



Providers
Clinical Support
System

Methadone in Acute Care Settings

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- PCSS-MOUD aims to increase the knowledge and skills of healthcare and counseling professionals about available evidence-based treatment approaches for substance use disorder (SUD) with a particular focus on opioid use disorder (OUD). PCSS-MOUD provides free training and mentoring to practitioners on the use of medications for OUD (MOUD) and the integration of these services into mainstream health care.

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Educational Objectives

At the conclusion of this activity participants should be able to:

- Describe the process of methadone initiation in acute care settings (both Emergency Department and hospital)
- Review regulations impacting acute care methadone use, including the three-day dispensing rule
- Analyze updated data and best practices for rapid methadone initiation

Terminology

The following acronyms will be used throughout this presentation. Familiarity with these terms will support understanding of key concepts.

ACRONYM	STANDS FOR
ED	Emergency Department
OD	Opioid Use Disorder
MOD	Medications for Opioid Use Disorder
OT	Opioid Treatment Programs
SAMHSA	Substance Abuse Mental Health Services Administration
MTD	Methadone
MME	Morphine Milligram Equivalents

Outline

- 1) Initiating Methadone in the ED
- 2) Updates to the Three Day Rule
- 3) Initiating Methadone During Inpatient Hospitalizations
- 4) Transitions of Care and Best Practices



Case #1

- Mike, a 29-year-old male truck driver and father of 2 young children with severe opioid use disorder (OUD) arrives at ED by EMS on Friday night at 10 pm after an unintentional opioid overdose after inhaling fentanyl. Overdose is reversed with naloxone in the field, and naloxone infusion is continued in ED.
- By 9 am on Saturday morning, the overdose has resolved, and Mike expresses a desire to start methadone.
- Local methadone clinic is not open until Tuesday for new admissions and is a 2-hour drive from your ED.

Question:

How do you treat this patient's OUD?

- A. Give methadone 30mg in the ED**
- B. Give methadone 40mg in the ED**
- C. Give buprenorphine in the ED**
- D. Refer to methadone clinic to receive methadone**

Case #1 – Audience Response Question



Can you dispense methadone to this patient to bridge until Monday?
(It is currently Saturday)

- A. No – you cannot dispense methadone for the patient to take-home. It can only be administered in the ED.
- B. No – you can only dispense one day at a time for up to 3 days. The patient must return again each day.
- C. Yes, you can dispense up to 3-day supply at one time

Methadone Initiations in the ED

- Patients with OUD frequently present to ED for OUD, including overdoses, but only 11% receive medications for OUD (MOUD)¹
- Growing evidence that ED-initiated methadone is safe and feasible with similar linkage rate to ED-initiated buprenorphine^{2,3}
- Can use updated Three Day Rule to dispense up to 3-day supply of methadone for the ED

1. Lee et al., 2024.

2. Huo et al, 2024.

3. Wolfson et al, 2024

Updated 3-Day Dispense Rule

- In Jan. 2022, DEA (Drug Enforcement Administration) announced Exception to 21 CFR 1306.07(b) - “Three Day Dispense”, which was made permanent on Aug. 8, 2023
- Any DEA-registered hospital/clinic can dispense up to 3 days of methadone at one time (rather than 1 day at a time)

Acute Care Applications:

- Patients being discharged from ED/hospital when opioid treatment program (OTP or methadone clinic) is closed (ex. holiday or weekend) or delay until patient can next travel to OTP (including new methadone starts)^{1,2}
- Patients being discharged from hospital to post-acute care facilities → send with 3 day supply to give OTP time to deliver methadone to facility

1. Bowman et al., 2024.

2. Skogrand et al., 2024.

Case # 1 continued

- Mike is given methadone 40mg orally x 1 in ED with stabilization of opioid withdrawal symptoms
- Peer recovery coach meets with patient and identifies an Opioid Treatment Program (OTP, or methadone clinic) near their home and confirms clinic hours and intake days. The clinic is closed when the patient is seen, but the peer calls the clinic on Monday to let them know about the patient.
- ED providers, nurse and pharmacist coordinate so that patient is discharged from ED on Saturday with 2-day supply of methadone (dispensed from inpatient pharmacy) to bridge to methadone clinic intake on Tuesday

Take Home Points: ED Methadone Initiation

1. EDs are under-utilized settings for methadone initiations
2. Under updated Three Day Rule, can discharge patients from ED with up to 3-day supply of methadone to bridge to ongoing care at an OTP



Case #2

Theresa, a 45-year-old woman with moderate OUD (daily injection fentanyl use) is admitted to the hospital for injection-related osteomyelitis of cervical spine. She is currently unemployed and has been staying in an abandoned rowhouse.

- Initial substance use screening is done by the patient's nurse – patient reports injecting fentanyl three times a day
- Further clinical assessment by provider:
 - Previously on buprenorphine 24mg sublingual (SL) daily but did not control cravings
 - Expresses desire to start methadone
 - Normal hepatic and renal function. No significant cardiac or pulmonary disease.

Case #2 – Audience Response Question



What starting dose of methadone do you give?

- A. 30 mg
- B. 40 mg
- C. 50 mg
- D. 60 mg

Case #2 – Audience Response Question



How long can you treat the patient with methadone while they are hospitalized?

- A. You can't give them methadone – they must be enrolled in a methadone clinic (OTP)
- B. Up to 72 hours (3 days)
- C. As long as they are hospitalized

Improved Outcomes for Hospital-Initiated MOUD

- Decreased 6-month overdose after MOUD initiation¹
- Decreased risk of patient-directed discharge²
- Decreased 30-day readmissions³
- As part of shared decision-making, should offer all forms of medications for OUD (MOUD) - not just buprenorphine
 - Patients may prefer methadone due to its full-agonist properties, intolerance of buprenorphine (particularly nausea from SL buprenorphine), or history of precipitated withdrawal

1. Weiner et al., 2024.

2. Alrawashdeh et al., 2023.

3. Lambert et al., 2025.

Regulations Regarding Methadone in Acute Care Hospitals

- Lots of confusion about what regulations apply to acute care hospitals that leads to over-restriction of methadone use¹
 - **Interprofessional partnerships key to interpreting and applying regs**
 - Lots of flexibility for methadone starts; OTP regs don't apply
- Patients hospitalized for primary diagnosis other than OUD/opioid withdrawal are NOT subject to rule [21 CFR 1306.07(c)] that restricts administration of methadone to 3 days
 - Acute care hospitals can administer methadone for OUD to patients as long as they remain hospitalized
- No regulations on dosing → guided by clinical judgement
 - In fentanyl era, consider higher starting doses than 30mg
 - Hospital policies play a key role, including Pharmacy and Therapeutics (P + T) committees
- Allowed to administer other opioids for pain/withdrawal
- At time of discharge, can now dispense up to 3 days supply at once to facilitate linkages to care

Barriers to Accessing Methadone

- As outpatient, methadone for OUD is only available from federally regulated opioid treatment programs (OTPs) → can be difficult to access.
- Significant inequalities in who has access to methadone:
 - Geographic disparities in access (particularly limited in rural settings) ¹
 - Gender disparities (women can face longer wait times at clinics, but stay in treatment longer) ²
 - Racial and ethnic disparities → Black and Hispanic patients less likely to receive take-homes ³

**HOSPITALIZATIONS AND ED VISITS
ARE A KEY TIME TO INTERVENE!**

When does the "Three Day Rule" Apply?

Correspondence from John J. Purcell, Policy Analyst, DEA:

- *"Three Day Rule", [21 CFR 1306.07\(b\)](#), is to allow DEA-registered practitioners to treat patients who present with the **primary condition of opioid use disorder (OUD)**, for up to 3 days, while arrangements are being made for referral for the patient for continuing treatment for OUD.*
- *Conversely, the purpose of [21 CFR 1306.07\(c\)](#) is to allow a practitioner to initiate or maintain a patient on narcotic drugs for the treatment of OUD in cases where the patient is being treated for a condition other than OUD. This includes treatment for mental health conditions. In this scenario, i.e. **where the patient is being treated for a condition other than OUD, the "three day rule" does not apply and the patient may be treated for OUD for as long as they remain hospitalized.***

Rapid Methadone Initiations in the Fentanyl Era

- Higher tolerance in fentanyl era; we are still learning how to how quickly we can safely titrate methadone and keep patients engaged in care
- Consider higher starting doses than 30mg (under new SAMHSA guidance, consider up to 50mg starting dose)
- Need to consider overall risks/benefits and involve patients more in dosing decisions - not just risks of too high of methadone dose but also risk of ongoing fentanyl use and overdose if methadone titrations are too slow

Inpatient Methadone Initiation

- Hospitals allow for more frequent monitoring and daily provider assessment to titrate methadone faster than OTPs
- No RCTs (randomized controlled trials) of methadone dosing in fentanyl era
- Evidence base: mostly retrospective case series from academic hospitals with addiction consult service
- Emerging evidence from recent case series that even more rapid starts are feasible in the hospital

Inpatient Methadone Initiations

Study	Number of Participants	Mean Initial Dose	Mean Max Dose	Time to Max Dose (days)	Adverse Events
Racha et al., 2023	25	30mg (10-50)	61.6mg (60-80)	5	2 instances of sedation (neither requiring naloxone)
Casey et al., 2023	112	32mg (10-90)	76mg (30-165)	5.6 (1-19)	30% with sedation, but only 4 cases deemed related to MTD
Klaire et al., 2023	168*	41mg (SD 9.6)	65mg (SD 20.9)	7	<ul style="list-style-type: none"> Serious AE (sedation leading to naloxone or ICU): 2 (1.2%) Mild sedation: 12 (8.9%)
Rodgers et al., 2023**	12	30mg (30-42.5)	65mg (60-70)	7	None

*168 hospitalizations of 98 unique individuals

**Canadian study of pregnant patients hospitalized for opioid withdrawal

OHSU (Oregon Health & Science University)

Rapid Methadone Initiation Pilot

Retrospective case series at OHSU

25 patients between Dec. 2022 - Aug. 2023

Inclusion Criteria:

- Routine fentanyl use
- High tolerance
- Inpatient addiction consult
- History of OUD for 1 year

Exclusion Criteria:

- End organ failure such as pulmonary disease (including OSA), cirrhosis, ESRD, heart failure
- Ventricular arrhythmias, QTc >500
- Concurrent use of benzodiazepines, alcohol
- Meds that affect methadone metabolism (CYP3A4 inhibitors/inducers)
- Age >65
- Social factors that may impact a patient's ability to access methadone clinic on discharge

Day	Max Total Daily Dose (TDD) Methadone	Recommended Dosing
1	60mg	30 or 40mg x1 + 10mg q3hrs PRN x 2 or 3 doses
2	70mg	50mg x1 + 10mg q3hrs PRN x 2 doses
3	80mg	60mg x1 + 10mg q3hrs PRN x 2 doses
4-7	100mg	70mg (or average of TDD from prior days) x1 10 mg q3h PRN x 3 doses

OHSU Avg Total Daily Dose (TDD) Methadone and MME of Other Full Opioid Agonists

Day of Addiction Consult	Day -1	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Average TDD methadone (mg)	39 +/- 14.5	54 +/- 12.9	69 +/- 11	75 +/- 14.5	79.5 +/- 15.6	87 +/- 13.6	87 +/- 13.6	97 +/- 16.6
# patients who received methadone	11	25	25	23	21	17	16	16
N (%) of patients who received other opioids	11 (100%)	21 (84%)	20 (80%)	18 (78%)	17 (80%)	13 (76%)	10 (63%)	11 (68%)
Median MME of other full opioid agonists	43 (24-105)	92 (45-160)	128 (81-169)	158 (73-233)	120 (48-240)	120 (75-210)	169 (109-198)	120 (51-161)

UCSF (University of California San Francisco) Case Series (Martin et al., 2025)

- Retrospective case series of 19 hospitalizations (17 unique patients) with fentanyl use disorder who received rapid methadone titration
- Protocol allowed maximum daily dose 60-80-100mg on day 1-3
 - Required evaluation by addiction consult team for additional doses
 - Few adverse events: 4 sedation events, none requiring naloxone

UCSF – Median Daily Methadone Dose and Full Agonist Opioids Received in Rapid Methadone Pilot

Day	Total Patients	Methadone (MTD)		Full Agonist Opioids (FAO)	
		# who received methadone	Median daily MTD dose mg (IQR)	# who receive FAO	Median FAO dose in MMEs (IQR)
1	19	19	40 (30-40)	18	90 (30-180)
2	19	19	60 (50-60)	19	108 (62 – 255)
3	18	18	80 (60-80)	17	121 (63 – 188)
4	18	18	80 (80-100)	17	117 (60-180)
5	12	12	90 (77.5 - 100)	12	144 (60-180)
6	11	11	100 (80-100)	10	90 (57-190)
7	8	8	100 (87.5-105)	8	68 (45 – 135)

Adjunctive Treatments

- Use adjunctive meds, including short-acting opioid agonist treatment (sOAT) while titrating methadone
 - Patients in UCSF study received average of 90-140 MME per day
- In a pharmacist-led pilot sOAT (escalating doses of PO oxycodone or hydromorphone scheduled every 4hrs, IV hydromorphone prn and non-opioid adjuvants) (N=23) was associated with decreased rate of patient-directed discharge (44% vs. 69%), longer LOS (5 vs 3 days) and higher rate of OAT on discharge (69% vs. 33%)¹

Summary of Strategies

Day 1:

- Based on updated SAMHSA guidance, consider initial dose of 30-50mg
- Can give additional doses of methadone (ex. 10mg every 3-4 hours) for ongoing withdrawal
- Can also treat breakthrough withdrawal/pain with short-acting opioids (ex. oxycodone, hydromorphone)

Consider increase by 10-20mg per day to minimum therapeutic dose of 60-90mg daily for most patients

- Adjust/decrease for sedation

Linkage to Care After Hospital Discharge

- Have a risk-benefit discussion with patient about post-discharge plan and inpatient dose titration
- Discuss and address potential barriers to ongoing care including transportation, ID, insurance
- Don't withhold methadone just because the discharge plan is uncertain!
- Build relationships with community OTP partners to ensure methadone doses started in the hospital are continued on discharge and they know about how a patient was doing on that dose
 - Can advocate on behalf of patients who need increased number of take-home doses (ex. patient is home bound or has limited transportation, other health issues, etc)

Back to our case ...

- Methadone (MTD) is started –
 - Day 1: 40mg x 1, plus 10mg x 2 [total daily dose (TDD): MTD 60mg]
 - Day 2: 60mg in AM, plus 10mg x 1 (TDD: MTD 70mg)
 - Day 3: 70mg in AM, plus 10mg x1 (TDD: MTD 80mg)
 - Day 4: 80mg in AM, plus 10mg x1 (TDD: MTD 90mg)
 - Additionally required hydromorphone 6mg PO every 4 hours for breakthrough pain/withdrawal, plus hydromorphone 2mg IV every 3 hours as needed
- There are times throughout the hospital (especially day 1), when Theresa expresses desire to leave hospital due to opioid withdrawal, but nurse offers the additional doses of 10mg (and works with pharmacist for quick verification of methadone orders)
- Nurse also works with provider to determine that dose increases are safe (no sedation, serial withdrawal assessments)

Case 2 cont.

- Meanwhile, infectious disease is consulted and recommends 6 weeks of IV antibiotics to treat osteomyelitis.
- Social work assessment determines that patient is unstably housed, but willing to go to a skilled nursing facility to complete antibiotics
- Peripherally inserted central catheter (PICC) is placed and patient is unstably housed and discharged to skilled nursing facility to complete antibiotics
- Hospital social worker coordinates with OTP to use hospital H+P + telehealth for other parts of intakes to enroll them in OTP prior to discharge. Patient is discharged with 3-day supply of methadone to bridge until OTP can delivery ongoing methadone to skilled nursing facility (SNF)

Takeaways: Inpatient Methadone Initiation

- Hospitals have more flexibility in methadone initiation than OTPs (dosing is based on clinical judgement, not regs)
- 72 hour rule doesn't apply if hospitalized for reason other than OUD
- Consider rapid titration for patients using fentanyl
- Patient selection is key for rapid methadone titration – consider both tolerance and comorbidities

Case #3 – Dose Adjustments

- Tracy, a 65-year-old woman with OUD (on methadone 75mg daily) is admitted to the hospital for congestive heart failure exacerbation. She is a retired secretary and rents an apartment with her husband. She has been on methadone for 10 years and on current dose for years. She reports intranasal use of 1 pill fentanyl daily due to opioid cravings in addition to methadone. Her last dose of methadone was the day prior to admission (confirmed with OTP by the patient's nurse).

Questions:

- **Do you make any changes to their methadone?**
- **If so, how would you adjust their dose?**

Case #3 – Audience Response Question



What dose of methadone would you give this patient?

- A. 75mg (home dose)
- B. 80mg (increase of 5mg)
- C. 85mg (increase of 10mg)
- D. 60mg (decrease dose due to ongoing fentanyl use)

Methadone Dose Adjustments

- Inpatient hospitalizations are opportunity to optimize methadone dose for patients on subtherapeutic doses
- For patients with ongoing cravings or illicit opioid use, consider initial increase of 5-10mg
- Should coordinate with OTP about any dose changes (may include dose decrease due to change in health status – ex. new decrease in renal function)

Other Best Practices

- Dose verification:
 - Call OTP to verify methadone enrollment and dose (they are required to have 24/7 availability for verification)
 - Report to your State Opioid Treatment Authority (SOTA) when there are issues
 - If there are delays in verifying methadone dose, give **at least** 30mg to treat withdrawal
- Coordination of Care:
 - Notify OTP that patient is admitted – any new meds, changes in health status, change in methadone dose

Methadone Restarts

- Lack of evidence for how quickly methadone can be restarted after missed doses
- Can likely be more aggressive than what we are doing, particularly if patient has maintained tolerance by ongoing daily opioid use
 - Consider giving at least 50% of reported dose
 - If no loss of tolerance or significant change in patient's health (ex. new decrease in renal function), can likely restart their prior dose or at least be more aggressive in titrating methadone back to prior therapeutic dose

Back to our case ...

- After discussion with patient, provider increases methadone to 85mg daily
- Prior to hospital discharge, hospital provider communicates dose change to patient's OTP
- At time of hospital discharge, a copy of discharge summary showing methadone dose is faxed to OTP
- Patient is also discharged with hospital paperwork showing methadone dose increase that they can take to OTP

Take Home Points: Continuation of Methadone

- Give methadone while confirming dose
- Can likely be more aggressive with methadone restarts than we have historically been depending on clinical context and shared decision making with patient
- Communicate any dose changes to patient's methadone clinic

Stigma as a Barrier



Despite evidence that methadone saves lives, it is stigmatized by both health care professionals, patients, and recovery communities

- Patients labelled as "drug-seeking"
- "Replacing one drug with another"
- Stigmatized view of methadone in many recovery settings
- Stigma against higher doses
- Fear of dispensing methadone on discharge

Addressing Dose Related Stigma

- Many outdated beliefs about safe maximum doses of methadone
- Tolerance is much higher in fentanyl era and literature supports better retention on higher doses
- **Look at the patient in front of you, not the dose of methadone (or other opioids) they are receiving**
 - Are they alert?
 - Is their withdrawal controlled?
 - Is the dose of methadone therapeutic – both suppressing opioid cravings and allowing them to focus on other life and functional goals (working, taking care of family members, addressing other medical issues), etc?

Ongoing Challenges / Structural Barriers

Misunderstanding of state and federal regulations of methadone for OUD

- Misunderstanding of regulations often cause health professionals (and health systems) to be overly restrictive
- High-level regulations don't always have specific guidance on how to operationalize

Segregation of methadone from rest of medical care

- Methadone not accessible in prescription-drug monitoring programs (PDMP) -- delays in dose confirmation
- Unable to prescribe methadone for OUD

Clinically, fentanyl dependence can be difficult to treat --> hard to get to effective dose of methadone quickly enough

Systems-Level Considerations

Evaluate your institution's policies

- Is methadone on the formulary and easily accessible?
- Are there dose restrictions not supported by evidence?
- Do you have a way to dispense methadone for discharge?

Importance of interprofessional teams and community partnerships

- Build relationships with community OTPs and treatment centers
- SW/CM, peers can help with identifying follow-up clinic and scheduling intake
- For successful linkage to ongoing treatment, discuss and address potential barriers (transportation, insurance, housing, etc)

Final Takeaways

1. EDs and hospitals are a key time to start and optimize methadone dosing
2. Lots of regulatory flexibility in acute care settings
3. Updated Three Day Rule allows dispensing of up to 3 day supply at discharge
4. Higher methadone doses needed for people using fentanyl
5. Advocacy from interprofessional teams can help with providing best care for patients

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PCSS-MOUD Mentoring Program

- PCSS-MOUD Mentor Program is designed to offer general information to clinicians about evidence-based clinical practices in prescribing medications for opioid use disorder.
- PCSS-MOUD Mentors are a national network of providers with expertise in **addictions, pain, and evidence-based treatment including medications for opioid use disorder (MOUD)**.
- 3-tiered approach allows every mentor/mentee relationship to be unique and catered to the specific needs of the mentee.
- No cost.

For more information visit:

<https://pcssNOW.org/mentoring/>

PCSS-MOUD Discussion Forum

Have a clinical question?

Ask a Colleague

A simple and direct way to receive an answer related to medications for opioid use disorder. Designed to provide a prompt response to simple practice-related questions.

<http://pcss.invisionzone.com/register>

Addiction Policy Forum	American College of Emergency Physicians*
Addiction Technology Transfer Center*	American College of Medical Toxicology
African American Behavioral Health Center of Excellence	American Dental Association
All Rise	American Medical Association*
American Academy of Child and Adolescent Psychiatry	American Orthopedic Association
American Academy of Family Physicians	American Osteopathic Academy of Addiction Medicine*
American Academy of Neurology	American Psychiatric Association*
American Academy of Pain Medicine	American Psychiatric Nurses Association*
American Academy of Pediatrics*	American Society for Pain Management Nursing
American Association for the Treatment of Opioid Dependence	American Society of Addiction Medicine*
American Association of Nurse Practitioners	Association for Multidisciplinary Education and Research in Substance Use and Addiction*
American Association of Psychiatric Pharmacists	Black Faces Black Voices
American Chronic Pain Association	Coalition of Physician Education

Columbia University, Department of Psychiatry*	Northwest Portland Area Indian Health Board
Council on Social Work Education*	Partnership to End Addiction
Faces and Voices of Recovery	Physician Assistant Education Association
Mobilize Recovery	Project Lazarus
NAADAC Association for Addiction Professionals*	Public Health Foundation (TRAIN Learning Network)
National Alliance for HIV Education and Workforce Development	Sickle Cell Adult Provider Network
National Association of Community Health Centers	Society for Academic Emergency Medicine*
National Association of Social Workers*	Society of General Internal Medicine
National Council for Mental Wellbeing*	The National Judicial College
National Council of State Boards of Nursing	Veterans Health Administration



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