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

SOURCE: CDC/NCHS National Vital Statistics System, Mortality
Fentanyl-Related Deaths Surpassed Heroin or Rx Opioids in 2016

Graphs from NY Times Article based on CDC MMWR Report 2017
Overdose Deaths Involving Other Synthetics, by Race, United States, 2010-2016

SOURCE: CDC/NCHS National Vital Statistics System, Mortality
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

- Opioids & Benzodiazepines: 2.3
- Opioids & Alcohol: 2.4
- All Opioids: 11.8

SOURCE: CDC/NCHS National Vital Statistics System, Mortality
Overdose Deaths By Sex, Non-Hispanic AI/AN, United States, 2010-2016

![Bar Chart]

**Any Opioid**
- Female: 10 deaths per 100,000
- Male: 13.6 deaths per 100,000

**Heroin Only**
- Female: 1.8 deaths per 100,000
- Male: 4.2 deaths per 100,000

**Source:** CDC/NCHS National Vital Statistics System, Mortality
Overdose Deaths, Non-Hispanic AI/AN by Age Group, United States, 2010-2016

**Any opioids**
- 15-24 years: 5.1
- 25-34 years: 14.7
- 35-44 years: 16.5
- 45-54 years: 16.2
- 55-64 years: 9.4

**Heroin Only**
- 15-24 years: 1.1
- 25-34 years: 3.6
- 35-44 years: 3.2
- 45-54 years: 2.7
- 55-64 years: 1.4

SOURCE: CDC/NCHS National Vital Statistics System, Mortality
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

Current estimates
Treatment gap
90% goal

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

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

![Map of the United States with states colored to indicate opioid use disorder rates, with some states in blue indicating higher rates.](image)


![Bar chart showing percentage of treatment programs offering FDA-approved SUD medications.](image)

<table>
<thead>
<tr>
<th>Medication</th>
<th>MAT</th>
<th>No MAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine</td>
<td>25%</td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td>9%</td>
<td></td>
</tr>
<tr>
<td>Tablet naltrexone</td>
<td>17%</td>
<td></td>
</tr>
<tr>
<td>Injectable naltrexone</td>
<td>9%</td>
<td></td>
</tr>
<tr>
<td>Disulfiram</td>
<td>16%</td>
<td></td>
</tr>
<tr>
<td>Acamprosate</td>
<td>19%</td>
<td></td>
</tr>
</tbody>
</table>

[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
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
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
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, Probuphine) 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.
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.

Cynthia Price, University of Washington
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.
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).
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.
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
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!
Kathy Etz
ketz@nih.gov