The NIH Response to the Opioid Crisis from a Research Perspective

Wilson M. Compton, M.D., M.P.E., Deputy Director, National Institute on Drug Abuse

Martha J. Somerman, DDS, PhD, Director, National Institute of Dental and Craniofacial Research

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April 3, 2019
The U.S. Opioid Crisis: 
Science = Solutions

Wilson M. Compton, M.D., M.P.E.
Deputy Director
National Institute on Drug Abuse
Drug Overdose Rates are Increasing:
Estimated Age-adjusted Death Rates per 100,000 for Drug Poisoning by County.

Sustained Impact of the **Opioid Crisis**:
U.S. Overdose Death Rates over 50 years

70,237 Deaths in 2017
(47,600 from Opioids [Rx and Illicit])

Source: CDC WONDER
ENVIRONMENTAL AVAILABILITY: Current Opioid Crisis Originated with Prescribing Increases

Opioid prescriptions *Tripled to MORE THAN 200 MILLION prescriptions in recent years*
**Direct and Indirect Pathways** from Prescriptions to Misuse

- People misusing analgesics **Directly & Indirectly** obtain them by prescription

*Source where pain relievers obtained for most recent misuse*

- Prescription: 36%
- Friend/Relative: 54%
- Other: 10%

- Prescription: 87%
- Friend/Relative: 10%
- Other: 3%

Source: Han, Compton, et al. Annals of Internal Medicine 2017
Evolution of Drivers of Opioid Overdose Deaths:

Analgesics ➔ Heroin ➔ Fentanyl

Source: NCHS WONDER
HHS Five-Point Opioid Strategy

1. Better addiction prevention, treatment, and recovery services
2. Better data
3. Better pain management
4. Better targeting of overdose reversing drugs
5. Better research
Enhancing Pain Management

- Advance effective treatments for pain through clinical research
- Accelerate discovery and development of pain treatments
- Expand Therapeutic Options
- Enhance Treatments for Infants with NAS/NOWS
- Develop New and Improved Prevention & Treatment Strategies
- Optimize Effective Treatments

www.nih.gov/heal-initiative
Science = Solutions:

- Complex biological, developmental and social aspects of pain, substance use and addiction suggest **multipronged responses**.
- The severity of the opioid crisis demands **urgent action**.

**NIDAMED**

Opioid Education

[www.drugabuse.gov](http://www.drugabuse.gov)

**NIH Pain Consortium**

Centers of Excellence in Pain Education

[Web training on pain assessment and treatment](https://painconsortium.nih.gov/Funding_Research/CoEPEs)
NIDCR: Advancing Research on Pain Management and Combatting the Opioid Crisis
ADA–NIDA–NIDCR Webinar

Martha J. Somerman, DDS, PhD
Director, NIDCR

April 3, 2019
In 2030, we imagine a world where...

- Dental, oral and craniofacial health and disease are understood in the context of the whole body
- Research informs the strategies we use to promote health, prevent and treat disease, and overcome disparities in health
- All people have the opportunity to lead healthy lives
The Opioid Epidemic: A Concern for Patients, Clinicians and Researchers

• ADA and ADEA released policies on opioids and alternative pain management
• ADA visit to NIH (NIDA and NIDCR) to discuss policy on opioids and opportunities for collaboration
• Robust trans-NIH efforts to improve treatment for opioid misuse disorders and addiction and enhance pain management through the HEAL initiative
• 2018 Commentary in *JADA*

**Commentary**

The role of the oral health community in addressing the opioid overdose epidemic

Martha J. Somerman, DDS, PhD; Nora D. Volkow, MD
Opioids may be prescribed to treat acute pain after dental procedures or orofacial surgery

- **Acute dental pain**
  - Est. that more than half of 14- to 17-year-olds receive opioid prescriptions from dentists following wisdom tooth extractions

- **Prescribing practices**
  - In 2010, dentists were 3rd-most-frequent prescribers of opioids
  - Now down to 5th because of increased awareness of the potential for opioid prescription abuse

How is NIDCR Investing in Opioid Research?

- Developing non-opioid treatments
- Implementing and disseminating alternative pain management strategies
- Working across NIH and federal agencies: HEAL Initiatives, Pain Committees
- Training programs
- Partnering with dentists
NIDCR Pain Research Funding
FY2013–2017

~5% of total NIDCR budget in FY2017

Research on Pain Conditions include:
- Oral Cavity (dental, pulpitis, etc)
- Post–surgical
- Oral Cancer
- Neuropathic
- Temporomandibular Joint Disorders
- Burning Mouth Syndrome

† Award count includes supplements and co-funded projects
Sex Differences in Pain Hypersensitivity

- Different immune cells mediate mechanical pain hypersensitivity in male and female mice

Orofacial Pain: Prospective Evaluation and Risk Assessment (OPPERA)

- Effects of genes, behavior, and psychology on orofacial pain and temporomandibular joint disorder (TMD)
- Women are more likely to transition from acute to chronic pain
- Role of MRAS gene in painful TMD in males but not females

National Dental Practice-Based Research Network

- Engaging practitioners (~7,000, 50 states) to generate the evidence base to improve precision health
- 60,000 participants, 55 studies
- Studies include:
  - Opioid prescribing and implementation of risk mitigation
  - Management of painful temporomandibular disorders
  - Pain outcomes following root canal therapy

NIDCR contact: Dr. Dena Fischer dena.fischer@nih.gov
NIDCR Participation in the HEAL Initiative

**HEAL Initiative to bolster research across NIH to:**
- Prevent addiction through enhanced pain management
- Improve treatments for opioid misuse disorder and addiction

**NIDCR HEAL Supplements**
- Investigating the mu- opioid activation mechanism in chronic TMD
- De-implementing opioid use and implementing optimal pain management following dental extractions

**NIDCR Participation in HEAL RFAs**
- Tissue Chips to Model Nociception, Addiction, and Overdose
- Optimization of Non-Addictive Therapies [Small Molecules and Biologics] to Treat Pain
- Analytical and/or Clinical Validation of a Candidate Biomarker for Pain
- Discovery of Biomarkers, Biomarker Signatures, and Endpoints for Pain
- Pain Management Effectiveness Research Network: Clinical Trial Planning and Implementation Cooperative Agreement
- Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing
National Academies Consensus Study on Temporomandibular Disorders

- Identified the need for a comprehensive study *Temporomandibular Disorders (TMD): From Research Discoveries to Clinical Treatment*
- National Academies will lead stakeholder activities, including public workshops (March 28–29)
- Supported by NIDCR and NIH OD

http://www.nationalacademies.org/hmd/Activities/PublicHealth/TemporomandibularDisorders.aspx
2020 Surgeon General’s Report on Oral Health in America

• Commissioned by Dr. Jerome Adams, SG of the US
  o 20th anniversary of the first report in 2000

• SG Priorities:
  o Opioid crisis, health disparities, economy and oral health, military readiness, disabilities

• NIDCR Project Leads:
  o Capt. Bruce Dye
  o Dr. Judith Albino

https://www.nidcr.nih.gov/news-events/SGRoralHealth
Facilitating Communication

Facilitating communication between practitioners, communities, patients and researchers
Thank You!

- **Stay engaged**
  - NIDCR website & subscribe to our Gov delivery email updates
  - Quarterly e-newsletter
  - Twitter
  - Linked In

- **Contact:** Dr. Yolanda Vallejo  *Yolanda.Vallejo@nih.gov*
RFA-DE-18-001: Implementation Science Research to Improve Dental, Oral and Craniofacial Health (U01)

Funding for this project provided by the National Institute of Dental and Craniofacial Research Grant #U01DE027441
HealthPartners

• 55 primary care clinics, 22 dental clinics
• 28 general dentists; 4 oral surgeons
• EHR includes medical and dental
**PERCENT ENCOUNTERS OPIOIDS PRESCRIBED**

- **General Dentist**
  - 2013: 37.11%
  - 2014: 32.07%
  - 2015: 29.04%
  - 2016: 25.99%

- **Oral Surgeon**
  - 2013: 82.47%
  - 2014: 74.83%
  - 2015: 81.07%
  - 2016: 82.87%

- **DDS/OS Combined**
  - 2013: 52.75%
  - 2014: 49.80%
  - 2015: 50.14%
  - 2016: 51.87%

**Total encounters**
- General Dentist: 12,099
- Oral Surgeon: 29,793
- DDS/OS Combined: 17,694

**MEAN (# of tablets)**

<table>
<thead>
<tr>
<th>Year</th>
<th>General Dentist</th>
<th>Oral Surgeon</th>
<th>DDS/OS Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>22</td>
<td>22</td>
<td>22</td>
</tr>
<tr>
<td>2014</td>
<td>22</td>
<td>22</td>
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</tr>
<tr>
<td>2015</td>
<td>17</td>
<td>22</td>
<td>22</td>
</tr>
<tr>
<td>2016</td>
<td>16</td>
<td>22</td>
<td>22</td>
</tr>
</tbody>
</table>
Reduce opioid use for extractions

Approach

• Patient-centered (conditions/medications)
• Default to non-opioid combinations
• Enhanced analgesic decision making
Reduce opioid use for extractions

Implementation Strategies

- Systems Environment (*push*)
- Patients (*pull*)
Primary objective

Test the efficacy of two interventions (CDS and CDS-E) compared to treatment-as-usual to decrease opioid prescribing for dental extractions
Secondary objectives

- Test the efficacy of two interventions to increase non-opioid pain management for dental extractions
- Compare the degree of shared provider and patient decision-making concerning pain management options for dental extractions
- Compare differences in patient post-extraction pain experiences
Randomize providers in equal allocation

- **SP arm**: ~17 Providers (~2300 pts)
  - Usual Care

- **CDS arm**: ~17 Providers (~2300 pts)
  - Providers receive point-of-care information within the EHR.

- **CDS-E arm**: ~17 Providers (~2300 pts)
  - CDS arm intervention + Patients receive before and after extraction pain management education.
CDS Embedded in EHR

• CDS advantages
  – Improved fidelity
  – Fidelity can be measured
• Brings relevant information into one interface
• Time saver for provider
• Provides personalized talking points to communicate to patient and/or parent
Patient has limited history in our system.

Name: Epicest, Emrops  Gender: male  Date of Birth: Dec 22, 1979

Allergies/Intolerances
Non identified

Medication considerations

- Erythromycin Base 250 MG 3 drug interactions

- buPROPion SR (WELLBUTRIN SR) 100 MG 12 hour release tablet 2 drug interactions
  - With Opioid ⇒ Salicylate: May result in increased risk of bleeding depending on duration of use
  - With Opioid ⇒ If low dose consider increasing dose of aspirin; short term use of NSAID is low risk; evidence that Naproxen least risk for myocardial infarction

- Ardeparin 1 drug interaction

- Hydrochlorothiazide 1 drug interaction

- sodium fluoride (AKA DENTA,PREVIDENT) 1.1 % cream 1 drug interaction

Condition considerations

- COPD (chronic obstructive pulmonary disease) (HRC)
  Opioids can lead to respiratory depression and increase the risk for a respiratory event. APAP is the safest analgesic.
Proctor’s Implementation Model

Phase 1: Engagement
Phase 2: Piloting CDS
Phase 3: cluster-RCT
Phase 4: Evaluation
Developing Patient Education

• Team created analgesic information sheet about the benefits, limitations and side effects
• Provider feedback
• Patient feedback
Addressing Workflow Issues

15 clinic observations to understand provider-patient interactions and EHR use when prescribing analgesics
<table>
<thead>
<tr>
<th>Pre-extract</th>
<th>Post-extract</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Review of info given prior to appointment</strong></td>
<td><strong>Review discussion initiated by:</strong></td>
</tr>
<tr>
<td>Provider</td>
<td>Patient</td>
</tr>
<tr>
<td>Types of info given prior to appointment</td>
<td>Types of info given prior to appointment</td>
</tr>
<tr>
<td>□ Paper</td>
<td>□ Paper</td>
</tr>
<tr>
<td>□ Verbal</td>
<td>□ Verbal</td>
</tr>
<tr>
<td>□ Online</td>
<td>□ Online</td>
</tr>
<tr>
<td>□ Patient found/brought in additional info</td>
<td>□ Patient found/brought in additional info</td>
</tr>
<tr>
<td>□ None was given</td>
<td>□ None was given</td>
</tr>
<tr>
<td><strong>Notes:</strong></td>
<td><strong>Notes:</strong></td>
</tr>
<tr>
<td><strong>Medical History sought/reviewed:</strong></td>
<td><strong>Medical History sought/reviewed:</strong></td>
</tr>
<tr>
<td>□ Provider asked, unprompted</td>
<td>□ Provider asked, unprompted</td>
</tr>
<tr>
<td>□ Provider used chart prompts</td>
<td>□ Provider used chart prompts</td>
</tr>
<tr>
<td>□ Provider used EHR prompts</td>
<td>□ Provider used EHR prompts</td>
</tr>
<tr>
<td>□ Not discussed</td>
<td>□ Not discussed</td>
</tr>
<tr>
<td><strong>Conditions/medications discussed:</strong></td>
<td><strong>Conditions/medications discussed:</strong></td>
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<tr>
<td><strong>Provider solicited patient’s expectations for recovery</strong></td>
<td><strong>Provider solicited patient’s expectations for recovery</strong></td>
</tr>
<tr>
<td>□ Length of recovery:</td>
<td>□ Length of recovery:</td>
</tr>
<tr>
<td>□ Symptoms from procedure:</td>
<td>□ Symptoms from procedure:</td>
</tr>
<tr>
<td>□ Symptoms from medications being prescribed:</td>
<td>□ Symptoms from medications being prescribed:</td>
</tr>
<tr>
<td>□ Not addressed</td>
<td>□ Not addressed</td>
</tr>
<tr>
<td><strong>Discussed Pain Management</strong></td>
<td><strong>Discussed Pain Management</strong></td>
</tr>
<tr>
<td>Pain discussion initiated by:</td>
<td>Pain discussion initiated by:</td>
</tr>
<tr>
<td>□ Provider</td>
<td>□ Provider</td>
</tr>
<tr>
<td>□ Patient</td>
<td>□ Patient</td>
</tr>
<tr>
<td>Rx given? Yes / No</td>
<td>Rx given? Yes / No</td>
</tr>
<tr>
<td>For what:</td>
<td>For what:</td>
</tr>
<tr>
<td>□ Infection (Antibiotic)</td>
<td>□ Infection (Antibiotic)</td>
</tr>
<tr>
<td>□ Pain (specify med: ____________)</td>
<td>□ Pain (specify med: ____________)</td>
</tr>
<tr>
<td><strong>Contents of discussion (and WHO discussed with patient):</strong></td>
<td><strong>Contents of discussion (and WHO discussed with patient):</strong></td>
</tr>
<tr>
<td><strong>PMP accessed or referenced</strong></td>
<td><strong>PMP accessed or referenced</strong></td>
</tr>
<tr>
<td>Notes:</td>
<td>Notes:</td>
</tr>
<tr>
<td><strong>Provider referred back to EHR during Interaction</strong></td>
<td><strong>Provider referred back to EHR during Interaction</strong></td>
</tr>
<tr>
<td>□ # of times:</td>
<td>□ # of times:</td>
</tr>
<tr>
<td>□ EHR use was ongoing throughout</td>
<td>□ EHR use was ongoing throughout</td>
</tr>
<tr>
<td>□ Didn’t refer back</td>
<td>□ Didn’t refer back</td>
</tr>
<tr>
<td>Notes:</td>
<td>Notes:</td>
</tr>
<tr>
<td><strong>Patient had additional questions</strong></td>
<td><strong>Patient had additional questions</strong></td>
</tr>
<tr>
<td>Additional questions:</td>
<td>Additional questions:</td>
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<tr>
<td><strong>Follow-up plans discussed</strong></td>
<td><strong>Follow-up plans discussed</strong></td>
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<tr>
<td>□ Follow-up appointment made</td>
<td>□ Follow-up appointment made</td>
</tr>
<tr>
<td>□ Patient instructed to contact provider if complications or problems related to extraction arose</td>
<td>□ Patient instructed to contact provider if complications or problems related to extraction arose</td>
</tr>
<tr>
<td>□ Handout provided</td>
<td>□ Handout provided</td>
</tr>
<tr>
<td>□ No follow-up care discussed</td>
<td>□ No follow-up care discussed</td>
</tr>
<tr>
<td><strong>Notes:</strong></td>
<td><strong>Notes:</strong></td>
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Learning from Observations

- When provider-patient discuss of pain medications
- How the EHR was utilized
- Workflow variation
- Patient request changed prescribing from non-opioid to opioid
Patient expectations for pain management

- Patients expect medication to lessen the pain of having a tooth removed
  - Many (62%) believe over-the-counter medications are enough to manage this pain
  - More interested in over-the-counter medication than non-medication or prescription pain management options
- Most (70%) expect the pain from having a tooth removed to last 1-3 days
If you needed to have a tooth removed, how interested would you be in the following information related to your pain management options?

- Best options for me given the medications I take
  - Very interested: 87%
  - Somewhat interested: 10%
  - Not interested: 3%

- Best options for me given my medical history
  - Very interested: 85%
  - Somewhat interested: 12%
  - Not interested: 3%

- Potential side effects
  - Very interested: 79%
  - Somewhat interested: 18%
  - Not interested: 3%

- Out-of-pocket costs
  - Very interested: 70%
  - Somewhat interested: 26%
  - Not interested: 4%
Temporal Trends

• Federal (FDA, CDC)
• State of Minnesota
• American Dental Association
  – policy supporting prescription limits and mandatory continuing education for dentists
• HealthPartners
Supplement

• Pain management decisions (adolescent/parents) for extractions
• Diffusion of intervention effects for non-extraction procedures
• Opioid prescribing across patient groups

This award is co-funded by the National Institute of Dental and Craniofacial Research and the National Institutes of Neurological Disorders and Stroke in support of HEAL (Helping to End Addiction Long-Term).
Our Study Team

Brad Rindal, Co-PI
- Steve Asche
- Sheryl Kane
- Prasad Pasumarthi
- Tracy Shea
- Anjali Truitt
- Don Worley
- Haifeng Zhang
- Jeanette Ziegenfuss

Shannon Mitchell, Co-PI
- Jan Gryczynski
- Robert Schwartz

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PCSS Mentoring Program

- PCSS Mentor Program is designed to offer general information to clinicians about evidence-based clinical practices in prescribing medications for opioid addiction.

- PCSS Mentors are a national network of providers with expertise in addictions, pain, evidence-based treatment including medication-assisted treatment.
  - 3-tiered approach allows every mentor/mentee relationship to be unique and catered to the specific needs of the mentee.
  - No cost.

For more information visit:  
https://pcssNOW.org/mentoring/
PCSS Discussion Forum

Have a clinical question?

Ask a Colleague

A simple and direct way to receive an answer related to medication-assisted treatment. Designed to provide a prompt response to simple practice-related questions.

Ask Now

http://pcss.invisionzone.com/register
**PCSS** is a collaborative effort led by the American Academy of Addiction Psychiatry (AAAP) in partnership with:

<table>
<thead>
<tr>
<th>American Academy of Family Physicians</th>
<th>American Psychiatric Association</th>
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<tr>
<td>American Academy of Neurology</td>
<td>American Society of Addiction Medicine</td>
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<tr>
<td>Addiction Technology Transfer Center</td>
<td>American Society of Pain Management Nursing</td>
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<tr>
<td>American Academy of Pain Medicine</td>
<td>Association for Medical Education and Research in Substance Abuse</td>
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<tr>
<td>American Academy of Pediatrics</td>
<td>International Nurses Society on Addictions</td>
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<td>American College of Emergency Physicians</td>
<td>American Psychiatric Nurses Association</td>
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<td>American College of Physicians</td>
<td>National Association of Community Health Centers</td>
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<tr>
<td>American Dental Association</td>
<td>National Association of Drug Court Professionals</td>
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<tr>
<td>American Medical Association</td>
<td>Southeastern Consortium for Substance Abuse Training</td>
</tr>
<tr>
<td>American Osteopathic Academy of Addiction Medicine</td>
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Webinar Evaluations (Post and 30-Day)

- Each partner organization is asked to distribute a post and 30-day evaluation to participants for their completion.

- Participants in today’s webinar will be emailed the link to complete their evaluations.

- Thank you for your feedback!
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