THE OPIOID EPIDEMIC AND EMERGING PUBLIC HEALTH POLICY PRIORITIES

PRESENTED TO THE
AMA NATIONAL ADVOCACY CONFERENCE
February 13, 2019
THE STATE OF OPIOID MISUSE IN AMERICA (2017)

11.4 million people misused opioids in the past year
- 11.1 million misused pain relievers
- 886,000 used heroin
- 562,000 both misused pain relievers and heroin

2.1 million people had an opioid use disorder
- 1.7 million people with a prescription pain reliever use disorder
- 652,000 people with a heroin use disorder
- 252,000 had both pain reliever and heroin use disorders

Main reasons for opioid misuse: Pain 62.6%

53.1% obtained the last pain reliever they misused from a friend or relative
36% from a prescription from a healthcare provider

Office of the Assistant Secretary for Health
NSDUH, 2017 Data; published Sept. 2018
U.S. DRUG OVERDOSE DEATHS
THE MOST CRITICAL PUBLIC HEALTH CHALLENGE OF OUR TIME

SOURCE: NCHS, National Vital Statics System, Mortality
### OVERDOSE MORTALITY BY CLASS OF DRUG
ADAPTED FROM CDC STATISTICS, JANUARY 2019

<table>
<thead>
<tr>
<th></th>
<th>HEROIN</th>
<th>NAT &amp; SEMI – SYNTHETIC</th>
<th>METHADONE</th>
<th>SYNTHETIC OPIOIDS</th>
<th>COCAINE</th>
<th>PSYCHO-STIMULANTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>JUNE 2017 *</td>
<td>16,622</td>
<td>15,546</td>
<td>3,357</td>
<td>26,057</td>
<td>13,367</td>
<td>9,446</td>
</tr>
<tr>
<td>JUNE 2018 *</td>
<td>15,283</td>
<td>13,929</td>
<td>3,283</td>
<td>31,551</td>
<td>15,095</td>
<td>11,741</td>
</tr>
<tr>
<td>Change</td>
<td>-8.06%</td>
<td>-10.04%</td>
<td>-2.20%</td>
<td>21.08%</td>
<td>12.93%</td>
<td>24.30%</td>
</tr>
</tbody>
</table>


>70% of Cocaine Deaths also have Opioids Detected

- Number of predicted deaths for the 12 months ending in June of the indicated year
SHOCKING LEVELS OF ILLICIT DRUG SMUGGLING

Feds make largest fentanyl bust in U.S. history
Jan. 31, 2019

- CBP officers seized:
  - 254 pounds of fentanyl in a floor compartment of a truck trailer loaded with cucumbers
  - 395 pounds of methamphetamine
  - Fentanyl sufficient to kill >50 million people

CBP estimates the fentanyl street value at $3.5 million
LAST MONTH SUBSTANCE USE AMONG PREGNANT WOMEN

ILLICIT DRUGS

<table>
<thead>
<tr>
<th>Year</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>109,000</td>
<td>4.7%</td>
</tr>
<tr>
<td>2016</td>
<td>143,000</td>
<td>6.3%</td>
</tr>
<tr>
<td>2017</td>
<td>194,000</td>
<td>8.5%</td>
</tr>
</tbody>
</table>

TOBACCO PRODUCTS

<table>
<thead>
<tr>
<th>Year</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>319,000</td>
<td>13.9%</td>
</tr>
<tr>
<td>2016</td>
<td>239,000</td>
<td>10.6%</td>
</tr>
<tr>
<td>2017</td>
<td>334,000</td>
<td>14.7%</td>
</tr>
</tbody>
</table>

ALCOHOL

<table>
<thead>
<tr>
<th>Year</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>214,000</td>
<td>9.3%</td>
</tr>
<tr>
<td>2016</td>
<td>187,000</td>
<td>8.3%</td>
</tr>
<tr>
<td>2017</td>
<td>261,000</td>
<td>11.5%</td>
</tr>
</tbody>
</table>

NSDUH, 2017 Data; published Sept. 2018
NEWBORN VICTIMS OF THE OPIOID EPIDEMIC

Outcomes in the fetus
- Growth restriction
- Prematurity
- Death

Outcomes in the Newborn
- Low birthweight
- Small head circumference
- Neonatal abstinence syndrome

Outcomes in the Child
- Developmental disorders

Source: AHRQ HCUP State Inpatient Databases

McQueen, NEJM 2016
GASTROSCCHISIS LINK TO OPIOID PRESCRIPTION RATES

- 2011-2015: 2.5 per 10,000 live births
- 2006-2010: 10% increase
- Ecologic analysis: higher prevalence of gastroschisis in areas where opioid prescription rates were higher
- Supports epidemiologic data suggesting link between gastroschisis and opioid use during pregnancy

Graphic Courtesy of CDC

Short et al, MMWR, Jan 18, 2019
INCIDENCE OF OPIOID AND AMPHETAMINE RELATED DELIVERIES (US, 2004-2015)

- Increased disproportionately across rural compared with urban counties in 3 of 4 census regions between 2008 to 2009 and 2014 to 2015
- Amphetamine-related deliveries were associated with higher incidence of preeclampsia, preterm delivery, and severe maternal morbidity and mortality

INFECTIOUS CONSEQUENCES OF THE OPIOID EPIDEMIC

• HIV
• Hepatitis C
• Hepatitis B
• Endocarditis
• Skin, bone, and joint infections

National Academies Workshop
Sponsored by OASH, Report July 2018
HHS 5-POINT STRATEGY TO COMBAT THE OPIOIDS CRISIS

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

https://www.hhs.gov/opioids/
HHS OPIOIDS OVERALL STRATEGY UPDATE
RELEASED SEPTEMBER 17, 2018

“The five-point HHS strategy to end the opioid crisis, unveiled under President Trump in 2017, uses the best science and evidence to directly address this public health emergency. Now, HHS is expanding the scope and improving the effectiveness of the strategy.”

Secretary Alex Azar

WHAT IS EVIDENCE-BASED TREATMENT?

- **FDA-approved Medication (MAT)**
  - Naltrexone: once a month injectable medication, blocks effects of opioids (Any prescriber)
  - Methadone: long acting, once-daily, opioid from specially licensed programs (OTP programs only)
  - Buprenorphine/naloxone: long acting, once daily/once monthly, opioid from doctor's offices (Waivered prescribers)

- **Psychosocial Therapies**
  - Education, coping skills, contingency management and cognitive behavioral therapy

- **Recovery Services - Rebuilding One’s Life**
  - Social supports to welcome into a healthy community: family, friends, peers, faith-based supports
  - Assistance with needs that can impact treatment - recovery housing, transportation and child care
  - Employment/Vocational training/education

- **Naloxone**
CLINICIANS RECENTLY WAIVERED FOR BUPRENORPHINE PRESCRIBE BELOW THEIR LIMIT OR NOT AT ALL

• **Survey:** 4225 clinicians receiving data waiver or increase in authorized patient limit in 2017

• **Main Findings**
  - Only 75% had prescribed buprenorphine since obtaining the waiver
  - Mean number of patients treated in past month = 26.6
  - **Clinicians prescribing at or near their limit = 13.1%**

• **Barriers to prescribing buprenorphine at or near limit**
  - Lack of patient demand = 19.4%
  - Time constraints in practice = 14.6%
  - Insurance requirements = 13.2%

*Jones and McCance-Katz. *Addiction*, Sept 8, 2018*
NALOXONE: AN ESSENTIAL PART OF THE OPIOIDS SOLUTION

Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.

Surgeon General’s Advisory on Naloxone and Opioid Overdose

I, Surgeon General of the United States Public Health Service, ADM 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.
Bystander Presence and Naloxone

Significant Opportunity for Improvement

<table>
<thead>
<tr>
<th></th>
<th>Prescription Opioids (%)</th>
<th>Illicit Opioids (%)</th>
<th>Prescription and Illicit Opioids (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In Category</strong></td>
<td>17.4</td>
<td>58.7</td>
<td>18.5</td>
</tr>
<tr>
<td><strong>Previous OD</strong></td>
<td>9.3</td>
<td>15.1</td>
<td>13.5</td>
</tr>
<tr>
<td><strong>Bystander present</strong></td>
<td>41.6</td>
<td>44.0</td>
<td>45.0</td>
</tr>
<tr>
<td><strong>Bystander naloxone</strong></td>
<td>0.8</td>
<td>4.3</td>
<td>4.4</td>
</tr>
</tbody>
</table>

11,884 Opioid Deaths *(CDC ESOOS Data, 11 States, July 2016 – June 2017)*

Mattson et al., MMWR, Aug 31, 2018
LACK OF NALOXONE CO-PRESCRIBING TO PATIENTS AT RISK

- **PDX, Inc**
  - April – June 2018 (verbal report to HHS)
  - 8600 pharmacies nationwide
  - For patients on MME > 50, rate of naloxone co-prescribing was 0.3%
  - For those prescribed naloxone, 40% never picked up prescription

- **MEDICARE, 2017**
  - MME > 50: rate of naloxone co-filling was 1.3%
  - MME = 90 – 120: rate of naloxone co-filling was 1.6%
  - MME > 120: rate of naloxone co-filling was 5.2%

  ✓ Primary drivers of co-prescribing are states with mandatory co-prescription laws
HHS RECOMMENDATION: PRESCRIBE NALOXONE TO ALL PATIENTS AT HIGH RISK OF OPIOID OVERDOSE

- Reinforces and expands upon prior CDC guidelines
- Clinicians should also educate patients and those who are likely to respond to an overdose, including family members and friends, on when and how to use naloxone in its variety of forms

Prescribe or co-preserve naloxone to individuals at risk for opioid overdose including individuals who

- are on relatively high doses of opioids
- take other medications which enhance opioid complications
- have underlying health conditions

ACHIEVING RESULTS IN COMBATING THE OPIOID EPIDEMIC

PROGRESS (JANUARY 2017 – NOVEMBER 2018)

- The total morphine milligram equivalents dispensed monthly by retail and mail-order pharmacies declined by 25.6%.
- Number of unique patients receiving buprenorphine monthly from retail pharmacies increased by 21.9%.
- The number of naltrexone prescriptions per month from retail and mail pharmacies has increased more than 46.9%.
- Naloxone prescriptions dispensed monthly by retail and mail-order pharmacies have increased by 338%.

ACHIEVING RESULTS IN COMBATING THE OPIOID EPIDEMIC PROGRESS (2015 to 2017)

- The number of individuals who misused pain relievers decreased from 12.5 million to 11.1 million.
- The number of individuals with pain reliever use disorder decreased from 2.0 million to 1.7 million.
NATIONAL SURVEY ON DRUG USE AND HEALTH, 2017
FIRST TIME HEROIN USERS DROPPED BY >60% (2016-2017)

Past Year Heroin Initiates among People Aged 12 or Older (in thousands): 2002-2017

NSDUH, 2017 Data; published Sept. 2018
ED VISITS FOR SUSPECTED DRUG OVERDOSE (% CHANGE)
Q2 2017 – Q2 2018

* 22 States

* 24 States

Source: CDC Enhanced State Opioid Overdose Surveillance Program (ESOOS)
OVERDOSE MORTALITY (PREDICTED): CDC JANUARY 2019

Figure 1b. Percent Change in Predicted 12 Month-ending Count of Drug Overdose Deaths, by Jurisdiction: June 2017 to June 2018

Percent Change for United States
-0.9

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

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH
12 MONTH OVERDOSE MORTALITY: CDC JUNE 2018

HHS OPIOIDS TEAM GOAL
Reduce US drug overdose mortality by at least 15% (>10,000 lives annually) by January 2021

12-months ending in June 2018
IMPLEMENT SUPPORT ACT (1)

SUPPORT FOR PATIENTS AND COMMUNITIES ACT
ENABLES HHS TO BUILD AND EXPAND PROGRAMS THAT ALIGN WITH FIVE-POINT OPIOID STRATEGY

**Key SUPPORT Act Provisions**

- Improve prescription drug monitoring programs and encourages data sharing between states
- Require the development of evidence-based opioid analgesic prescribing guidelines for treatment of acute pain
- Increase the number of waived healthcare providers that can prescribe or dispense MAT
- Authorize grants to support the development of curriculum that will help healthcare practitioners obtain a waiver to prescribe MAT
TRANSFORM TO A SUSTAINABLE MODEL (2)

Transitioning from a “crisis framework” into an integrated, sustainable, predictable, and resilient public health system for preventing and treating substance use and other behavioral health disorders.
MATERNAL OPIOID MISUSE (MOM) MODEL

The MOM model is a patient-centered, service-delivery model, which aims to improve the quality of care and reduce costs for pregnant and postpartum Medicaid beneficiaries with OUD and their infants through state-driven care transformation.

GOALS

1. Improve quality of care and reduce costs
2. Expand access to treatment, service-delivery capacity, and infrastructure
3. Create sustainable coverage and payment strategies

Notice of funding opportunity release: early 2019 / Application period: Spring 2019
$64.5M available for state awardees over five-year model
RESEARCH AND POLICY ISSUES (3)
DEVELOPING NATIONAL INFRASTRUCTURE TO TRACK, STUDY, AND IMPROVE OUTCOMES OF BABIES WITH NAS

LEVERAGE EXISTING HEALTH IT TOOLS
- Electronic Health Record
- Share/Exchange Data
- Interface Data

NEW NAS-SPECIFIC DATA ELEMENTS SET
- Development/clinical
- Social/non-clinical
- Maternal/child dyad

NATIONAL NAS TRACKING SYSTEM
Understanding Outcomes & Improving Long-term Care
## HHS CROSS CUTTING INITIATIVES (4)

<table>
<thead>
<tr>
<th>INITIATIVE</th>
<th>OBJECTIVE</th>
<th>AGENCIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEALing Communities</td>
<td>Reduce overdose fatalities by 40% in 3 years across communities highly affected by the opioid crisis</td>
<td>NIH, SAMHSA, HRSA, ACF, CMS, ASPE, AHRQ, OASH, CDC; DOJ, HUD, Education</td>
</tr>
<tr>
<td>Indication-Specific Opioid Prescribing Guidelines</td>
<td>Develop and implement indication-specific best practices for opioid prescribing by 2021</td>
<td>CDC, AHRQ, NIH, OASH, CMS, FDA, IHS, SAMHSA</td>
</tr>
<tr>
<td>Opioid Rapid Response Public Health Teams</td>
<td>Establish health “strike teams” to ensure that following a DOJ intervention, 100% of patients have a warm-handoff to a provider.</td>
<td>CDC, Commissioned Corps, Departments of Justice, SAMHSA</td>
</tr>
<tr>
<td>Technological Solutions to Prevent Overdose Mortality</td>
<td>Develop and evaluate at least one wearable device that overdose mortality by 2021</td>
<td>BARDA/ASPR, NIH, HHS CTO, DARPA</td>
</tr>
<tr>
<td>Transforming the US Healthcare Workforce</td>
<td>Define a novel model(s) for behavioral health care delivery, and increase providers by net 8000 by 2021</td>
<td>HRSA, SAMHSA, CMS, ASPE, IHS, CDC, AHRQ, CDC</td>
</tr>
</tbody>
</table>
HIV HAS COST AMERICA TOO MUCH FOR TOO LONG

700,000
American lives lost to HIV since 1981

$20 billion
Annual direct health expenditures by U.S. government for HIV prevention and care

Without intervention and despite substantial progress another

400,000
Americans will be newly diagnosed over 10 years despite the available tools to prevent infection
ENDING THE HIV EPIDEMIC: A PLAN FOR AMERICA

GOAL:

75% reduction in new HIV infections in 5 years
and at least 90% reduction in 10 years.

FOCUSED EFFORT

- 48 Counties, DC, and San Juan account for 50% of new infections
- 7 States with substantial rural HIV burden
ENDING THE HIV EPIDEMIC: A PLAN FOR AMERICA

ACHIEVING THE GOALS

☐ DIAGNOSE
All people with HIV as early as possible after infection

☐ TREAT
The infection rapidly and effectively to achieve sustained viral suppression

☐ PROTECT
People at highest risk of HIV with potent evidence-based interventions

☐ RESPOND
Rapidly and effectively to clusters and outbreaks of new HIV infections

☐ HIV HEALTHFORCE
A boots-on-the-ground team that ensures implementation of HIV elimination plans

Now is the time.
Our goal is ambitious. Our pathway is clear.