The Changing Role of Government in Addressing the Opioid Crisis: Opportunities and Challenges

Elinore F. McCance-Katz, MD, PhD
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
Mental and Substance Use Disorders in the U.S.

- Opioids Crisis
- Tragedy, but Opportunity
- Roles
  - Federal Government
  - State Government
    - Communities
    - Families
    - Individuals
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

7.6%
(18.7 MILLION)
People aged 18 or older had a substance use disorder

3.4%
(8.5 MILLION)
18+ HAD BOTH substance use disorder and a mental illness

18.9%
(46.6 MILLION)
People aged 18 or older had a mental illness

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

- Substance Use Disorder (SUD) 12+: 57.4% No Treatment
- Any Mental Illness (AMI) 18+: 92.3% No Treatment
- Serious Mental Illness 18+: 33.3% No Treatment
- Co-Occurring AMI & SUD 18+: 91.7% No Treatment
- Major Depressive Episode (MDE) 12-17: 58.5% No Treatment

Total: 46.6M

19.7M

11.2M

3.2M

8.5M
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

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

- **11.1 MILLION** Rx Pain Reliever Misusers (97.2% of opioid misusers)
- **886,000** Heroin Users (7.8% of opioid misusers)
- **6.3 MILLION** + Rx Hydrocodone
- **3.7 MILLION** Rx Oxycodone
- **245,000** Rx Fentanyl
- **562,000** Rx Pain Reliever Misusers & Heroin Users (4.9% of opioid misusers)

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.

Significant decrease from 12.7 M misusers in 2015
Sources Where Pain Relievers Were Obtained for Most Recent Misuse Among People Who Misused Prescription Pain Relievers in the Past Year, 2017, 12+ years old

- Given by, Bought from, or Took from a Friend or Relative: 53.1%
- From Friend or Relative for Free: 38.5%
- Bought from Friend or Relative: 10.6%
- Took from Friend or Relative without Asking: 4.0%
- Got through Prescription(s) or Stole from a Health Care Provider: 36.6%
- Some Other Way: 4.6%
- Bought from Drug Dealer or Other Stranger: 5.7%
- Prescription from One Doctor: 34.6%
- Prescriptions from More Than One Doctor: 1.5%
- Stole from Doctor’s Office, Clinic, Hospital, or Pharmacy: 0.5%

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

### Heroin Initiation Among People Nonmedically Using Prescription Opioids

<table>
<thead>
<tr>
<th>Muhuri et al., 2011</th>
<th>Carlson et al., 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.6% of nonmedical users of Rx opioids had initiated heroin use within 5 years of initiating nonmedical use</td>
<td>Followed 18-23 year olds for 3 years</td>
</tr>
<tr>
<td>Initiation rate of &lt;1.0%/yr</td>
<td>27 of 362 (7.5%) initiated heroin use over 36 months</td>
</tr>
<tr>
<td>Risk factors</td>
<td>Initiation rate of 2.8% per year</td>
</tr>
<tr>
<td>• Frequent nonmedical use</td>
<td>Risk factors</td>
</tr>
<tr>
<td>• Rx opioid abuse/dependence</td>
<td>• Rx opioid dependence</td>
</tr>
<tr>
<td>• History of injection drug use</td>
<td>• Early age at initiation</td>
</tr>
<tr>
<td></td>
<td>• Non-oral route of abuse</td>
</tr>
<tr>
<td></td>
<td>• Only use Rx opioids to get high</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Behavior or experience</th>
<th>APR</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular heroin use</td>
<td>4.07</td>
<td>1.24–13.3</td>
<td>0.020</td>
</tr>
</tbody>
</table>

Source: Carroll et al, Int. J. Drug Policy, 2017 and CDC Epi-Aid 2015-2016 OH and MA
What Does All of This Tell Us?

• Most opioid misuse/use disorders remain in those using prescription opioid pain relievers
• Prescribers continue to be a major part of the problem
• Lack of public and patient education/awareness of the addictive potential and danger of prescription opioid misuse is a continuing problem
• Heroin and illicit opioid pills contaminated by fentanyl and other potent opioids are responsible for the majority of deaths
• 45% got no treatment for heroin use disorder
• 79% got no treatment for prescription pain reliever use disorder
  • Don’t believe they need treatment
  • Stigma
  • Lack of resources
  • Lack of providers
  • Lack of evidence-based treatment availability/community recovery supports
Federal Response

HHS FIVE-POINT OPIOID STRATEGY

1. Strengthening public health surveillance
2. Advancing the practice of pain management
3. Improving access to treatment and recovery services
4. Targeting availability and distribution of overdose-reversing drugs
5. Supporting cutting-edge research
Plan to Address the Opioids Crisis

- STR grants to states: 500 million/yr through Cures FY 17 and 18;
- **FY 19 State Opioid Response (SOR): 1.5B**
- Public outreach: prevention/education/treatment/recovery services
- Naloxone access/First Responders/Peers: **FY 19: $49M**
- MAT-PDOA: **FY 19: $89M**
- Pregnant/post partum women/NAS: **FY 19: $29.9M**
- CJ programs with MAT; drug courts and offender re-entry; **FY 19: $89M**
- Building Communities of Recovery **FY 19: 6M**
- Reinstatement of Drug Abuse Warning Network (DAWN) **$10M**
- To address prevention and treatment of other SUDs:
  - Block grants to states **FY 19: $1.86B**
- NSDUH continuation with more rapid release of data
- Collaboration: federal/states/stakeholder groups/philanthropists/public awareness
Addressing the Opioids Crisis

**Resources to Rural America:**
- Telehealth
  - Direct service provision
  - Training/mentoring
- Working with DEA on revised regulations
- Technology Transfer Centers: Substance Abuse Prevention, Addiction, Mental Health
- Collaboration with USDA
  - Supplements to Cooperative Extensions to train/raise public awareness on opioids/risks
  - Recovery housing
  - Mobile units planned
- Community Recovery Supports
  - Peers: ED, Outreach
- Engagement of Faith-Based Community
  - Recovery supports
  - Recovery housing
- HIPAA/42 CFR: Family inclusion in medical emergencies: overdose
  - National Privacy TTC
  - NPRM in 2019 to better align with HIPAA while still providing 42 CFR protections
Healthcare Practitioner Training/Preparation

- STR Technical Assistance/Training Grant: individualized training according to state needs by local teams of addiction treatment providers.
- DATA waiver training in pre-graduate settings: medical school, advance practice nursing, physician assistant programs: *PCSS Universities*
- Encourage national certification program for peer workforce.
- Establish training on recognition and treatment of substance misuse/abuse/use disorders in healthcare professional training programs.
- Integration of BH including OUD treatment into primary care/FQHCs.
- Use of Telehealth/ECHO/HIT to increase ability of practitioners to provide needed care and as an alternative training method.
SAMHSA: Technical Assistance and Training Programs in a Variety of Formats

Evidence-Based Practice Repository in NMHSUPL

National Technical Assistance/Training Centers:
State Targeted Response to Opioids, Providers’ Clinical Support System for Medication Assisted Treatment, Clinical Support System for Serious Mental Illness, National Child Traumatic Stress Network, National Center on Substance Abuse and Child Welfare, Center for Integrated Health Services, Veterans, GAINS (Criminal Justice), Disaster, Social Inclusion/Public Education, SOAR, Suicide Prevention, Eating Disorders, Privacy

Combined Efforts at the Regional, State, and Local Levels Oriented to All Health Professionals

Regional Substance Abuse Prevention, Addiction, Mental Health/School Based Services Collaborating Technology Transfer Centers

Region 1, Region 2, Region 3, Region 4, Region 5, Region 6, Region 7, Region 8, Region 9, Region 10

National Hispanic/Latino TTC
National American Indian/Alaska Native TTC
What States Can Do

• Accurately assess needs: how much of an opioids problem? Where are the greatest gaps?
• Prevention, treatment and recovery needs of its people?
• Provide education to youth on dangers of substance misuse/opioids misuse
• Invest in first responder training on opioid overdose reversal and naloxone purchase
• Government officials/decision makers: Learn about OUD and evidence-based treatment
• Require prescribers/other healthcare professionals to learn about OUD and treatment
• Consider requiring that all eligible prescribers obtain the DATA waiver
• Require use of the PDMP prior to prescribing controlled substances and periodically thereafter (e.g.: q 3 mos.)
• Require evidence-based treatment for opioid use disorder: pharmacotherapy (MAT) + psychosocial and recovery supports
• Be aware that ‘detox’ alone is not effective for OUD; require injectable naltrexone following detox
• Require all providers to offer/have providers easily accessible who will provide all 3 MAT
• Provide funding for recovery supports: housing, employment, education, childcare
Consider applying for an 1115 waiver to lift the IMD exclusion on SUDs/serious mental illness—plan needs to include use of levels of care:

- Inpatient
- Residential
- Outpatient
- Intensive outpatient
- Partial hospital program
- Community supports: Recovery coaches, vocational assistance, benefits assistance, housing assistance

- Require that programs receiving funding provide these services
- Remove prior authorization from MAT
- Remove limits on MAT duration
Pay for the cost of substance abuse treatment services:

- Physical healthcare
- Substance Use Disorder care
- Psychiatric care
- Care coordination
- Opioid Use Disorder pharmacotherapy (MAT)
- Laboratory testing
- Psychosocial services: counseling, motivational interviewing, cognitive behavioral therapy, contingency management crisis intervention, individual/group/couples therapy
- Psychoeducation
- Family involvement
Continued Increases in Providers Seeking DATA Waiver

DATA 2000 waived providers through April 20, 2019

Total Maximum Potential Patient Capacity = 3,992,365
34 states have a higher OUD rate than the maximum buprenorphine rate.

16 states and the District of Columbia have a higher maximum buprenorphine rate than the OUD rate.

1 state has an equal OUD rate and maximum buprenorphine rate.

Source: Analysis of 2015-2016 NSDUH data and SAMHSA DATA 2000 Program data.
What Providers Can Do

Invest the time to learn and use:
Screening, Brief Intervention and Referral to Treatment (SBIRT)
Assessment and Treatment of Substance Use Disorders

Particularly Opioid Use Disorders

If you are in a profession that can do so: get a DATA waiver
Expand SUD/OUD treatment services in your clinical settings
Develop partnerships with community recovery supports: Peer recovery coaches,
faith-based groups, community resources: e.g.: vocational/educational/housing
Advocate to state leadership about need for resources to provide services
What Else is Coming to Assist with the Opioids Crisis?

- National, interoperable PDMP and required use
- Widespread adoption of inclusion of PDMP in EHR
- Electronic defaults in EHRs to prompt appropriate quantities and guideline concordant prescribing
- Increased monitoring for best practices in prescribing
- Blister packaging of opioids with what would be the typical number/dose of pills for clinical indications
- Research: analgesics without abuse liability, non-opioid alternatives, more potent naloxone formulations
- Payment policies to expand access to opioid alternatives and support multidisciplinary team based care: bundled payments for levels of care
Prescription Pain Reliever Misuse

PAST YEAR, 2015 - 2017, 12+

+ Difference between this estimate and the 2017 estimate is statistically significant at the .05 level.
Heroin Use

No difference between this estimate and the 2017 estimate is statistically significant at the .05 level.
Past Year, 2015 - 2017, 12+

Heroin-Related Opioid Use Disorder

Estimates of less than 0.1% were rounded to 0.0%

No difference between this estimate and the 2017 estimate is statistically significant at the .05 level.
The difference between this estimate and the 2017 estimate is statistically significant at the .05 level.

P = 0.0008

P = 0.0337

P = 0.0090

+ Difference between this estimate and the 2017 estimate is statistically significant at the .05 level.
Signs of Progress: Morphine Milligram Equivalents (MME) Prescribed per Month (US)

27% decrease since January 2017
Signs of Progress: Receipt of MAT from Treatment Programs

Source: SAMHSA NSSATS
Increasing Number of Patients Receiving Buprenorphine and Injectable Naltrexone by Prescription (Pharmacy data)

Patients receiving buprenorphine

Injectable naltrexone prescriptions

Source: IQVIA National Prescription Audit and Total Patient Tracker, Data Extracted May 2018
Methadone:
  381,867 (March, 2017)

Buprenorphine: 690,473
  - 667,408 (December, 2018) unique patients through retail or mail order prescriptions
  
  23,065 (March 2017) (from Opioid Treatment Programs)

Injectable Naltrexone (Vivitrol):
  - 74,370 (2018)
    (data per Alkermes, 2019)

Approximately 1,146,710 patients are currently receiving MAT
Signs of Progress: Dramatic Increases in Naloxone Dispensing from U.S. Pharmacies

Source: IQVIA National Prescription Audit, data extracted 2016-2018

State laws changing on naloxone at rapid pace
2017:

- Prescription opioid misuse modestly declining
- Heroin use:
  - Fewer new users
  - Modest decline in heroin use in 18-25 y.o.
  - Increase in 18-25 y.o. with use disorder
- Significant increases in numbers of individuals with OUD getting specialty treatment
- Plateauing of overdose deaths involving commonly prescribed opioids, but still with overall increases in opioid-associated overdose deaths mainly due to illicit synthetic opioids
- Some states seeing a leveling off of opioid overdose deaths
The opioid epidemic continues to evolve

Urgent need to prepare workforce rapidly and deliver evidence-based prevention, treatment and recovery services

Some emerging signs of progress

Actions must focus comprehensively to address underlying contributors to the crisis

Substantial efforts underway to combat the opioid epidemic, but gaps in the evidence base remain

Work continues to aggressively address the epidemic
Other Concerns: Stimulants

Methamphetamine

<table>
<thead>
<tr>
<th>Year</th>
<th>12-17</th>
<th>18-25</th>
<th>26 or Older</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>40K</td>
<td>329K</td>
<td>1.3M</td>
</tr>
<tr>
<td>2016</td>
<td>0.2%</td>
<td>0.8%</td>
<td>0.6%</td>
</tr>
<tr>
<td>2017</td>
<td>0.1%</td>
<td>375K</td>
<td>1.1%</td>
</tr>
<tr>
<td></td>
<td>0.2%</td>
<td>265K</td>
<td>1.0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.2M</td>
<td>0.6%</td>
</tr>
</tbody>
</table>

Source: SAMHSA
Other Concerns: Stimulants
Methamphetamine

Percentages of People Aged 12 or Older

- Dark Blue: 0.98–1.57
- Orange: 0.74–0.97
- Medium Blue: 0.54–0.73
- Green: 0.33–0.53
- Light Green: 0.08–0.32

Differences in colors across states does not indicate significant differences in estimates.
Other Concerns: Stimulants

Cocaine

- 2014: 39K (0.2%), 28K (0.1%), 26K (0.1%)
- 2015: 53K (0.2%), 18-25 (1.7%), 26 or Older (0.5%)
- 2016: 580K (1.7%), 552K (1.6%), 26 or Older (0.6%)
- 2017: 473K (1.4%), 665K (1.9%), 26 or Older (0.7%)
Other Concerns: Stimulants
Cocaine

Percentages of People Aged 12 or Older

- 2.52-5.02
- 1.96-2.51
- 1.70-1.95
- 1.39-1.69
- 0.67-1.38

Differences in colors across states does not indicate significant differences in estimates.
Cocaine and Methamphetamine

No effective medication treatments despite numerous research efforts:

Psychotropics
  • Antidepressants
  • Antipsychotics
  • Anticonvulsants
  • Stimulants

Naltrexone

- Psychotherapies/counseling relied upon
- One of the more promising approaches:
  - Contingency Management

  Abstinence: reinforced by contingency
  Example: Voucher-Based Treatment

Positive reinforcement of desired behavior
Reward given for drug-free urine sample
Helpful in engaging for longer treatment periods (e.g. 24wks)
Means of achieving abstinence for a period long enough to help patients learn new skills that will help sustain sobriety

OIG: Allows “Gifts of nominal value” ($15/gift; $75/yr) to Medicare and Medicaid beneficiaries

Stimulant Use Disorder Treatment: It’s not Like Opioid Use Disorder
And One More Thing---Accumulating Data on Potential Adverse Impacts of Marijuana Use: Does This Look Like a Treatment for Opioid Use Disorder?

Adverse outcomes linked to marijuana use by youth:
- Poor school performance and increased drop out rates
- Chronic use in adolescence has been linked to decline in IQ that may not recover with cessation (Meier et al. 2012)
- Marijuana use in adolescence is associated with an increased risk for later psychotic disorder in adulthood (D’Souza, et al. 2016)
- Marijuana use linked to earlier onset of psychosis in youth known to be at risk for schizophrenia (McHugh, et al. 2017)
- Significant numbers who try marijuana will become addicted (Lopez-Quintero, et al. 2011)
- Higher overall rates of car crashes in states that have legalized (WAPO, June 2017)
- Association of marijuana use with abuse of prescription pain medications (Olfson et al. 2017)

Marijuana and Pregnancy:
- Fetal growth restriction
- Stillbirth
- Preterm birth
- May cause problems with neurological development
  - Hyperactivity
  - Poor cognitive function

(Metz TD and Stickrath EH, 2015)
Behavioral Health Treatment Services Locator

findtreatment.samhsa.gov

Elinore.mccance-katz@samhsa.hhs.gov