Understanding Opioid Treatment Programs (OTPs)

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COLORADO
Department of Health Care Policy & Financing

COLORADO
Behavioral Health Administration

HMA
Health Management Associates

Learning Objectives

Following this training, participants will be able to:

- Describe the regulatory and accreditation requirements for opioid treatment programs (OTPs)/narcotic treatment programs (NTPs)
- Characterize at least three outcomes, beyond reduction in opioid use, that are associated with OTP/NTP treatment
- Identify at least three recent regulatory changes to OTP/NTP treatment standards
- Discuss at least two opportunities for expansion of OTP/NTP services outside of the traditional OTP/NTP setting

OTP Overview

OTPs Are More Than Just Methadone

‘‘… a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication’’ that is also ‘‘registered under 21 U.S.C. 823(h)(1)’’ is described as an ‘‘Opioid Treatment Program’’ (OTP).

- ✓ Dispense opioid agonist medications for the treatment of opioid use disorders (OUD)

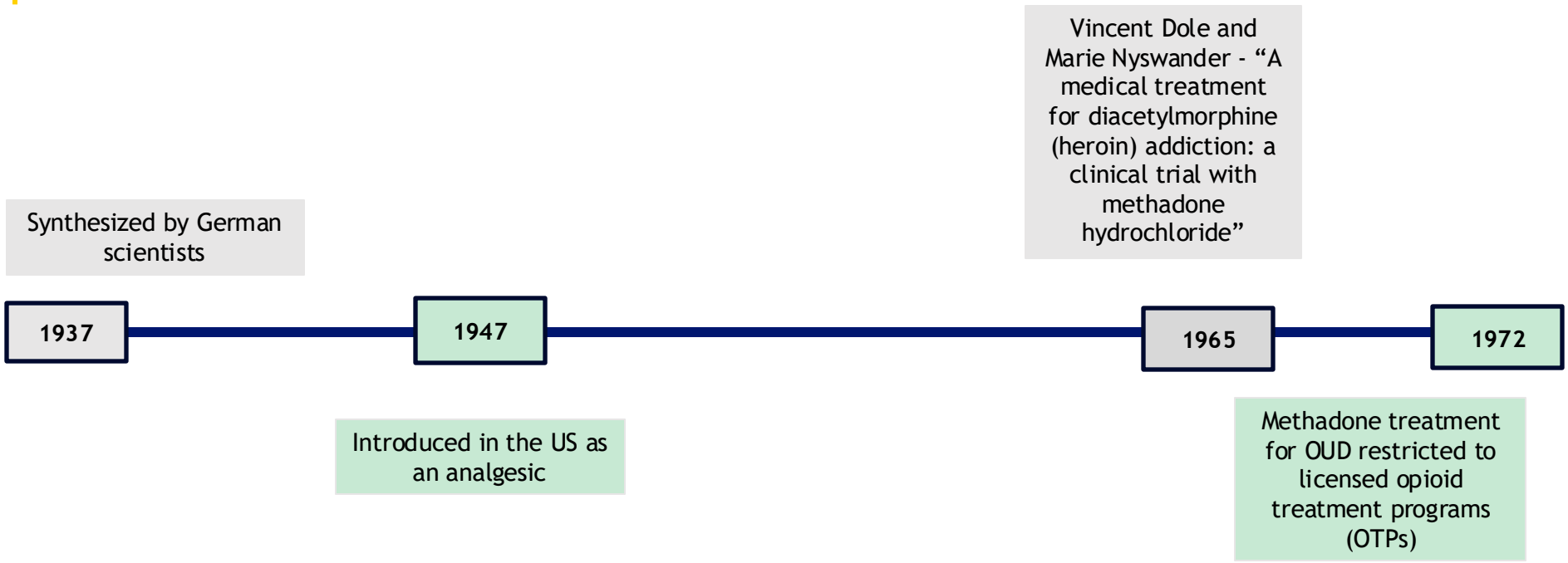
Required Services

- ✓ Supervised dosing
- ✓ Toxicology testing
- ✓ “Adequate medical, counseling, vocational, educational, and other screening, assessment and treatment services to meet patient needs…”
  - Combination of services and frequency of delivery individually tailored on shared decision-making treatment/recovery planning process
  - Services must be provided onsite, except when a formal agreement exists with another organization to provide the services

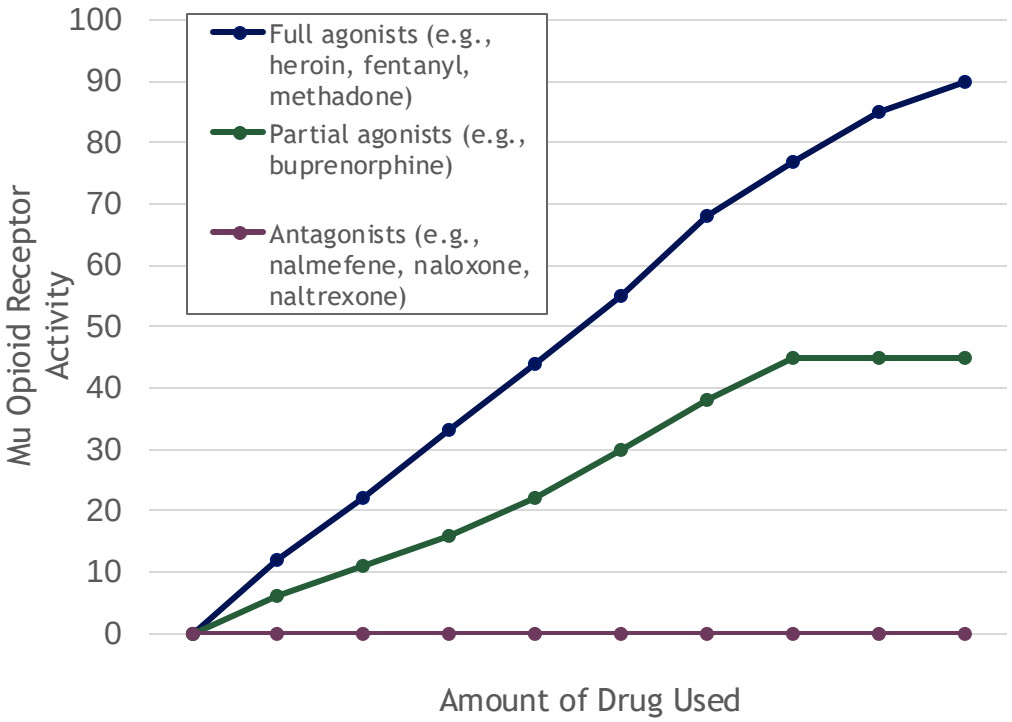
OTP Staff

- Administrative Staff
  (e.g., Executive Director, Clinical Director)
- Medical Director
- Other Qualified Practitioners
  (e.g., other physicians, NPs, PAs)
- Nurses
- Counselors
- Case Managers
- Peers

History of Methadone



Methadone Overview



- Schedule II controlled substance
- Full mu (μ) opioid receptor agonist
- At increasing doses:
  - Suppresses opioid withdrawal (cross tolerance)
  - Reduces opioid craving
  - Blocks acute effects of other opioids (e.g., heroin, fentanyl)
- Dose required to control withdrawal symptoms ≠ dose required to control cravings
  - Higher doses needed to control cravings

Benefits of Methadone in Treating Opioid Use Disorder (OUD)

- Decreased illicit opioid use
- Increased treatment engagement
- Decreased mortality
  - 2-3x reduction in risk of mortality
  - Those who receive MOUD are 75% less likely to have an addiction-related death than those who do not receive MOUD
- Decreased transmission of infectious diseases (HIV, Hepatitis)
  - 3.5% vs. 22% HIV seroconversion rate
- Decreased criminal recidivism
- Increased employment
- Improved birth outcomes among pregnant persons with OUD

Old Methadone Take-Home Dose Rules

- Any patient may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays
- 1st 90 days of treatment: limited to a single take-home dose each week
- 2nd 90 days of treatment: up to 2 doses per week
- 3rd 90 days of treatment: up to 3 doses per week
- Remainder of 1st year: up to 6 doses per week
- After 1 year of continuous treatment: up to 2-week supply
- After 2 years of continuous treatment: up to 1-month supply
- Anything outside of these parameters requires formal request to SAMHSA and SOTA
- 8 other criteria for consideration: Absence of recent substance use, regular clinic attendance

Buprenorphine Dispensing in OTPs

2000: Drug Abuse Treatment Act (DATA)

- Allowed for buprenorphine (Schedule III) prescribing in treatment settings other than OTPs

2003: SAMHSA published interim rule allowing for buprenorphine dispensing in OTPs.

2015: Regulation removed time in treatment regulations for buprenorphine dispensing.

2022: Consolidated Appropriations Act of 2023 eliminated the DATA 2000 waiver requirement and removed all caps on patient limits.

Benefits of Medications for Opioid Use Disorder

Benefit	Methadone	Buprenorphine	Naltrexone
Decreases withdrawal symptoms	Yes	Yes	No
Decreases cravings	Yes	Yes	Yes
Decreases illicit opioid use	Yes	Yes	Yes
Decreases transmission of infectious diseases (HIV, Hepatitis C)	Yes	Yes	Yes
Decreases criminal activity	Yes	Yes	Yes
Decreases overdoses	Yes	Yes	No
Decreases risk of death	Yes	Yes	No
Improves treatment retention	Yes	Yes	Yes
Improves birth outcomes	Yes	Yes	Data not available
Increases employment	Yes	Yes	Yes

Knowledge Check #1

Since 2003, OTPs have been able to prescribe both methadone and buprenorphine.

A. True

A. False

Knowledge Check #1 - Answer

Since 2003, OTPs have been able to prescribe both methadone and buprenorphine.

A. True

A. False

OTPs do not prescribe methadone. Methadone cannot be prescribed for treatment of opioid use disorder. Methadone is **dispensed** from the OTP. OTPs also dispense buprenorphine. OTP providers can prescribe buprenorphine, as originally allowed by the DATA 2000 waiver, but that falls outside of OTP regulations.

Knowledge Check #2

In addition to reduction in illicit opioid use, methadone and buprenorphine have been associated with which of the following?

A. Reduced mortality
B. Reduced transmission of infectious diseases (i.e. HIV, Hepatitis)
C. Increased employment
D. A, B, and C

Knowledge Check #2 - Answer

In addition to reduction in illicit opioid use, methadone and buprenorphine have been associated with which of the following?

A. Reduced mortality
B. Reduced transmission of infectious diseases (i.e. HIV, Hepatitis)
C. Increased employment
D. A, B, and C

Methadone and buprenorphine have been associated with reduction in overdose and all-cause mortality, reductions in HIV and Hepatitis C transmission, and increased employment.

OTP Regulation

Highly Regulated

- Must be accredited by SAMHSA-approved accrediting body
  - Joint Commission
  - CARF
  - Council on Accreditation
  - National Commission on Correctional Health
  - Missouri Department of Health
  - Washington State Department of Health
- Must be certified
  - Substance Abuse and Mental Health Services Administration (SAMHSA)
- Must be licensed by the state in which they operate
  - State Opioid Treatment Authority (SOTA)
- Must be registered with the Drug Enforcement Administration (DEA)

Certification

Done by the Substance Abuse and Mental Health Services Administration (SAMHSA)

Need to demonstrate compliance with OTP Standards in 42 CFR, part 8

Must be accredited before can be certified

Can get a provisional certification for 1-year while pursuing accreditation

Accreditation

- Accreditation requirement established in 2001
- SAMHSA-approved accreditation organization
- Have 1 year to get accredited: Apply to SAMHSA for provisional certification for up to 1 year
- Must have completed DEA registration process
- Must be currently serving patients and providing medications to be eligible for survey
- Involves in-person site visit and survey: Policy and records review, and interviews

DEA Registration

Registration is applicable to Schedule II (methadone) and Schedule III (buprenorphine) for treatment of OUD

If an organization owns/operates multiple OTPs, each OTP must be separately registered

Site visit and investigation conducted by local DEA field office includes the following:

- Review of record-keeping
- Site for storage of methadone and buprenorphine
- Inspection and testing of the safe where medication will be stored
- Verification of state licensure
- Verification of SAMHSA certification

Registration is valid for 1 year and must be renewed annually

State Licensing

Requires completion of application and state licensing fee

- Colorado controlled substances license
- Colorado Behavioral Health Entity License (BHE)

State Opioid Treatment Authority (SOTA)

- Housed within the Behavioral Health Administration
- Ryan Mueller – ryan.mueller@state.co.us

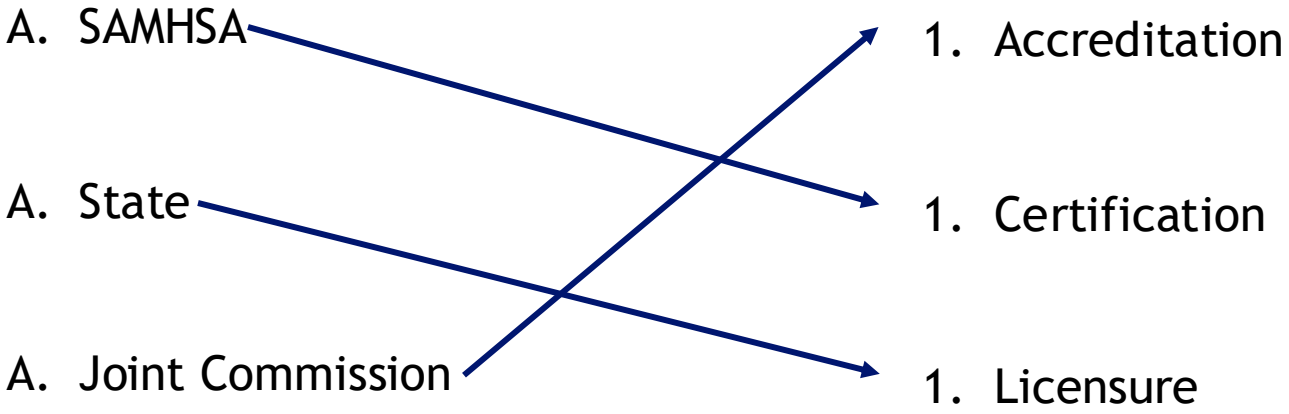
Knowledge Check #3

OTPs are highly regulated and must be accredited, certified, and licensed. Match the entity to the role they play in OTP regulation.

A. SAMHSA	1. Accreditation
A. State	1. Certification
A. Joint Commission	1. Licensure

Knowledge Check #3 – Answer

OTPs are highly regulated and must be accredited, certified, and licensed. Match the entity to the role they play in OTP regulation.



Updates to OTP Standards: The Final Rule

“The Final Rule”

Code of federal regulations Title 42, Part 8 originally in effect as of 2001 contains standards for OTPs:

- Review of record-keeping
- Site for storage of methadone and buprenorphine
- Inspection and testing of the safe where medication will be stored
- Verification of state licensure
- Verification of SAMHSA certification

With the COVID-19 public health emergency, relaxed take-home restrictions.

February 2, 2024, updated final rule published.

- Went into effect April 2, 2024
- Programs allowed until October 2, 2024, to be compliant

Final Rule Changes: Treatment Standards

- ✓ Emphasizes shared decision-making
- ✓ Individualized treatment
- ✓ Use of clinical judgment
- ✓ Incorporates principles of harm reduction

Rationale: “Recognizes the need to meet patients where they are with their opioid and other substance use disorders, and help patients make positive change, reducing harm along the way.”

https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/final-rule-table-changes

Final Rule Changes: Admissions

- Removes requirement for 1-year history of opioid addiction
- Promotes priority treatment for pregnant individuals
- Removes the requirement for two documented instances of unsuccessful treatment for people under age 18
- Allows consent for treatment to be obtained electronically
- Allows for initiation of methadone after a screening examination and does not require delay of initiation until comprehensive examination is completed

Final Rule Changes: Admissions, continued

- Allows for screening examination to be conducted via audio-visual telehealth
- OTPs can accept screening examinations performed by other practitioners, if done within 7 days of admission, with verification by OTP practitioner
- Full in-person physical examination to be completed within 14 calendar days
- While there is an expectation that counseling be offered, denial of medication to people who decline counseling is discouraged

Rationale: “Removes unnecessary barriers to medication access by focusing on individual patient needs. Adds protections for vulnerable groups.”

https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/final-rule-table-changes

Final Rule Changes: Methadone Initiation

Old	New
Maximum initial dose of 30mg on first day	Initial dose up to **50mg** on first day
Could give additional 10mg for persistent withdrawal symptoms Maximum Day 1 dose = **40mg**	Provider can use clinical judgment to give higher starting dose with appropriate documentation

Final Rule Changes: Take-Home Doses

- ✓ Made Covid-19 flexibilities permanent:
  - Up to 7 days of take-homes in the first 14 days of treatment
  - Up to 14 days of take-homes from day 15 of treatment
  - Up to 28 days of take-homes from day 31 in treatment

Rationale: “Makes permanent the COVID-19 flexibilities which demonstrated that wider access to methadone improves outcomes, without increasing rates of diversion, when paired with individualized, clinical judgment, safeguards, and patient education.”

https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/final-rule-table-changes

Colorado DHS and SOTA Response to the Final Rule

- BHA Rule Change Intentions
  - Realignment with SAMHSA
  - Increased access to life-saving medication
  - Improved quality of care
  - Reduced overall community harm
  - Reduced Stigma
  - Increased Trust
- Extensive process for inclusion of stakeholders
- Multiple layers of approval
- Anticipated date for new rules: 2/1/2025

Knowledge Check #4

With the new Final Rule patients have to complete a comprehensive examination before medication can be started.

A. True

A. False

Knowledge Check #4 - Answer

With the new Final Rule patients have to complete a comprehensive examination before medication can be started.

A. True

A. False

The Final Rule published February 2024 allows for a screening examination to be done prior to starting medication. A comprehensive examination must be completed within 14 days of admission.

Opportunities for Methadone Expansion

Mobile Opioid Treatment Unit

Stock Photo.

- Expand access to marginalized communities
- Multiple models for buprenorphine
- In July 2021, the DEA issued new regulations related to mobile methadone
  - Must be part of a fixed-site OTP
  - Can only operate in the state where OTP registered
- Advancements in technology may allow for engagement in counseling as well

Breve, et. al. Cureus. 2022

Medication Unit

"Medication unit means an entity that is established as **part of, but geographically separate from, an OTP** from which appropriately licensed OTP practitioners, contractors working on behalf of the OTP, or community pharmacists may dispense or administer MOUD, collect samples for drug testing or analysis, or provide other OTP services. Medication units can be a **brick-and-mortar location** or mobile unit."

Activities of a medication unit are performed in accordance with all pertinent state laws and regulations.

Certification Exempt Medication Unit

"**Certification as an OTP under this part is not required** for the initiation or continuity of medication treatment or withdrawal management of a patient who is admitted to a **hospital, long-term care facility, or correctional facility, that is registered with the Drug Enforcement Administration as a hospital/clinic**, for the **treatment of medical conditions other than OUD, and who requires treatment of OUD with methadone during their stay**, when such treatment is permitted under applicable Federal law."

Is required to have a separate DEA registration as an NTP.

Medication Unit DEA Requirements

- Required to have a separate DEA registration as an NTP
- Prohibited from prescribing approved narcotic controlled substances

Summary

- OTPs are an important part of the OUD treatment continuum.
- Benefits extend beyond reduction in substance use and treatment attendance.
- Recent federal regulations made significant changes in OTP operational standards:
  - Emphasis on individualized, patient-centered treatment
  - Shared decision-making
  - Increased allowance for clinical judgement
  - Integration of harm reduction
  - Discourages denial of medication to people who decline counseling
  - Increased take-home dose flexibilities
- Mobile and medication units offer opportunities for expansion of medications for opioid use disorder outside of brick-and-mortar OTP.

Knowledge Check #5

Hospitals, long-term care facilities, and correctional facilities that want to operate a medication unit allowing them to dispense methadone for the treatment of OUD must be certified by SAMHSA.

A. True

A. False

Knowledge Check #5 - Answer

With the new Final Rule patients have to complete a comprehensive examination before medication can be started.

A. True

A. False

Hospitals, long-term care facilities, and correctional facilities that want to operate a medication unit **do not** have to be certified by SAMHSA if they are registered with the DEA as a hospital or clinic for the treatment of conditions other than OUD.

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https://bit.ly/bhprovidertrainingsurvey

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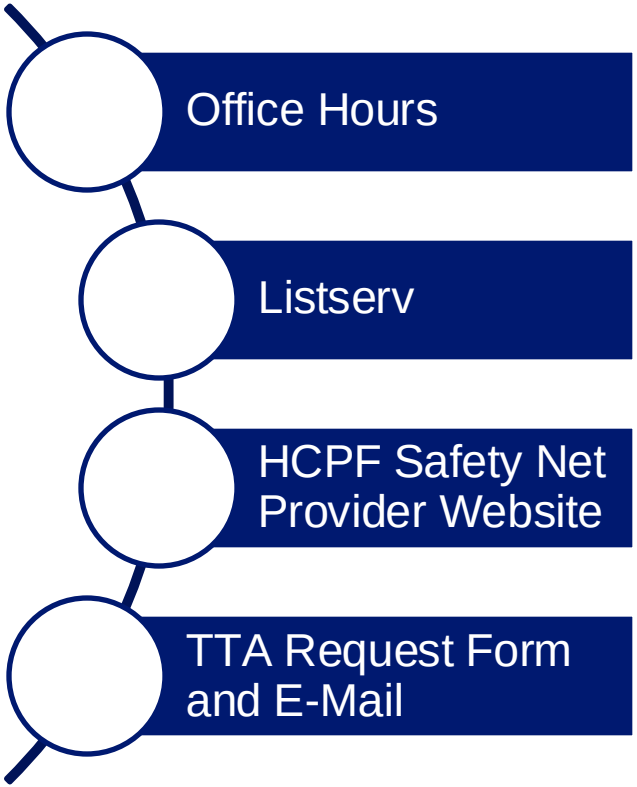
Appendix A: Additional Resources



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Join the Listserv to receive notifications of trainings, technical assistance, and other stakeholder engagement opportunities: Register Here

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Request TTA support or share your ideas, questions and concerns about this effort using the TTA Request Form or e-mail questions and comments to: info@safetynetproviders.com

Appendix B: References

- https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/final-rule-table-changes
- Dole VP, Nyswander M. A Medical Treatment for Diacetylmorphine (Heroin) Addiction: A Clinical Trial With Methadone Hydrochloride. *JAMA*. 1965;193(8):646–650. doi:10.1001/jama.1965.03090080008002
- Krupitsky, E., Nunes, E. V., Ling, W., Illeperuma, A., Gastfriend, D. R., & Silverman, B. L. (2011). Injectable extended-release naltrexone for opioid dependence: a double-blind, placebo-controlled, multicentre randomized trial. Lancet, 377(9776), 1506-1513.
- Larochelle, et al. (2018) Medication for opioid use disorder after nonfatal opioid overdose and association with mortality. A cohort study. Annals of Internal Medicine. 169:3;137-45.

Appendix B: References

- Lee, J. D., Friedmann, P. D., Kinlock, T. W., Nunes, E. V., Boney, T. Y., Hoskinson, R. A. Jr., Wilson, D., McDonald, R., Rotrosen, J., Gourevitch, M. N., Gordon, M., Fishman, M., Chen, D. T., Bonnie, R. J., Cornish, J. W., Murphy, S. M., & O'Brien, C. P. (2018). Extended-release naltrexone to prevent opioid relapse in criminal justice offenders. American Journal of Psychiatry, 175(6), 547-555.
- Lobmaier, P., Gossop, M., Waal, H., & Bramness, J. (2008). The pharmacological treatment of opioid addiction—a clinical perspective. European Addiction Research, 14(1), 1-10.
- Lutgen-Nieves, L. et. al. (2021) From the General Public to America's Jails: MAT Saves Lives. NCCHC Foundation. Chicago, IL.
- Mattick, R. P., Kimber, J., Breen, C., & Davoli, M. (2014). Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. Cochrane Database of Systematic Reviews, (2).

Appendix B: References

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- Mattick, R. P., Breen, C., Kimber, J., & Davoli, M. (2009). Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence. Cochrane Database of Systematic Reviews, (3).
- Metzger, D. S., Woody, G. E., McLellan, A. T., O'Brien, C. P., Druley, P., Navaline, H., DePhilippis, D., Stolley, P., & Abrutyn, E. (1993). Human immunodeficiency virus seroconversion among intravenous drug users in- and out-of-treatment: an 18-month prospective follow-up. Journal of Acquired Immune Deficiency Syndromes, 6(9), 1049-56.

Appendix B: References

- National Academies of Sciences, Engineering, and Medicine; Action Collaborative on Countering the U.S. Opioid Epidemic; Health and Medicine Division; Board on Health Care Services; Board on Health Sciences Policy; Stroud C, Posey Norris SM, Bain L, editors. Methadone Treatment for Opioid Use Disorder: Improving Access Through Regulatory and Legal Change: Proceedings of a Workshop. Washington (DC): National Academies Press (US); 2022 Jul 15. 3, The History of Methadone and Barriers to Access for Different Populations. Available from: https://www.ncbi.nlm.nih.gov/books/NBK585210/
- Payte JT. A brief history of methadone in the treatment of opioid dependence: a personal perspective. J Psychoactive Drugs. 1991 Apr-Jun;23(2):103-7. doi: 10.1080/02791072.1991.10472226. PMID: 1765883.

Appendix B: References

- Santo, T. Jr., Clark, B., Hickman, M., Grebely, J., Campbell, G., Sordo, L., Chen, A., Tran, L. T., Bharat, C., Padmanathan, P., Cousins, G., Dupouy, J., Kelty, E., Muga, R., Nosyk, B., Min, J., Pavarin, R. M., Farrell, M., & Degenhardt, L. (2021). Association of opioid agonist treatment with all-cause mortality and specific causes of death among people with opioid dependence: A systematic review and meta-analysis. JAMA Psychiatry, 78(9), 979-993.
- Tsui, J. I., Evans, J. L., Lum, P. J., Hahn, J. A., & Page, K. (2014). Association of opioid agonist therapy with lower incidence of hepatitis C virus infection in young adult injection drug users. JAMA Internal Medicine, 174(12), 1974-1981.