MEDICATIONS FOR OPIOID USE DISORDER (MOUD) UPDATE

DAVID BEST, DO, MS, ABAM

MOA SPRING CONFERENCE

SOUTHFIELD, MI

MAY 22, 2022

OBJECTIVES

- To advocate for treatment of opioid use disorder (OUD) with standard of care medications
- Review why targeting doctors prescribing opioids is not helpful.
- To review both forms of MOUD
  - Opioid Agonist Treatment: methadone maintenance treatment and buprenorphine maintenance treatment
  - Opioid Antagonist Treatment: Naltrexone
- Outline the pros and cons of each.

DISCLOSURES: NONE

Opioid Safety is a high priority topic for the MOA and I made special mention of this in my MOA presidential address in May 2021.

Best Medical Services was designated as an opioid health home in 2021 ☺

OPIOID HEALTH HOME (OHH)

- Under Section 2703 of the Patient Protection and Affordable Care Act of 2010 (ACA), the Health Home service model is meant to help chronically ill Medicaid and Healthy Michigan Plan beneficiaries manage their conditions through an intensive level of care management and coordination.
- The OHH is centered on whole-person, team-based care.
- The OHH will provide comprehensive care management and coordination services to Medicaid beneficiaries with opioid use disorder.
- MDHHS distributes payments through Prepaid Inpatient Health Plan (PIHP)
- $328 per patient per month for enrolled patients


Connecting enrollees with
recovery-centered care.

OHH RECEIVES REIMBURSEMENT FOR PROVIDING THE FOLLOWING FEDERALLY MANDATED CORE SERVICES:

- Comprehensive care management
- Care coordination
- Health promotion
- Comprehensive transitional care
- Individual and family support
- Referral to community and social support services

BEST MEDICAL SERVICES PATIENT DATA 2015-2021 N=OUD PATIENT

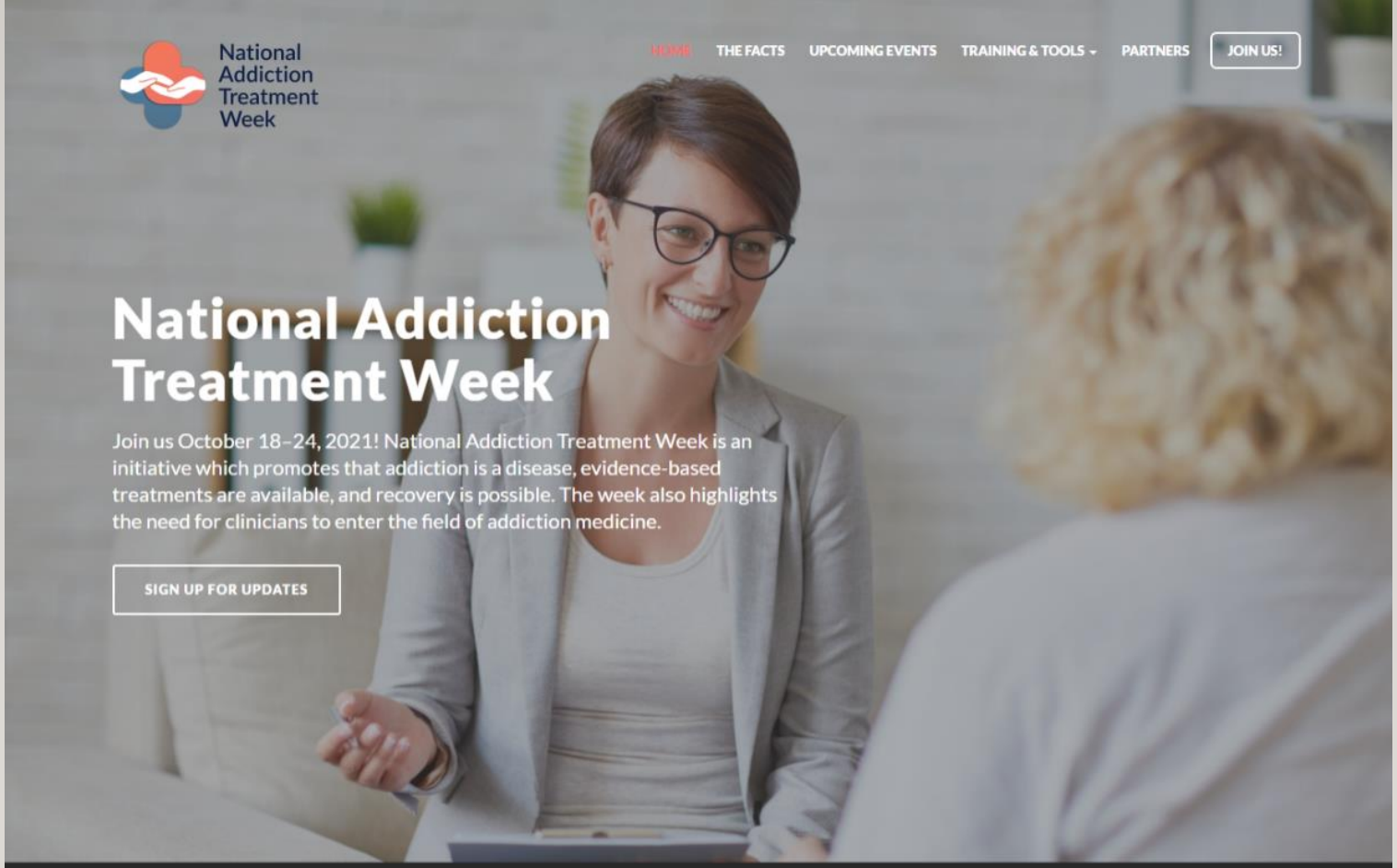
Date	N	Bup dose (mg)	Avg Age	% on Benzo	% Working
12/1/2021	263	13.7	42.0	14.4	52.1
12/1/2018	227	14.0	43.7	11.0	65.2
2/1/2016	97	13.5	38.0	27.0	58.0
12/1/2015	93	11.3	37.2	21.5	58.0

JUSTICE DEPARTMENT STATES DISCRIMINATION AGAINST PEOPLE UNDERGOING TREATMENT FOR OPIOID USE DISORDER VIOLATES ADA (AP REPORT)

- **“Treatment for opioid addiction often brings discrimination”**
- By GEOFF MULVIHILL and CLAUDIA LAUER
- April 9, 2022
- “It’s a problem people in the addiction recovery community have dealt with for decades: On top of the stigma surrounding addiction, people who are in medical treatment for substance abuse can face additional discrimination — including in medical and legal settings that are supposed to help.”

TAKING THE AMERICAN WITH DISABILITIES ACT SERIOUSLY.

- The U.S. Department of Justice published new guidelines aimed at dealing with the problem: They assert that it's illegal under the ADA to discriminate against people because they are using prescribed methadone or other medications to treat opioid use disorder.
- One of the government's recent settlements was with a Colorado program that helps house and employ people who are homeless. A potential client filed a complaint claiming she was denied admission because she uses buprenorphine to treat her addiction. As part of the settlement, Ready to Work is paying the woman $7,500. The organization's staff is being trained to comply with the law.



National Addiction Treatment Week

A week dedicated to recognizing the critical gap between the number of patients who need addiction treatment and qualified medical professionals available to treat patients using evidence-based approaches.

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ADVOCATE FOR INCREASED ACCESS TO MOUD

- Drug Treatment Court Virtual Seminar, Sept 24, 2021
  - Education for Grand Traverse Count Treatment Court
  - I presented on MOUD and participated in case study review
- MOUD availability for Incarcerated Individuals Under Correctional Control
  - AOA Resolution passed at 2021 House of Delegates

EVIDENCE FOR RECEIVING MOUD WHILE INCARCERATED

- Information Presented at 2021 American Society of Addiction Medicine Conference
  - 85% less likely to die of drug poisoning in first month upon release
  - 97% continued treatment after release

ACCESS TO MOUD IN CORRECTIONAL FACILITIES

- Few facilities offer MOUD
- Persons on MOUD prior to incarceration in many (most?) face cessation of treatment and forced opioid withdrawal.
- Philosophical opposition and stigma are main barriers to patients getting standard of care and ethical treatment.
    - Non-medical personnel (judges, prosecutors, jail staff) practicing medicine without a license?

LEGAL CLAIMS FOR LACK OF MOUD ACCESS

- Eighth Amendment to the U.S. Constitution
  - "Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted."
- Federal Civil Rights Act
- Americans with Disabilities Act

Opioid Use Disorders – DSM V

The diagnosis of Opioid Use Disorder under DSM V can be applied to someone who uses opioid drugs and has at least two of the following symptoms within a 12 month period:

- Taking more opioid drugs than intended.
- Wanting or trying to control opioid drug use without success.
- Spending a lot of time obtaining, taking, or recovering from the effects of opioid drugs.
- Cravings opioids.
- Failing to carry out important roles at home, work or school because of opioid use.
- Continuing to use opioids, despite use of the drug causing relationship or social problems.
- Giving up or reducing other activities because of opioid use.
- Using opioids even when it is physically unsafe.
- Knowing that opioid use is causing a physical or psychological problem, but continuing to take the drug anyway.
- Tolerance for opioids.
- Withdrawal symptoms when opioids are not taken.

SAMHSA

OUD DSM 5 CRITERIA CAVEAT

- Tolerance and withdrawal criteria do not count if patient is under appropriate opioid medication management

OUD: MILD, MODERATE OR SEVERE?

- Mild: 2-3 criteria met
- Moderate: 4-5 criteria met
- Severe: 6-11 criteria met

OPIOID PRESCRIBING IS WAY DOWN, OVERDOSE DEATHS CONTINUE TO GO UP

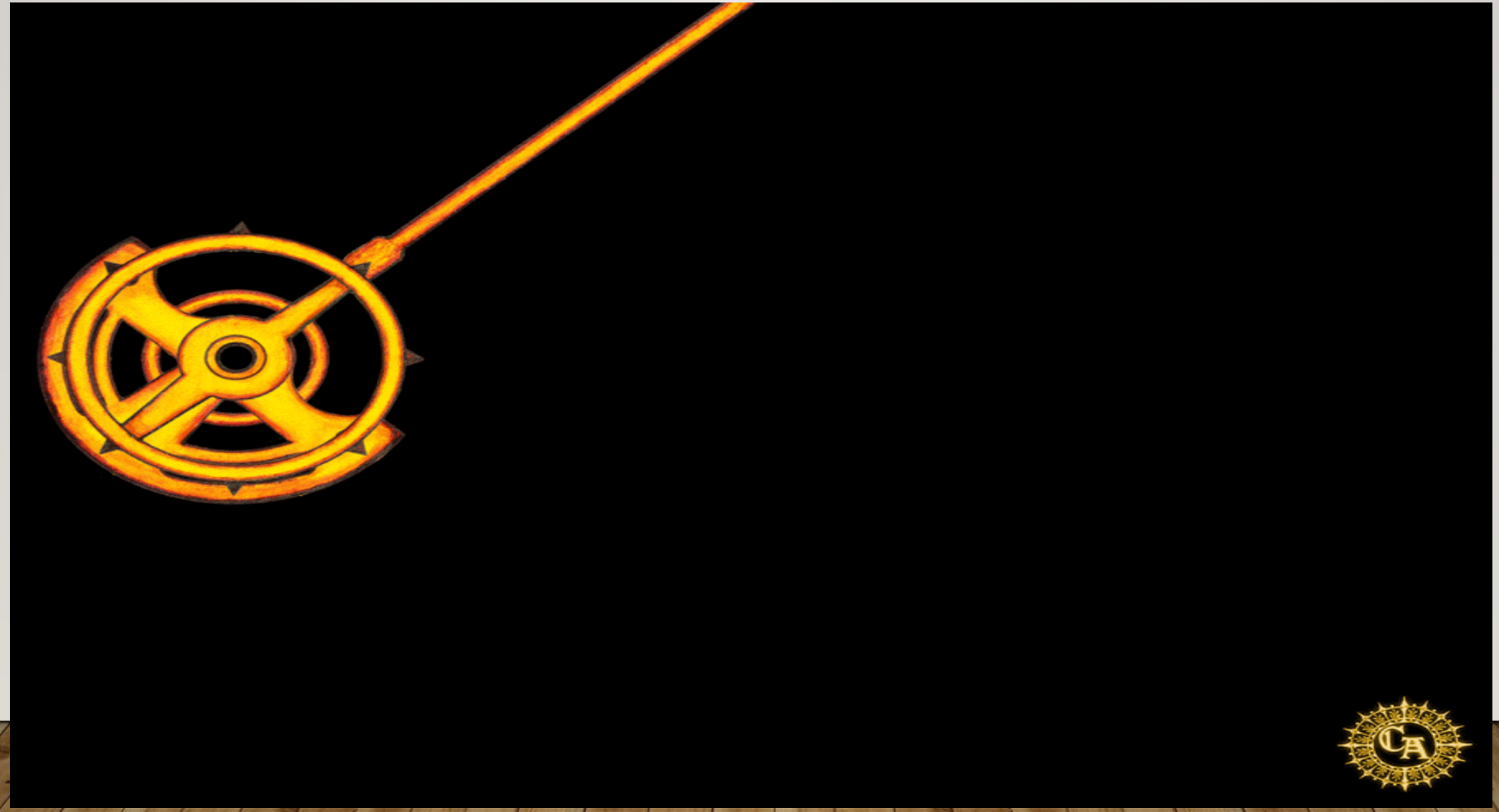
- What is the solution to this problem?
- Reducing demand!!!
  - Prevention
  - Treatment for opioid use disorder
- And of course, continue efforts to reduce supply
  - Safe prescribing
  - Reducing illicit trafficking

DRUG OVERDOSE DEATHS IN THE US TICK UP AGAIN TO ANOTHER RECORD HIGH, ACCORDING TO CDC DATA

BY DEIDRE MCPHILLIPS, CNN
PUBLISHED 10:49 AM EDT, WED APRIL 13, 2022

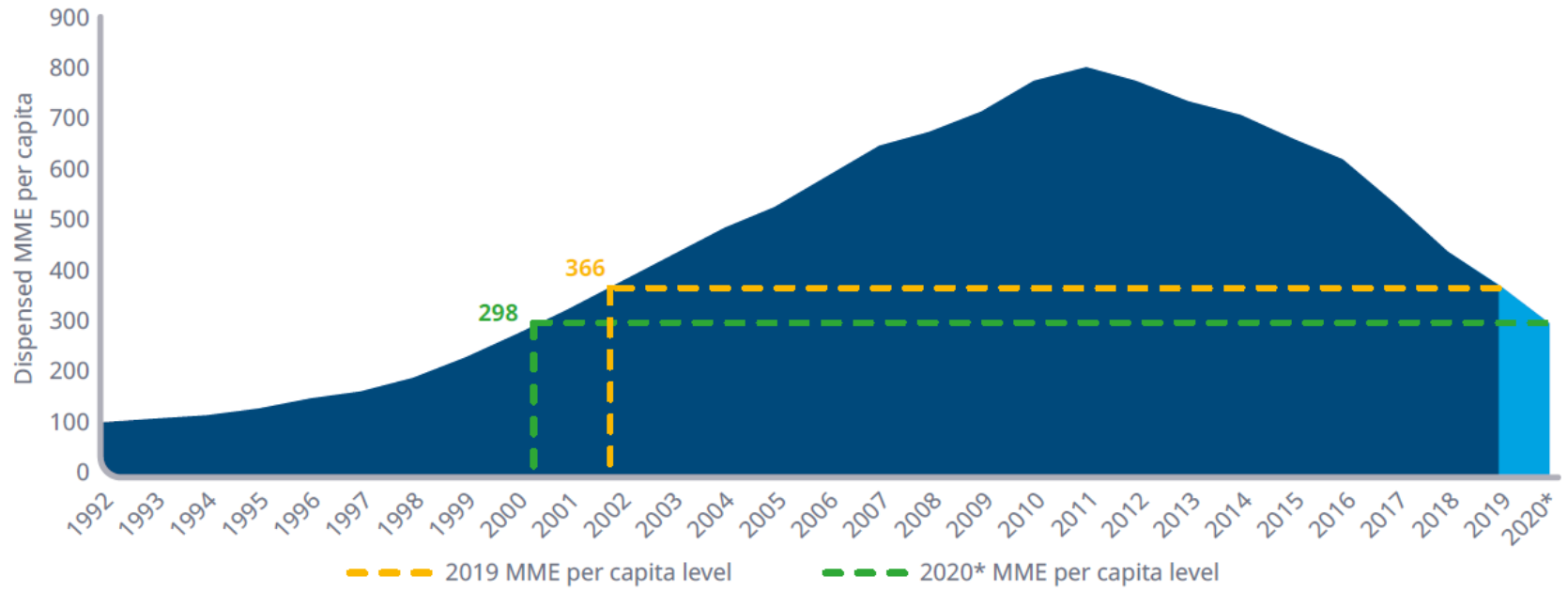
- The CDC estimates that 106,854 people died due to drug overdose in the 12-month period ending November 2021. Annual drug overdose deaths have more than doubled over the past six years, jumping 16% over the past year alone.
- Synthetic opioids – including fentanyl – were involved in about two-thirds of drug overdose deaths over the past year.

SUPPLY OF PRESCRIPTION OPIOIDS IS DOWN 60%

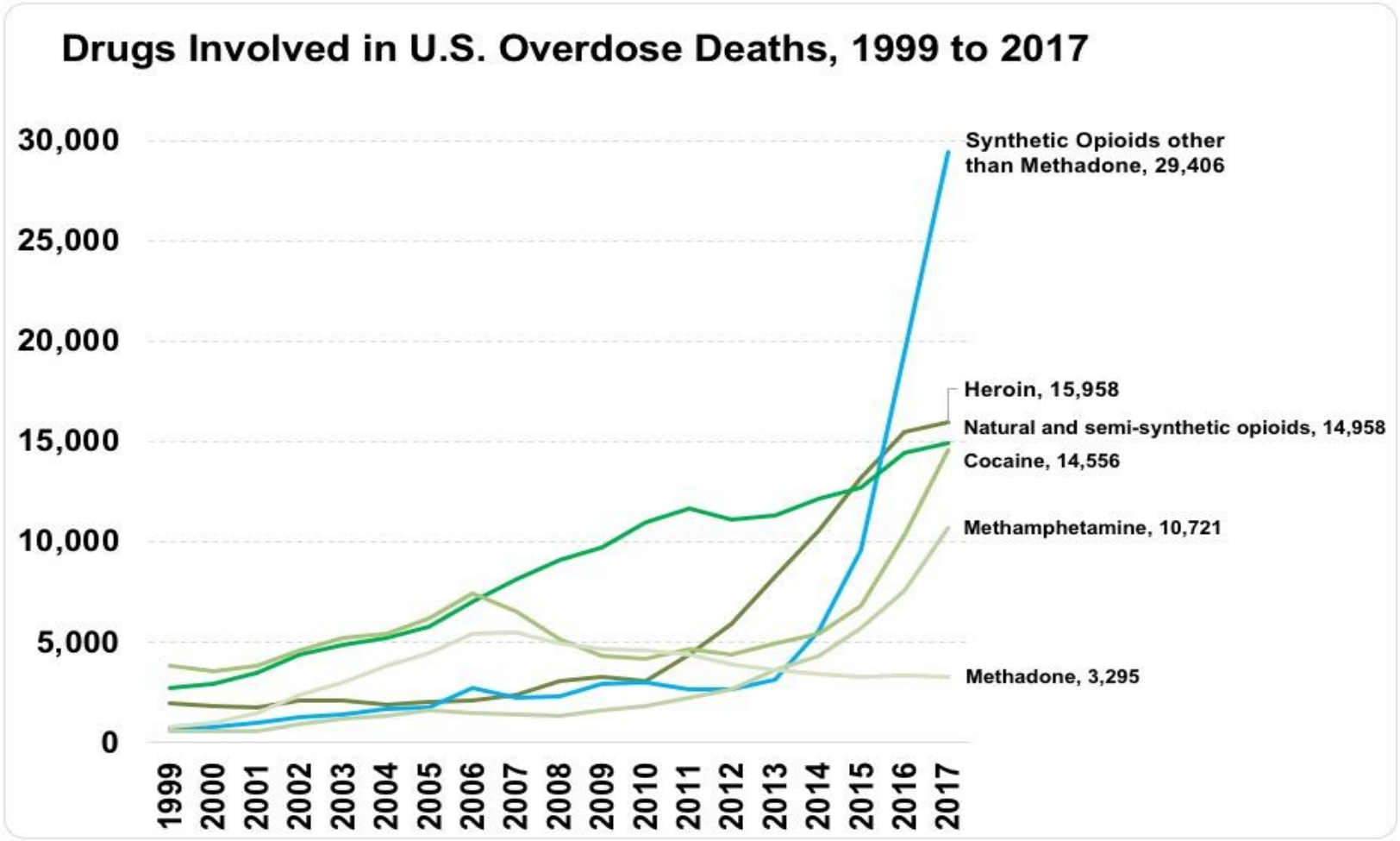


Continued declines have brought normalized per capita prescription opioid use below the 2001 level

Exhibit 2: Prescription Opioid Use in Morphine Milligram Equivalents (MME) per Capita, 1992–2020*



Source: IQVIA Xponent, Mar 2020; IQVIA National Prescription Audit; IQVIA Institute, Nov 2020


Drugs Involved in U.S. Overdose Deaths, 1999 to 2017
30,000
25,000
20,000
15,000
10,000
5,000
0
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
Synthetic Opioids other than Methadone, 29,406
Heroin, 15,958
Natural and semi-synthetic opioids, 14,958
Cocaine, 14,556
Methamphetamine, 10,721
Methadone, 3,295

- **Podcast in 2021: Ronald Chapman II Discusses CDC Guidelines, DOJ/DEA Investigations Fueling a 'Race to the Bottom' for Physicians and Pain Medicine**
- ***"It's been very easy for federal prosecutors to get quick, snap convictions against doctors by leveraging large datasets. That's a lot easier to do than chasing after drug cartels. That's a lot easier to do than chasing after illicit fentanyl dealers. And they get more bang for their buck, and that's why we've seen this myopic view of prosecutions."***

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Health Care Attorneys

ILLICIT DRUGS ARE FLOODING INTO OUR COMMUNITIES

NEED TO JUSTIFY USE OF MOUD

If my patient is on buprenorphine maintenance treatment this is documented in their plan:

"Harm reduction approach with buprenorphine maintenance treatment continues to effectively reduce risk of toxic opioid exposure."

NEED TO REDUCE TREATMENT GAP.

- Evidence based treatments are not routinely used for alcohol, drug, and mental health conditions.
- The Institute Of Medicine (IOM) has noted that health policy has more impact on patient outcomes than variation in individual practitioner abilities.
  - Examples of improvements are:
    - Some Drug treatment courts allowing for MOUD
    - Comprehensive Addiction and Recovery Act (CARA); enacted in 2018
      - More funding, new limit for providers is 275 buprenorphine patients
    - Medicaid Expansion and better coverage for buprenorphine, started in 2014
    - Mental Health Parity and Addiction Equity Act, passed in 2007

WHAT IF WE TREATED CAD LIKE OUD?

- 63 year-old male (non-smoker) with coronary artery disease (CAD) who had MI 3 months ago.
  - Prescribed metoprolol, atorvastatin, clopidogrel and aspirin after MI (and angioplasty with 1 stent).
  - Total cholesterol reduced from 226 to 176 and HDL increased from 35 to 62 since starting atorvastatin
  - BP improved from 152/92 to 122/72
  - He is going for 1 mile walk 4 times per week
  - No longer has chest pain
  - Weight unchanged at 200 pounds
  - Not going to cardiac rehab as recommended

RISK FACTORS FOR MI HAVE BEEN REDUCED: FRAMINGHAM RISK SCORE HAS GONE FROM 16% TO 8%

- 50% reduction in cardiac event in the next 10 years with current treatment
- However, Patient not "fully engaged" in treatment plan.
- Since he is not going to cardiac rehab, he is not serious about recovery
  - Pt. advised to stop his atorvastatin, aspirin, and metoprolol
    - Of course, this would not actually happen!

FOLLOW THE CHRONIC DISEASE MODEL

- Treat OUD the same as you would with any other chronic illness
- MOUD should be continued as long as symptoms of OUD are reduced.
- Unfortunately, there is a treatment gap and patients are not getting treatment despite the drastic reduction in risk factors and the vastly improved function when in remission from OUD with the use of buprenorphine or methadone.

CHRONIC DISEASE MODEL NEEDS TO BE FOLLOWED!

- Addiction Treatment faces challenges that other chronic illnesses do not
  - Impact of addiction is more visible and less socially acceptable (stigma of OUD).
  - Expectation that patients with OUD will remain symptom free after treatment ends

- Chapter 31: Quality Improvement for Addiction Treatment; Principles of Addiction Medicine The Essentials; 2011.

HARM REDUCTION APPROACH IS NEEDED

- Harm reduction refers to policies, programs and practices that aim to minimize negative health, social and legal impacts associated with drug use, drug policies and drug laws.
- Harm reduction is grounded in justice and human rights. It focuses on positive change and on working with people without judgement, coercion, discrimination, or requiring that they stop using drugs as a precondition of support.

RISK FACTORS FOR OUD

- Family History of substance use disorder
- History of anxiety, depression, ADHD
- Adverse Childhood Experiences (ACE)
- Environment and socioeconomic stressors
- Chronic Pain: 11% who use prescribed opioids have Opioid Use Disorder

- Gavin Bart, MD (2012): Medication Maintenance for Opiate Addictions: The Foundation of Recovery, Journal of Addictive Diseases, 31:3, 207-225

USE EVIDENCED BASED TREATMENT

- Expanding access to addiction treatment services is an essential component of a comprehensive response.
- Like other chronic diseases (diabetes, HTN), addiction is generally refractory to cure but effective treatment and recovery are certainly possible.
- Medication Assisted Therapies (MAT) are available and need to be used more to save lives.
  - 50% fewer heroin overdoses in Baltimore from 1995-2009 when methadone and buprenorphine treatment availability was increased.
- NEJM 2014; 370:2063-2066

KNOW WHAT DOESN'T WORK

- Behavioral interventions alone have extremely poor outcomes
- 80% returning to drug use
- Poor results with medication assisted detox
- Behavioral intervention alone is not 1st line treatment (despite conventional wisdom that it is)!

- Gavin Bart, MD (2012): Medication Maintenance for Opiate Addictions: The Foundation of Recovery, Journal of Addictive Diseases, 31:3, 207-225

EXAMPLES OF PATIENT GOALS

- Get Back to Work
- Stop wasting all my time and money on drugs (and chasing drugs)
- Be a better parent and partner
- To not die and get back to "normal life"
- Have integrity

OPIOID REPLACEMENT THERAPY AND THE "LAZARUS LIKE EFFECT"

- Demonstrated as early as 1965 with methadone maintenance treatment and now also with buprenorphine maintenance treatment
  - Craving relief
  - Blockade of the euphoria of heroin (or other opioid use)
  - Improved Psychosocial functioning (and success!) in work, school, relationships.

    - Sarah Wakeman, MD: "Using Science to Battle Stigma in Addressing the Opioid Epidemic", May 2016, The American Journal of Medicine.

TREATMENTS FOR OUD

- Standard of care:
  - Medications for Opioid Use Disorder (MOUD)
    - Opioid Replacement Therapy
      - Methadone Maintenance Treatment (MMT)
        - Only at Opioid Treatment Program (OTP)
      - Buprenorphine Maintenance Treatment (BMT)
        - Outpatient Based Opioid Treatment (OBOT) or at OTP
    - Naltrexone oral or injection
  - Psychosocial Treatment
    - Cognitive Behavioral Therapy
    - Supportive Counseling
    - Mutual Self Help Meeting
    - Recovery Coach Service

WHY USE MOUD?

- Prevention of overdose deaths, prevention of: HIV, HCV
- Improved Quality of life for patients and families.
- MOUD needed due to poor success rate of abstinence-based treatment.

WHAT IS OBOT?

- Outpatient Based Opioid Treatment
  - Provider required (until some point in 2021) to have XDEA number to prescribe buprenorphine to OUD patient
  - Outpatient clinic-based setting
  - Buprenorphine Options Include:
    - Transmucosal buprenorphine: daily dosing
      - Buprenorphine-naloxone
        - Zubsolv tabs, Suboxone film, Bunavail film, generic tab
      - Generic buprenorphine tablets ("Subutex")
    - Monthly Subcutaneous Injection
      - Sublocade

KEY TAKEAWAYS THAT EVERY CLINICIAN SHOULD KNOW ABOUT BUPRENORPHINE:

- **Buprenorphine is a schedule III narcotic pain medication** and is a high affinity partial agonist at the mu receptor, antagonist at the kappa receptor (helping prevent opioid induced hyperalgesia aka OIH and tolerance) and possesses anti-NMDA and activity. The kappa and NMDA activity are thought to help prevent OIH. This unique pharmacology presents several benefits to utilizing buprenorphine.
- **Buprenorphine is an estimated 25-100x more powerful than morphine** when it comes to analgesic effect and can be dosed IV, SL or via patch.
- **Buprenorphine is many times safer than normal opioid agonists because it has a ceiling effect on respiratory depression and sedation, making it ideal for physiologically fragile patients.** The CDC specifically excludes Buprenorphine from its MME table because it is not likely to be associated with overdose in the same dose-dependent manner as are pure opioid agonists.
- **Buprenorphine has less side effects than full agonist opioids**, although some side effects are still common (nausea, constipation, etc.).
- **Buprenorphine shows a distinct benefit in improving neuropathic pain syndromes** due to its unique pharmacology.

Compass Opioid Stewardship Program

(MORE) KEY TAKEAWAYS THAT EVERY CLINICIAN SHOULD KNOW ABOUT BUPRENORPHINE:

- **It is possible to cross taper patients from full agonist opioids to Buprenorphine** and hence minimize or avoid withdrawal symptoms.
- **Buprenorphine sometimes requires prior authorization** - especially Belbuca (SL) and Butrans (Transdermal). However, several states have added Buprenorphine products to the Medicaid preferred formulary list and/or do not require prior authorization for certain products.
- To prescribe Buprenorphine products for **pain**, you **do not** need an X-waiver.
- To prescribe Buprenorphine products for **OUD**, you **do** need an X-waiver (?).

Compass Opioid Stewardship Program

SIGNED BY HHS SECRETARY XAVIER BECERRA ON 4-27-21

- *Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder* exempt eligible physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives from federal certification requirements related to training, counseling and other ancillary services that are part of the process for obtaining a waiver to treat up to 30 patients with buprenorphine.
- Bottom Line: Ok to start prescribing without waiver.
  - BENEFIT OUTWEIGHS RISK!

WHAT IS AN OTP?

- Opioid Treatment Program
  - Guidelines are in 42 CFR Part 8
    - Higher barrier to start clinic than OBOT
  - Traditionally thought of as "Methadone Clinics"
  - Allow all forms of M-OUD at the discretion of the physician

WHY IS ORT BEST CHOICE FOR MOUD?

- 12 Month Retention in treatment >60% with Opioid Replacement Therapy
  - Methadone maintenance treatment (MMT) or buprenorphine maintenance treatment (BMT)
- Only 6 Month Retention in treatment 53% with IM Naltrexone injection (vivitrol)
  - (Extrapolate to 30% or so at 12 months?)
- When Patients stay in treatment they are at lower risk for relapse, co-morbidities, and death

MORTALITY RISK DURING AND AFTER OPIOID SUBSTITUTION TREATMENT

- Data from systemic review and meta-analysis of 122,885 people treated with MMT and 15,831 with BMT
- All cause mortality rate per 1000 person years
  - 11.3 during MMT and 36.1 after MMT
  - 4.3 during BMT and 9.5 after BMT
- Overdose mortality rate per 1000 person years
  - 2.6 during MMT and 12.7 after MMT
  - 1.4 during BMT and 4.6 after BMT
- Note: MMT patients typically with more severe OUD
- BMJ2017:357:j1550 (April 26, 2017)

BUPRENORPHINE MAINTENANCE TREATMENT (BMT)

- Evidence for the effectiveness of BMT: High
- Treat patients in clinic setting or at OTP
- Improved treatment retention
- Reduced illicit opioid use compared with placebo
- No reduction in non-opioid illicits however
  - Psychiatry Serv., 2014 Feb; 65(2) 158-170
- 1 year retention in treatment is 60%
  - Bart (2012)

METHADONE MAINTENANCE TREATMENT (MMT)

- Evidence for effectiveness of treatment: High
- Only available at OTP
- Clear benefit in terms of retention in treatment and reduced illicit opioid use.
- Less clear, but still some benefit: reducing mortality, non-opioid illicit drug use, criminal activity and drug related HIV risk
- Limited evidence of dose >100mg or <60mg daily
  - Psychiatric Serv., 2014 Feb 1; 65(2); 146-157
- 1 year retention in treatment is 60%
  - Bart (2012)

OTHER PROS AND CONS

- Advantage of BMT
- Greater access and lower barrier to treatment
- Weekly to monthly appointments typically
- Well-tolerated
- Disadvantage:
  - Less structured environment for high-risk patient

OTHER PROS AND CONS

- Advantage of MMT
  - Provides more structure and potentially less diversion risk
  - Dispensing of med at OTP
  - Medication is cheaper
- Disadvantages of MMT
  - Requires much more staff and high barrier to start OTP
  - More side effects with full agonist opioid
  - Sedation, lack of 24-hour coverage with daily dosing
  - Travel to clinic daily can limit job opportunities especially in rural communities
  - Access not evenly distributed
    - e.g. 2 OTPs in Otsego County, population 23,000
    - No OTPs in Grand Traverse and surround 6 counties, population 230,000

EXTENDED RELEASE BUPRENORPHINE

- "Using Extended Release Buprenorphine Injection to Discontinue Sublingual Buprenorphine: A Case Series"
- Journal of Addiction Medicine, Volume 15, Number 3, May/June 2021

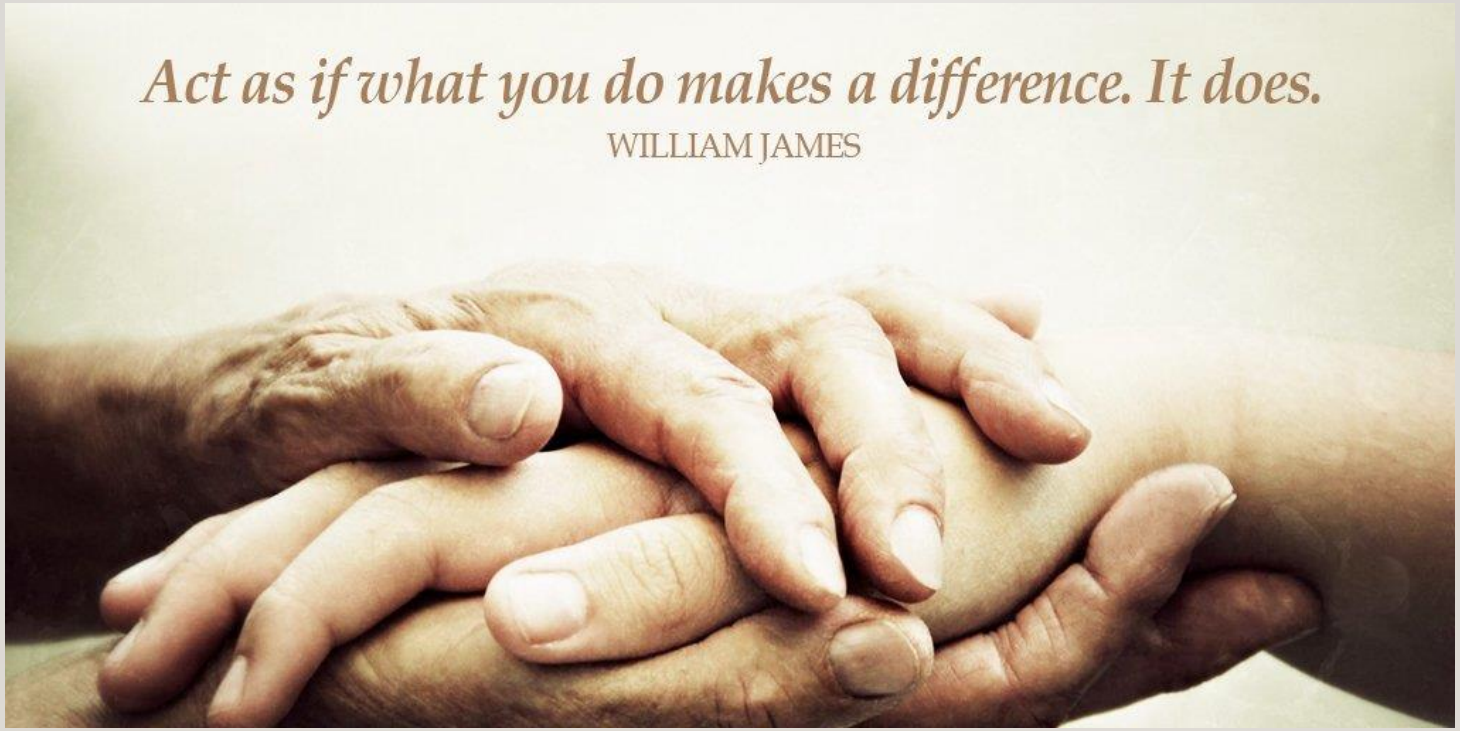
RATIONALE FOR MONTHLY INJECTION VS. DAILY DOSING

- Tapering off buprenorphine can be challenging due to intolerable withdrawal symptoms, including malaise, anxiety, and dysphoria.
- A single dose of extended-release buprenorphine may facilitate discontinuation of buprenorphine by mitigating prolonged, debilitating opioid withdrawal symptoms.
- Minimal to no withdrawals with several patients I have who had injection prior to being incarcerated.
  - Note: symptoms of OUD returned upon release and MOUD generally is re-started.

NALTREXONE

- Oral and IM dosage forms indicated for both alcohol and opioid use disorder.
- Less clear evidence than MMT or BMT
- Potential Benefit for oral formulation vs. placebo for patients who have external mandates (legal requirements)
- Injectable naltrexone trial demonstrates benefit vs. placebo. However, high drop-out rate of 45% at 6 months.
    - ASAM National Practice Guideline, 2015
- IM form with 53% retention in treatment at 6 months
- 20% treatment retention at 1 year with oral naltrexone
    - Bart (2012)

WE CAN DO THIS!



ANOTHER WILLIAM JAMES QUOTE

- "A great many people think they are thinking when they are merely rearranging their prejudices."

THANK YOU

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- www.asam.org
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