*Opioid Agonist Therapy 101:*
*An Introduction to Clinical Practice* Workshop

# Integrating Opioid Agonist Therapy into Pharmacy Practice

## Part 1: Examining the Current Guidelines

# Disclosure of Commercial Support

- This program has received financial support from ***The College of Physicians and Surgeons of Manitoba*** in the form of ***funding for payment of presenters and organizers.***
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  - None identified

# Faculty/Presenter Disclosure

- **Faculty:** Mike Sloan
- **Relationships with commercial interests: (list None if no disclosures)**
  - **None**

# Overview

- Part 1 – Examining the Current Guidelines
  - New prescriptions, preparing doses of OAT, billing
- Part 2 – Witnessed Ingestion
  - Identification, assessment, documentation
- Part 3 – Special Situations
  - Transfer of care, missed doses, hospitalization, incarceration

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# Learning Objectives

- Develop basic decision-making skills useful for dispensing safe and effective opioid agonist therapy (OAT).
- Gain a thorough understanding of material in the current CPhM legislation governing our members.
- Discuss and resolve the challenges a pharmacist can face when observing witnessed ingestion of OAT.
- Describe special situations that can arise when your patient is on OAT, and discuss ways of managing these situations.
- Emphasize the importance of utilizing a collaborative multi-disciplinary framework for managing OAT in your patients.

# Competency – Education & Training

- Pharmacy managers must keep record of which pharmacists are extensively knowledgeable in OAT and documentation of training they have completed.
  - Must keep records of training other pharmacists and staff as well
- Pharmacists must keep a copy of their certificate as well
- Site-specific OAT policies and procedures must readily available.
  - E.g., managing missed doses, overdose protocols, billing procedures
  - Especially important for new and relief staff.

# Prescriptions for OAT

- A prescription for methadone (OAT) or buprenorphine must contain:
  - The DAILY DOSE AND TOTAL QUANTITY (mg) written both numerically and alphabetically
  - Start and end date
    - Pharmacist must ensure that the total quantity written is sufficient to cover the entire date range
  - Witnessed and carried doses must be indicated on the prescription or on an agreement (*changes* to carry schedule can also be taken verbally or by fax)

# Prescriptions for OAT: Prescribing Approval

- It is the responsibility of the dispensing pharmacist to verify that the prescriber has the appropriate prescribing approval
  - In Manitoba, see list in CPhM Registrant Portal
  - For out-of-province prescribers, call the pharmacy regulatory and licensing authority in that province.
- Sublocade – prescriber must fax certificate of authorization to pharmacy.

# Pharmacy-Patient Agreement

- Have both the Pharmacist and Patient sign a Pharmacy-Patient Agreement
  - Include hours of operation, discussion on witnessing procedures, etc.
  - Change and re-sign as necessary (e.g., switching OAT medications, hours/procedural changes, etc.)

# Methadone Stock Solution

- Available in multiple **10mg/mL** formulations:
  1. Red, cherry flavoured oral concentrate
     - Methadose®, ODAN
  2. Dye-free, sugar-free, unflavoured oral concentrate
     - Methadose®, ODAN, Metadol-D
  3. Blue, sweetened oral concentrate
     - Jamp

- Exercise caution when switching to a different formulation. (Health Canada, 2020)
- Methadone brands are NOT interchangeable on the formulary.

# Cherry Flavoured Methadone

- Hypertonic concentrate containing sucrose 40%
  - Does not lend itself to injection, even when undiluted
- Can be dispensed without further dilution
  - Pharmacists should use their clinical discretion whether to dilute
  - Considerations: Small volumes, risk of diversion, carries

# Unflavoured Methadone Concentrate

- Not hypertonic
  - **MUST BE DILUTED with coloured, flavoured diluent (NOT WATER)**
  - Dilute to final volume of 60 to 100 ml
- Dilution with a crystalline liquid is required to minimize risk of abuse and/or injection
- Some patients may require sugar-free diluent
  - ONLY for diagnosed medical conditions (e.g., diabetes)
  - Need approval from prescriber

# Unflavoured Methadone Concentrate (con't)

- Must keep a dilution record
  - Document directly on individual Tx, or keep separate record
  - Include:
    - Date of dilution / Beyond-use date (BUD)
    - Diluent
    - Initials of pharmacist and any other staff involved in preparation
- Doses prepared in advance need to be appropriately labelled

# Measuring Methadone Concentrate

- Measuring devices must be accurate
  - Enforce calibration procedures
  - Use frequent inventory counts to discover irregularities

# Measuring Methadone Concentrate

- All equipment and devices used in the preparation of methadone should be designated/labeled for methadone use only
  - Keep in designated area
  - Wipe counters and wash hands

# Stability and Sterility

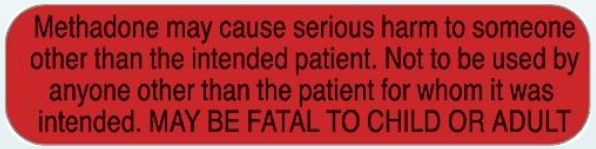
- Stability and sterility of methadone concentrate diluted with crystalline liquid is unknown.
- Diluent (sugar) supports bacteria growth
- All diluted methadone products must be refrigerated, and permitted to a max expiry date of 14 days from dilution date (with a few exceptions – see chart)
- Dispensing methadone in fruit juices or diluents not identified in product monograph or in following table is discouraged, unless it is necessary.

# Storage in Pharmacy

- Diluted methadone preparations must be refrigerated.
- Place any diluted methadone in a locked/secure fridge
  - NCR: 43 – A pharmacist shall take all reasonable steps necessary to protect narcotics on the Premises against loss/theft.

# Labeling of Patient Bottles: Methadone

- Indication of the total dosage in the bottle with a notation that the dosage was made up to a common volume
- Methadone warning label required
- Ingestion date required
- Start & end date in sig required
- Refrigeration AUX label recommended




# Labeling: Buprenorphine

- Buprenorphine warning label required
- Proper instructions for administration required
  - (e.g., “Dissolve two tablets under the tongue along with two 2mg tablets..”)
- Start / end date in sig required
- Total DAILY dose, if appropriate

# Labeling: SROM (Slow-Release Oral Morphine)

- Start / end date in sig required
- Total DAILY dose, if appropriate

# Inventory Records

- All of the legal requirements for inventory records of narcotics apply to methadone and buprenorphine
- More frequent inventory counts (e.g., monthly, daily) are recommended if OAT is dispensed in high frequency

# Billing

- Billing is to be submitted to Drug Programs Information Network (DPIN) on the date of service provision
- Missed doses must be reversed in DPIN before the end of the business day (will discuss more later)
- See the *Methadone Reimbursement Procedure* from Provincial Drug Programs for more information

# Critical Care Codes and Drug Interactions

- Pharmacists are to review the critical patient care codes and drug interactions (e.g., ME codes) that are generated by DPIN, decide on an appropriate action, and document the response in the appropriate place(s).
- *Remember:* Pharmacists must ensure that concerns about unauthorized prescribing of mood-altering medications or other safety concerns are reported to the OAT prescriber.
- Recommend printing a DPIN with every new prescription for OAT and/or periodically with minor intervention codes (ME codes).

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## Integrating Opioid Agonist Therapy into Pharmacy Practice : Part 2 - Witnessed Ingestion

# Witnessed Ingestion

- Witnessing ingestion must be direct observation by a pharmacist and CANNOT BE DELEGATED to a non-pharmacist staff member.

# Witnessed Ingestion: Identification

- Must ID the patient before dispensing OAT to the patient for the first time
  - If patient does not have ID, call the prescriber or another pharmacy staff member to verify
- Confidentially confirm the patient's name and dose each time

# Witnessed Ingestion: Identification

- Misidentification is one of the major sources of error and can cause for patients to receive a dose meant for someone else!
- Have clear procedures for all pharmacists to accurately identify patients when they arrive for their dose.
  - E.g., use a secondary identifier

# Witnessed Ingestion: Case

- Frank
  - 62 years old
  - Methadone 35mg OD – been on MMT for over 5 years
  - On Monday morning you give Frank his methadone dose for witnessing. You go into the fridge and lose your sight line on his bottle. When you return, you notice he seems crouched down a bit, and when he presents you the empty bottle back, he appears to pull it out of his pocket. What should you do?

# Frank

# Witnessed Ingestion: Methadone

- Once the patient receives methadone, the pharmacist must maintain a sight line with the dose until it is ingested to prevent diversion
- After the patient drinks, converse with the patient to ensure the methadone has been swallowed
- If the patient is given *cherry* flavoured methadone oral concentrate, the patient MUST be provided with water to rinse the cup/bottle and swallow to ensure that any residual medication is ingested

# Case (Frank)

- Frank
  - Asked him what he was doing with his pockets.  Observed that the label of the bottle he gave back to me appeared to be more “used”.
  - Looked at video tape later to confirm he pocketed dose.  All his carries were removed indefinitely by the MD
  - Incident report

# Witnessed Ingestion: Buprenorphine SL Tablets

- Dissolution time: 2-10 minutes
  - Ask to observe when tablet becomes pulpy mass (1 to 5 minutes) and then when tablet is completely dissolved
  - If approved by the prescriber, you may let the patient leave the pharmacy once the tablet(s) become a pulpy mass.
- Patient may drink water first to moisten oral cavity
- Do not chew or swallow, avoid swallowing saliva during dissolution, nothing to drink after
- It doesn't matter if patient vomits after the tablet has dissolved – absorption is SL

# Witnessed Ingestion: Other

- **Buprenorphine SL Films**
  - Verify that the film is properly affixed under the tongue on the inside of the either cheek.
- **SROM**
  - Open capsule and sprinkle pellets into small cup for ingestion
  - Follow with appr. 30mL water
  - Instruct not to chew, crush or dissolve pellets!

# Assessing the Patient

- Prior to dispensing OAT, the pharmacist must assess the patient for signs of intoxication, changes in appearance and behavior
  - Signs of intoxication: Slurred speech, drowsiness, smelling of alcohol, ataxia, unfocused gaze, etc.

# Assessing the Patient (Continued)

- If patient is intoxicated, DEFER MEDICATING
  - Withdrawal is not life threatening… Safer to Delay!
- If dose is withheld, this must be reported to prescriber
  - Determine when it is best to reassess patient for their dose
- Remember if you are refusing a dose, it is for their own safety

# Releasing Take-Home Doses ("Carries")

- Patient must be counselled regularly to store safely
  - For methadone, must present lock box to pharmacy prior to first carry (unless the pharmacist can confirm this has already been done by the prescribing clinic)
  - Do not need to bring lock box each time if safety concerns
  - Re-confirm lock box when travelling and from time to time
- Patient is the only person who can pick up carries

# Documentation

- Pharmacies must keep a log of witnessed and take-home doses (carries) for all forms of OAT
- Patient must sign the log
- Indicate whether the log is for methadone or buprenorphine
- Always use the “mg” unit for documentation
- Retain administration logs for a minimum of 5 years
  - Physical or electronic record is acceptable

# Example of Patient OAT Log

Patient's Name:
Patient's Address or DOB:
Witness/Carry Schedule:

Patient's Picture:

| Date | Time | Dose | Drink(√) | Number of Carries | Pharmacist's Initials | Patient's Signature |
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# Witnessed Ingestion Off-Site

- A pharmacist witnessing the self-administration of OAT off the pharmacy premises (i.e., off-site witnessing) is not typically acceptable.
  - Only for exceptional circumstances, with prescriber approval
- All requirements for witnessed ingestion still need to be met, including:
    - Confidentiality
    - Pt assessment
    - Counseling
- Must consider safety and willingness of pharmacist

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Part 3: Special Situations

# Buprenorphine Extended-Release Injection (i.e., Sublocade)

- Sublocade® is covered by Pharmacare (Part II EDS) and NIHB (Prior Approval)
- Must order direct from manufacturer
  - Set up account (1 to 2 business days)
  - Pharmacist can order online, but may take 1 to 5 days to receive
- Ensure Cold-Chain Management Protocol for storage and delivery
- Must be delivered direct to clinic, or picked up by prescriber or nurse
- If Pt elects not to use, pharmacy must reverse billing and can re-stock medication if cold-chain maintained.

# Buprenorphine Extended-Release Injection (i.e., Sublocade). Cont'd…

- Pharmacists may administer Sublocade to patients.
  - Must complete training at www.sublocadecertification.ca
  - A private area with an exam table is required
  - See CPhM document: "Guidance on the Administration of Sublocade by a Pharmacist"

# Buprenorphine Micro-dosing & Unwitnessed Inductions

- You may start to see Rx's for Micro-dosing and/or Unwitnessed inductions (a.k.a., home inductions)
- See the CPSM documents:
  - *Recommendations Regarding Unwitnessed Induction with Buprenorphine/naloxone,* or
  - *Recommendations for buprenorphine/naloxone induction using the micro-dosing method.*

# Transfer of Care and Guest Prescriptions

- May have a transfer of care or temporary OAT patient from another pharmacy
- Patient may have new prescription, or Rx is transferred between pharmacies
- Can accept OAT prescriptions from other provinces
  - Needs to be written by an authorized OAT prescriber
  - OAT Rx needs to meet the requirements in place in that jurisdiction in order to fill it in Manitoba

# Transfer of Care Continued…

- Must confirm the time and amount of the last witnessed dose and the number of carries provided – along with pharmacy name (name of pharmacist recommended).
  - Prevents double dosing, missed doses, dosing errors

  e.g., Last witness dose 50mg on Mar 15 + 2 carries released as per Jim at ABC Pharmacy

- If there were refills at the previous pharmacy after a new Rx is issued, then the previous prescription must be inactivated.

# Missed Doses

- Must reverse missed doses in DPIN before end of business day
- Notify prescriber of all missed doses before next scheduled dose
- A relapse to opiate use can be problematic, especially with buprenorphine.

# Missed Doses

- After 3 consecutive missed doses of methadone, 6 consecutive missed doses of buprenorphine, or 2 consecutive days of SROM, the current Rx must be inactivated, and the patient must be assessed by their prescriber.
  - Restart always requires a new prescription

# Vomited Doses: Methadone

- Emesis must be witnessed by a health care professional to be replaced
- Prescriber must be contacted and authorize replacement if needed
  - Written replacement Rx is required!
- Pregnancy is a special circumstance

# OAT in Hospital

- No exemption is needed in hospitals to prescribe OAT to inpatients that are already taking OAT prior to admission.
- Hospital must verify patient's last dose and carries
  - Make note of this call on admin log and halt current OAT prescription
  - Notify OAT prescriber

# Case

- Peter
  - 35 years old
  - Buprenorphine 24mg OD – been on OAT for about 3 years , attends M/Tu/F
  - Grade 7 Teacher, Married with 2 boys (5 and 7 yrs)
- Peter is admitted to H.S.C. on Tuesday for severe chest pain . The hospital calls you to confirm his last dose (Mon) and tells you they will dose him for now. You halt his current buprenorphine Rx. Peter is discharged on Friday evening and shows up at your pharmacy for his next dose. You call his MDs office and he is away in Northern Manitoba until Monday and there is no covering MD. What is your next course of action?

# On Discharge

- Hospital *cannot* provide discharge prescription for OAT, unless an authorized prescriber is available.
- The hospital will ideally notify external pharmacy of last dose and time.  Needs to be confirmed
- Ideally patient should have appointment with OAT prescriber same day as discharge or day after

# On Discharge

- If a prescription is on "hold" at the pharmacy, the end date has not elapsed, and there are no relevant changes in the patient's treatment, it can be activated upon discharge from hospital ONLY after consultation and confirmation from the prescriber
  - On "Hold" = Prescriber has proactively submitted Rx to use on discharge OR reactivate most recent Rx
- Confirm and consider:
  - If the patient is discharged
  - The strength and time of last dose
  - Any remaining carry doses from before admission

# Cases (Peter)

- Peter:
  - Made contact with MD on his cell phone. Restarted old prescription until he could see MD.

# OAT in Incarceration

- When a patient is incarcerated, OAT Rx's are often transferred to a contracted pharmacy for the prison, and they coordinate the delivery of OAT doses.
- However, OAT doses may need to be delivered to the Winnipeg Remand Centre from the community pharmacy in some cases.

# Lessons from Errors

1. **Why** did the error occur?
2. **How** could it have been prevented?

- Patient ingests 10x methadone dose
- Patient ingests 7x methadone dose
- Patient ingests another patient's methadone dose
- Patient does not receive an OAT dose even though the end date hasn't not elapsed
- Patient receives methadone instead of prescribed buprenorphine

# Lessons from Errors (cont'd)

- Patient self-tapers off buprenorphine without pharmacist's or prescriber's knowledge
- Patient travels to remote community for work and his carries are stolen from his room.
- Patient jumps over counter, grabs stock bottle of methadone, and consumes it

# Overdose Protocol

- All pharmacies dispensing OAT should have a succinct overdose protocol in place. (See CPhM Winter 2019 Newsletter)
- An overdose protocol should cover:
  - Effort to contact patient
  - Contact physician
  - Appropriate emergency room recommendation
  - Appoint a trusted person to care for patient
  - Management of other meds
  - Naloxone kit (*plus* education)
  - Documentation/Incident Report

# In Summary

- Developed better decision-making skills for dispensing OAT.
- Gained a more thorough understanding of the current CPhM legislation.
- Discovered ways to resolve challenges in the witnessed ingestion process.
- Looked at special situations that may arise with your OAT patient.
- Throughout the presentations, emphasized the importance of having good communication channels with the prescriber.

# References and Resources

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