williams AR, Nunes E, Olfson M. Health Affairs Blog, 2017

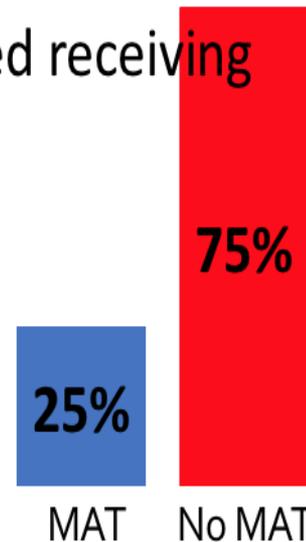
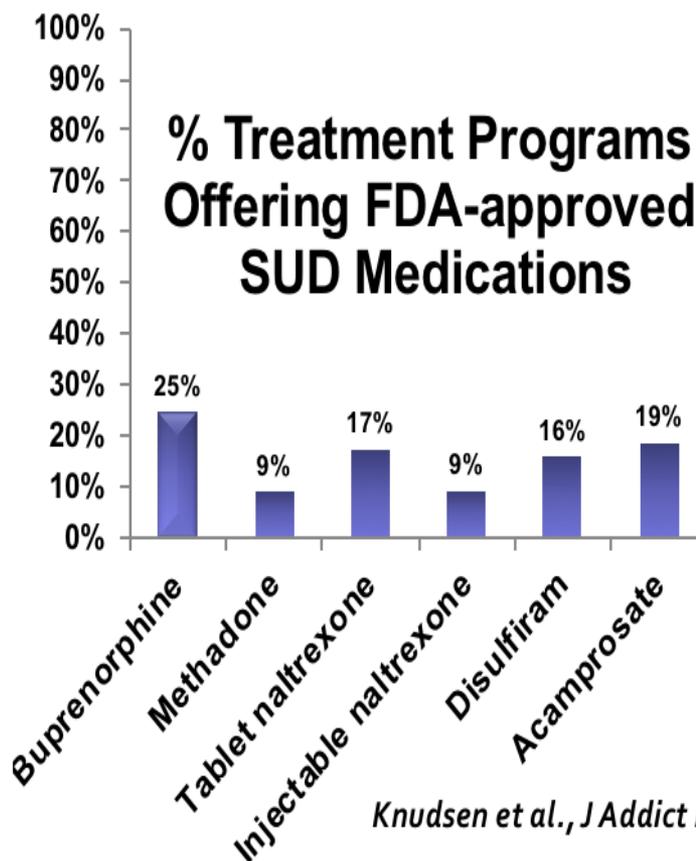
Medications are Underused

In 48 states and D.C., Opioid Use Disorder Rates Exceed Buprenorphine Treatment Capacity



Jones C et al., Am J Public Health 2015.

In 2014, only 25% of opioid admissions had treatment plans that included receiving medications.



Treatment Episode Data Set (TEDS): 2004-2014.

Knudsen et al., J Addict Med 2011



Other Opioid-Related Activities

- NIDA convened a meeting on May 4, 2017 titled Future Directions for Medication Assisted Treatment for Opioid Use Disorder with American Indians and Alaska Natives
 - developed a poster targeted to AI AN women with information on accessing treatment for OUD.
- NIDA held a workshop on Cultural Considerations for Implementing Medication Assisted Treatments for Opioid Use Disorder at the American Indian and Alaska Native National Behavioral Health Conference in August, 2017.

High-Priority Research Questions Developed at the Meeting

- Which social factors contributing to the opioid crisis present malleable social change targets -- or reliable risk predictors?
- How can prescribing practices be modified to minimize the transition from acute to chronic opioid use, without causing drug seeking elsewhere?
- Do the psychosocial components of MAT improve effectiveness over medications alone for OUD?
 - Can we reliably predict which individuals will respond to which psychosocial interventions?
- How can social and behavioral interventions be integrated better into the clinical care of chronic pain, including nonpharmacological interventions?

Responding to Opioid Use Disorders in Tribal Communities in the Context of SAMHSA Tribal Funding



Background and Justification: Opportunities

- **Unique opportunities exist for responding to OUD in AI/AN Communities grounded in strength based approaches**
 - Opportunity for Comprehensive Approach
 - Traditional practices
 - Close communities
 - Extended families

Background and Justification: Barriers

■ Also unique barriers

- Funding
- No published outcome studies of MAT for AI/AN
- Idea of substituting one drug for another
- Culturally incongruent treatment, failing to incorporate traditional practices or drawing on strengths
- Stigma
- Access including distance

\$50,000,000 for SAMHSA to fund Tribal response to OUD

One Hundred Fifteenth Congress of the United States of America

SUBSTANCE ABUSE TREATMENT

For carrying out titles III and V of the PHS Act with respect to substance abuse treatment and title XIX of such Act with respect to substance abuse treatment and prevention, \$3,182,306,000: *Provided*, That \$1,000,000,000 shall be for State Opioid Response Grants for carrying out activities pertaining to opioids undertaken by the State agency responsible for administering the substance abuse prevention and treatment block grant under subpart II of part B of title XIX of the PHS Act (42 U.S.C. 300x-21 et seq.): *Provided further*, That of such amount \$50,000,000 shall be made available to Indian Tribes or tribal organizations: *Provided further*, That 15 percent of the remaining amount shall be for the States with the highest mortality rate related to opioid use disorders:

SAMSHA FOA - TI-18-016

- **Treatment**
- **Prevention**
- **Recovery**
- \$50,000,000 to tribes and tribal organizations to build prevention, treatment and/or community-based recovery support services. The FOA also focuses on increasing access to culturally appropriate evidence-based treatment, including medication-assisted treatment (MAT) and improving retention in care.

Research Goals

- **Assess interventions implemented with SAMHSA funding to identify the most efficacious strategies for preventing and treating OUD in tribal communities**
 - Partnerships between researchers and AI/AN communities, using community engagement and/or CBPR
 - Identify efficacious prevention strategies, including multi-pronged strategies facilitated by engagement across tribal departments
 - Identify and address barriers to appropriate treatment and hasten the availability of MAT
 - Develop and assess culturally appropriate interventions
 - Assess telehealth approaches in remote communities
 - Assess whether the use of long acting MAT (Sublocade, Vivitrol, Probuaphine) helps in making MAT available to remote communities

Informed by Previous FOAs

- Expanding Medication Assisted Treatment for Opioid Use Disorders in the Context of the SAMHSA Opioid STR Grants (R21/R33)RFA DA 18-005
- Behavioral Interventions for Prevention of Opioid Use Disorder or Adjunct to Medication Assisted Treatment-SAMHSA Opioid STR Grants (R21/R33) RFA AT 18-001
- Clinical Trials or Observational Studies of Behavioral Interventions for Prevention of Opioid Use Disorder or Adjunct to Medication Assisted Treatment-SAMHSA Opioid STR Grants (R21/R33)RFA AT 18-002

R21/R33

Phased Innovation Award



R21: Exploratory/Developmental Research Grant Award

- Seeks to foster the introduction of novel scientific ideas, model systems, tools, agents, targets, and technologies
- The R21 phase provides up to two years of funding for innovative, hypothesis-driven projects, supported by limited or no preliminary data, to allow investigators to demonstrate feasibility of the proposed product, developed technology, or innovation. The applicant is required to include one to three well- defined, quantifiable milestones that can be used to judge the success of the R21 project. If the applicant achieves the proposed milestones, the award of the R33 phase will be considered.

R33: Exploratory/Developmental Research Grant Phase II Award

- Provides the second phase of support for the research initiated under the R21 phase for a period of up to three additional years.
- The R33 phase will provide the support required to move the innovative discoveries of the R21 phase into the preclinical/clinical development pipeline.

Research Example from 2018 RFA

- This study leverages recent federal and state opioid use disorder treatment initiatives as a platform for testing a promising mind-body intervention, Mindful Awareness in Body-oriented Therapy (MABT) as an adjunct to MAT in two clinical settings funded through the Washington Opioid State Targeted Response (STR) program. MABT, a novel mindfulness-based intervention, uniquely addresses aspects of awareness, interoception, and regulation that may be associated with pain, mental health distress, and behavioral control that increase risk of relapse and poor treatment outcomes. Each setting employs a variation of the nationally recognized Massachusetts Nurse Care Manager model. Using a randomized, two- group, repeated measures design, we will compare those who receive MABT+ MAT to MAT only. The overarching goal of this application is to test MABT to improve MAT health outcomes among patients receiving buprenorphine to treat OUD.

Example Specific Aims: R21

- Solidify partnerships with proposed clinical program sites, develop plan for implementing the study intervention and procedures, and to finalize study related documents necessary for the R33, including: study protocols, data collection and informed consent forms, intervention manuals and fidelity assessment checklists, training plans for research staff, data safety and monitoring plans.

Example Specific Aims: R33

- Evaluate the effectiveness of MABT + MAT compared to MAT only (treatment-as-usual) in reducing opioid use (primary outcome), opioid craving, MAT discontinuation, and non-opioid drug use (secondary outcomes) at the six-month time point.
- Examine the effectiveness of MABT + MAT for improving mental health distress (i.e. depression, anxiety, somatization, emotion regulation difficulties) compared to MAT only at 6 months.
- Explore the effectiveness of MABT + MAT compared to MAT only in reducing co-morbid pain severity and interference (Brief Pain Inventory) and pain sensitivity (cold pressor test).

Comparing Medication Maintenance in Comprehensive Community and Pharmacy Settings to Enhance Engagement

- Green, Traci
- The new STR grant funds introduce nurse-based supports to buprenorphine/naloxone (BNX) prescribers in community healthcare settings, but other health professionals could also help expand MAT reach, namely pharmacists. **The goal** of this study is to examine how the pharmacy can better optimize treatment expansion by **providing pharmacy-based MAT for maintenance**. This study aims to develop (R21 phase) then test (R33 phase) a model of MAT maintenance and coordinated care in the pharmacy

Patient Decision Aid for Medication-Assisted Treatment for Opioid Use Disorder

- Hser, Yih-ing
- This project will develop and test a patient decision support tool called Patient Decision Aid for Medication-Assisted Treatment (PtDA- MAT) for use in the CA H&SS. The PtDA- MAT is designed to (1) improve patient knowledge and involvement and to subsequently improve treatment adherence and outcomes and (2) to support clinicians in informing and communicating with their patients with OUD along a continuum of care.

Other Funded Projects

- Sharon Reif: [Hub and Spoke Model to Improve Pharmacotherapy Use for Opioid Addiction and Promote Recovery](#)
- Christy Scott: [Recovery Initiation and Management after Overdose \(rimo\) Experiment](#)
- Dennis Watson: [Project Point: Effectiveness and Scalability of an Overdose Survivor Intervention](#)

Situating AI AN Research in Broader Context



Situating in Broader Research Context

- Marginalization versus empowerment
 - Examples of empowered research:
 - Oral Rehydration Therapy
 - Vaccine for Hib disease and bacterial meningitis
 - Strategies for empowerment
 - At what conferences is work presented? And in what track/sessions?
 - What unique opportunities exist in HD research that can be used to showcase strengths of this field?

Contribution to General Substance Research

- AI/AN substance abuse research has much to contribute to advancing science with all populations
 - Advancing Small Sample Research
 - Design – Employing RCT in ways that work for this population or finding alternatives
 - Statistical work to address idiosyncrasies (e.g. rolling admission to intervention)
 - Data Sharing Agreements
 - Innovative Intervention Strategies
 - Integrating traditional practice\
 - Holistic Approach

Examples of Unique Opportunities

- Complex real world research
- Dissemination
 - Finding ways to narrow gap between research findings and implementation of scientifically supported best practices or, in other than intervention research, quickly using data to support policy or other decisions
- Measurement Strategies
 - Qualitative and mixed methods research
- Strength Based/Resilience perspective
- Community Engagement
 - Community Based Participatory Research

Thank you!
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