*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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- **<u>Potential for conflict(s) of interest</u>:**
  - 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
  - An extensive look at the most up-to-date guidelines (as of Dec 2020)
- Part 2 – Witnessed Ingestion
  - Methadone and buprenorphine
- Part 3 – Special Situations
  - Cases

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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 Opioid Agonist Therapy Guidelines for Manitoba Pharmacists
- 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.

# Prescriptions for OAT

- A prescription for methadone (OAT) or buprenorphine must contain:
  - The DAILY DOSE AND TOTAL DOSE written both numerically and alphabetically
    - See additional note in Guidelines
  - First and Last day for dose
    - N.B. Even if a patient misses a dose and has refills remaining, they are not to receive a dose beyond the last date
  - 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 (continued)

- Methadone and buprenorphine prescriptions can be faxed to the pharmacy *only* for the purpose of a methadone/buprenorphine maintenance program
  - Prescription must be written on an M3P form
  - Daily dosage must be clearly indicated as a separate note on the fax
  - Must meet requirements in Joint Statement for Facsimile Transmission of Prescriptions

# Prescriptions for OAT: Prescribing Approval

- Prescribers need to obtain "prescribing approval" for methadone and/or buprenorphine from their respective provincial jurisdiction in order to prescribe methadone or buprenorphine
- Is Rx for Agonist Therapy or Analgesia?
- 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.

# Communication with Prescriber

- Communication with the prescriber and patient is essential
- If the prescriber has not contacted the pharmacy and the OAT Rx was not faxed, consider contacting the prescriber's office.
- Have both the Pharmacist or Pharmacy Manager and Patient sign a Pharmacy-Patient Agreement

# Methadone Stock Solution

- Available in two dosage forms:
  1. 10 mg/ml red, cherry flavoured oral concentrate
  2. 10 mg/ml dye-free, sugar-free, unflavoured oral concentrate (Methadose™ and Metadol-D®)
  3. Other generics may soon be available.

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

# Cherry Flavoured Methadose™

- 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

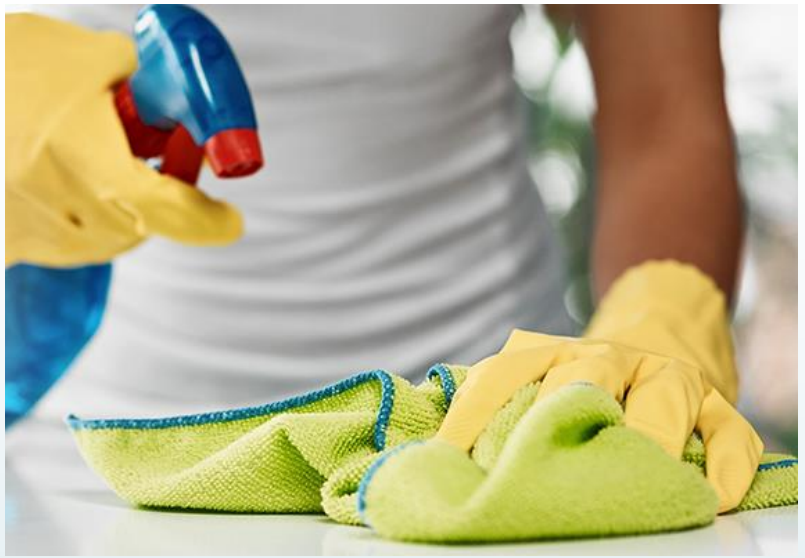
- Not hypertonic
  - **MUST BE DILUTED with coloured, flavoured diluent (NOT WATER)**
  - Dilute to final volume of 60 to 100 ml
- Dilution with a crystalline liquid is required to minimize risk of abuse and/or injection
- Some patients may require sugar-free diluent
  - ONLY for diagnosed medical conditions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

# Measuring Methadone Concentrate

- Measuring devices must be accurate
  - Accuracy of measuring liquids can be additionally verified with frequent inventory counts

# 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

- Stability and sterility of Methadose™ diluted with crystalline liquid is unknown.  Metadol-D® dilutions vary from 7 to 14 days.
- Diluent (sugar) supports bacteria growth
- All diluted Methadose™ or Metadol-D products must be refrigerated, and carries are 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.

# Stability (continued…)

- The following additional information was reported in August 1994 by Health Canada in *Dispensing of Methadone for the Treatment of Opioid Dependence*

| Diluent | Days of Stability Room Temp (20-25ºC) | Days of Stability Refrigerated (5ºC) |
|---|---|---|
| Grape Flavored Kool Aid® | 17* | 55 |
| Orange Flavored Tang® | 11* | 49 |
| Allen's Apple Juice® | 9* | 47 |
| Grape Flavored Crystal Light® | 8* | 34 |
| Grape Flavored Crystal Light® with 0.1% sodium benzoate | 29 | |

For all, stability is unknown for dilution with Methadose, and varies from 7 to 14 days with Metadol-D

*Visible microbial growth was noted beyond the specified time period.

# Storage in Pharmacy

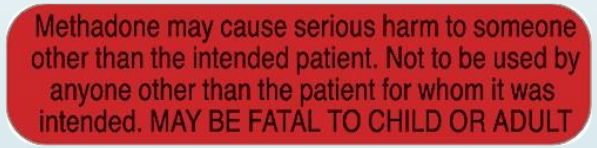
- Methadone stock solution is to be stored at room temperature.
  - Diluted preparations must be refrigerated
- Place any diluted methadone in a locked/secure fridge (required).
  - NCR: 43 – A pharmacist shall take all reasonable steps necessary to protect narcotics on the Premises against loss/theft.

# Disposal of Bottles

- Any bottles returned by the patient need to be discarded via a medical waste company (e.g. Stericycle), or disposed locally after removing the personal health information and sufficiently cleaning the bottle entirely of all remaining medicine.

# Labeling of Patient Bottles: Methadone

- Labels need to be compliant with The Pharmaceutical Act and Regulations
- 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
- Start / end date in sig required
- Ingestion date(s), if appropriate
- 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 (eg. 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 day of service provision
- Methadone is entered into DPIN as milliliters dispensed.  Buprenorphine is entered as tablets.
- If patient receives carries, Manitoba Health requires that the total quantity of methadone received by the patient must be entered into DPIN along with the days supply, on the day of service provision
- Missed doses must be reversed in DPIN before the end of the business day
- See the Methadone Reimbursement Procedure from Provincial Drug Programs for more information

# Critical Care Codes and Drug Interactions

- Methadone and buprenorphine will flag most interactions and critical care codes with other drugs when billed to DPIN
- Pharmacists should still review the DPIN record periodically to ensure there is no unauthorized prescribing of mood-altering medications or other safety concerns.
- Pharmacists are to review the critical patient care codes and drug interactions (eg. ME codes) that are generated by DPIN, decide on an appropriate action, and document the response in the appropriate place(s).
- Recommend printing a DPIN with every new Prescription for OAT and/or periodically with minor intervention codes (ME codes).

# Third Party Payers

- Methadone and buprenorphine/naloxone are covered by almost all third-party payers. Please contact the third-party payers directly for billing requirements.
- Be familiar with the NIHB – Client Safety Program (NIHB-CSP). Covers the following:
  - Opioids
  - Benzodiazepines
  - Stimulants
  - Gabapentin-pregabalin
  - Nabilone

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

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

# Witnessed Ingestion

- The pharmacist is responsible for:
  - Confirming the patient's identity
  - Reviewing the patient's profile
  - Assessing the patient for intoxication
  - Documenting the witness dose ingestion
  - Monitoring the patient post-ingestion
  - Ongoing monitoring and trouble shooting

# Witnessed Ingestion Continued…

- Witnessing ingestion within a pharmacy must be performed by a pharmacist or physician and CANNOT BE DELEGATED
- If prescriber wants daily witnessed doses, and the pharmacy is not open 7 days per week, the prescriber must be contacted to authorize carries or make other arrangements
  - If a pharmacy dispenses OAT to a patient only on the weekends, the pharmacist must have a way of verifying that the patient has had their doses during the week

# Witnessed Ingestion Continued…

- Deliveries of methadone and buprenorphine directly to the patient are not typically acceptable.
  - A pharmacist or physician must witness the ingestion.

# Witnessed Ingestion Continued…

- Deliveries are acceptable to a "hospital" and to a "community health facility". (see CDSA – Subsection 56(1) Exemptions)
  - "Hospital" = (a) Licensed, approved or designated by a province to provide care or treatment of persons OR (b) owned or operated by federal or provincial government.
  - "Community Health Facility" = health-care facility managed by a nurse (LN, RPN, or LPN)
    - Need an order signed and dated by the nurse and practitioner to authorize the delivery

Winnipeg Remand Centre

# 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 state 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

# Case

- Frank
  - 62 years old
  - Methadone 35mg OD – been on MMT for over 5 years
  - Prescribed clonazepam, mirtazapine, fluoxetine from Psychiatrist

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 Methadose™ *cherry* flavoured oral concentrate, the patient MUST be provided with water to rinse the cup/bottle and swallow to ensure that any residual medication is ingested
- This will also reduce the risk of 'cheeking'

# 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

- Dissolution time: 2-10 minutes
  - Ask to observe when tablet becomes pulpy mass (1 to 5 minutes) and then when tablet is completely dissolved
  - NEW (Dec 2020) – If approved by the prescriber, you may let the patient leave the pharmacy once the tablet(s) become a pulpy mass.
- Should not be handled
- 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

# 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, un-coordination, etc.

# Case

- Pam
  - 25 years old
  - Methadone 45mg OD for 4 weeks
  - No other comorbidities or prescribed medications
- Pam presents to your pharmacy Monday morning for her methadone dose. She is slurring her words, and has an unsteady gait. When speaking with her, she cannot focus on properly on you. There is no noticeable odor. She states that she is very tired. What should you do?

# Assessing the Patient (Continued)

- If patient is intoxicated, DEFER MEDICATING
  - Withdrawal is not life threatening… Safer to Delay!
- All changes or unusual behavior should be reported to prescriber
- Remember if you are refusing a dose, it is for their own safety

# Case (Pam)

- Pam:
  - After a lengthy discussion, she agreed to go home and sleep.  I said I would discuss with MD and told Pam to call me in a couple hours to see what the MD decided.
  - Dosed her after 3:00pm after reassessment.

# Take Home Doses "Carries"

- Given to stable patients and are considered privileges… and can be taken away or decreased
- Patient must have ability 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
- Patient is the only person who can pick up carries
- Max of 2 to 4 wks carries for vacation supply (Methadone)

# Documentation

- Pharmacies must keep a log of witnessed and take-home doses (carries) for all forms of OAT
- Include the time of dosing of witnessed ingestions
  - Do not allow dosing within 15 hours of each other
- Patient should sign the log (as well as pharmacist)

# Documentation

- 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

# 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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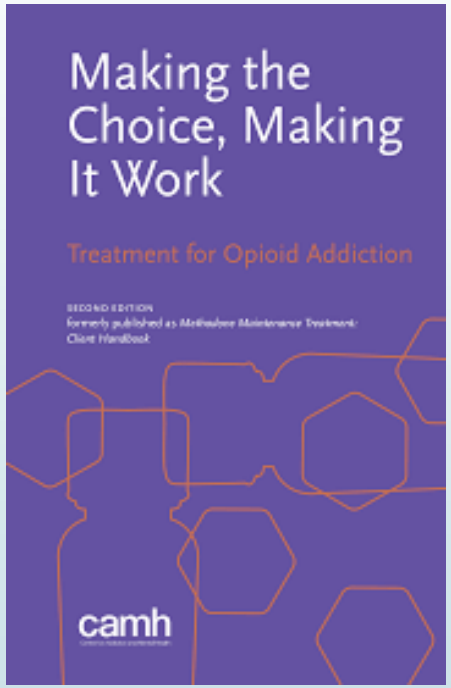
# Counseling

- Pharmacists need to provide information and counseling to patients receiving OAT
- Patient may or may not have received the *CAMH Client Handbook* - good resource and available as a free PDF online, or hard copy for purchase
- Create a positive and supportive environment
- Pharmacists can make a difference in a patient's recovery
- Treat every patient with respect!



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# Integrating Opioid Agonist Therapy into Pharmacy Practice

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
- Must be delivered direct to clinic, or picked up by prescriber or nurse
  - Maintain cold-chain with delivery
- 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). Con't…

- 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 needs a new prescription
- 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…

- When there is a transfer of care in OAT, the pharmacist is responsible for contacting the previous pharmacy
  - Prevents double dosing or missed doses
- Note the time and amount of the last witnessed dose and the number of carries provided – along with pharmacy name (name of pharmacist recommended).

  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, the prescription must be cancelled, and a new prescription is required when they return

# Missed Doses

- Must reverse missed doses in DPIN before end of business day
- If a patient misses their dose, they cannot receive the missed amount when they return to the pharmacy in the future
- Notify prescriber of all missed doses.
  - May be required to make up witness dose on a future scheduled carry day
- A relapse to opiate use can be problematic, especially with buprenorphine.

# Missed Doses

- After 3 consecutive missed doses of methadone, or 6 consecutive missed doses of buprenorphine, the current Rx must be cancelled, and the patient must be assessed by their prescriber.
  - Communicate with prescriber before Rx is necessarily cancelled
  - Try to communicate with patient
  - Requires a new prescription

# Vomited Doses: Methadone

- Emesis must be witnessed by a health care professional to be replaced
  - Within 15 mins - Consider replacing 50 to 75% of dose
  - Within 15 to 30 mins - Consider replacing 25 to 50% of dose
  - After 30 mins - Do not replace
- 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 buprenorphine/naloxone or methadone to inpatients that are already taking OAT prior to admission.
- Goal is to provide continuity of care
- 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

e.g. Jane (Phm) from HSC called Mar 21 to confirm last dose – They will dose him starting Mar 21st (MS 21/3/21)

# 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 cancel your current buprenorphine Rx and inform his OAT prescriber why you are doing so. 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, 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

- All jails are considered “hospitals” for the purposes of delivery
- The same rules that apply to community OAT prescriptions when a patient is hospitalized also apply when a patient is incarcerated.
  - Ie. You can keep an OAT Rx “on hold” for use when the patient gets released.

# Cases

- Joe
  - 35 years old
  - Methadone 70mg OD for over one year.  Witnessed Tu/F only
  - No comorbidities.  Prescribed Zopiclone 7.5 HS dispensed on his witness days
- On Tuesday morning, while filling Joe's methadone you get an MZ code for Tylenol #3 (30 tabs/3 days) filled the previous day and prescribed by a dentist.  Joe has not yet attended.  What should you do?
- What should you do if you were a pharmacist at a pharmacy that received the Tylenol #3 Rx?

# Cases cont…

- Janice
  - 50 years old – married
  - Methadone 100mg – been on MMT for over 6 months
  - Currently prescribed diazepam from methadone MD
- Janice comes into your pharmacy at 3pm and receives her dose of methadone. 45 minutes later, one of your technicians tells you that Janice had also come in the pharmacy in the morning. Upon further inspection, you discover that the pharmacist in the morning also dosed her, but incorrectly documented the witness. What is your best course of action?
- What if Janice was on Buprenorphine 8mg daily?

# 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
  - Documentation/Incident Report

# Overdose Protocol (con't)….

- Higher incidence of harm/death with the following risk factors:
  - Induction Phase
  - Overdose is greater than 50% of usual dose
  - Other sedating meds
  - Contributing medical conditions (ie. Asthma)
  - Usual dose is low (ie. methadone below 40mg)
  - Patient has carry-home doses
  - Uncertain level of opioid tolerance

# In Summary

- Developed better decision-making skills for dispensing OAT.
- Gained a more thorough understanding of the OAT Guidelines in Manitoba
- 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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