Fentanyl Patch

Prescribed Safer Supply Protocols

BRITISH COLUMBIA
BRITISH COLUMBIA CENTRE ON SUBSTANCE USE
Networking researchers, educators & care providers
phs COMMUNITY SERVICES SOCIETY

Acknowledgements

This protocol was adapted from the Fentanyl Patch Policy by PHS Community Services Society. The BCCSU acknowledges with gratitude both PHS Community Services Society and the PHS authorship committee, which includes Christy Sutherland MD CCFP(AM) dABAM, Jessica Anderson LPN, Sarah Foster LPN, Kathryn Campbell LPN, Stephanie Lai RN(C), Rupi Brar MD CCFP(AM) CISAM, Lindsay Mackay MD CCFP, Leah Bennet LPN, Olivia Brooks MD CCFP, Kelsey Bissegger LPN, Mithra Bahrami LPN, Jenny Ballesteros LPN, Sukhpreet Klaire MD CCFP, Vera Khramova MD CCFP, Gabrielle Rabu MD, Courtney Amoraal RN, Sandra Tran LPN, Ben Trepanier MD CCFP cISAM, Riley Davidson MD CCFP, Ashley Palen LPN, Carol Fawcett RPh, Candace Waung RPh, Ahmad Ghahary BScPharm PharmD, Crystal Adams LPN, and Mi Kyung Choi LPN.

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1.0 Introduction

1.1 Background

In July 2021, the Ministry of Mental Health and Addictions, Ministry of Health, and Office of the Provincial Health Officer released *Access to Prescribed Safer Supply in British Columbia: Policy Direction*, which enables individuals to access a range of medications through prescription to reduce the risk of drug toxicity death due to accessing the illicit drug supply. The first phase of implementation of this policy allows for the prescribing of certain opioids including fentanyl patches through regional health authority-run programs and federally funded programs (e.g., SAFER). Prescribed pharmaceutical alternatives is not intended for treatment of substance use disorders but is primarily a harm reduction approach for reducing the risks of illicit drug toxicity events and deaths.

This document provides a standardized protocol for the provision of fentanyl patches to reduce reliance on the illicit drug supply and associated harms. Provision of other medications for harm reduction is outside the scope of this protocol. See the BCCSU's *Risk Mitigation in Dual Health Crises: Interim Clinical Guidance* for guidance on supporting individuals who use drugs to self-isolate or quarantine due to COVID-19; the BCCSU's Opioid Use Disorder Practice Update for information on prescribing hydromorphone and/or M-Eslon to help reduce individuals' reliance on the illicit drug supply and, thus, overdose risk; and the BCCSU's forthcoming Stimulant Use Disorder Practice Update for information on trialing stimulant prescribing to help reduce individuals' reliance on the illicit drug supply and related harms.

This protocol is adapted from PHS Community Services Society's Fentanyl Patch Policy and Vancouver Coastal Health's Fentanyl Patch Clinical Operational Manual.

1.2 Evidence Supporting this Intervention

Providing fentanyl patches to reduce harms associated with illicit opioid use is not an evidence-based intervention. To date, there is no evidence supporting this intervention or established best practices for when and how to provide it. However, limited clinical experience has shown this practice to be a beneficial intervention for individuals with opioid use disorder using unregulated/illicit opioids.

In response to continued and accelerated toxicity of the illicit drug supply and illicit drug toxicity deaths and harms, this protocol provides standardized guidance for the off-label use of fentanyl patches in an effort to reduce reliance on the illicit drug supply and the harms associated with it.

1.3 Evaluation

See the Ministry of Mental Health and Addictions, Ministry of Health, and Office of the Provincial Health Officer's *Access to Pharmaceutical Alternatives to a Toxic Drug Supply Policy* for information on the evaluation and monitoring framework for this intervention.

Although the evaluation and monitoring framework is still in progress, sites are encouraged to include the following measures in program assessment and evaluation in order to facilitate evaluation and consistency across sites:

- Current substance use (amount, frequency, route)
- Recent overdose history
- Visits to emergency department/acute care since last assessment
- Cravings
- Withdrawal symptoms and severity
- Review of overdose prevention safety plan
    - How is the patient currently keeping themselves safe and preventing overdose?
    - What support do they need?
- Overall wellbeing
- Income/employment
- Patient-identified goals
- Seeking or gaining employment or volunteer activities
- Integrating new activities
- Reconnecting with family and friends (e.g., improved social connection)
- Housing/underhoused
- Care team
    - Who is involved in their care?
    - What connections do they have to the community?
- Missed doses (including partial doses)
- Urine drug test results

Programs are also encouraged to develop a consistent approach to documentation in patients' charts, to facilitate evaluation efforts.

1.4 Planned Review

As this is a new and emerging practice, this protocol will be regularly reviewed and updated to align with emerging evidence and amassing clinical experience. The next planned review period for this protocol begins in January 2023.

2.0 Program Models

Implementation of the Ministry of Health & Ministry of Mental Health and Addictions' *Access to Prescribed Safer Supply in British Columbia—Policy Direction* includes provision of fentanyl patch programs through regional health authority-operated/funded programs and federally funded programs (e.g., SAFER). This may include adding fentanyl patch provision to a variety of existing programs and services, including opioid agonist treatment (OAT), injectable opioid agonist treatment (iOAT), and overdose prevention/supervised consumption sites.

In sites where a fulsome, wraparound fentanyl patch clinic (for example, co-located in an OAT clinic) is not possible, an extension of the health-authority run program may be feasible (for example, in rural and remote settings where a nurse is regularly available and a prescriber is not). In this extension model, a non-prescriber regulated health professional (i.e., nurse or pharmacist) acting within their scope and competence can perform maintenance dose patch changes, while the prescriber sees the patient regularly for monitoring, follow-up, and any dosage changes. In this model, the non-prescriber regulated health professional is responsible for patch change visits (and urine drug testing, depending on agreement with prescriber, and program capacity), including assessment and patient counselling. Regular (e.g., monthly) case conferences between prescriber, care team, and non-prescriber regulated health professional should be conducted.
Throughout this document, actions that must be performed by a prescriber (i.e., physician or nurse practitioner) are described as such, and actions that may be performed by another, non-prescriber regulated health professional[a] within scope and individual competency are described as such. Registrants should follow the standards, limits, conditions, and responsibilities set forth by their regulatory college.

This model may serve to reduce some barriers (e.g., in communities that do not have the infrastructure to support a fulsome, wraparound fentanyl patch program) and help to support continued engagement in care.

Two possible models are described below, one in which a nurse performs maintenance dose changes and one in which a pharmacist performs maintenance dose changes. Either or both of these models may be adapted, depending on local context and resources.

2.1 Nursing-led Medication Administration

This model requires nurses (RN, RPN, LPNs) working within their professional scope of practice, education, and training, and within the requirements of provincial and federal regulatory structures

[a] In practice, currently most maintenance dose patch changes are performed by nurses acting within their scope and capability. Other non-prescriber registrations should follow the standards, limits, conditions, and responsibilities set forth by their regulatory college.

and any applicable exemptions, to work closely with the care team to ensure that the following actions are performed:

- Patient identification
- Assessment and communication of assessment results back to prescriber
  - See Patch Change Assessment
- Ensuring the safe and appropriate use of new patches by confirming all previously dispensed patches have been removed and exchanged prior to or applying new patches
- Ensuring patients' privacy needs are met during patch application
- Destroying returned or changed patches
- Missed dose protocol
  - The missed dose protocol in this model aligns with the missed dose protocol outlined in this clinical protocol
  - Patients who have missed 5 or fewer days can attend the pharmacy and receive their usual dose
  - Patients who have missed 6 or more days must visit the clinic for a restart and the prescription must be cancelled
  - Missed doses are to be destroyed per regional health authority or organizational requirements at the earliest possible opportunity. They should not be held and provided to the specified patient or to any other patient at a later time
- Updating PharmaNet regarding any missed or adjusted doses
- Notifying the prescriber and pharmacist of any missing patches
  - If the patient presents without patch(es), they may still receive their next dose provided it is within the 5-day missed dose protocol; however, missing patch(es) should be considered as an instance of diversion, communicated to the prescriber and pharmacist by end of clinic day, and addressed per the program's diversion policy
- Patient education and counselling
- Documentation of all aspects of clinical care

In programs using the extension model outside wraparound fentanyl patch clinics, the program planning phases should also address additional items such as:

- Developing new workflows including communication of assessments, hand-offs, chain of responsibilities, and evaluation of workflow
- Additional training (e.g., the Provincial Opioid Addiction Support Treatment Program) for nurses or pharmacists seeking more training on opioid use disorder and opioid agonist treatment
- Additional costs for compensation of personnel and services, supplies for patch changing and proper disposal

In all models, the dispensing pharmacist is responsible for the following actions:

- Reviewing the patient's PharmaNet profile
- Ensuring the therapeutic appropriateness of the therapy
    - Including checking for and following up on potential drug–drug interactions
- Providing counselling to the patient
    - This may occur through one of two mechanisms, based on patient preference and clinical judgement and availability of health care professionals:
        - Pharmacist conveys counselling points to program nurse to provide to the patient, if authorized by the patient
        - Pharmacist provides counselling in person, by phone, or virtually

2.2. Pharmacist-led Medication Administration

In practice, many programs currently rely on nursing staff to perform ongoing assessment and medication management as well as fentanyl maintenance patch changes. However, given a complexity of factors, relying on nursing can present a number of barriers to engagement. In an effort to reduce barriers, PHS has also piloted a model in which patients receive their medication at their pharmacy from a pharmacist rather than the clinic site from a nurse.

In this model, working within their knowledge, skills, abilities, and scope of practice, the pharmacist dispenses the patches to the patient. Either the patient or the pharmacist may apply and remove the patches at the pharmacy. If the prescription indicates that witnessed application is not required, the pharmacist may dispense the patches to the patient, who would be responsible for applying and removing the patches as well as returning them to the pharmacy for disposal.

The pharmacist in this model would be responsible for:

- Patient identification
- Assessment and communication of assessment results back to prescriber
    - See Patch Change Assessment
- Ensuring the safe and appropriate use of new patches by confirming all previously dispensed patches have been removed and exchanged prior to dispensing and/or applying new patches
- Ensuring patients' privacy needs are met during patch application
- Destroying returned or changed patches
- Following the missed dose protocol, when applicable
    - The missed dose protocol in this model aligns with the missed dose protocol outlined in this clinical protocol

    - Patients who have missed 5 or fewer days can attend the pharmacy and receive their usual dose
    - Patients who have missed 6 or more days must visit the clinic for a restart and the prescription must be cancelled
    - Missed doses are to be destroyed per regional health authority or organizational requirements at the earliest possible opportunity. They should not be held and provided to the specified patient or to any other patient at a later time
- Updating PharmaNet regarding any missed or adjusted doses
- Notifying the prescriber of any missing patches
    - If the patient presents without patch(es), they may still receive their next dose provided it is within the 5-day missed dose protocol; however, missing patch(es) should be considered as an instance of diversion, communicated to the prescriber, and addressed per the program's diversion policy
- Patient education and counselling
- Documentation of all aspects of clinical care

2.3. Case Conferences

Regular (e.g., monthly) case conferences between prescriber, care team, and non-prescriber regulated health professional should be conducted.

During this case conference review, the team should discuss engagement, progress toward care plan goals, and any clinical concerns for each patient.

Case conferences will differ by program and may include only the prescriber and non-prescriber regulated health professional, or a larger team, as appropriate.

2.4 Regional Adaptation

Note: This document is meant to provide a standardized protocol for the provision of fentanyl patches. However, certain contexts (e.g., rural and remote) may need to adapt the protocols to their regional contexts based on capacity, resources, and geographic realities in order to reduce barriers to access. Any such adaptations should balance individual patient access, public safety, and clinical judgment.

3.0 Eligibility

It is strongly recommended that this intervention be trialed only in situations where established, evidence-based opioid agonist treatment (oral and/or injectable) has not been successful in reducing the patient's reliance on the illicit drug supply and associated risks.

The following considerations for eligibility should be assessed and documented in the patient's health record:

- Opioid use disorder diagnosis

AND

- Ongoing active illicit opioid use

AND

- At high risk of overdose or other harms related to illicit opioid use by a detailed clinical assessment including overdose history

In addition to the criteria above, youth age < 19 patients may be eligible if:

- There is informed consent by the patient to receive treatment from the program and extra education about the risks associated with this population
- In collaboration with the patient, referral to health and social services and connection to resources related to their population

3.1 Assessment

Assessment for eligibility should include the following:

- Active substance use assessment (i.e., type of substance, quantity used, frequency and route of use)
- Substance use and treatment history
    - Including previous oral OAT and iOAT trials (e.g., dosage, duration on treatment) as well as other psychosocial treatment interventions, including recovery-oriented care

- History of overdose and other drug-related harms (e.g., infections, criminalization)
- Comorbid mental and physical health conditions
- Prescribed and non-prescribed medication(s) and natural health products
  - See drug–drug interactions below
- Urine drug test (positive for opiates or fentanyl)
- Baseline liver and renal function tests
- Precautions (see below)
- Contraindications (see below)

If another physician or nurse practitioner in the community follows the patient, that clinician should be consulted prior to starting the fentanyl patch. Depending on the results of the eligibility assessment, a second prescriber review may be necessary. See Precautions, below.

3.2 Contraindications

The following conditions preclude an individual from being eligible for the fentanyl patch:

- No history of opioid use disorder
- Any disabling medical or mental health condition as assessed by medical history, physical exam, vital signs and/or laboratory assessment that, in the opinion of the prescriber, precludes the safe participation or the ability to provide fully informed consent, including[b]:
  - Severe respiratory illness requiring long-term oxygen
  - Acute or severe bronchial asthma
  - Known or suspected mechanical gastrointestinal obstruction (e.g., bowel obstruction, strictures) or any diseases/conditions that affect bowel transit (e.g., ileus of any type)
  - Suspected surgical abdomen (e.g., acute appendicitis, pancreatitis)
  - Severe CNS depression, increased cerebrospinal or intracranial pressure, head injury
  - Current or recent (<14 days) monoamine oxidase inhibitors (MAOI)
- Any clinical condition that would increase the risk of an adverse event with the use of the fentanyl patch, based on clinical judgment
- Pregnancy
  - There may be exceptional circumstances in which this intervention would be appropriate for a pregnant person. Consultation with a perinatal addiction specialist is recommended if this intervention is being considered
  - Rapid Access to Consultative Expertise (RACE) for Addictions is available M-F 8am-5pm for additional consultation and support, including for managing concurrent pain and substance use, for physicians and nurse practitioners

[b] Sandoz Canada Inc. Sandoz fentanyl patch: Product monograph. Boucherville, Quebec2020. https://www.sandoz.ca/sites/www.sandoz.ca/files/Sandoz%20Fentanyl%20Patch%20Product%20Monograph_0.pdf.

If any of these contraindications newly arise during care, the prescriber should be notified immediately and the care plan reassessed.

3.3 Precautions

If any of the following precautions are identified during the assessment process, they should be documented and a second prescriber should review. The second prescriber review, discussion, and final decision should be documented.

- Youth (<19 years of age)
- Active moderate to severe benzodiazepine, alcohol, or other CNS depressant (i.e. gabapentin, dimenhydrinate, etc) use disorder(s)
    - Individuals intentionally using illicit benzodiazepines should be considered separately from those who are unintentionally exposed via contaminated drug supply
        - Clinical judgment should be used, with safety prioritized, when considering this intervention for individuals who intentionally use illicit benzodiazepines and meet a moderate to severe benzodiazepine use disorder
        - For individuals who are unintentionally exposed to benzodiazepines through the contaminated drug supply,[c] it is reasonable to start the program, as long as the patient is not sedated.
    - Consider sending UDT for confirmatory testing, as etizolam and other benzodiazepine analogues may not be detected by point-of-care testing
        - See the BCCSU's *Urine Drug Testing—Breakout Resource* for more information on urine drug testing
- Any acute or chronic medical condition that may make this intervention unsafe
    - Examples of acute conditions: hepatic/renal/cardiac failure, injection-related infections (i.e. cellulitis, sepsis, osteomyelitis, infectious endocarditis), recent head injury
    - Examples of chronic conditions: heart disease, liver cirrhosis, kidney failure, cognitive impairments, dementia, severe mental illness
- History of behavioral concerns including violence or aggression towards staff
- Individuals who are on anti-retroviral (ARV) medications
- Frailty

If any of these precautions newly arise during care, the prescriber should be notified immediately and the care plan reassessed.

[c] See "Benzodiazepines and Opioids" for guidance on providing care to individuals who have been exposed to benzodiazepines through the use of adulterated opioids.

3.4 Drug–drug Interactions

The following list of drug-drug interactions is based on the product monograph for fentanyl patch.[d] The examples within each category should not be considered comprehensive; prescribers should consult the product monograph of any drug co-administered with fentanyl and other sources of information on drug–drug interactions, including a pharmacist.

- CNS depressants
  - Patients should be warned of the risk of combining multiple CNS depressants and a substantial dose reduction should be considered
  - Patients should be carefully monitored
- CYP3A4 inhibitors
  - The concomitant use of drugs that inhibit CYP3A4 metabolizing enzymes (e.g., clarithromycin, fluconazole, erythromycin, certain antiretrovirals—see below) may result in an increase in fentanyl plasma concentrations
  - Concomitant use of CYP3A4 inhibitors is not recommended, unless patient is closely monitored
- CYP3A4 inducers
  - The concomitant use of drugs that induce CYP3A4 metabolizing enzymes may reduce the efficacy of the fentanyl patch, requiring a dose adjustment
  - After stopping treatment with a CYP3A4 inducer, the effects of the inducer will decline gradually, which may result in an increase in fentanyl plasma concentration
- MAO inhibitors
  - Fentanyl patch is contraindicated in patients taking MAOIs or within 14 days of use due to the risk of severe and unpredictable potentiation of opioid effects
- Serotonergic drugs
  - Concomitant use of a serotonergic agent, such as a selective serotonin re-uptake inhibitor (SSRI) or serotonin norepinephrine re-uptake inhibitor (SNRI) may increase the risk of serotonin syndrome
  - Use caution and monitor the patient closely if co-prescribed
- Partial agonists/antagonists
  - Partial agonists (e.g., buprenorphine) and antagonists (e.g., naltrexone) may induce withdrawal symptoms in individuals on the fentanyl patch, due to their high affinity for opioid receptors and low intrinsic activity
- Muscle relaxants
  - Concomitant use may lead to respiratory depression
  - Monitor patient for signs of respiratory depression and decrease dosage of fentanyl patch and/or muscle relaxant as necessary

[d] Sandoz Canada Inc. Sandoz fentanyl patch: Product monograph. Boucherville, Quebec 2020. https://www.sandoz.ca/sites/www.sandoz.ca/files/Sandoz%20Fentanyl%20Patch%20Product%20Monograph_0.pdf

- Diuretics
  - Opioids can reduce the efficacy of diuretics
  - Monitor patient for signs of diminished diuresis or effects on blood pressure
- Anticholinergic drugs
  - Concomitant use may increase risk of urinary retention and/or severe constipation
  - Monitor patient for signs of urinary retention or reduced gastric motility

SPECIAL CAUTION—Antiretoviral medications

There is a strong interaction between fentanyl and some antiretroviral (ARV) drugs used for HIV treatment. Certain ARV products, particularly those containing the "boosters" cobicistat or ritonavir, inhibit CYP3A4, which can lead to significant increases in fentanyl levels. These ARVs include combination tablets with elvitegravir-cobicistat (Stribild, Genvoya), darunavir-cobicistat (Prezcobix, Symtuza) and lopinavir-ritonavir (Kaletra), all ritonavir-boosted protease inhibitors, and unboosted atazanavir.

Individuals who are stable on a potentially-interacting ARV regimen may be started on fentanyl if they meet the above eligibility criteria; however, fentanyl titration should be slower than for other patients, and patients must be monitored closely for sedation.

In individuals who take potentially-interacting ARVs, and who might stop and restart ARVs without medical supervision, or who often miss ARV doses, starting fentanyl patch is not recommended, due to the risk of fluctuating fentanyl levels. Consider alternatives to fentanyl patch or reviewing for potential ARV regimen modification to avoid drug–drug interactions.

Individuals currently using the fentanyl patch are at risk of fentanyl toxicity if they start an ARV regimen including cobicistat or ritonavir. Modify the ARV regimen to avoid drug–drug interactions or monitor closely for fentanyl toxicity and reduce the fentanyl dose as required.

If an individual has already been stabilized on a fentanyl patch in combination with cobicistat or ritonavir, and the ARV regimen is subsequently changed to remove cobicistat/ritonavir, a fentanyl dose adjustment may be needed to manage opioid withdrawal symptoms.

A clinician who specializes in HIV care should be consulted prior to initiating or changing ARVs.

If any of these drug–drug interactions newly arise during care, notify the prescriber immediately.

4.0 Coverage

Special Authority coverage must be secured for each patient enrolled in a fentanyl patch program. Once Special Authority is approved, coverage is available through PharmaCare, including Plan G and Plan W for those eligible.

Once approved, the approval period lasts for one year, at which point coverage must be renewed. Note: Tegaderm occlusive dressing is not covered by PharmaCare.

In order to avoid delays:

- Complete **all** request form fields
- Write **legibly**
- **Sign** the form
- Include the **diagnosis**
- Submit a request **once** only

The following forms, resources, and pages provide relevant information on applying for Special Authority coverage for fentanyl patch:

- Limited Coverage Drugs—Fentanyl (Patch)
- Special Authority Request
- Submitting a Special Authority Request—Information for Prescribers
- Prescriber Checklist

5.0 Protocols and Procedures

The protocols outlined in this section are based on limited clinical experience. These protocols and processes may be updated as clinical experience increases.

Following assessment and confirmation of eligibility and confirmation of Special Authority coverage, the pre-application checklist should be completed prior to application of the first patch.

5.1 Informed Consent

The informed consent process should include a discussion and documentation of the potential risks and benefits of fentanyl patch prescribing as a safer supply option, as well as a discussion of continuing care and harm reduction education. This should include a discussion of patient goals, as well as which clinical and psychosocial parameters would indicate that the patient is benefitting from the intervention, and which clinical and psychosocial parameters would indicate that the patient is not benefitting from the intervention, and how the treatment plan would change if the patient is not benefitting. See Patient Benefit Assessment for more information on clinical and psychosocial parameters indicating benefit.

Prescribers should also provide education on the risk of ingesting multiple CNS depressants (e.g., opioids and benzodiazepines or alcohol).

5.2 Pre-application Checklist

Before applying the first patch, and following confirmation of eligibility and coverage, the following pre-application checklist must be completed by a prescriber or non-prescriber regulated health professional working within their scope and capability:

- ☐ Confirmatory urine drug test positive for opioids and negative for benzodiazepines
    - Note: Given increased adulteration of the illicit drug supply, individuals may be unintentionally exposed to benzodiazepines and benzodiazepine analogues. A UDT positive for benzodiazepines must be discussed with the prescriber prior to initiating this intervention (see Precautions for more information)
- ☐ Negative urine pregnancy test (if applicable)
- ☐ Baseline vital signs and weight
- ☐ PharmaNet review (check for benzodiazepines, OAT, iOAT, and any other prescribed medication)
- ☐ Provide education regarding potency of fentanyl patch and inherent significant risk to those without opioid tolerance (including other adults, children, and pets)

- ☐ Discuss the risk to pets in the case of a patch falling off and being stuck to a pet
- ☐ Confirm that prescriber approval for starting the patch program (with 2 prescriber approval when certain cautions exist, see Precautions)
- ☐ Confirm baseline liver and renal bloodwork results within past 3 months that have been reviewed by prescriber (not a requirement, but a consideration with other comorbidities)
- ☐ Set reminder for 11 months after approval date to reapply for Special Authority
- ☐ Confirm patient has had overdose training and received a take-home naloxone kit
- ☐ If patient receives OAT at another pharmacy, ensure pharmacy has been notified that patient is beginning fentanyl patch program, to avoid the patient being cut off of OAT
    - Indicating that the other medication can be dispensed on each prescription will prevent delays caused by the pharmacy calling the prescriber to double check
        - e.g., "Aware of potential drug interaction between x and y, OK to dispense."
- ☐ Provide education on the patch:
    - It is a slow release of medication over 72 hours
    - Leave the patch untouched with the clear occlusive dressing (Tegaderm) over top
    - If a patch falls off early, fold patch so that adhesive side sticks to itself and secure the patch in a safe place until able to bring it to the clinic
    - High heat can affect metabolism of drug from patch, such as having a fever or hot bath
- ☐ Discuss patient goals and indicators that the patient is benefitting and should continue to receive this intervention, including
    - Current substance use (amount, frequency, route)
    - Recent overdose history
    - Visits to emergency department/acute care since last assessment
    - Cravings
    - Withdrawal symptoms
    - Review of overdose prevention safety plan
        - How is the patient currently keeping themselves safe and preventing overdose?
        - What support do they need?
    - Overall wellbeing
    - Income/employment
    - Patient-identified goals
    - Seeking or gaining employment or volunteer activities
    - Integrating new activities
    - Reconnecting with family and friends (e.g., improved social connection)
    - Housed/underhoused

- Care team
  - Who is involved in their care?
  - What connections do they have to the community?
- Missed doses
- Urine drug test results

5.3 Patch Visit Assessment

The following assessment should be performed and documented at every patch change. This assessment can be performed by prescribers or regulated health professionals acting within their scope and competency. If the assessment is performed by a non-prescriber regulated health professional, the prescriber should be consulted if any concerns are raised by the assessment. If performed by a non-prescriber regulated health professional outside the program site, a process must be in place to ensure the visit assessment is communicated to the prescriber and team and documented in the patient's chart (see Program Models).

Subjective

- How the patient is doing
- How well the current treatment is supporting the patient's goals
- Any changes the patient would like to be better supported
- Substance use since last visit
  - Specify drug, amount, and route of use
- Any overdoses since last visit?
- How the patient is keeping themself safe (e.g., preventing overdoses)
- How the patient's physical and mental health are
- What the patient has been doing to keep themselves well
- Any new prescription medications since last visit
- Mood
- Sleep

Objective

- General appearance
- Signs of intoxication
  - Severe agitation
  - Dyskinesia
  - Sedation
  - Slurred speech

    - Smelling of alcohol
- Level of consciousness
- Pupil size
- Number and location of patches
- Any signs of tampering
    - e.g., Tegaderm not intact, patient removed patches prior to assessment
- Vitals (monthly)
- Weight (monthly)
- UDT (monthly)
    - If a patient has not provided a UDT in 3 months, advise that their next dose will be held until they can provide a sample
- Any other health-related assessments

Assessment

- Number of patches removed and safely disposed of
- Flovent spray applied prior to patch application (Y/N)
    - Note: Flovent reduces skin reactions; not all patients will require Flovent application
- Number of patches applied (and dosages) and location
- Covered with Tegaderm or Mepore dressing, signed, and dated
    - Note: Occlusive dressings help secure the patch to the skin and prevent accidental exposure to others

Patient Benefit Assessment (Monthly)

- Current substance use (amount, frequency)
- Recent overdose history
- Visits to emergency department/acute care since last assessment
- Cravings
- Withdrawal symptoms
- Overall wellbeing
- Income/employment
- Patient-identified goals
- Seeking or gaining employment or volunteer activities
- Integrating new activities
- Reconnecting with family and friends (e.g., improved social connection)
- Attaining or maintaining safe housing
- Accessing social services
- Missed doses
- Urine drug test results

Plan

- Next dose due
- Expected dose
- Follow up or referral to other services

In addition, provide whole person care, including assessing for other issues not related to fentanyl patch administration, including:

- Wound and infections
- Pregnancy and contraceptive management needs when applicable
- Social determinants of health
    - Goals
    - Needs to support connection and stabilization
    - Barriers to improved health and wellbeing

5.4 Patch Application and Removal Procedures

5.4.i Application

The patient's chart and medication administration records (MAR) should be checked in order to ascertain when the last patch change occurred and how many patches were placed, in order to ensure removal of all patches before the new application. There is ongoing fentanyl absorption from a patch for many days after it is due to be changed.

A prescriber or non-prescriber regulated health professional working within their scope and competency should perform patch administration. Institution or site-specific protocols for handling controlled substances should be followed.

Special caution:
Wear gloves to avoid the transfer of medication. If you have been exposed to the fentanyl patch (e.g., not wearing gloves and adheres to skin), remove the patch immediately and irrigate the exposed area under cold water. Call Poison Control (604-682-5050). Do not wash the exposed area with soap or any solvent, as this will increase absorption. Follow program protocols regarding notification (e.g., nurse lead).

Generally, the following procedure should be followed:

- Follow medication standards
- Assess for the current medication order
- Assess where the original patch was administered on the patients' body
- Locate and remove the old patch(es) before applying a new one. Check beneath the skin folds, if necessary
    - All old patches must be removed, regardless of how long they have been in place
    - Using gloves, remove the patch and carefully fold adhesive (medicated) sides together. Avoid contact with the medication. Dispose of as per removal procedure below.
    - Ensure to rotate sites. Patches should not be reapplied to the same site within 7 days to avoid skin irritation. Refer to Appendix 5 for a diagram of patch rotation sites
- Select a flat surface for application. Areas in the upper torso are most ideal: arms, chest, or back. Rotate application sites at each patch change
- On the outer edge of the actual patch write the date and time of when the patch was applied and initial
- Using gloves, apply the patch to a clean, dry, hairless area. The skin should not be burned, cut, irritated, or damaged in any way. Hair should be clipped, not shaved. Press firmly for 10–30 seconds
    - Alcohol, lotions, oils, soaps and shaving may change permeability of the skin
    - Use only water to clean the application site
    - For clients who experience skin irritation related to the fentanyl patch or covering dressing, Flovent can be misted on the skin prior to each patch application
- Do not apply heating pads or hot water bottles to the site due to potential increased drug absorption
- Cover with occlusive dressing (e.g., Tegaderm or Mepore) to secure patch. Date and sign the patch
- Leave patch on for the time period indicted in the prescriber's order. When a dose is increased or decreased, remove the old patch(es) immediately and apply the new patch(es). Do not wait until the next scheduled change
- Post-dose assessment: It can take up to 12 hours for patch to take effect after application and it takes 17 hours or more for serum concentrations to fall by 50% when patch removed. Educate the patients to self-monitor for adverse reactions for at least 12 hours after application
- Ask patient to check the patch(es) regularly to ensure application is intact
- Document in MAR of date, time, and location of application. Two regulated health professionals (e.g., nurses, pharmacists, prescribers) to sign for disposal of previous patch
- Document in Narcotic Record and EMR

5.4.ii Removal

- Removal of the previous fentanyl patch or patches requires inspection for any damage or tampering
    - If the patch is not intact, alert the prescriber before proceeding
    - If patch falls off prior to next scheduled application, contact prescriber for dose directions
- Using gloves, remove patch from the patient's skin. Fold the patch in half so that the adhesive side is stuck to itself
- Follow health authority protocol for disposal of controlled substances

5.4.iii Titrating patients

- If a patient is in the titration phase, complete the patch visit assessment, and determine if they would like to go up on their dose, or remain at their current dose
- If the patient would like to go up on the dose, confirm that they have been on the current dose for at least 2 patch changes (that is, 3 consecutive patches at the same dose), document your assessment, and consult the prescriber
- The prescriber may want to see the patient for a visit for each titration, or they may feel comfortable going up on a dose based on the case conference with the non-prescriber regulated health professional (depending on health authority policies)
- The case conference (e.g., prescriber/non-prescriber regulated health professional and any other team members) must be documented
- Fax the new prescription to the patient's pharmacy
    - Note: The original prescription should be sent to the pharmacy as soon as possible
- Apply the new patch dose to the patient as per the patch application protocol

5.4.iv Maintenance patients

- If the patch is intact and the patient is at a therapeutic dose, apply the patch(es) for the prescribed dose, rotate the site to a different area of skin, as per the patch application protocol
- The patch change schedule will depend on program or pharmacy hours and capacity and patient preferences. A clearly established schedule is important
    - Example patch schedules that have been used include:
        - Monday/Wednesday/Friday (3 per week)
        - q2d dosing (7 days per week program)
        - q3d dosing (7 days per week program)
- Be cautious when a combination of patches is required to obtain the correct dose

- Confirm the correct combination of patches before application
  - Consider having another clinician or staff member double-check, if feasible
- If the wrong patches are administered, follow health authority protocol for disposal of controlled substances. This must be documented and the prescriber must be notified

5.5 Titration Methods

Note: The protocols outlined in this section are based on limited clinical experience. Additional titration methods may be developed as clinical experience increases.

There are two options available to initiate the fentanyl patch. The first involves titrating on to SROM to a maintenance dose and then converting to the fentanyl patch. The second involves titrating the fentanyl patch alone.

Fentanyl patch dose and oral OAT dose cannot be titrated at the same time.

Note: **All dose changes must be performed by a physician or nurse practitioner, and require a chart note for documentation.**

5.5.i Slow-release Oral Morphine to Fentanyl Patch

Patients can undergo an SROM titration, as per the SROM titration schedule outlined in the BCCSU Opioid Use Disorder Practice Update. When they have reached a dose where they are comfortable (e.g., managing withdrawal symptoms and cravings) the prescriber can convert the dose over to the fentanyl patch, with a maximum starting dose of 300mcg/hr (see below for instructions on calculating dose and Appendix 4 for a conversion table).

Note: If a patient is on multiple oral OAT medications, they should be transitioned to SROM alone (e.g., up-titrate SROM dose while lowering methadone dose) prior to starting fentanyl patch.

Calculating Dose

Typically, when converting between opioids, a 25% dose reduction is required to account for incomplete cross tolerance. However, the conversion charts in fentanyl patch product monographs are more conservative than conversion charts for other opioids, in order to minimize the risk of overdose when switching to the fentanyl patch. For this reason, a dose reduction is not typically required when switching from SROM to fentanyl patch, to a maximum starting dose of 300mcg/hr fentanyl patch. See Appendix 4 for a conversion table.

A 25% dose reduction from the stable SROM dose may result in significant under-dosing upon rotation to the patch, unless the reason for a dose reduction is not related to the issue of cross tolerance. If clinically indicated (e.g., significant concern about tolerance), a smaller dose reduction (< 25% may be considered).

Bridging Opioids

While transitioning from SROM to fentanyl patch, most patients will require some PRN short-acting opioids to alleviate discomfort during the transition.

- The prescribing protocol in BCCSU's Opioid Use Care Practice Update may be used
  - Prescribe hydromorphone tablets 8mg 1–2 tablets q1h up to 14 tablets per day PRN for dose titration to fentanyl
- Hydromorphone tablets may be dispensed as carries, at the discretion of the prescriber, with detailed education to the patient that this is only for the duration of titration onto fentanyl patch
- Adjust based on fentanyl patch dose and known opioid tolerance

Administration of Patch

The fentanyl patch(es) are ideally administered 12 hours after the last SROM oral dose, as it takes 12 hours for the patch to start to take effect, and 24 hours for the patch to reach the expected serum concentration.

Slow-release oral morphine remains at steady state for 24 hours, then serum concentration drops quickly. This schedule provides a smooth cross titration over 24 hours.

However, 12 hours post-SROM dose may be challenging due to program hours of operation. Less or more time may appropriate for this change, as the clinician is able to accommodate with clinic hours; in practice, the patch has generally been started the same day as the patient's last dose of SROM.

5.5.ii Fentanyl Patch Only Titration

There are two fentanyl patch titration options for individuals not currently on OAT, depending on the person's known tolerance.

Patches can be changed every 2–3 days. After 3 consecutive doses (or 2 patch changes at the same dose), the dose can be increased by 25–50mcg.

Unknown Tolerance

For individuals with an unknown tolerance, the below titration schedule can be used.

Starting Dose	Weekly Increase
25mcg	25–50mcg

An example titration in a 7-day per week program with patch changes every 2 days follows.

Day	Dose
1	25mcg
2	–
3	25mcg
4	–
5	25mcg
6	–
7	50mcg
8	–
9	50mcg
10	–
11	50mcg
12	–
13	75mcg

Known High Tolerance

For individuals with a known high tolerance, a more rapid titration schedule can be used. Examples of when a more rapid titration schedule may be appropriate include ongoing documentation of fentanyl-positive urine drug tests, and recent experience with the fentanyl patch; however, prescribers should be aware that fentanyl may be detected for up to a month in the context of chronic, ongoing use.

With the rapid titration schedule, the fentanyl patch dose can be adjusted after two consecutive doses.

An example titration in a 7-day per week program with patch changes every 2 days follows.

Day	Dose
1	50mcg
2	–
3	50mcg
4	–
5	100mcg
6	–
7	100mcg
8	–
9	150mcg
10	–
11	150mcg
12	–
13	175mcg

An example schedule with doses Monday/Wednesday/Friday follows.

Day	Dose
Monday	50mcg
Wednesday	50mcg
Friday	100mcg
Monday	100mcg
Wednesday	150mcg
Friday	150mcg

Bridging Opioids

While titrating the fentanyl patch, most patients will require some PRN short-acting opioids to alleviate discomfort during the titration.

- The prescribing protocol in BCCSU's Opioid Use Disorder Care Practice Update may be used
  - Prescribe hydromorphone tablets 8mg 1–2 tablets q1h up to 14 tablets per day PRN for dose titration to fentanyl
- Hydromorphone tablets may be dispensed as carries, at the discretion of the prescriber, with detailed education to the patient that this is only for the duration of titration onto fentanyl patch
- Adjust based on fentanyl patch dose and known opioid tolerance

5.5.iii Fentanyl Patch Titration for Individuals on OAT

Some individuals on OAT may be experiencing benefits from their OAT medication but continue to use illicit opioids to seek euphoria, manage cravings, and withdrawal symptoms. Based on patient preference and goals along with clinical judgment, the addition of a fentanyl patch may help reduce their reliance on the illicit drug supply and reduce associated harms.

Ideally, the same health provider is prescribing both OAT and fentanyl patch. If this is not possible, communication with the OAT prescriber should be documented in the patient's medical record.

Once a fentanyl patch titration has begun, the patient's OAT dose should not be increased until they have been on a stable fentanyl patch dose for 1 week. The OAT dose can be decreased at any point during fentanyl patch titration.

For those on a stable dose of OAT, their fentanyl dose can be adjusted by 25–50mcg after two patch changes at each dose. When titrating, consider if the person is still feeling withdrawal or cravings.

Day	Unknown Tolerance	High Tolerance
Monday	25mcg	50mcg
Wednesday	25mcg	50mcg
Friday	50mcg	100mcg
Monday	50mcg	100mcg
Wednesday	100mcg	150mcg
Friday	100mcg	150mcg
Monday	125mcg	200mcg

Individuals with a known high tolerance (e.g., documented fentanyl-positive urines and report large amounts of fentanyl use) may be started at 50mcg/hr and can increase their weekly dose by 10–20% or 50mcg (whichever is higher).

The fentanyl patch titration schedule is considerably slower than oral OAT titrations. When someone is titrating up on their fentanyl patch, oral OAT cannot also be titrated up the same day; the OAT dose may be tapered down on the same day as a fentanyl patch dose increase.

Fentanyl Patch and OAT Co-Prescribing

In order to avoid mixing long-acting opioids, the goal should be to taper the OAT dose down and to stabilize on the fentanyl patch alone. However, in some exceptional, well-documented circumstances, the patient may remain on both the patch and a low dose of oral OAT.

Exercise caution when doing cross titrations between OAT and the fentanyl patch.

Fentanyl Patch and Injectable Opioid Agonist Treatment

Clients on iOAT have the option of using the fentanyl patch as their long-acting opioid medication to pair with their injections. The fentanyl patch would replace their long-acting OAT medication (i.e., methadone or SROM).

In this circumstance, the patient has to be fully discontinued from their oral long-acting OAT medication before starting the fentanyl patch. They cannot be on iOAT, oral OAT, and the fentanyl patch at the same time.

The titration schedule would be the same as if starting the fentanyl patch while on oral OAT (see 9.3 Fentanyl Patch Titration for Individuals on OAT, above), with a start at 50mcg, and an increase weekly or every second patch change, depending on clinical discretion.

Some patients may benefit from a fixed dose PRN iOAT schedule while doing the patch titration.

5.6 Maintenance

There is no maximum dose in this program[e]; however, the physical room to apply patches may create an upper limit for some patients. Each dose increase is performed by a prescriber and

[e] It should be noted that 1000mcg is a typical dose in the PHS Fentanyl Patch Program.

includes patient evaluation, history, discussion of goals, physical exam, and mental status exam. Above 1000mcg is a watchful dose where the prescriber should be more cautious and consider asking a second prescriber to review the patient's chart or consult the 24/7 Addiction Medicine Clinician Support Line.

Once the patient is on their maintenance dose, they will present to the care provider three times weekly for patch changes, ongoing (e.g., Monday/Wednesday/Friday). Each visit should include a Patch Visit Assessment and be documented in the patient's medical record.

5.7 Prescriptions

Before writing the prescription, confirm Special Authority approval by checking the chart for confirmation fax, or contacting Health Insurance British Columbia (HIBC) directly at 1-866-456-6950.

5.7.i Duration of prescription

Titration prescriptions should be 1–4 weeks (3–12 doses) in duration. Ideally prescriptions should be dispensed on the day of application, however, dispensation will differ with program needs. For example, some programs may arrange pharmacy delivery weekly, while others will have pharmacy deliver the day before the patch is due. Programs with on-site pharmacies could have day-of dispensation to nursing or other staff.

The length of maintenance prescriptions will depend on each program's operational needs and capacity; however, prescriptions should be written in a way that avoids the prescription ending on a day that a prescriber is not available (e.g., weekend or statutory holiday). As with titration prescriptions, maintenance prescriptions will differ with program needs. Ideally, maintenance prescriptions should be dispensed on the day of application.

It is best practice to make prescriptions end on a day when the same prescriber is in clinic for continuity of care. Ensure that the prescription does not end on days the program is closed (e.g., weekends or statutory holidays).

5.7.ii Writing Prescriptions

When ordering a fentanyl patch the physician will indicate on the prescription:

> **Medication:** Fentanyl patch
> **Quantity:** Refers to the total number of patches you are prescribing
>
> For example: "Fentanyl 200mcg/hr patch. Patch change Mon/Wed/Fri. Dispense 6 patches every 7 days"
>
> Then the pharmacy can interpret this and dispense 12 x 100mcg/hr patches each week x 2 weeks[f]
>
> **Directions for use:**
> Fentanyl patch 200mcg/hour
> Patch change Monday/Wednesday/Friday by nurse
> Dispense on [patch change day or weekly dispense depending on your location protocol]
> Deliver to [site]
> Date range
> SA

An example prescription follows.

[f] Note, the prescribed strength can be achieved through multiple patches (e.g., 2 x 100mg patches or 4 x 50mg patches) if required (e.g., for doses that do not align with available patch strengths or due to product shortage)

----------BC CONTROLLED PRESCRIPTION FORM----------

PERSONAL HEALTH NO. 1234 567 890

PRESCRIBING DATE 05 (DAY) 07 (MONTH) 22 (YEAR)

PATIENT NAME FIRST (GIVEN): Generic | MIDDLE / INITIAL: A | LAST (SURNAME): Name

PATIENT ADDRESS STREET: 123 Main Street | CITY: Victoria | PROVINCE: BC

DATE OF BIRTH 16 (DAY) 12 (MONTH) 76 (YEAR)

Rx: DRUG NAME AND STRENGTH — ONLY ONE DRUG PER FORM — **VOID IF ALTERED**

Fentanyl patch 100mcg/hr

QUANTITY (IN UNITS)

NUMERIC: 12 patches | ALPHA: Twelve patches

THIS AREA MUST BE COMPLETED IN FULL FOR OPIOID AGONIST TREATMENT (OAT)

START DATE: _____ (DAY) _____ (MONTH) _____ (YEAR) **END DATE:** _____ (DAY) _____ (MONTH) _____ (YEAR)

TOTAL DAILY DOSE NUMERIC | ALPHA | mg/day

NUMBER OF DAYS PER WEEK OF DAILY WITNESSED INGESTION NUMERIC | ALPHA

☐ **NOT AUTHORIZED FOR DELIVERY**

DIRECTION FOR USE, INDICATION FOR THERAPY, OR SPECIAL INSTRUCTIONS

Fentanyl patch 200mcg/hour
Patch change Monday/Wednesday/Friday by nurse
Weekly dispense on Monday
Deliver to Generic OAT Clinic [123 Health St]
Rx: July 8 - July 21

SA

NO REFILLS PERMITTED

VOID AFTER 5 DAYS
UNLESS PRESCRIPTION IS FOR OAT

PRESCRIBER'S SIGNATURE

PRESCRIBER'S CONTACT INFORMATION
Generic Prescriber
123 Health Street
Victoria BC V8Z 4H4
Tel: 250-999-9911
Fax: 250-999-9119

91-09898
PRESCRIBER ID

FOLIO

PHARMACY USE ONLY

RECEIVED BY: PATIENT OR AGENT SIGNATURE

SIGNATURE OF DISPENSING PHARMACIST

PHARMACY COPY - PRESS HARD YOU ARE MAKING 2 COPIES
PRINTED IN BRITISH COLUMBIA

5.8 Missed Doses

Note: This missed dose protocol assumes that the patch is still on the skin, and intact. If the patch is not in situ and the patient cannot present the patch, refer to Diversion in this document.

In models in which a non-prescriber regulated health professional provides patch changes, the prescriber must be consulted in the event of missed doses. Count the days beginning with the first day after a patch change as Day 1 (see Appendix 6 for missed dose tables and a decision support tool). Each patch contains enough medication to last for 3 days (72 hours), but due to the accumulation of fentanyl, and based on clinical experience, this protocol does not require a dose decrease until 6 days after the last patch change.

Days Missed Since Last Patch Change	Action
≤5	No change to dose
6–7	Decrease dose by 30%
8–9	Decrease dose by 50%
10–14	Re-start titration from beginning
≥15	See prescriber for assessment and to discuss plan to restart

For dose decreases, round up to the nearest 25mcg/hr. For example, if someone is on 175mcg/hr, and needs a 50% dose reduction, they would receive 100mcg/hr.

For restarts, patients should generally be restarted at 50mcg/hr; however, prescribers may decide on a case-by-case basis to restart at 100mcg/hr. Patient safety, tolerance, and risk of undertreatment should be balanced when deciding on a starting dose for retitration. For example:

- An individual who missed a weekend and received no OAT (e.g., incarceration, unexpected travel) should be restarted on 50mcg
- An individual who missed 10 days and reports they were using large amounts of fentanyl multiple times per day may be started at 100mcg

When performing restarts, dosing should revert to the usual patch change schedule (e.g., Monday/Wednesday/Friday) by the second dose.

Missed doses are to be destroyed per regional health authority requirements at the earliest possible opportunity. They should not be held and provided to the specified patient or to any other patient at a later time.

See Appendix 6 for example case scenarios of missed doses.

5.8.i Missed Patch Change During Planned Dose Increase

Days Missed Since Last Patch Change	Action
≤3	Increase dose as planned
4–5	Maintain previous stable dose
6–7	Decrease dose by 30%
8-9	Decrease dose by 50%
10–14	Re-start titration from beginning
>15	See prescriber for assessment and to discuss plan to restart

See Appendix 6 for example case scenarios of missed doses.

5.8.ii Re-titration

Clients who have been on a stable dose of the fentanyl patch for at least 4 weeks and have had a dose reduction due to missed doses may be eligible for a more rapid re-titration. This will be decided by the prescriber on a case-by-case basis.

The prescriber may decide to restart at 100mcg. The dose can be increased by 50mcg or 10–20% (whichever is greater) at every patch change.

5.9 Documentation

- All clinical care related to assessment, patch changes, and patch disposals must be documented per program requirements and regulatory medication management standards, including documentation on a medication administration record if administered by a non-prescriber.
- Patches must be accounted for in the narcotic count.
- Follow health authority procedure for narcotic counts.

6.0 Clinical Considerations Regarding Dosing

Clinicians should consider the following when making adjustments to dosing:

- Client's body composition.
  - Those with low body fat may require more frequent patch changes
    - Fentanyl's lipophilic nature causes it to be stored in body fat; those with low body fat may not build up a storage of fentanyl and thus require more frequent patch changes
  - This may not be relevant for programs that change patches every 48 hours
- Drug-drug interactions
  - Including CYP inhibitors and inducers (commonly prescribed—ritonavir, fluoxetine, paroxetine, trimethoprim/sulfamethoxazole, ciprofloxacin, fluconazole, cimetidine)
- High heat can affect metabolism of drug from patch, such as having a fever or hot bath/shower
- Performing intense physical activity can increase absorption

Prescribers are encouraged to consult their pharmacist when considering these clinical factors.

Note: Doses increases and decreases always require a documented assessment and prescriber's order. The pharmacy should be contacted to ensure they have the appropriate number and strength of patches in stock.

[g] Mather LE. Clinical pharmacokinetics of fentanyl and its newer derivatives. Clinical pharmacokinetics. 1983; 8(5):422-446. 10.2165/00003088-198308050-00004

7.0 Urine Drug Testing

Clients will be required to provide monthly point-of-care urine drug testing, with confirmatory testing per prescriber, for this program, including a fentanyl confirmation test. Ongoing use of illicit fentanyl will not be discerned by urine drug testing, unless the person is using illicit fentanyl analogues such as carfentanil or furanyl-fentanyl, which can only be detected through confirmatory testing. The goal is to have cessation of opioid use outside the program.

Ongoing positive urine drug tests are not a reason to discharge someone from the program as the patient may have experienced other benefits such as decreased illicit drug use, housing stability, and engagement in primary care.

8.0 Assessment and Continuing Care

Following an initial trial period and at regular intervals, a thorough assessment of clinical and psychosocial indicators, as well as patient goals, should be performed, to determine whether the patient is benefitting from the intervention. The results of this assessment along with expert consultation, where appropriate, and patient preference should inform the decision to continue or discontinue this intervention. Clear indication of patient benefit, supported by clinical judgment and aligned with patient goals, supports the continuation of this intervention. Clinical experience at PHS has found that it takes 3–6 months on average to determine if the patient is benefitting from the intervention. An assessment of the following measures is included in the Patch Visit Assessment template, above.

Indications that the patient is benefitting

Clinical

- Reduction or cessation of illicit substance use
- Reduction in overdoses
- Reduced acute care visits
- Lack of cravings
- Management of withdrawal symptoms
- Improved overall wellbeing

Psychosocial[h]

- Reduced need to engage in high-risk and criminalized activities (e.g., sex work) to support substance use
- Seeking or gaining employment or volunteer activities
- Integrating new activities
- Reconnecting with family and friends (e.g., improved social functioning)
- Attaining or maintaining safe housing and accessing other social services

[h] MStructural barriers such as lack of affordable and accessible housing or suitable employment may make these difficult to achieve for individuals who are otherwise benefitting from the intervention. Improvements in these domains are not required, but—where possible—may be additional indications that the patient is benefitting and should continue to receive this intervention.

Indications that the patient is not benefitting

Clinical

- No change or increased intensity of illicit substance use
- No change or increased overdose risk
- Ongoing cravings and withdrawal symptoms
- Urine drug tests consistently negative for prescribed substance or other indications of diversion
- No change in wellbeing
- Consistently missed doses

If thorough assessment of patient-identified goals and indicators of clinical and psychosocial stability indicate that the patient is not benefitting from the intervention despite attempts at optimizing dosing and psychosocial supports, it may be appropriate to discontinue the intervention and explore alternative harm reduction, treatment, and recovery options. Alternative options may include initiating opioid agonist treatment, increasing existing OAT dose, trial of another opioid medication available through the pharmaceutical alternatives policy, or a combination. The assessment, treatment plan, and rationale should be documented in the patient's medical record. It may be helpful to consult the 24/7 Line for assistance in determining whether the intervention is or is not beneficial, and next steps.

An example checklist that may be included in regular assessments is available in Appendix 2.

8.1 Ongoing Monitoring

The following should be performed at least monthly:

- If patient is not seen by the prescriber for each prescription refill, case conference review by the clinical team
  - During this case conference review, the team should discuss engagement, progress to recovery, and any clinical concerns for each patient
  - Note: Case conferences will differ by program and may include only the prescriber and non-prescriber regulated health professional, or a larger team, as appropriate
- Vitals measured and recorded (monthly)
- Urine drug testing (monthly)
- Weight measured and recorded (monthly)
- Visit with prescriber

9.0 Diversion

The following are considered to be diversion of medication:

- Missing patches that cannot be accounted for
- A patch that has signs of tampering (cut, damaged, or changed in any way)

The following is not considered diversion:

- When patient reports that their sweat or shower caused the patch to fall off and are able to present the intact patch in a timely manner

Each program may develop their own approach to diversion, prioritizing patient safety, continuity of care, and community safety. The reasons for diversion should be documented, discussed and addressed where possible. Patients should not be abruptly discontinued from the fentanyl patch without being offered transition to OAT.

10.0 Holding Medication

- If it is determined the patient should NOT receive their fentanyl patch (e.g., due to intoxication), the doses will be held and documented
- If the patient is too intoxicated based on pre-dose assessment they can be asked to return in a few hours for a reassessment:
    - This must be explained to the patient and documented
- Client needs to be reminded of the risks of administering their medication if they have used other medication or street drugs
- Oral OAT doses will be adjusted or held for reassessment as per *A Guideline for the Clinical Management of Opioid Use Disorder*'s missed dose protocols

11.0 Discontinuation

Individuals may discontinue the fentanyl patch due to patient choice to transition to oral OAT or due to repeated diversion.

11.1 Voluntary Transition to Oral OAT

Expert advice should be sought, if needed, when calculating the dose conversion. The conversion table in Appendix 4 should not be used when converting fentanyl patch dose to oral OAT. The conversation to fentanyl patch is conservative and will result in an overestimation of the dose of the oral opioid and may result in an overdose. For patients who chose to transition to oral OAT alone, their fentanyl patch should be stopped and converted to an equivalent SROM dose. Due to the variability in methadone metabolism, patients should not be directly converted to oral methadone.

If the patient prefers methadone for their oral OAT medication, they should be converted and stabilized onto SROM, and then transition from SROM to methadone following the guidance in the BCCSU's *Guideline for the Clinical Management of Opioid Use Disorder*.

11.2 Transition Due to Repeated Diversion

11.2.i Fentanyl Patch Alone

Individuals who are on the fentanyl patch alone who are being discharged from the program due to diversion should be offered a standard oral OAT titration following the guidance in the BCCSU's *Guideline for the Clinical Management of Opioid Use Disorder* and Opioid Use Disorder Practice Update.

Titration of OAT should not begin until the day after patch removal. Given that the OAT start is due to diversion, OAT can be started immediately, in the absence of other contraindications.

11.2.ii Fentanyl Patch and OAT

Individuals who are on both the fentanyl patch and OAT who are being discharged from the program due to diversion should be continued on their OAT dose following discontinuation of the

patch. The dose can be increased following a standard dose increase process (see *Guideline for the Clinical Management of Opioid Use Disorder*); however, **titration should not begin until at least 17 hours after the patch has been removed**.

Appendix 1: Intake Form (EMR Typing Template)

Substance History

Substance(s) currently using: «»
How many overdose have you had: «»
    In the last month: «» in the last 6 months: «»
Do you have a THN kit («Y/N»)
    Offer THN and provide education
Are you on OAT program currently? («Y/N»)
    If no, have you ever been on OAT in the past? («Y/N»)

Medical History

Are you receiving primary care: («Y/N»)
    If yes, primary care physician: «»
    Other provider: «»
Medical condition/co-morbidities: «»
Pharmacy: «»
Allergies: «»

Clinical

Signs/symptoms of substance withdrawal: «»
Signs/symptoms of sedation: «»
To do:

- Vitals: «BP_, RR_, PR_, Temp_, sO2_»
- PharmaNet review: «»
- UDS result: «»
- Pregnancy test (for females)
- HIV/STI/HCV testing
- Collect pending bloodwork

Social Status

Housing status: «Apt/house, SRO, shelter: , NFA, other: »
Financial income source: «Employed, PWD, social assistance, other: »

Client Priorities and Goals

What are your short-term goals: «»
What are your long-term goals: «»
Plans/strategies to achieve goals: «»

Signs Patient is Benefitting from Program

Current illicit substance use (amount, frequency): «»
Recent overdose history: «»
Visits to acute care since last assessment: «»
Cravings: «»
Withdrawal symptoms: «»
Overall wellbeing: «»
Engagement in high-risk and criminalized activities (e.g., sex work) to support substance use: «»
Seeking or gaining employment or volunteer activities: «»
Integrating new activities: «»
Reconnecting with family and friends (e.g., improved social functioning): «»
Attaining or maintaining safe housing: «»
Accessing social services: «»
Missed doses: «»
Urine drug test results: «»

Agreement and Consent

Orientation Form: («Y/N»)
Program consent: («Y/N»)

Appendix 2: Ongoing Monitoring—Patient Benefit Assessment (EMR Typing Template)

Current illicit substance use (amount, frequency): «»
Recent overdose history: «»
Visits to acute care since last assessment: «»
Cravings: «»
Withdrawal symptoms: «»
Overall wellbeing: «»
Engagement in high-risk and criminalized activities (e.g., sex work) to support substance use: «»
Seeking or gaining employment or volunteer activities: «»
Integrating new activities: «»
Reconnecting with family and friends (e.g., improved social functioning): «»
Attaining safe housing: «»
Accessing social services: «»
Missed doses: «»
Urine drug test results: «»

Appendix 3: Example Consent Form

Fentanyl patch programs are trialing fentanyl patches to help people with opioid use disorder to separate from the illicit drug supply and reduce their risk of overdose. Currently, this practice does not have an evidence base to support it, and it is considered an "off-label" use of the medication. This approach has been trialed in the Downtown Eastside in Vancouver, BC, with some positive benefits.

Potential benefits of this program may include:

- Reduced cravings and withdrawal symptoms
- Reduced illicit opioid use
- Reduced overdose risk
- Improved overall wellbeing

In this program, I understand and agree that:

1. I am being enrolled in this program to try to decrease my overdose risk.
2. For safety reasons, the program staff will contact my current health care providers to review my enrollment in this program.
3. My prescriber will work with me to develop a clinical plan and set goals. These goals will be reviewed regularly and changed as needed.
4. In addition to the program medication, I can choose to participate in counselling, peer support groups, or other groups. My prescriber can review these resources with me.
5. I can expect confidentiality from my medical team about my care, and my personal information will not be shared.
6. I can choose to stop this program at any time and my prescriber will help create a plan with alternative options for me.
7. I will not remove my fentanyl patch or tamper with it in any way. If the patch falls off, I will report to the clinic as soon as possible with the patches for the team to inspect and dispose of. I understand that failing to return the patches that fell off will be considered diversion and will result in [program diversion rules].
8. During the duration of this program, I will only receive opioids or other sedative prescriptions (e.g., sleeping pills, benzodiazepines) from my prescriber here, and I will notify my prescriber if I receive these medications elsewhere.
9. If I am not benefitting from the program, I will have a discussion with my care team and make a plan for different medication options.
10. While on this program, I will not operate a motor vehicle or heavy machinery.

I understand that I am expected to:

1. Provide urine for testing on a regular basis.
2. Avoid using alcohol, benzodiazepines, or other drugs that, when combined with opioids, can lead to overdose or other serious harms.
3. Notify my prescriber if I become pregnant, suspect that I am pregnant, or am planning to become pregnant.
4. Notify my prescriber if my health changes or I start taking any new medications
5. Notify any health care provider in my care that I am in this program.

Appendix 4: Conversion Chart

Morphine Equivalence Table

The following conversion table can be used when converting oral opioids to fentanyl patch. However, it should be noted that this chart was developed for palliative analgesia dose conversions, so should be used with caution. When converting from slow-release oral morphine to fentanyl patch, a maximum starting dose of 300mcg/hr should be observed.

Typically, when converting between opioids, a 25% dose reduction is required to account for incomplete cross tolerance. However, the conversion charts in fentanyl patch product monographs are more conservative than conversion charts for other opioids, in order to minimize the risk of overdose when switching to the fentanyl patch. For this reason, a dose reduction is not typically required when switching from SROM to fentanyl patch, to a maximum starting dose of 300mcg/hr fentanyl patch.

A 25% dose reduction from the stable SROM dose may result in significant under-dosing upon rotation to the patch, unless the reason for a dose reduction is not related to the issue of cross tolerance. If clinically indicated (e.g., significant concern about tolerance), a smaller dose reduction (< 25% may be considered).

Note: This conversion table should not be used when converting fentanyl patch dose to oral OAT. The conversion to fentanyl patch is conservative and will result in an overestimation of the dose of the oral opioid and may result in an overdose.

Morphine Milligram Equivalents (MME) Table

Calculating Morphine Milligram Equivalents (MME)		
Opioid (Oral Dose)	Dose Equivalent to oral Morphine Sulfate (30mg) as example	Conversion Factor (convert to MME)
Morphine	30	1
Codeine	200	0.15
Oxycodone	20	1.5
Hydromorphone	6	5
Meperidine	300	0.1
Methadone & Tramadol	Dose equivalents unreliable	
Transdermal fentanyl	60 to 134mg oral morphine = 25mcg/hr 135 to 179mg oral morphine = 37mcg/hr 180 to 224mg oral morphine = 50mcg/hr 225 to 269mg oral morphine = 62mcg/hr 270 to 314mg oral morphine = 75mcg/hr 315 to 359mg oral morphine = 87mcg/hr 360 to 404mg oral morphine = 100mcg/hr	

To Calculate the total daily MME dose to start Transdermal Fentanyl:

1. Determine the total daily doses of current opioid medication
2. Convert each dose into MMEs by multiplying the dose by the conversion factor.
3. If more than one opioid medication, add together THEN
4. Refer to the chart above for fentanyl patch dose
5. If fentanyl patch dose is higher than 100mcg/hr consult another experienced prescriber or the 24/7 Line (778-945-7619)

A conversion calculation would follow these steps:

1. Patient taking 400mg slow-release oral morphine per day

400mg oral morphine → 100mcg/hr fentanyl patch

2. Patient taking 120mg Oxycontin per day

120mg x 1.5 = 180mg MME

180mg oral morphine → 50mcg/hr fentanyl patch

Appendix 5: Patch Rotation Sites

Patches should not be reapplied to the same site within 7 days to avoid skin irritation when rotating. However, if the patch is changed in 24 hours or less, the patch should be applied to the same site as the previous patch. This is to prevent additional fentanyl from being absorbed when a patch must be changed faster than the regular schedule.

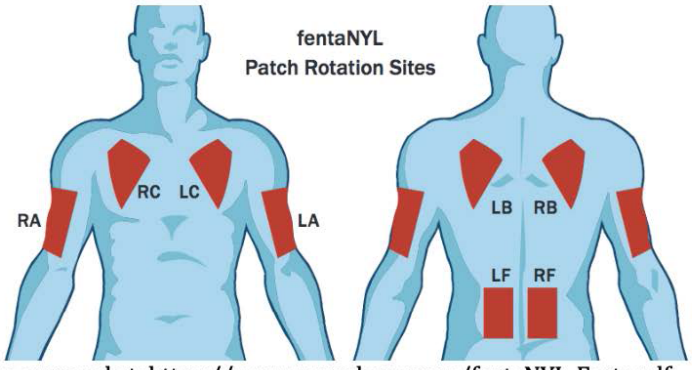


Image accessed at: https://www.remedysrxsp.ca/fentaNYL_Facts.pdf

SITES	CODE
Left Upper Arm	LA
Right Upper Arm	RA
Left Chest	LC
Right Chest	RC
Left Upper Back	LB
Right Upper Back	RB
Left Flank	LF
Right Flank	RF

An example scenario follows:

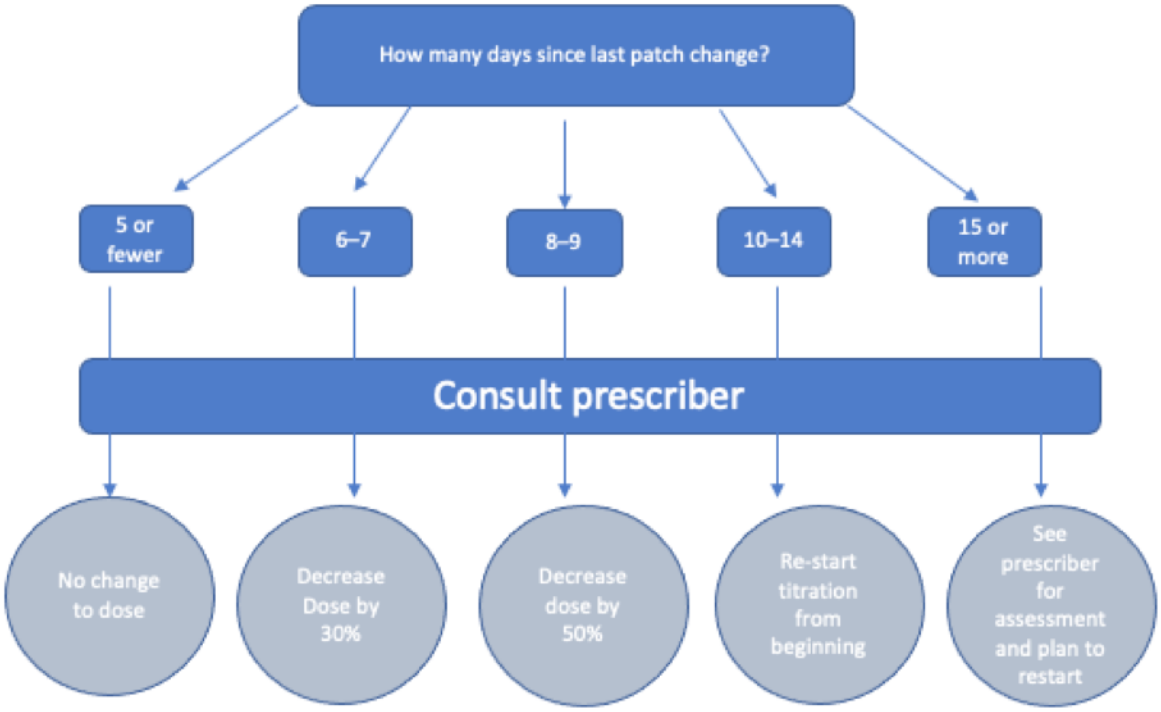
Latisha misses her patch change on Wednesday and receives a new patch on Thursday. The nurse places it on her left deltoid. On Friday, the old patch is removed and a new patch is placed on her left deltoid. When she returns on Monday, the new patch must be placed on a different site.

Appendix 6: Missed Dose Tables

The following table provides direction on actions to take after each missed day up to 15 missed days, at which point the patient must be assessed by the prescriber.

Day of the week	Patch change	Day Counter	Dose
Monday	Gets a new patch		
Tuesday		1	
Wednesday	Misses patch change	2	
Thursday		3	No change
Friday		4	No change
Saturday		5	No change
Sunday		6	30% reduction
Monday		7	30% reduction
Tuesday		8	50% reduction
Wednesday		9	50% reduction
Thursday		10	Restart titration
Friday		11	Restart titration
Saturday		12	Restart titration
Sunday		13	Restart titration
Monday		14	Restart titration
Tuesday		15	Not eligible for restart; must see prescriber

The following decision support tool may also be used when determining how to manage missed doses.



A6.1 Missed Patch Change During Planned Dose Increase

Days Missed Since Last Patch Change	Action
≤3	Increase dose as planned
4–5	Maintain previous stable dose
6–7	Decrease dose by 30%
8-9	Decrease dose by 50%
10–14	Re-start titration from beginning
>15	See prescriber for assessment and to discuss plan to restart

Case Scenarios

Yoseph

Yoseph gets his patched changed on Monday. He is scheduled for a dose increase on Wednesday; however, he misses this visit and presents to clinic on Thursday.

Since it is still within 3 days of his last patch on Monday, he is still eligible for a dose increase.

Mac

Mac gets their patch changed on Friday and is scheduled for a dose increase on Monday; however, they miss this visit and present to the clinic on Tuesday. They are not eligible for a dose increase since Tuesday is 4 days since their last patch change. Mac will stay on the same dose as they received on Friday.

A6.2 Restarting After Missed Doses—Re-establishing Mon/Wed/Fri Dosing

It is safe to get patients back on the Monday/Wednesday/Friday schedule as soon as possible, even if this means a patch is changed within only 24 hours.

Note: The patch site should not be rotated when doing short patch changes (within 24 hours).

The table below provides guidance for the following example scenario:

Ramon gets his usual dose patch on Monday. He is scheduled for a patch change on Wednesday; however, he misses the appointment and presents the following Tuesday for a patch change. A new patch with a 50% dose reduction is applied on Tuesday. In order to re-establish Monday/Wednesday/Friday dosing for Ramon, there are two options:

1. Apply a new patch on Wednesday at the same dose and in the same site as the patch applied on Tuesday.
2. Apply a new patch on Friday at the same dose but in a different site than the patch applied on Tuesday.

Day of the week	Patch change	Day Counter	Dose
Monday	Gets a new patch		
Tuesday		1	
Wednesday	Misses patch change	2	
Thursday		3	No change
Friday		4	No change
Saturday		5	No change
Sunday		6	30% reduction
Monday		7	30% reduction
Tuesday	Comes in for a new patch	8	50% reduction
Wednesday	Option 1: May get another new patch today. **Must be same site as Tues patch** Back on M/W/F schedule		
Thursday			
Friday	Option 2: If patient did not get a new patch Wed, they could get a new patch today without any change to their dose. Patch must be on a different site than Tuesday		
Saturday		1	

A6.3 Missed Dose on Thursday with Mon/Weds/Friday Dosing

For programs that use Monday/Wednesday/Friday dosing, patients with missed doses who come in on Thursday will receive a patch on Thursday and then receive a new patch on the Friday, in order to ensure they have adequate dosing over the weekend. The table below provides guidance for this scenario.

Day of the week	Patch change	Day Counter	Dose
Monday	Gets a new patch		
Tuesday		1	
Wednesday	Misses patch change	2	
Thursday	New patch		No change
Friday	New patch on same site as Thursday's patch—patient is back on MWF patch change schedule		No change
Saturday		1	
Sunday		2	
Monday	Patch change		No change
Tuesday		1	
Wednesday	Patch change		This is the first opportunity for a dose increase, as patient has had two patch changes on schedule
Thursday		1	
Friday	Patch change		
Saturday		1	
Sunday		2	
Monday	Patch change		

A6.4 Multiple Missed Doses Requiring Restart

DeVante is titrating his fentanyl patch dose, but has had many missed doses. He comes into the clinic on Thursday for a restart after not presenting to the clinic for more than 7 days. He has the old patch on his skin, intact.

DeVante is restarted at 50mcg and instructed to return to clinic the following day (Friday) for a patch change. DeVante gets his dose as planned on Friday and presents again to clinic on Monday for his next patch change.

DeVante reports he is experiencing cravings and withdrawal on his current dose and would like to increase his dose. He is eligible for a dose increase on Wednesday, as he will have had two patch changes since his last dose adjustment.

The following table provides guidance for this scenario.

Day of the week	Patch change	Day Counter	Dose
Thursday	Restart at 50mcg	Has missed many days	50mcg
Friday	New patch (same site as Thursday's patch)		50mcg
Saturday		1	
Sunday		2	
Monday	New patch—ask him if he would like to go up on the next dose and discuss with the physician		50mcg
Tuesday		1	
Wednesday	New patch—first opportunity to increase dose		100mcg
Thursday		1	
Friday	New patch		100mcg
Saturday		1	

A6.5 Missing Patch

Andres presents to clinic for his patch change on a Tuesday and reports that he has lost his patch. Upon inspection, there are no patches on his body.

This is considered a first-time diversion. Andres should be reminded that if a patch falls off, he should come to the clinic immediately and bring the patch with him to be inspected. The prescriber may determine the new patch dose, based on individual circumstances, or the missed dose protocol can be applied as if the last patch change did not occur at all. Since Andres received his patch on Friday the missed dose protocol would apply from the Wednesday prior, the last time he received a patch that was still in situ at the following patch change. This diversion should be documented in Andres chart.

Andres is restarted at 50mcg and instructed to come back on Friday for his next patch change. He will be eligible for a dose increase on Monday, after 2 patch changes.

The following table provides guidance for this situation.

Day of the week	Patch change	Day Counter	Dose
Tuesday	Restart titration New patch	Does not apply due to diversion	50mcg
Wednesday		1	
Thursday		2	
Friday	Patch change Discuss with prescriber about dose adjustment		50mcg
Saturday		1	
Sunday		2	
Monday	New patch—increased dose		100mcg

A6.6 Fentanyl Patch and OAT Dose Increase

Amanda is currently on methadone 60mg and fentanyl patch 250mcg. She would like to increase her dose of both medications.

Explain to Amanda that she cannot go up on both medications at once. After discussion, she decides that she would like increase her fentanyl patch dose. Following this dose increase, she needs at least 2 changes at this new dose before she can adjust her OAT dose.

The following table provides guidance for this situation.

Day of the week	Patch change	Day Counter	Dose
Wednesday	Patch change—would like to increase dose		250mcg
Thursday		1	
Friday	New patch—increased dose		300mcg
Saturday		1	
Sunday		2	
Monday	Patch change		300mcg
Tuesday		1	
Wednesday	Patch change		300mcg This is the first day she can adjust her methadone dose, as she has had 2 patch changes at 300mcg
Thursday		1	
Friday	Patch change		300mcg
Saturday		1	

Appendix 7: Resources

- Ministry of Health & Ministry of Mental Health and Addictions: Access to Prescribed Safer Supply in British Columbia—Policy Direction

Prescribers should follow institutional policies for opioid patch handling and safe disposal. However, the following resources may help inform the development of policies or be consulted in the absence of institutional policies.

- College of Pharmacists of BC: Safe Disposal of Fentanyl Patches
- Alberta Health Services: Opioid Patch Handling