



## The Opioid Epidemic: Logistics, Legislation, and Real Life

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## Substance Abuse

• It is the worst of plagues. It knows no season, no boundaries, no microbe isolated, no vaccine invented to end its reign. It is a pestilence with all the classic trappings of social disruption, suffering and death - and on terrible, defining difference: we invite it to kill, maim, and diminish us. And because its vector is pleasure and its mask is time, we have not even recognized its horror fully enough to grant it a name worthy of its grisly power. Is it inadequate to call this filler of graves and plunderer of nations by so pallid a name as Substance Abuse.

• Robert Wood Johnson Foundation

## Topics for Today

- Opioid Data
- Pain and the Opioid Epidemic
- Race and the Opioid Epidemic
- Federal Opioid Legislation (SUPPORT legislation)
- State Opioid Legislation (HOPE legislation)
- Can WE Be a Part of Ending the Epidemic?

## The Opioid Epidemic

- 130 people A DAY die in the United States after from an opioid overdose
- CDC estimates that the total "economic burden" in the United States is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment and criminal justice involvement

CDC/NCHS, [National Vital Statistics System](#)

## The Opioid Epidemic

- Roughly 21-29% of people prescribed opioids for chronic pain do not take as prescribed
- Between 8-12% develop an opioid use disorder (OUD)
- About 80% of people who use heroin first misused prescription opioids
- Opioid overdoses > 30% from July 2016 through September 2017 in 45 states

CDC/NCHS, [National Vital Statistics System](#)

## Opioids in Wisconsin

- Between 2005-2016 the rate of opioid use disorder more than tripled
- In 2018- 839 people in WI died from opioid overdoses, more than the number killed in car crashes
- From 2016-2018 deaths in WI decreased by 1.3%
- 16.9 deaths per 100,000 persons, and higher than the national rate of 14.6 deaths per 100,000 persons

WDHS (2019)

## Hospital Utilization in Wisconsin

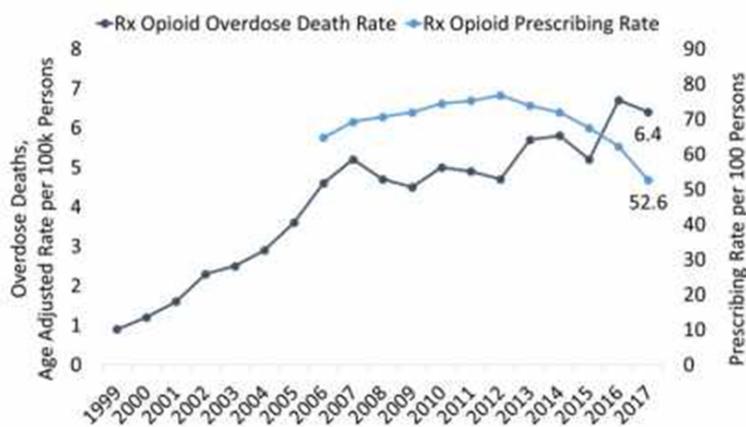
- In 2018 there were 2,426 opioid-related ED visits, down 2.4% from 2016-2018
- In 2018 there were 1,245 opioid-related inpatient stays, down 2.4% from 2016-2018

## Prescription for Opioids in Wisconsin

- 2017= WI providers wrote 52.6 opioid prescriptions for every 100 persons
- Among the lowest prescribing rates in the country and less than the average U.S. rate of 58.7 prescriptions
- Rate of overdose deaths involving opioid prescriptions has risen steadily from 0.9 deaths in 1999 to 6.4 deaths per 100,000 persons in 2017

WDHS (2019)

## Prescription for Opioids in Wisconsin

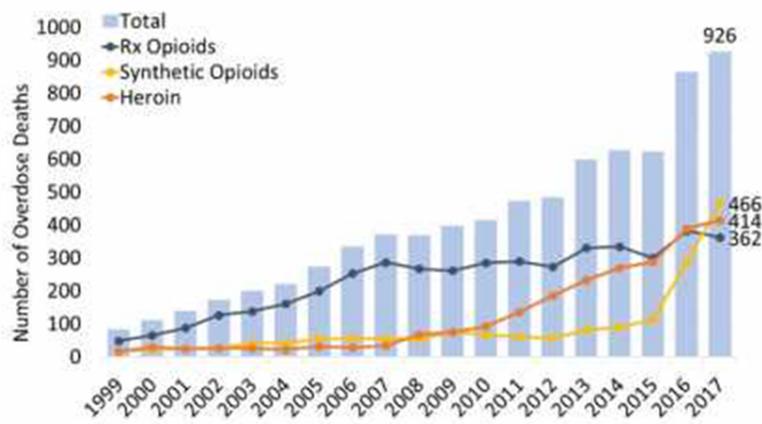


## Opioids in Wisconsin

- Greatest increase in opioid deaths was seen in cases involving synthetic opioids (mainly fentanyl)
  - 56 deaths in 2012 to 466 deaths in 2017
- Deaths involving heroin increased in the same 5-year period

WDHS (2019)

## Opioid Deaths in Wisconsin



## Fentanyl

- Fentanyl 50x as potent as heroin
- Strong economic incentives to mix fentanyl with heroin and other drugs because smaller volumes equally powerful effects with lower costs and easier transport
- Limited data about the effectiveness of interventions to prevent overdoses related to illicitly manufactured fentanyl

## Emerging Trends

- Increases greatest for OD related to illicitly manufactured fentanyl more than doubling from 2015-2016
- Since 2010, OD deaths involving predominantly illicit opioids (heroin, synthetic nonmethadone opioids, or both) > more than 200%
- Contamination of heroin supply with fentanyl is driver of the recent > opioid-related overdose deaths
- Other possibilities- younger users who might be less experienced, and might use heroin in riskier ways

Center for Behavioral Health Statistics and Quality (CBHSQ). 2017

## Current Treatment Trends

- Among >100 million people with commercial insurance = people dx with Opioid Use Disorder (OUD) quadrupled between 2010-2014
- Number of prescriptions for medications used to treat OUD > but did not keep up with the rise in diagnosis (<11% prescribed a med to treat OUD)
- Significant barriers to treatment of OUD

Center for Behavioral Health Statistics and Quality (CBHSQ). 2017

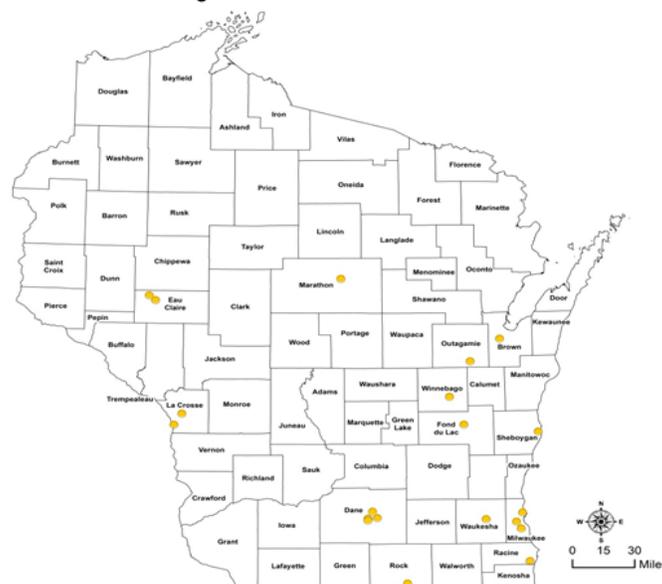
## Human Rights to Be Considered

- Pain
- Ethical Prescribing Practices
- Education
- Access to OUD Treatment
- Access to Health Care

## Treatment Options

- Medication Assisted Treatment (MAT)- effective medications exist to treat opioid use disorders including methadone, buprenorphine and naltrexone
- Impact of Access
- Cost

## Opioid Treatment Programs in Wisconsin



### Opioid Treatment Facilities

- Opioid Treatment Programs (20)

### County Boundaries

- Boundary Line

## Pain and the Opioid Epidemic

- 2016 CDC opioid guidelines published
- Impact of guidelines
  - Within a year of release, sample survey of 3,100 pain pts found 71% had their opioid stopped or reduced
  - Nearly 85% said their pain and quality of life were worse

Kroenke et al. 2019

## Pain and the Opioid Epidemic

- Actually, opioid prescribing peaked four years before the CDC guidelines were introduced
- Recent CDC report states the rate of opioids prescribed is lower than at any time in the past 10 years
- Pain needs are not being met for many people

Kroenke et al. 2019

## Pain and the Opioid Epidemic

- Review of CDC Treatment of Pain Guidelines
- American Academy of Pain Medicine Foundation convened multidisciplinary panel of physician experts -clinical, research, and academic
- Working group of 15
  - Met 12/9/17 to review core recommendations of the CDC guideline, discuss relevant literature, and identify challenges related to guideline implementation
  - Two conference calls held in 9/18 and through several rounds of manuscript drafts
- Panel reached consensus on proposals to address the challenges identified and recognized divergent opinions on some topics

## Pain and the Opioid Epidemic

- Panel commended many facets of the guideline
  - Opioids not first line therapy for chronic pain
  - Discuss the risks, benefits, and availability of nonopioid treatments with patients
  - Establish and measure goals for pain and function
  - Emphasize patient-centeredness and individualized care
  - Evaluate risk factors for opioid-related harms specific to the individual patient;
  - Avoid concurrent benzodiazepine and opioid prescribing
  - Prescribe opioids only in needed quantities and durations
  - Initiate opioids at the lowest effective dose with frequent follow-up and monitoring
  - Ensure opioids, when indicated, are part of a comprehensive, multimodal pain treatment plan
  - Use prescription drug monitoring programs and urine drug testing to monitor patient adherence to the treatment plan
  - Arrange treatment for OUD if indicated

## Pain and the Opioid Epidemic

- Challenges caused by guideline misapplication identified by the panel include:
  - Inflexible application of recommended ceiling doses or prescription durations as hard limits
  - Abrupt opioid taper or cessation in physically dependent, opioid-treated people
  - Lack of availability and coverage for recommended comprehensive, multimodal pain care
  - Difficulty of OUD diagnosis and barriers to accessing evidence-based OUD treatment
  - Underutilization of naloxone
  - Incomplete data in reporting of overdose death statistics

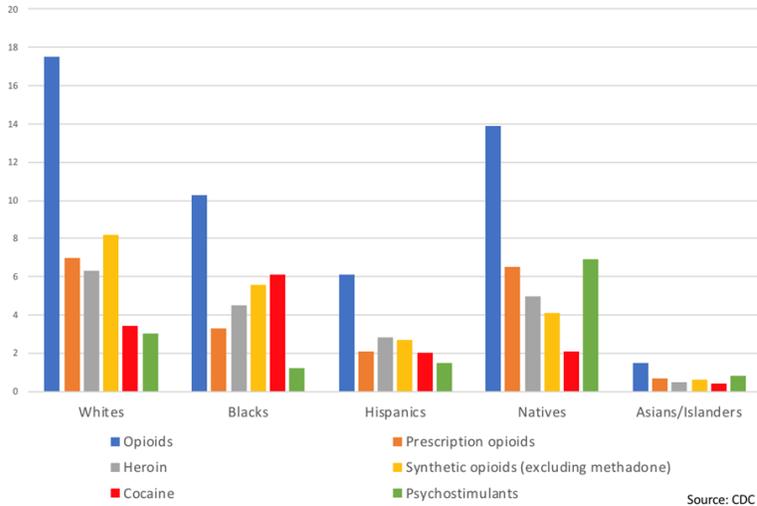
## Race and the Opioid Epidemic

- 1979 - 2015 long-term trends in opioid-related mortality data did not study differences in use among differing ethnic groups
- Retrospectively data was collected on white and black Americans
- Three successive waves of opioid use based on race
  - First wave-1979 to the mid-1990s- epidemic affected both populations and was driven by heroin
  - Second wave- mid-1990s to 2010- increase in opioid mortality was driven by natural/semi-synthetic opioids (e.g., codeine, morphine, hydrocodone, or oxycodone) among white people while there was no increase in mortality for black people
  - Current wave, increases in opioid mortality for both populations have been driven by heroin and synthetic opioids (e.g., fentanyl and its analogues).

## Lethality

- Opioids are the leading cause of drug-related deaths among all races/ethnic groups
- Drug-related mortality rate (per 100,000) in 2016 for white people was 25.3, black people 17.1, and Latinix people 9.5
- White people were roughly 50% and 167% likelier to die from drug overdoses than black people and Latinix people respectively
- Asians/Pacific Islanders have the lowest rates of overdose and use of all ethnicity

**Drug Overdose Deaths (per 100,000) by Drug Type and Race/Ethnicity in the U.S. in 2016**



## Neonatal Abstinence Syndrome

- NAS rising faster in rural vs urban
- Huge variation of NAS between states
- Clinical uncertainty exists about which opioid-exposed infant will develop withdrawal
- Variation in interventions used for treatment are widespread across the US

## NAS Emerging Evidence

- NAS > 30-60% with co-exposure to antidepressants, benzodiazepines, and gabapentin
- Co-exposure to atypical antipsychotics or non-benzodiazepine hypnotics (e.g., Zolpidem) did NOT > risk of withdrawal
- MJ most commonly used illicit drug in pregnancy and the role of co-exposure on modifying NAS expression and severity is unclear
- O'Connor et al. performed retrospective study of nearly 200 maternal-infant dyads in which the mother was maintained on buprenorphine and had marijuana exposure third trimester <sup>(2016)</sup>
  - likelihood of an infant requiring pharmacologic treatment for NAS or duration of infant hospital stay were not significantly associated with mj exposure

## Neonatal Abstinence Syndrome

- NAS – postnatal drug withdrawal syndrome exhibited by some opioid-exposed infants that is characterized by hyperactivity of the central and autonomic nervous system and gastrointestinal tract
- US incidence of NAS has > from 1.19 per 1000 hospital births in 2000, to 5.63 in 2012
- Number of infants treated in ICUs increased five-fold

## NAS Emerging Evidence

- Finnegan Neonatal Abstinence Scoring System (FNASS) - most commonly used tool to assess for signs of withdrawal but tool has not been validated to show utility in improving outcomes for infants with NAS
- New functional assessment uses 3 parameters:
  - Infant's ability to eat, to sleep, and to be consoled
  - Infant able to be breastfed or take >1 ounce from a bottle per feed, to sleep undisturbed for >1 hour, and could be consoled if crying within 10 minutes, pharmacologic treatment with morphine was not started or increased regardless of other signs of withdrawal
- This intervention reduced proportion of methadone-exposed infants treated with morphine from 98% to 14%
- Suggest that FNASS guided approach encourages providers to treat a number and not a patient, and call for change in practice to the assessment of withdrawal signs

## NAS Emerging Evidence

- In adults, single-nucleotide polymorphisms (SNPs) in the mu-opioid receptor (OPRM1), multidrug resistance (ABCB1) and catechol-o-methyltransferase (COMT) genes associated with risk for opioid addiction
- Among newborns OPRM1 and COMT SNPs were associated with prolonged hospital length of stay and treatment for NAS
- Recent pilot study of 21 methadone exposed newborns and their mothers found infants treated for NAS were more likely to carry the homozygous allele of the CYP2B6 gene that encodes a cytochrome P450 mono-oxygenase enzyme and is present in 75% of the Caucasian population
- Recent advances in understanding genomic variation and differential antenatal exposures contribute to NAS risk and severity may lead to tailored approaches to tx based in risk profile

## NAS Emerging Evidence

- NAS often treated in NICU, newborn nursery, inpatient pediatric
- Separate the dyad which creates barriers to breastfeeding and rooming, both of which may decrease length of treatment and hospital stay
- Holmes et al. demonstrated decreased hospital cost and length of stay for infants with NAS who experienced full rooming-in for observation and treatment on mother-infant pediatric units
  - Parental presence associated with 5.7 fewer days of opioid therapy
  - Shorter LOS by >5 days
  - Data suggest that strategies that promote rooming-in and minimize the separation of the maternal-infant dyad hold promise as non-pharmacologic treatment
  - When family or maternal presence is limited, programs using volunteers to provide comfort to infants with NAS may provide an alternative

## WI Hope Legislation

- WI leg strategy to combat opioid abuse was introduced in a group of bills presented as the HOPE (Heroin and Opioid Prevention and Education) Agenda
- Rep. Nygren was the lead author of all bills
- Waves of the seven bills in the package: four were introduced in October 2013, three were introduced in January 2014, and all carried bipartisan support

## WI Hope Legislation – 2013-14

- Required EMTs to carry a supply of naloxone and keep records of how it is administered
- Allowed prescribers to prescribe naloxone to trained individuals who were attempting to assist a person at risk of an overdose
- Created immunity from civil and criminal liability for prescribers and administrators of naloxone

## NAS; Key Points

- Polysubstance exposure and specific genetic polymorphisms influence severity of NAS and should be considered when designing clinical prediction tools aimed at personalizing the care of infants with NAS
- Utilizing modified tools, when observing opioid exposed infants for withdrawal, that focus on clinically relevant infant characteristics may drastically reduce the number of infants treated pharmacologically for NAS.
- Buprenorphine treatment NAS has been shown to decrease days of treatment and length of hospital stay
- State based data is key to identify the changing epidemiology of NAS and provides the necessary framework for policy, public health, and clinical interventions

## WI Hope Legislation – 2013-14

- 2013-2014 = first wave of legislation
- Represented strategies and recommendations proposed in the SCAODA reports on prescription drug abuse and heroin abuse
- First four bills focused on
  - Administration of naloxone by safety officers and Good Samaritans
  - Addressing issues related to obtaining and disposing of opioid prescriptions
  - Expanding or creating treatment programs on the local level

## WI Hope Legislation – 2013-14

- Required a person to show identification when picking up a prescription for a schedule II or schedule III drug
- Required pharmacist record the name of the person and send that information to the PDMP
- Regulated drug disposal programs through the Department of Justice and local governments
- The final three bills focused on the ways that people who abuse opioids are sanctioned or receive treatment by expanding existing treatment programs by increasing funding and created pilot treatment programs in underserved areas
- Created system of short-term but impactful sanctions for habitual drug offenders who violate probation or parole by possessing drugs

## WI HOPE Legislation - 2014-2015

- Built on the leg of the previous session
- Expanding access to naloxone and broadened reporting requirements for the PDMP
- Allocating more money to TAD programs
- Authorized a physician to issue a standing order to one or more persons and allowed a pharmacist to dispense naloxone under that standing order
- Allows pharmacy to sell naloxone without a specific written prescription and further clarifies the intentions of the 2013

**law** (signed into law on December 8, 2015. Fall of 2017, the CMO at DHS signed a statewide standing order for Wisconsin pharmacies, effective September 2017.)

## WI HOPE Legislation - 2014-2015

- Amount of time that prescribers have to report prescription was filled was shortened from 7 days to 24 hours
- Practitioners check PDMP before issuing an opioid prescription
- Required law enforcement officers to report to the PDMP the inappropriate or illegal use of monitored prescription drugs, opioid-related drug overdoses and reports of stolen prescription drugs and PDMP must then disclose that information to the relevant practitioners, pharmacists, and others

## WI HOPE Legislation - 2014-2015

- Gave the DHS oversight of pain management clinics and defined a “pain clinic” as privately owned facility that devotes the majority of its practice to pain management and prescribes opioids for that purpose
- Expanded tx by funding for TAD programs and aligning WI statutes on tx services with federal standards- transferred \$2 million from the DHS to the DOJ
- Prohibited the use of a masking agent in order to pass a lawfully administered drug test and penalty for using, possessing, or advertising a masking agent

## Federal Opioid Legislation

- October 24, 2018- Pres. Trump signed Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act
- Comprehensive, bipartisan legislation, passed overwhelmingly in House and Senate
- Final leg contains provisions related to Medicaid’s role in helping states provide coverage and services to people who need SUD tx, particularly OUD tx

## Federal SUPPORT Act

- Most controversial measure amends prohibition against the use of federal Medicaid funds for services in “institutions for mental disease” for nonelderly adults by creating a state option from 10/1/19 to 9/30/23 to cover those services up to 30 days in a year for individuals with a SUD
- Requires state Medicaid to cover MAT, including ALL FDA-approved drugs, counseling services, and behavioral therapy unless state certifies that statewide implementation is infeasible due to provider shortages (most states cover buprenorphine and naltrexone, while fewer cover methadone)
- Creates state plan providing residential pediatric services to infants with NAS

## Federal SUPPORT Act

- Prohibits states from terminating Medicaid eligibility for under 21 or foster care youth up to 26 while incarcerated and requires states to redetermine eligibility prior to release without requiring a new application and restore coverage upon release
- Requires states to have drug UR for opioid refills, monitor concurrent prescribing of opioids and monitor antipsychotic prescribing for children
- Requires Medicaid providers check PDMP before prescribing controlled substances

## Federal SUPPORT Act

- HHS Secretary to issue guidance on Medicaid-covered services and payment models for infants with NAS and their families, state options for SUD telehealth services and Medicaid services for non-opioid pain management
- Make recommendations to improve Medicaid coverage and payment for MAT, non-opioid pain management, and SUD tx
- Report to Congress on best practices for reducing children's barriers to Medicaid SUD telehealth services; report state-level data on Medicaid SUD prevalence/tx services; and report and provide tech assistance to states on Medicaid housing-related services
- Issue guidance on state options to use Medicaid funds for family-focused residential treatment programs

## End the Opioid Epidemic

- **To prevent and treat, education works.**
  - A 2015 study -National Institute on Drug Abuse-found that 'Life Skills Training' for 12-13yo helped avoid misusing prescription opioids throughout their teenage years
  - A nationwide health education campaign to counter ignorance and stigma surrounding addiction and medication-assisted treatment, (Ex:'Understanding AIDS,' CDC campaign in the 1980s sent to every residential mailing address in the United States)

## End the Opioid Epidemic

- **Treating associated conditions works.**
  - >50% of people with SUD live with comorbid MI
  - Mental Health Parity and Addiction Equity Act of 2008 prohibits insurers from providing less-favorable coverage for mental health and addiction treatment than the for other medical treatment
  - Some insurers defy the law, imposing arbitrary treatment limits or onerous authorization requirements. Compliance with the Act is essential to meaningfully address the epidemic.

## End the Opioid Epidemic

- **To save lives, naloxone works.**
  - Naloxone is relatively affordable and easy to administer
  - Federal and state health agencies have ability to negotiate lower prices and expand access to naloxone
  - Encourage its uptake through public health education campaigns

## End the Opioid Epidemic

- **Medication-assisted treatment works. "Lock 'em up and throw away the key" does not.**
  - 31 states participate in Police Assisted Addiction and Recovery Initiative offering treatment for people who ask authorities for help
  - DEA implemented the "360 Strategy" - includes criminal prosecutions of trafficking organizations, partners with community organizations, schools, pharmaceutical manufacturers, health practitioners, and pharmacists
  - Many conventional drug treatment centers in US currently provide ineffective, costly, short-term programs with no follow-up

## End the Opioid Epidemic

- **To save lives and fund treatment, Medicaid expansion works.**
  - The ACA originally mandated that states significantly expand access to Medicaid. However, Supreme Court ruling allowed states to opt in to Medicaid eligibility expansion under the ACA. To date, 36 states and DC have adopted; 14 have not.
  - Dayton, OH had highest opioid overdose death rates in 2017. From 2017-2018 death rate<56%. Credit due to Governor Kasich's Medicaid expansion in 2015, a move that gave nearly 700,000 low-income adults access to free addiction and mental health treatment.
  - 2017 the US DHHS declared opioid epidemic as nationwide public health emergency

## Creating Positive Change

- In response to the opioid crisis, the U.S. Department of Health and Human Services (HHS) is focusing its efforts on **5 major priorities**:
  - Improving access to treatment and recovery services
  - Promoting use of overdose-reversing drugs
  - Strengthening our understanding of the epidemic through better public health surveillance
  - Providing support for cutting-edge research on pain and addiction
  - Advancing better practices for pain management

## Creating Positive Change

- Clinicians need to refer people to accessible treatment quickly. The ability to treat opioid use disorder should become a routine part of medical care.
- Collaboration with law enforcement is necessary to link preventive services and effective treatment.
  - Providing medication-assisted treatment in prisons increases the probability that incarcerated persons with opioid use disorder, who are at high risk of overdose after release, will engage with treatment after release
  - First responders need adequate supplies of naloxone. Patients and communities must be educated about the risks of opioid use.

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