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Dispensing Methadone at Hospital Discharge: One Hospital's Approach to Implementing the "72-hour Rule" Change

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Abstract

Objectives: Methadone for opioid use disorder (OUD) treatment in ambulatory settings is restricted to federally licensed opioid treatment centers (OTP) in the United States. However, these restrictions do not apply during hospitalization. A recent change to the rule governing methadone in non-OTP settings created an opportunity to dispense methadone at hospital discharge for up to 72 hours.

Methods: Here, we describe one hospital's approach to dispensing methadone at discharge in alignment with the "72-hour rule," including implementation challenges and considerations for other hospitals planning on adopting this practice. Implementation included; creating a workflow and detailed documents outlining dispensing procedure, educating interprofessional staff, and coordinating with local OTPs.

Results: Our experiences highlight the importance of pharmacy champions to support implementation and interdisciplinary staff education, the need to consider electronic health records capabilities, and the importance of having policies and practices that support appropriate interpretation of the "72-hour rule" renewal timeline.

Conclusions: Exceptions to federal regulations allow greater flexibility in discharge planning for patients with OUD; however, dispensation workflow falls outside standard hospital care and may be challenging to implement.

Keywords

Methadone; hospital discharge; opioid use disorder

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Introduction:

An estimated 7.6 million Americans have an opioid use disorder (OUD) [1] and in 2021, the CDC reported over 100,000 overdose deaths in the United States[2]. Medications for OUD (MOUD) – methadone and buprenorphine - are the most effective treatments for OUD, yet they remain under-utilized and methadone continues to be highly restricted outside the hospital setting [1].

Offering MOUD with connection to treatment after discharge is an emerging standard [3], yet post hospital methadone linkage is often challenging. In the US, current laws prohibit clinicians from prescribing methadone[4] for OUD in ambulatory settings. Instead, methadone must be administered by a federally accredited opioid treatment program (OTP). OTPs often have long wait times for new admissions, limited hours and do not admit patients on the weekend. This means that in many US hospitals, a patient who is otherwise ready for discharge on Friday would need to stay until their methadone dose is provided on Sunday morning to avoid missed doses and withdrawal symptoms. Navigating OTP barriers and coordinating care amidst tight hospital discharge timelines pose significant challenges and may increase hospital length of stay.

A March 2022 Drug-Enforcement Agency (DEA) rule update modified existing regulations to allow clinicians to administer or *dispense* up to 72 hours of opioids for withdrawal management while arranging referral for ongoing treatment (called the "72-hour rule")[5]. This change expands the previous rule which required that practitioners administer methadone *one day at a time.* Now permitting practitioners to *dispense up to 3 days'* worth of medication[6]. This rule change introduces important avenues to support hospital-to-community care transitions, however it may be difficult to implement. Hospitals often lack process to dispense any discharge medication from inpatient pharmacies, and methadone dispensation and coordination is novel in this setting.

Here, we share our experiences implementing methadone dispensation at hospital discharge using a general implementation framework, including a description of pre-implementation planning and implementation efforts emphasizing process and considering contextual factors and strategies [7]. We then share implications for other hospitals planning to implement methadone dispensation (Table 1).

The Oregon Health & Science University institutional review board approved this work (eIRB 10846).

Setting

Our hospital has a well-established interprofessional addiction medicine consult service[8,9] that includes inpatient pharmacy champions. Before the March 2022 "72-hour rule" exception, our practice was to coordinate next day OTP intake for patients and to try to avoid Saturday discharge for patients stable on methadone to prevent disrupting OUD stability.

Pre-Implementation

When the March 2022 exception was announced, we anticipated the following implementation challenges:

1. Our hospital lacked standardized workflows to dispense methadone to inpatients
2. Confusion existed among many hospital staff surrounding the legality of methadone in hospital patients and at discharge
3. Care transitions with OTPs for methadone were already challenging

Implementation:

Here, we share how we addressed these challenges, including approaches to 1) evaluating electronic health record (EHR) capabilities; 2) developing procedures to support pharmacists; 3) staff education; 4) specifying institutional interpretation of the "72-hour" rule change; 5) partnering with OTPs. At the time of our implementation, the change was an exception, not a rule and thus our initial steps included applying for an exemption. The federal code has since been updated and applying for an exemption is no longer necessary[6].

Assuring EHR capabilities: Dispensing medications from the inpatient pharmacy at the time of discharge is not a routine process. Implementing methadone dispensation involved developing and building a new functionality within our EHR and staff training on utilization.

Supporting pharmacists: Methadone dispensing relies heavily on pharmacists. In our experience, a strong pharmacy champion who knows pharmacy workflows, EHR functionality, and federal laws describing methadone dispensing was vital. We found that staff pharmacists needed training, and clear step-by-step instructions of both EHR manipulations and delivery workflow. Pharmacy champions developed a detailed procedure document and offered in-person, real-time support to answer questions and troubleshoot challenges.

We found that Thursdays and Fridays were the busiest days, presumably because of local OTPs weekend closures and that they only allow for new intakes on weekdays. Hence, the pharmacy champions initially adjusted their schedules to accommodate days for higher volume methadone dispensing.

Educating interprofessional staff: We found that our interprofessional staff had varied understanding of the "72- hour rule". Hence, we provided staff education outlining the change to the federal code, tailoring it each discipline.

For nurses, we emphasized that methadone dispensation was legal, described how to coordinate discharge plans with pharmacists, and clarified nursing documentation.

For medical clinicians, we emphasized how to interpret the "72-hour rule", and noted clinician documentation and counseling recommendations. To reach as many clinicians as possible, we provided both in-person training and detailed email instructions. We

highlighted that methadone dispensing is pharmacist-driven and encouraged clinicians to communicate early with the pharmacist.

Specifying institutional interpretation of the "72-hour Rule": Federal code limits dispensing to 72 hours, which may not be renewed or extended; however, it lacks specific guidance on how to address repeat hospitalizations. We reviewed the federal code with our hospital legal team, who advised that if a patient was readmitted as a separate episode of care, we could offer repeat methadone dispenses.

Partnering with OTPs: OTPs have varied culture and flexibility around take-home dosing. We notified the two largest regional OTPs of our plans to dispense methadone for patients needing a bridge to care. OTP staff initially expressed legal and safety concerns, however, we offered information about the updated federal regulations and shared our anticipated documentation and patient counseling, which eased their concerns. We also modified our processes to respond to OTP concerns including instructing patients to bring empty containers to their intake appointment and providing lock boxes to store dispensed methadone.

Implications:

In the first three months of methadone dispensing, 37 patients received a total of 74 out-of-hospital methadone doses. The new standard at our hospital is to offer methadone dispensation and linkage to care to all patients that need it. Though as assessment of OTP linkage rates is beyond the scope of this study, our addiction medicine consult service peers are often in contact with patients after discharge and we regularly communicate with OTP partners. We are unaware of any unintended harms from methadone dispensation.

Our experience has important implications for other hospitals considering implementing methadone dispensation, summarized in Table 1.

Future work should assess patient experience, OTP linkage rates, readmission rates and include further monitoring for potential harms of dispensation.

Conclusion:

Updates to federal regulation supporting methadone dispensing allows for greater flexibility in discharge planning for patients with OUD on methadone. Workflows falls outside standard hospital care and can be challenging to implement. We offer tools and experiences gained by implementing methadone dispensing at our institution.

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References

1. Krawczyk N, Rivera BD, Jent V, Keyes KM, Jones CM, Cerdá M. Has the treatment gap for opioid use disorder narrowed in the U.S.?: A yearly assessment from 2010 to 2019". Int J Drug Policy. Dec 2022;110:103786. doi:10.1016/j.drugpo.2022.103786
2. O'Donnell J, Tanz LJ, Gladden RM, Davis NL, Bitting J. Trends in and Characteristics of Drug Overdose Deaths Involving Illicitly Manufactured Fentanyls - United States, 2019–2020. MMWR Morb Mortal Wkly Rep. Dec 17 2021;70(50):1740–1746. doi:10.15585/mmwr.mm7050e3 [PubMed: 34914673]
3. Calcaterra SL, Lockhart S, Callister C, Hoover K, Binswanger IA. Opioid Use Disorder Treatment Initiation and Continuation: a Qualitative Study of Patients Who Received Addiction Consultation and Hospital-Based Providers. Journal of General Internal Medicine. 2022/08/01 2022;37(11):2786–2794. doi:10.1007/s11606-021-07305-3 [PubMed: 34981359]
4. Drug Addiction Treatment Act of 2000. H.R.2634, 106th Cong. 2nd Sess. (July 27, 2000).
5. Brennan C. U.S. Drug Enforcement Administration, Diversion Control Division Exception to Limitation on Dispensing for OUD. Accessed 02/1/2023, https://www.deadiversion.usdoj.gov/drugreg/Instructions-to-request-exception-to-21-CFR%201306.07(b)-3-day-rule-(EO-DEA248R1).pdf
6. Dispensing of Narcotic Drugs to Relieve Acute Withdrawal Symptoms of Opioid Use Disorder. Fed Regist. 2023: 88 (151): 5337–53383. To be codified 21 CFR 1306.
7. Moullin JC, Sabater-Hernández D, Fernandez-Llimos F, Benrimoj SI. A systematic review of implementation frameworks of innovations in healthcare and resulting generic implementation framework. Health Research Policy and Systems. 2015/03/14 2015;13(1):16. doi:10.1186/s12961-015-0005-z [PubMed: 25885055]
8. Englander H, Weimer M, Solotaroff R, et al. Planning and Designing the Improving Addiction Care Team (IMPACT) for Hospitalized Adults with Substance Use Disorder. J Hosp Med. May 2017;12(5):339–342. doi:10.12788/jhm.2736 [PubMed: 28459904]
9. Englander H, Mahoney S, Brandt K, et al. Tools to Support Hospital-Based Addiction Care: Core Components, Values, and Activities of the Improving Addiction Care Team. J Addict Med. Mar/Apr 2019;13(2):85–89. doi:10.1097/adm.0000000000000487 [PubMed: 30608265]

TABLE 1

Recommended Steps to Implement Methadone Dispensation at Hospital Discharge

Step	Description	Considerations
Accountable Role		
1. Update or Create Policies Supporting Methadone Dispensation		
Pharmacy and Medical Champions	Develop hospital policy on methadone dispensation, potentially by updating existing MOUD policies.	We recommend hospitals adapt policies to include best practice and general guidance on methadone initiation and dosing. Include methadone dispensing procedure. Policies support staff comfort with adopting a new practice and help standardize work across individuals and clinical areas.
2. Develop Dispensing Procedure		
Pharmacy Champion	Ensure electronic health record (EHR) generates a label congruent with state prescription labeling requirements	Partner with informatics department to explore labeling options within your EHR
Pharmacy Champion	Determine methadone formulation and container type	Syringes may leak or have accidental depression of plunger leading to spilled doses. Sealed cups are likely more secure. Consider individual dose cups or bottle dispensing (i.e three cups each containing a single days dose).
Pharmacy Champion	Develop standard operating procedure and train pharmacy workforce on labeling and dispensing	Include screenshot and examples of manipulations within the EHR. Include documentation steps for both internal records and outpatient communication to OTPs. Include any state specific special labeling requirements such as controlled substance stickers or description of product dispensed.
Pharmacy Champion	Develop internal log to track methadone dispensed	Log may include details such as: date, copy of label, dose (mg), number of doses dispensed, total amount dispensed and initials of pharmacist/technician involved.
Pharmacy Champion	Communicate to pharmacy technicians	Highlight how this procedure differs from typical inpatient workflows. Include step-by-step instructions on manipulations within the EHR or controlled substance storage system that can be easily replicated by any technician. May be beneficial to include screenshots and specific instructions regarding documentation of labeling requirements.
3. Develop Clinician Workflows		
Pharmacy and Medical Champions	Develop a workflow whereby provider communicates need for methadone dispense with pharmacist	Communication can occur via consult order, page/instant message or direct verbal communication. Communication should include details about patient selection, guidance about dose, numbers of days needed and anticipated discharge date/time. Clinicians should document details regarding OTP availability and appointment time in the chart and/or include in communication to pharmacist. Consider processes to assure all patients have access to naloxone at discharge.
Pharmacy Champion	Determine your states requirement for counseling documentation	Provide patient education about how to take the doses and what day the dose is due next. Instruct patients to retain bottles and bring to OTP appointment.

Step	Description	Considerations
		Consider how your institution documents counseling in EHR. Standardize note template promotes consistency and generally reduces time required.
4. Determine Standard Documentation		
Pharmacy and Medical Champions	Develop standard language to include in discharge paperwork to send to OTP and patient instructions	Example: You were {started/continued} on methadone during your hospitalization. We dispensed (#) days of (#) mg of methadone to you at the time of hospital discharge with the plan for your methadone intake at the Opioid Treatment Program (specific name) on (date, time). Please do not throw out your empty containers. Bring them to your first visit at the methadone clinic to show clinicians there who may ask for them as proof of dose confirmation
Pharmacy and Medical Champions	Develop standard EHR documentation requirements to include dose amounts, number of doses, and counseling performed.	Example: This patient was dispensed (#) doses of methadone (mg) for doses on (dates) from the (institutional name) inpatient pharmacy. I counseled patient on how to take methadone, importance of taking it as ordered and risk of overdose if methadone is mixed with other substances. We discussed the importance of following up with the OTP to establish care and continue methadone treatment. I recommended that the patient keep all empty containers and bring them to OTP appointment as proof of dose.
5. Coordinate with Opioid Treatment Programs		
Pharmacy Champion	Early engagement of OTP partners	Discuss what OTP staff should expect regarding dispensation process and discharge documentation. Invite OTP input which may inform workflow. For example, one OTP requested that pharmacy staff counsel patients to bring empty bottles to new patient intake. Share examples of discharge documentation to prepare OTP staff.
6. Staff Education and Training		
Pharmacy and Medical Champion	Offer tailored education to various professionals	Consider which patient population will be high utilizers of this process and offer enhanced training (i.e obstetrics or general medicine). Focus provider education on how to initiate methadone dispensation process and how to document. Focus pharmacist education on dispensation logistics and counseling requirements. Focus nurse education on discharge documentation and coordination (i.e. with timing with transportation).

OTP- Opioid Treatment Programs

EHR- Electronic health record