Fentanyl Citrate Sublingual Tablet (FENTORA) Administration for Opioid Use Disorder

Site Applicability

St. Paul's Hospital (SPH) Acute Care

Practice Level

RN, RPN, LPN: Basic Skill

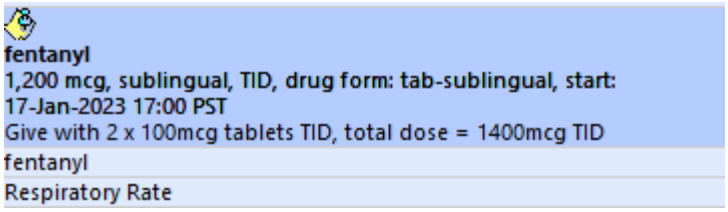
Need to Know

- Fentanyl is available in a transmucosal immediate-release formulation (FENTORA). This formulation is typically used to manage breakthrough cancer pain for individuals who are already receiving, and who are tolerant to, other opioids for persistent baseline cancer pain. The medication is available in buccal/sublingual, effervescent tablet form intended for oral use only.
- British Columbia is facing two public health emergencies, namely COVID-19 and the enduring drug poisoning (overdose) crisis, which combined are contributing to record toxic drug fatalities. In response, Health Canada provided funding for community programs to deliver a safe supply of pharmaceutical-grade opioids, such as transmucosal fentanyl, to people most at risk of overdose and focuses on those who have been diagnosed with an opioid use disorder (OUD) and who have not been helped by traditional substance use services and treatments.
- As part of these programs, transmucosal fentanyl is being prescribed for people who are daily opioid users who have a high tolerance to opioids and who inject or smoke opioids. It is an off-label use of this medication.
- The Addiction Medicine Consult Team (AMCT) will prescribe sublingual fentanyl for patients who are on transmucosal fentanyl in community while admitted to hospital for continuation of therapy. Transmucosal fentanyl is not bioequivalent to other fentanyl products. There is no way to safely convert someone from another form of fentanyl (e.g., injectable formulation) to transmucosal fentanyl.
- Sublingual fentanyl can only be prescribed by AMCT, and any orders by other providers will be rejected by pharmacy.
- Fentanyl is highly lipophilic and has a cumulative effect like methadone. Ensure at least 4 hours between ALL doses of FENTORA.
- FENTORA should not be used in patients who are receiving partial opioid agonists, such as buprenorphine, as this may reduce the analgesic effect of fentanyl citrate and/or precipitate withdrawal symptoms.

Protocol

Prescriber Orders

- The AMCT provider will enter an ad hoc non-formulary order for fentanyl sublingual tablet(s) in CST-Cerner. The medication will appear on the Medication Administration Record (MAR). This medication may be ordered as scheduled or PRN depending on how the patient receives the medication in the community.



- The product monograph does not currently include dosing recommendations for opioid use disorder - this is an off-label use of the medication. Doses prescribed for this indication can be much higher than what is listed as the maximum single dose in the product monograph (800 mcg) given patients' high opioid tolerances. The usual starting dose for titration is 400 mcg (as 200 mcg sublingual BID). Doses as high as 4800 mcg (as 2400 mcg BID) have been used.

NOTE: Patients may also have orders for other opioid agonist treatments (OAT), e.g., slow-release oral morphine or methadone that can be administered concurrently with sublingual fentanyl.

Pre-dose assessment	
• Obtain baseline level of sedation (LOS) using the Pasero Opioid-Induced Sedation Scale (POSS) [modified; see Appendix A]. *NOTE: Sedation always precedes respiratory depression in opioid toxicity.*	- **If patient's POSS score is 3 or 4**, hold the dose and notify AMCT and/or the AMCT Liaison Nurse *****OR***** most responsible provider (MRP) if after hours. - **If patient discloses using non-prescribed opioids**, assess POSS score and proceed with administering dose if POSS is S, 1 or 2. Hold the dose if POSS is 3 or 4. - See **Appendix A** for additional actions and directions in relation to patient's LOS, including continued monitoring. Patients may be able to receive their dose later when they are less sedated.
• Obtain baseline respiratory rate (RR) and general appearance.	- **If RR is less than 8 breaths per minute or patient demonstrates severe agitation, dyskinesia, slurred speech, and/or intoxication (e.g., odor of alcohol)**, hold the dose and notify AMCT and/or the AMCT Liaison Nurse *****OR***** most responsible provider (MRP) if after hours.

- If a dose is held for any reason or missed, contact prescriber/AMCT and/or AMCT Liaison Nurse *OR* MRP after hours.
  - Administration times of scheduled doses may be adjusted or rescheduled up until 23:59 on the same day if the dose is administered **4 hours apart** from any other scheduled or PRN doses of FENTORA and the patient is not too sedated (i.e., has a POSS of 3 or 4, see Appendix A). Nurses are not required to call AMCT when they do an adjustment within these parameters. After midnight, offer alternative opioid PRNs.
  - Patients may be at risk for withdrawal if they do not receive their doses. Prescribers and teams should work with patients to try to avoid missed doses.

Administration of sublingual fentanyl	
	Pharmacy will supply the sublingual tablets as patient-specific supply issued to the unit Automated Dispensing Cabinet (ADC aka Omnicell®). The drug is available in 100 mcg, 400 mcg or 800 mcg strength tablets. If multiple tablet strengths are required to make up one dose, each strength will be issued to a different bin in the ADC. Some doses will be a single tablet, while other doses will require a combination of tablets or tablet strengths. **Be vigilant about the dose and required combination or number of tablets**. • *Example: If the patient's dose is 1700 mcg, pharmacy would provide a supply of 800 mcg tablets and 100 mcg tablets in separate bins. The patient would need two of the 800 mcg tablets and one of the 100 mcg tablets to make up each dose.*
Preparation	1. Verify the order and check the MAR. **Ensure at least 4 hours between ALL doses of FENTORA, including sublingual fentanyl.** 2. Encourage the patient to have a drink of water prior to administration. This is not a requirement but will help moisten the mouth to aid in the tablet(s) dissolving. 3. Put on gloves. 4. **An Independent Double Check (IDC) is highly recommended** prior to administration. 5. **DO NOT** remove the tablet from the blister pack until the patient is ready for immediate administration. Peel back the blister backing (foil) to expose the tablet. **DO NOT** attempt to push the tablet through the blister foil as this may cause damage to the tablet. 6. Drop the tablet directly into a medication cup. The tablets are meant to be taken whole. **DO NOT** split the tablet(s). When removed from the blister packaging, the tablet(s) must be used right away. **DO NOT** store the tablet once it has been removed from the blister package as the tablet integrity may be compromised and, more importantly because this increases the risk of accidental exposure to the tablet.

Administration	1. Once the tablet is removed from the blister packaging, it should be administered sublingually **immediately**. **NOTE:** The tablets can also be administered buccally if the patient prefers and/or if AMCT orders the medication by this route (see Appendix B for buccal administration instructions). 2. The tablet(s) are meant to be used whole. Instruct patient not to split, suck, chew, or swallow the tablet(s). The patient will have less absorption of the medication this way (i.e., lower plasma concentrations than when taken as directed). 3. Tablet(s) should be left in place under the tongue until it has fully dissolved, which can take up to 14 to 25 minutes. Caution the patient against swallowing the tablet(s) or saliva during this time. 4. After 30 minutes, if remnants of the tablet(s) remain, they may be swallowed with a glass of water. 5. Advise the patient to stay on the unit for 25 minutes after initial administration of the dose for observation but understand that they may choose to leave. It is important to educate patients on the risks of leaving before post-dose observation is complete (see "Patient and Family Education" section for required education).

Post-dose and ongoing assessment	
• Assess LOS (using POSS; see Appendix A) 25 minutes after initial administration of each dose (i.e., not 25 minutes after the tablets have finished dissolving). *NOTE: Sedation always precedes respiratory depression in opioid toxicity.*	- **If patient's post-dose POSS score is 3 or 4, this indicates that the dose could be too high, and the patient is not tolerating the dose.** Notify AMCT and/or the AMCT Liaison Nurse *OR* MRP if after hours ASAP to assess the need to adjust dose and create a care plan for the patient. **Hold additional doses until provider has been contacted and informed.** - **Immediate management of opioid overdose** includes removal of the tablet(s), if still in the mouth, and naloxone can be administered with or without an order if needed. - See **Appendix A** for additional actions and directions in relation to patient's LOS, including continued monitoring.
• Assess RR and general appearance 25 minutes after initial administration of each dose (i.e., not 25 minutes after the tablets have finished dissolving).	- **If RR is less than 8 breaths per minute or patient demonstrates agitation, anxiety, slurred speech or mumbling words**, hold additional doses and notify AMCT and/or the AMCT Liaison Nurse *OR* MRP if after hours.

• If patient is missing multiple post-dose assessments, contact prescriber so they can discuss the program expectations with patient and determine if there are reasonable steps that can be taken by either the prescriber or the patient to help meet the patient's needs.	
• Assess the patient for effectiveness of treatment by asking the patient about opioid cravings and signs and symptoms of withdrawal (e.g., nausea/vomiting, diaphoresis, anxiety), and pain and offer PRNs accordingly.	- Document and bring forth any concerns to the prescriber. *Sample assessment questions:* ○ *"Are you having any withdrawal or cravings throughout the day?"* ○ *"Do you have any concerns about your treatment?"*

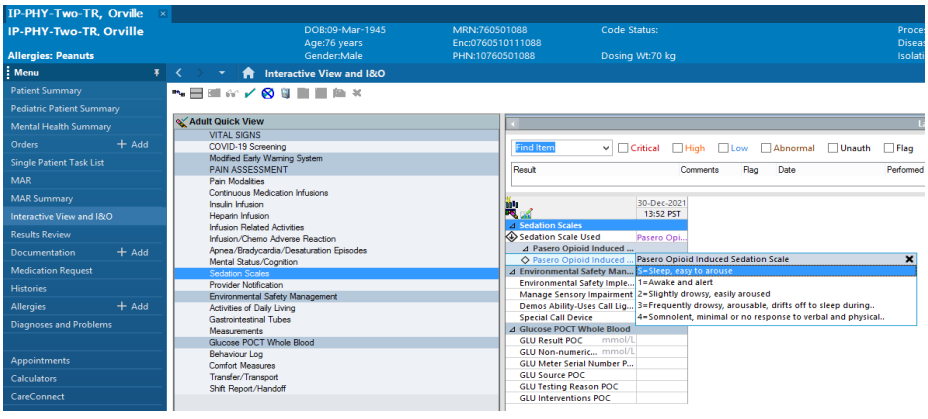
Interventions

- Strongly encourage the patient to wait on the unit for the full 25 minutes post-dose. If the patient chooses to leave, document that the patient was informed of potential risks.
- In the case of suspected opioid overdose, naloxone can be administered with or without an order. Notify prescriber/AMCT, or MRP if after hours, if any naloxone is administered.
- Offer a Take Home Naloxone kit and associated education to all patients on sublingual fentanyl.

Documentation

- Document medication administered on the MAR, including the recommended Independent Double Check (IDC) performed prior to administration.

- Document pre- and post-administration assessments of LOS (POSS) and RR in 'Interactive View and I&O' -> 'Adult Quick View'. POSS is found under 'Sedation Scales' -> double click the empty box that you would like to document in and the 'Sedation Scale Used' box will appear -> select POSS.



- Document any abnormal or significant findings and interventions in narrative charting, including patient/family education provided.

- See Appendix B for documentation of buccal administration and assessments.

Patient and Family Education

- Advise against smoking cigarettes or drinking caffeinated beverages for 1 hour prior to taking the medication, if possible, as being adequately hydrated will help the medication dissolve completely.
- Advise patient that the tablet(s) must dissolve completely, which can take up to 25 minutes. Instruct patient not to swallow their saliva or the tablet(s) and to refrain from talking, eating, or drinking fluids while the tablet(s) is dissolving.
- Educate patient on the rationale for the 25-minute post-dose observation period (to observe the patient following onset and at peak plasma concentration) and the risk of possible overdose or dose intolerance.
- Inform patient that taking sublingual fentanyl with other opioids, benzodiazepines, alcohol, or other central nervous system depressants (including non-prescribed substances) can cause severe drowsiness, decreased awareness, respiratory depression, hypotension, overdose, coma, and death.
    - If patients are using non-prescribed substances, provide information and education about harm reduction and interventions (e.g., the Overdose Prevention Site at SPH, Take Home Naloxone).

Related Documents

- B-00-13-10175 - Dispensing Take Home Naloxone Kits to Clients at Risk of Opioid Overdose (Adults and Youth)
- B-00-07-10098 - Independent Double Check and Double Check of Medication
- BCD-11-11-41006 - Medication Administration Policy
- BD-00-13-40094 - Opioid Overdose (Suspected): Management, Including Naloxone Administration without a Provider Order
- B-00-11-10125 - Philosophy of Care for Patients and Residents Who Use Substances
- BC College of Nurses and Midwives Practice Standard for Registered Nurses, Registered Psychiatric Nurses, Licensed Practical Nurses: Medication

References

1. Health Canada. (2020). Health Product InfoWatch Safety Brief: *Fentora (fentanyl citrate, buccal/sublingual effervescent tablets) safety reminders.* Retrieved from: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/health-product-infowatch/health-product-infowatch-may-2019.html#a4-1
2. Pasero, C. (2009). Assessment of sedation during opioid administration for pain management. *Journal of PeriAnesthesia Nursing, 24*(3), 186-190.
3. Pasero, C., & McCaffery, M. (2002). Monitoring sedation: It's the key to preventing opioid-induced respiratory depression. *American Journal of Nursing, 102*(2), 67-69.
4. PHS. (2021, February 05). *PHS to deliver multi-year safe supply program.* Retrieved from:

https://www.phs.ca/phs-to-deliver-multi-year-safe-supply-program/
5. SAFER Fentanyl Tablet Program Protocol. (2021, August).
6. Teva Canada Innovation. (2020, May 28). *Product monograph including patient medication information: ᴺFENTORA™ fentanyl citrate, buccal/sublingual effervescent tablets.* Retrieved from: https://www.tevacanada.com/en/canada/our-products/product-page/fentora-02408007(100mcg)02408015(200mcg)02408023(400mcg)02408031(600mcg)02408058(800mcg)
7. U.S. Food & Drug Administration. (2020, December 29). *Transmucosal Immediate-Release Fentanyl (TIRF) Medicines.* Retrieved from: https://www.fda.gov/drugs/information-drug-class/transmucosal-immediate-release-fentanyl-tirf-medicines

Definitions

Opioid agonist treatment

Opioid agonist treatment refers to the use of a substitution opioid to manage opioid use disorder. Methadone and buprenorphine are both long-acting opioids that are used in opioid agonist treatment. Opioid agonist treatment has been shown to reduce mortality, drug use and retain patients in treatment.

Precipitated withdrawal

Precipitated withdrawal can occur when someone is given an initial dose of buprenorphine/naloxone when they are not in moderate to severe opioid withdrawal. In this circumstance, the high affinity partial opioid agonist buprenorphine will displace the full agonist opioid (e.g., heroin, fentanyl, morphine) from the receptors causing a rapid decrease in receptor activity and the precipitation of opioid withdrawal symptoms.

Appendix A: Pasero Opioid-Induced Sedation Scale (POSS) [Modified to include interventions] located in Cerner PowerChart in 'Interactive View and I&O' under 'Sedation Scales' (see below)

Level of Sedation	Appropriate Action
S = Sleep, easy to arouse	Acceptable; no action necessary; may continue with opioid dose
1 = Awake and alert	Acceptable; no action necessary; may continue with opioid dose
2 = Slightly drowsy, easily aroused	Acceptable; no action necessary; may continue with opioid dose
3 = Frequently drowsy, arousable, drifts off to sleep during conversation	Unacceptable; hold opioid until improved; monitor respiratory status and sedation level closely until sedation level is stable at less than 3 and respiratory status is satisfactory
4 = Somnolent, minimal or no response to verbal or physical stimulation	Unacceptable; hold opioid and notify prescriber; consider administering naloxone; monitor respiratory status and sedation level closely until sedation level is stable at less than 3 and respiratory status is satisfactory

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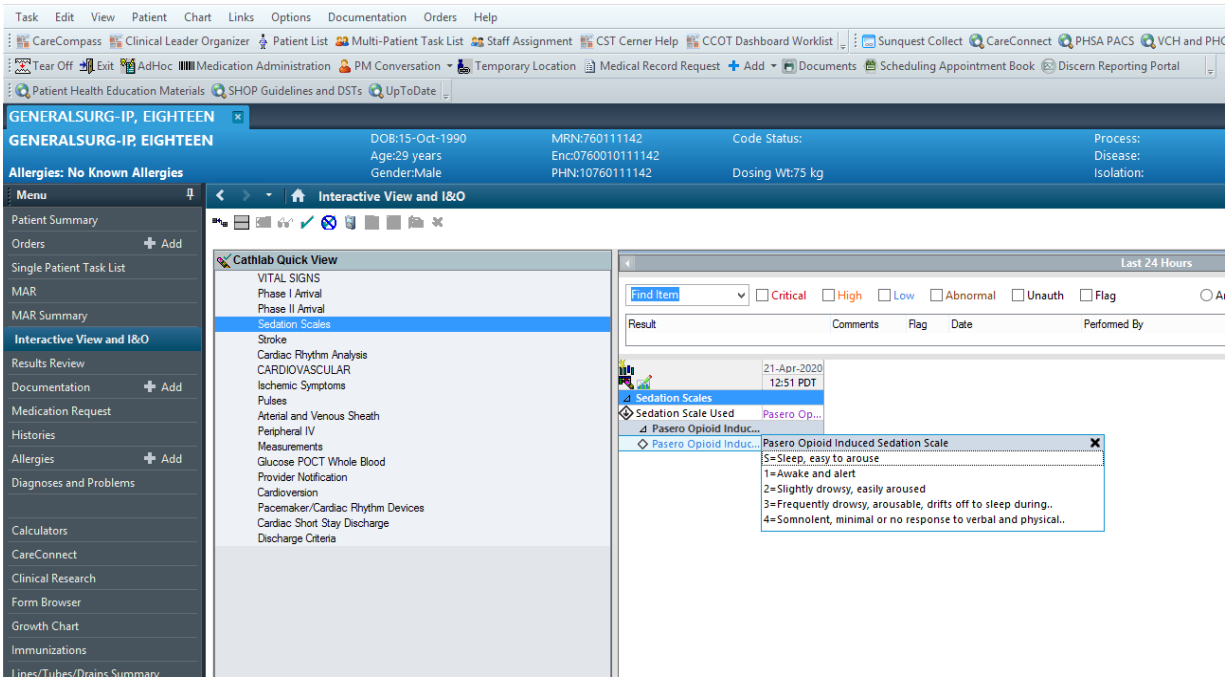


Appendix B: Instructions for Buccal Administration and Documentation

Administration

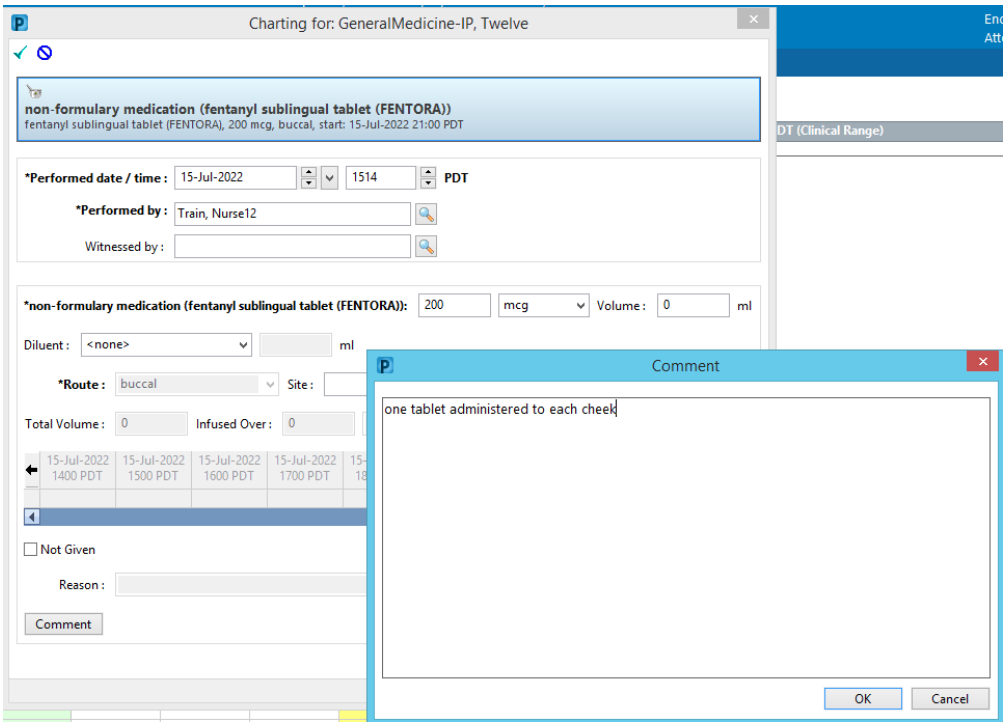
1. Once the tablet is removed from the blister package, the entire tablet should be placed in the buccal cavity **immediately** (above a rear molar tooth between the upper cheek and gum; see Figure 1).

Figure 1. Buccal administration (product monograph)

   If multiple tablets are to be administered simultaneously, instruct the patient to place tablets on each side of the mouth (e.g., for 400 mcg dose, place two 100 mcg tablets on each side of the mouth for a total of four 100 mcg tablets).
2. The tablet(s) are meant to be used whole. Instruct patient not to split, suck, chew, or swallow the tablet(s). The patient will have less absorption of the medication this way (i.e., lower plasma concentrations than when taken as directed).
3. Tablet(s) should be left in place between the cheek and gum against the mucous membranes until it has fully dissolved, which can take up to 14 to 25 minutes. Caution the patient against swallowing the tablet(s) or saliva during this time.
4. After 30 minutes, if remnants of the tablet(s) remain, they may be swallowed with a glass of water.
5. It is recommended that patients alternate sides of the mouth when administering subsequent doses of fentanyl buccally.
6. Advise the patient to stay on the unit for 25 minutes after initial administration of the dose for observation but understand that they may choose to leave. It is important to educate patients on the risks of leaving before post-dose observation is complete (see "Patient and Family Education" section for required education).

Documentation

- Document medication administered on the MAR, including the recommended Independent Double Check (IDC) performed prior to administration.
  - As it is recommended to alternate sides of the mouth when administering subsequent doses, document which side(s) of the mouth the tablet(s) was administered in the 'Comment' section of the medication administration window (e.g., "right upper, both sides").



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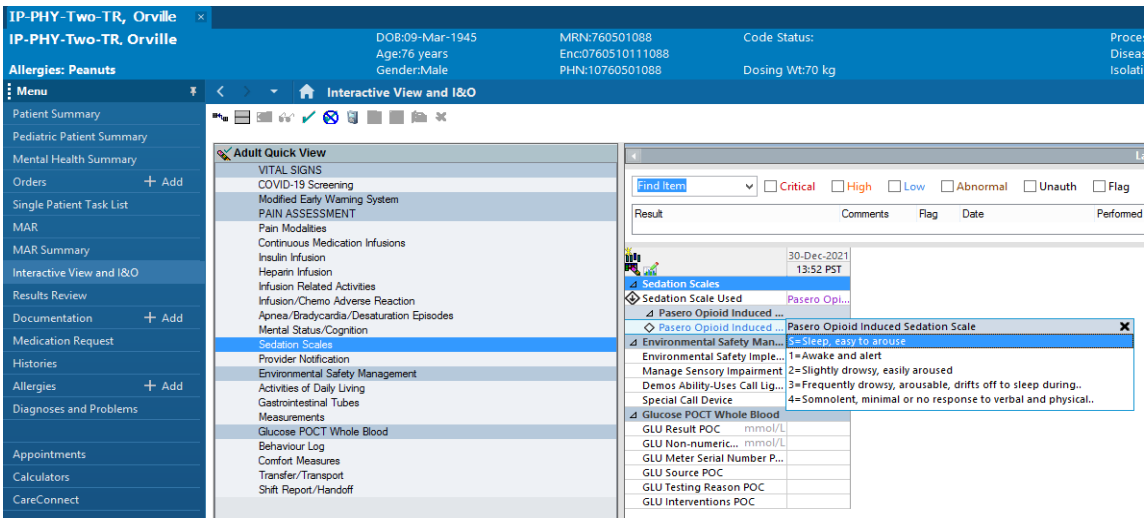

- Document any abnormal or significant findings and interventions in narrative charting, including patient/family education provided.

Persons/Groups Consulted:
Medical Lead, Addictions Medicine Consult Team (AMCT)
AMCT Physician, Medical Director - VCH/PHC Regional Addiction Program, Primary Care Physician – Portland Hotel Society Community Services
Clinical Pharmacy Specialist, AMCT
Nurse Educator, Substance Use
Nurse Educator, Urban Health (8A) / Clinical Nurse Leader, SPH Overdose Prevention Site
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