AMERICAN OSTEOPATHIC ASSOCIATION

# OMED® 2020

## ENVISION A PATH TO SUCCESS

OCT 15-18 — VIRTUAL

# Opioid Treatment Programs (OTP) in the Era of COVID-19

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# Disclosures

- I have no disclosures regarding conflict of interest
- I will not be discussing any off-label use of medications

# Educational Objectives

- At the conclusion of this activity participants should be able to:
  - Cite legislation and regulations that have shaped the treatment of opioid use disorder over the past century
  - Describe the Dole & Nyswander (1965) clinical trial of  methadone for treatment of heroin addiction
  - Discuss current OTP regulations
  - Understand how COVID-19 public health emergency has resulted in changes in OTPs

# Harrison Narcotic Act of 1914

- Attempt to carry out the International Opium Convention
- Any person dealing with derivatives of opium and cocaine was required to register annually and pay an annual tax of $1
- Made it illegal to sell or give away these drugs without a written order on a form issued by the commissioner of revenue

Harrison Narcotics Tax Act, 1914. https://www.naabt.org/documents/Harrison_Narcotics_Tax_Act_1914.pdf. Accessed September 2, 2017.

# Harrison Narcotic Act of 1914

- People who weren't registered couldn't partake in interstate trafficking of drugs
- People could not possess narcotics if they hadn't registered or paid the tax
  - Exception made for those prescribed medication in good-faith by a physician
- Penalty of up to 5 years in prison and up to $2000 fine

Harrison Narcotics Tax Act, 1914. https://www.naabt.org/documents/Harrison_Narcotics_Tax_Act_1914.pdf. Accessed September 2, 2017.

# Harrison Narcotic Act of 1914

- Despite the above exception, from 1914-1938 about 25,000 physicians were indicted under the Harrison Act; about 3000 were imprisoned and 20,000 paid substantial fines for prescribing opiates to treat opioid addiction

White WL. *Slaying The Dragon: The History of Addiction Treatment and Recovery in America*. Bloomington, Ill. :Chestnut Health Systems/Lighthouse Institute, 1998.

# Morphine & Heroin Clinics

- Open from 1912 to 1923
- Forty-four clinics were in existence by 1919
- Many opened in response to the Harrison Act and court decisions
  - People were no longer able to get drugs OTC forcing them to go to physicians
  - Provided maintenance or detoxification with morphine


- Treatment Improvement Protocol (TIP) Series, No. 43.Center for Substance Abuse Treatment. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2005.
- Tallaksen A. The narcotic clinic in New Orleans, 1919-21. *Addiction*. 2017;112(9):1680-1685. PubMed PMID: 28498547.

# Effect of Harrison Act

- Despite mixed findings by the court, doctors stopped treating people with addiction with opioids for the next four decades due to the threat of legal prosecution
- All of the morphine and heroin clinics closed by 1923

Padwa H & Cunningham J. *Addiction: A Reference Encyclopedia*. Santa Barbara: ABC-CLIO, LLC. 2010.

# Federal Narcotic Farms

- Two programs opened
  - Lexington, KY, 1935
  - Fort Worth, TX, 1938
- To rehabilitate people addicted to narcotics who were entering the federal prison system
- Some went for free, voluntary treatment for 6 months
- Program evaluations showed high relapse rates (70-95%)


- White W. History of drug problems and drug policies in America. In R. Coombs (Ed.), *Addiction counseling review: Preparing for comprehensive certification exams.* New York: Lahaska Press, 2004.
- Stephens R, Cottrell E. A follow-up study of 200 narcotic addicts committed for treatment under the narcotic addict rehabilitation act (NARA). *Br J Addict Alcohol Other Drugs*. 1972;67:45-53. PubMed PMID: 4504254.

# Methadone

- Synthetic drug invented in Germany during World War II (when opium and morphine were scarce)
- After the war, the factory where methadone was developed came under U.S. control and clinical trials of methadone began in 1947
- New Drug Application was granted for Dolophine® to Eli Lilly & Company
- Studied at the Addiction Research Center in Lexington, KY

Padwa H & Cunningham J. *Addiction: A Reference Encyclopedia*. Santa Barbara: ABC-CLIO, LLC. 2010.

# Dole & Nyswander (1965)

- Rockefeller Institute, New York
- Focused on addiction being a disease, not a character disorder
- Once one becomes addicted to heroin, there are changes in the brain that lead to craving and relapse
- Methadone should be effective in treating those addicted to heroin as it blocks euphoric effects and prevents withdrawal and craving

Dole VP, Nyswander M. A medical treatment for diacetylmorphine (heroin) addiction. A clinical trial with methadone hydrochloride. *JAMA*. 1965;193:646-50. PubMed PMID: 14321530.

# Dole & Nyswander (1965)

- 22 patients
  - Men
  - 19 – 37 years old
  - Heroin addiction
  - No other substantial addictions
  - Not psychotic
- Relapsed after prior withdrawal treatment

Dole VP, Nyswander M. A medical treatment for diacetylmorphine (heroin) addiction. A clinical trial with methadone hydrochloride. *JAMA*. 1965;193:646-50. PubMed PMID: 14321530.

# Dole & Nyswander (1965)

- Results
  - Disappearance of “narcotic hunger”
    - Could resist drugs
    - Tolerated frustration without feeling like using
    - Stopped dreaming about drugs
    - Largely stopped talking about drugs
  - Four subjects injected heroin while on methadone and reported they did not get high
  - Functioning at work and school was normal
  - Adverse effects: sweating and constipation
  - Well-tolerated, only two patients were discharged

Dole VP, Nyswander M. A medical treatment for diacetylmorphine (heroin) addiction. A clinical trial with methadone hydrochloride. *JAMA*. 1965;193:646-50. PubMed PMID: 14321530.

# Post-Dole & Nyswander Era

- 1967-1970:  FDA liberally issued INDs for methadone research
- 1968:  Fewer than 400 people were enrolled in methadone maintenance treatment (MMT) research programs
- 1970:  Methadone approved by FDA for detoxification
- 1973:  Methadone approved by FDA for maintenance treatment
- 1973:  73,000 people were enrolled in MMT

Institute of Medicine. *Federal Regulation of Methadone Treatment.* Washington, DC: The National Academies Press. 1995. https://doi.org/10.17226/4899.

# Early 1970s Criticism

- Methadone was being prescribed to those without serious addiction and thus created iatrogenic addiction
- Methadone was being diverted
- Children were being poisoned by methadone brought home by patients
- Just replacing one drug for another

Federal Regulation of Methadone Treatment. Institute of Medicine (US) Committee on Federal Regulation of Methadone Treatment; Rettig RA, Yarmolinsky A. (eds). Washington (DC): National Academies Press (US); 1995.

# April 1971 Regulations

- FDA IND regulations in response to concerns
- Strict requirements on
  - Starting dosage
  - Urinalysis
  - Recommendation for discharge
- Defined what efficacious treatment looks like

Federal Regulation of Methadone Treatment. Institute of Medicine (US) Committee on Federal Regulation of Methadone Treatment; Rettig RA, Yarmolinsky A. (eds). Washington (DC): National Academies Press (US); 1995.

# 1972 Regulations (37 FR 26795, December 15, 1972)

- Methadone for treatment of opiate addiction can be dispensed only by federally licensed programs
- No dual enrollments
- Eligibility for treatment based on
  - Age
  - Length of addiction

Federal Regulation of Methadone Treatment. Institute of Medicine (US) Committee on Federal Regulation of Methadone Treatment; Rettig RA, Yarmolinsky A. (eds). Washington (DC): National Academies Press (US); 1995.

# 1972 Regulations
# (37 FR 26795, December 15, 1972)

- Set maximum initial dose
- Set minimum amount of counseling
- Specified criteria for take-home methadone doses
  - Results of drug screens
  - Length of time in treatment
  - Dose under 100 mg

Federal Regulation of Methadone Treatment. Institute of Medicine (US) Committee on Federal Regulation of Methadone Treatment; Rettig RA, Yarmolinsky A. (eds). Washington (DC): National Academies Press (US); 1995.

# 1972 Regulations

- Regulations were criticized as burdensome interference to the practice of medicine
  - Federal, state, and local regulations
- Departure from allowing physicians to use their own professional judgment guided by a drug's labeling to determine how to prescribe a medication due to regulations

Federal Regulation of Methadone Treatment. Institute of Medicine (US) Committee on Federal Regulation of Methadone Treatment; Rettig RA, Yarmolinsky A. (eds). Washington (DC): National Academies Press (US); 1995.

# Changes since 1974

- 1980 & 1989: The period of dependence to qualify for treatment (1 yr vs. 2 yrs), ability to use procedures other than urine toxicology for drug testing, expanded counseling for pregnant women, etc.
- 1993: Interim maintenance treatment allowed – if clinic has a waiting list it could provide methadone without meeting other requirements, such as counseling, in response to HIV
- 2001: Oversight for MMT switched from FDA to SAMHSA Center for Substance Abuse Treatment

Federal Regulation of Methadone Treatment. Institute of Medicine (US) Committee on Federal Regulation of Methadone Treatment; Rettig RA, Yarmolinsky A. (eds). Washington (DC): National Academies Press (US); 1995.

# Current OTP regulations and practice

Add brief summary or subheading

OMED2020

# Methadone

- Methadone, when used for treatment of OUD, is dispensed at licensed OTP
  - Because it is administered and not prescribed, it will not show in PDMP
    - Recent changes in 42 CFR Part 2
- Full mu-agonist
- Half-life of 24-36 hours, peak at 2-4 hours
- Dosed once daily except for rapid metabolizers

# Methadone

- Metabolized by the liver (primarily CYP 3A4; also 2D6, 2C19, 2B6, 1A2)
- There are a number of medications that can interact with methadone, thereby decreasing  or increasing the level
  - Inducers:  phenobarbital, phenytoin, carbamazepine, rifampin, St. John's wort, dexamethasone
  - Inhibitors:  SSRIs, diazepam, macrolide antibiotics, grapefruit juice, ketoconazole, verapamil

Substance Abuse and Mental Health Services Administration. *Medications for Opioid Use Disorder*. Treatment Improvement Protocol (TIP) Series 63. Publication No. PEP20-02-01-006. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2020.

# Methadone and Benzodiazepines (BZD)

- BZD potentiate the rewarding and reinforcing effects of methadone
- Survey of 191 people taking methadone found 90 (47%) had history of BZD use
  - 45.5% responded that they used for their euphoric effects
- 6-month prevalence of BZD use among people taking methadone
  - Baltimore = 66%, Philadelphia = 53%, and New York City = 44%
- People who regularly used BZDs
  - Received higher daily methadone doses
  - Used alcohol more frequently
- BZD use with methadone is associated with poorer general health, injury, accidental death, legal problems, and increased alcohol use
  - BZD have been identified in 40–80% of methadone-related deaths

Chen KW, Berger CC, Forde DP, D'Adamo C, Weintraub E, Gandhi D. Benzodiazepine use and misuse among patients in a methadone program. *BMC Psychiatry*. 2011;11:90. Published 2011 May 19. doi:10.1186/1471-244X-11-90
Jones JD, Mogali S, Comer SD. Polydrug abuse: a review of opioid and benzodiazepine combination use. *Drug Alcohol Depend*. 2012;125(1-2):8-18. doi:10.1016/j.drugalcdep.2012.07.004

# Methadone

- Aims of treatment
  - Alleviate withdrawal symptoms
  - Block euphoric effects of self-administered opioids
  - Eliminate cravings for opioids
- Effective dose
  - Typically 80-120 mg daily
  - Should be able to function without impairment of physical or emotional responses
- Monitoring
  - Serum methadone levels do not tell you if a dose is therapeutic
  - Peak and trough typically for rapid metabolizer
  - ECG monitoring for prolonged QTc

Substance Abuse and Mental Health Services Administration. *Medications for Opioid Use Disorder*. Treatment Improvement Protocol (TIP) Series 63. Publication No. PEP20-02-01-006. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2020.

# Admission Criteria

- At least 1 year history of opioid use disorder

  Exceptions

  – Pregnant women
  – Released from correctional facility within last 6 mos
  – Previously treated patients up to 2 years after discharge

- Someone <18 years old
  – Must have been detoxed and/or undergone psychosocial treatment twice within 12 mos
  – Parents must consent in writing

- In Pennsylvania:

  Under 18 years old not allowed unless pregnant

Substance Abuse and Mental Health Services Administration. *Medications for Opioid Use Disorder*. Treatment Improvement Protocol (TIP) Series 63. Publication No. PEP20-02-01-006. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2020.
http://www.pacodeandbulletin.gov/Display/pacode?file=/secure/pacode/data/028/chapter715/chap715toc.html&d= Accessed 7/25/20

# Methadone: Induction

- Greatest risk of overdose death during induction
  - 42% methadone clinic deaths occur during first 2 weeks
  - Of 9835 people started on methadone in 1996,
    - 7 died in the first week = overall mortality rate of 7.1 per 10,000 inductions
  - Increased risk with increased dose and sedative use

Zador D, Sunjic S. Deaths in methadone maintenance treatment in New South Wales, Australia 1990-1995. Addiction. 2000;95(1):77-84. doi:10.1046/j.1360-0443.2000.951778.x
Zador DA, Sunjic SD. Methadone-related deaths and mortality rate during induction into methadone maintenance, New South Wales, 1996. *Drug Alcohol Rev*. 2002;21(2):131-136. doi:10.1080/09595230220139028

# Methadone overdoses: Three patterns

- **Single overdose** – accidental ingestion by intolerant individual (e.g., child) or purposeful ingestion by someone with low or lost tolerance
- **Accumulated toxicity** – toxicity develops gradually as doses accumulate with repeated dosing, typically overly aggressive induction
- **Combining methadone with another CNS depressant** (e.g., opioids, benzodiazepines, alcohol, antidepressants and antipsychotics)
  - When looking at deaths involving methadone and another drug, benzodiazepines are most frequently reported

Baxter LE Sr, Campbell A, Deshields M, et al. Safe methadone induction and stabilization: report of an expert panel. *J Addict Med*. 2013;7(6):377-386. doi:10.1097/01.ADM.0000435321.39251.d7

# Methadone: Induction

- Induction (weeks 1-2)
  - Typically started on no higher than 30 mg on day 1
  - If after 2-4 hours on reassessment withdrawal is still present, can give additional 5-10 mg and physician must document this
    - No higher than 40 mg on day 1
  - Takes 3-7 days to reach steady state, so dose changes should reflect this time period; typically 5 mg increase every 5 days
  - Do not use equianalgesic dose tables to calculate methadone dose
    - They do not take into account the effect of methadone accumulation before steady state is reached

Substance Abuse and Mental Health Services Administration. *Medications for Opioid Use Disorder*. Treatment Improvement Protocol (TIP) Series 63. Publication No. PEP20-02-01-006. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2020.

# Methadone: Early Stabilization

- Early stabilization (weeks 3-4)
  - Patients given the same dose for 3-4 consecutive days with no missed doses before the dose is increased
  - Once tolerance is demonstrated and patient is dosing regularly, can increase dose by 5-10 mg, with assessments every 3-5 days
  - Absences
    - Consecutive absences prevent tissue stores of methadone and it is difficult to evaluate the effect of the dose
    - Protracted absences make “regular” dose unsafe and dose needs to be re-evaluated after 3 consecutive absences
  - Avoid standing orders/automatic dose titrations

Substance Abuse and Mental Health Services Administration. *Medications for Opioid Use Disorder*. Treatment Improvement Protocol (TIP) Series 63. Publication No. PEP20-02-01-006. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2020.

# Methadone: Late stabilization

- Late stabilization (week 5 and beyond)
  - Patients may continue on same dose for years
  - Stable patients may wish to decrease dose
  - Change in health, meds, stress level may trigger cravings and withdrawal
  - Patients may attribute new s/s to methadone dose (e.g., cold symptoms)
  - May need increased dose to block euphoric effects of opioids or decrease cravings
  - Concurrent alcohol or benzo use may require dose to be lowered due to sedation, may result in opioid cravings

Substance Abuse and Mental Health Services Administration. *Medications for Opioid Use Disorder*. Treatment Improvement Protocol (TIP) Series 63. Publication No. PEP20-02-01-006. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2020.

# Potential Adverse Effects from Methadone

Low energy
Back pain
Swelling
Chills
Hot flashes
Malaise
**Weight gain**
**Constipation**
Dry Mouth
Blurred vision

QT prolongation
Abnormal dreams
Anxiety
Decreased libido
Depression
Euphoria
Headache
Insomnia
Somnolence
Sexual dysfunction

Cough
Rhinitis
Yawning
Postural hypotension
Bradycardia
Hyperprolactinemia
Amenorrhea
**Sweating**
Rash
Urinary retention

# Methadone Take-home Criteria

Automatically get 1 take-home dose for day clinic is closed (Sundays, state/federal holidays)

- Absence of recent drug & alcohol use
- Regular attendance at clinic
- Absence of behavioral problems at clinic
- Absence of known recent criminal activity
- Stable home environment & relationships
- Acceptable time in maintenance tx
- Assurance of safe storage
- Rehabilitative benefit of take-homes outweighs risk of diversion

Substance Abuse and Mental Health Services Administration. *Medications for Opioid Use Disorder*. Treatment Improvement Protocol (TIP) Series 63. Publication No. PEP20-02-01-006. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2020.

# Continuous Time in Treatment and Take-home Doses

## Federal Regulations

- Number of take-home doses based on time in continuous treatment
  - 0-90 days – 1 dose per week
  - 3-6 months – 2 doses per week
  - 6-9 months – 3 doses per week
  - 9-12 months – 6 doses per week
  - >1 year – 14 doses
  - >2 years – 28 doses
- No take-homes for short-term detoxification

## *All States are Different*

## Pennsylvania Regulations

- Observed dosing (days/week) based on time in continuous treatment
  - 0-90 days – 6 days/week
  - >3 months – 3 days/week, no more than 2 take-home doses at once
  - >2 years – 2 days/week, no more than 3 take-home doses at once
  - >3 years - 1 day/week

Substance Abuse and Mental Health Services Administration. *Medications for Opioid Use Disorder*. Treatment Improvement Protocol (TIP) Series 63. Publication No. PEP20-02-01-006. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2020.
http://www.pacodeandbulletin.gov/Display/pacode?file=/secure/pacode/data/028/chapter715/chap715toc.html&d= Accessed 7/25/20

# Counseling Requirements

## Federal Regulations

- OTPs must provide adequate substance abuse counseling to each patient as clinically necessary
- OTPs must provide the following services or referrals to services
  - Vocational rehab
  - Educational resources
  - Employment services

## *All States are Different*

## Pennsylvania Regulations

- Years 1-2 - an average of 2.5 hours of psychotherapy per month, 1 hour of which shall be individual psychotherapy
- Years 3-4 - at least 1 hour per month of group or individual psychotherapy
- >4 years - at least 1 hour of group or individual psychotherapy every 2 months

Substance Abuse and Mental Health Services Administration. Federal Guidelines for Opioid Treatment Programs. HHS Publication No. (SMA) XX-XXXX. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015.
http://www.pacodeandbulletin.gov/Display/pacode?file=/secure/pacode/data/028/chapter715/chap715toc.html&d= Accessed 7/25/20

# Methadone

- Drug testing (typically urine or oral fluid)
  - Federal regulations state must be done at least 8 times per year
    - States may require more frequent – PA requires monthly testing
  - Screen for presence of methadone and metabolite
  - Methadone is synthetic so you must test for it specifically (won't be +opiates)
  - Should also screen for oxycodone (won't be +opiates)
  - Must also test for other drugs prevalent in the area (e.g., fentanyl)

Substance Abuse and Mental Health Services Administration. Federal Guidelines for Opioid Treatment Programs. HHS Publication No. (SMA) XX-XXXX. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015.
http://www.pacodeandbulletin.gov/Display/pacode?file=/secure/pacode/data/028/chapter715/chap715toc.html&d= Accessed 7/25/20

# Hospitalized Patients

- Title 21, Code of Federal Regulations, Part 1306.07(c)
- A physician or other authorized hospital staff may maintain or detoxify a person with buprenorphine or methadone as an incidental adjunct to medical or surgical conditions
  - A patient  who is admitted to a hospital for a primary medical/psychiatric problem other than OUD, may be administered opioid agonist medications, methadone or buprenorphine, to prevent opioid withdrawal that would complicate the primary problem
  - A patient who is admitted to a hospital for primary medical/psychiatric problem other than OUD, may be maintained on usual dose of buprenorphine or methadone

https://www.ecfr.gov/cgi-bin/text-idx?SID=dd3324c93ad659b4a55e8cca8156a65c&node=se21.9.1306_107&rgn=div8 Accessed 7/25/20

# Methadone in Hospital

- When patient enrolled in an OTP is admitted to hospital always
  - Get a release signed and call their OTP to verify
    1. Methadone dose
    2. Date of last dose (if patient hasn't dosed in >3 days, dose is typically decreased due to presumed loss of tolerance)
    3. Patient is still enrolled in treatment
- On discharge patient is not discharged with prescription for methadone

# What happens if you remove the structure of the OTP?

Methadone Medical Maintenance

# Methadone Medical Maintenance (MMM)

- Started in 1983 at Rockefeller Univ through the FDA's IND program by Dr. Marie Nyswander, approved by DEA and OASAS
- Rationale:  Rules and some of the services offered by OTP are not needed by socially rehabilitated patients and can be too restrictive and counterproductive
- Methadone
  - Receive diskettes which dissolve in juice/water
  - Dispensed methadone to patients 1 or more times per month from privacy of physician office
- In 1985 program transferred to Beth Israel and St. Luke's (IM and FM docs)
  - Only 1 physician had experience with methadone
  - Trained by physicians who had experience with methadone

Salsitz EA, Joseph H, Frank B, et al. Methadone medical maintenance (MMM): treating chronic opioid dependence in private medical practice--a summary report (1983-1998). *Mt Sinai J Med*. 2000;67(5-6):388-397.

# MMM Admission Criteria

- In treatment for 5 years
  - 1996 modified to 4 years
- No drug use or criminal activity for at least 3 years prior to applying for MMM
- Engaged in productive activity (employed, homemaker, enrolled in school)
- Had been adherent with clinic regulations (responsible handling of take-homes, negative UDS, attending clinic as scheduled)
- Emotional stability
- Financially able to pay for visits
- No ties to people using substances
- Statement from clinic staff that patient meets criteria for admission to MMM and could benefit from program
- Patient believes MMM will benefit
- If patient has illness and is under care of another physician, needs to allow coordination of care
- Enters program voluntarily
- Not in the military
- Can safely store 1 month's supply of med

Salsitz EA, Joseph H, Frank B, et al. Methadone medical maintenance (MMM): treating chronic opioid dependence in private medical practice--a summary report (1983-1998). *Mt Sinai J Med*. 2000;67(5-6):388-397.

# MMM Process

- Initially reported every 2 weeks for 1 month, then placed on monthly visits
- Provided urine specimen at each visit
- Drank methadone in office to demonstrate tolerance to dose
- Physician
  - Verifies employment during visit
  - Discusses any challenges in the past month, offer counseling referral if needed
  - Discusses medical problems, refer to PCP or assume care
  - Performs annual physical exam
  - Dispenses up to 1 month supply of methadone diskettes

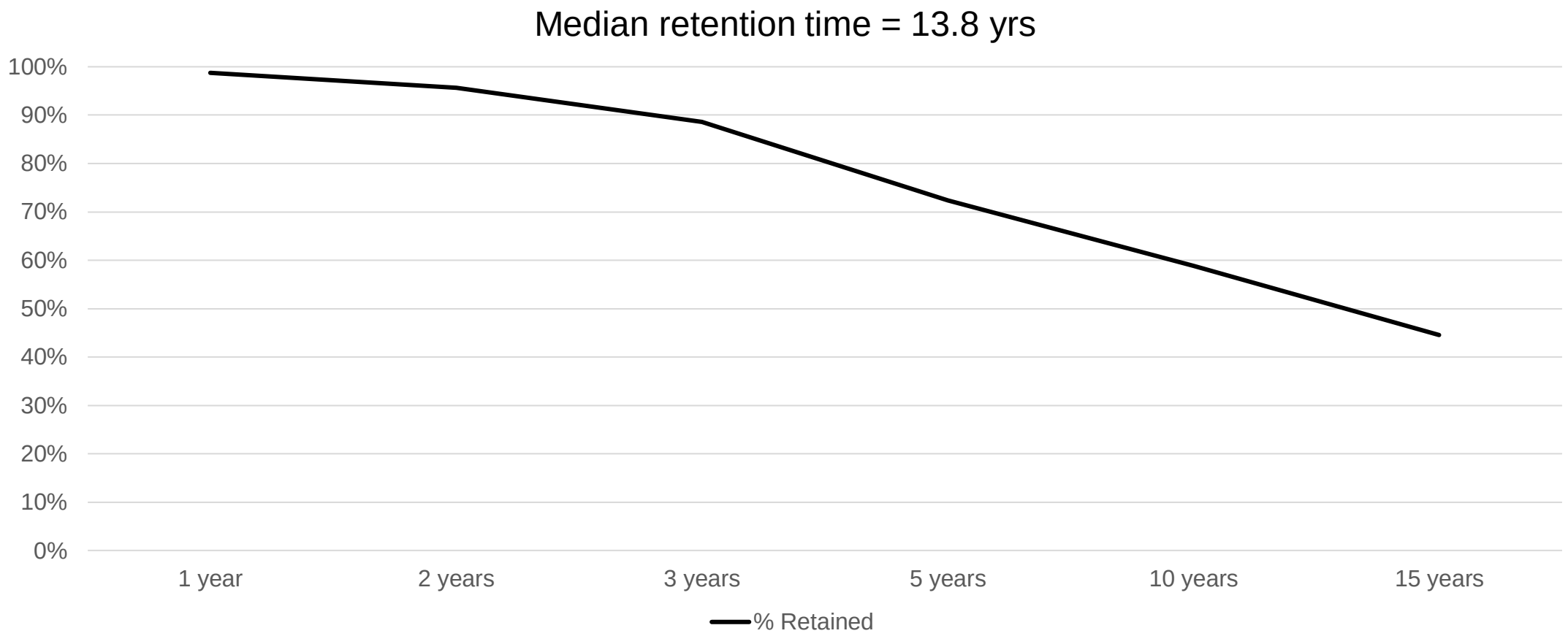
Salsitz EA, Joseph H, Frank B, et al. Methadone medical maintenance (MMM): treating chronic opioid dependence in private medical practice--a summary report (1983-1998). *Mt Sinai J Med*. 2000;67(5-6):388-397.

# MMM Outcomes

- 158 patients enrolled
  - 132 (83.5%) adherent
  - 26 (16.5%) nonadherent and terminated from MMM
- Significantly greater percentage of adherent patients compared to nonadherent were
  - married or in stable relationship (68% vs. 46%)
  - had 2 or more admissions to OTP (36% vs. 12%)
  - had longer duration of methadone treatment (15.8 yrs vs. 12.5 yrs)
- Doses ranged from 5 to 120 mg daily, with 42% of doses between 80 and 120 mg

Salsitz EA, Joseph H, Frank B, et al. Methadone medical maintenance (MMM): treating chronic opioid dependence in private medical practice--a summary report (1983-1998). *Mt Sinai J Med*. 2000;67(5-6):388-397.

# Percent Retained in MMM Over Time




Salsitz EA, Joseph H, Frank B, et al. Methadone medical maintenance (MMM): treating chronic opioid dependence in private medical practice--a summary report (1983-1998). *Mt Sinai J Med*. 2000;67(5-6):388-397.

# MMM Outcomes

## Adherent Patients (n=132)

- 62.7% in good standing
- 8.2% withdrew from methadone
- 0.6% returned to OTP voluntarily
- 12.7% died (smoking related, HIV, HCV, other causes not related to methadone)

## Nonadherent patients (n=26)

- Reason for discharge
  - 58% serious cocaine problems
  - 27% administrative
  - 15% misuse of medication
- Follow-up
  - 18 returned to OTP
  - 2 incarcerated
  - 6 unknown

Salsitz EA, Joseph H, Frank B, et al. Methadone medical maintenance (MMM): treating chronic opioid dependence in private medical practice--a summary report (1983-1998). *Mt Sinai J Med*. 2000;67(5-6):388-397.

# OTPs during COVID-19 Pandemic

Add brief summary or subheading

# Timeline of government actions and announcements

HHS Announces PHE
1/31/20

Gov Wolf issues Proclamation of Disaster Emergency
3/6/20

CMS announces expanded telehealth benefits under 1135 waiver and CPRSAA
3/13/20

Suspension of one in-person exam for controlled substance during telemed
3/16/20

SAMHSA: In-person exam still required for initial visit for methadone
3/16/20

SAMHSA: Telehealth can be used for follow-up visits for methadone
3/16/20

SAMHSA Blanket Exception for 14- and 28-day take-homes for stable individuals
3/16/20

SAMHSA allows alternate delivery of methadone for quarantined individuals
3/16/20

OCR Relaxes HIPAA Enforcement for Telehealth Tech
3/17/20

PA DDAP issues Licensing Alert 01-20 regarding suspension of 28 Pa. Code 715.16(e)
3/18/20

Announcement re:
42 CFR Part 2
3/19/20

SAMHSA and DEA announce telephonic visits okay for new buprenorphine pts
3/31/20

# Challenges for OTP staff and patients during COVID-19

## Public Health Measures

- Clinic closed on weekends
- Increased take-home doses
- Telemed & Teletherapy visits
- Mask-wearing by patients and staff
- Alternate delivery of methadone
- Naloxone dispensing and prescribing

## Potential Problems

- Diversion, lost, and stolen doses of methadone
- Not following dosing instructions
- Less engagement in treatment
- Less support for patients
- Toxicity and death

# Anecdotal reports in press

- Meridian Clinic in FL - Out of a total of 440 patients,
  - 197 (44.8%) are receiving extended take-homes (7, 14, or 28 days)
  - Most are receiving 28 days
  - “There are very few negative experiences,” Dr. Straubing told AT Forum.
    - No overdoses
    - 7 reports of stolen methadone (1.6%)
    - About 12 failed callbacks (2.7%)

https://atforum.com/2020/07/extended-methadone-take-homes-during-covid-nothing-but-success/ Accessed 7/25/20

# Anecdotal reports in press

- CODAC Clinic in RI – Out of 2700 patients over 8 sites,
  - The number of take-homes increased by about 50%
  - About 30% of CODAC patients got 28 days of take-home doses
  - Problems (0.15%)
    - 1 report of lost methadone
    - 1 report of stolen methadone
    - 2 reports of taking more than prescribed
    - 0 reports of selling methadone
  - No bump in illicit use or diversion of methadone according to RI state police

https://atforum.com/2020/07/extended-methadone-take-homes-during-covid-nothing-but-success/ Accessed 7/25/20

## Thank you!

- Questions/Comments