Introduction

This document is intended to provide a background and understanding of a Fentanyl Patch 4 Patch Initiative to law enforcement, Health care providers, industry professionals and patients prescribed fentanyl as part of their medical treatment. The contents of this document are not meant to replace existing guidelines or policies in any medical or professional organization that choose to participate in this initiative.

The OACP recognizes that the misuse of fentanyl is having a devastating impact in many communities throughout Ontario including many unnecessary deaths. This is an important and effective program that could assist in limiting the availability of fentanyl patches across many jurisdictions. The OACP encourages its members to engage local stakeholders to consider implementing this proactive program within their community. Limiting the supply and accessibility of fentanyl patches will contribute further to enhancing the overall health and safety of all communities across Ontario.

Ron Taverner
Superintendent, Toronto Police Service
Chair, Substance Abuse Committee
Ontario Association of Chiefs of Police
Fentanyl

theft from institutions with drug inventories
opioids including OxyContin with OxyNEO

In March 2012 Growing Concern
First Nation $150 Street Prices
and potentially death.

Users may experience slowed breathing, nausea, constipation, drowsiness, unconsciousness, coma and potentially death.

Non-Medical Use (or Illicit Use)
Fentanyl is known by several street names: Apache, China Girl, China White, Dance Fever, Friend, Goodfella, Jackpot, Murder 8, TNT and Tango and Cash. Aside from using patches in a prescribed manner, users will extract the gel from patches and eat, smoke, inject and dissolve it under their tongues. Because fentanyl is highly soluble, users will soak pieces of the patch in alcohol and then infuse herbs such as basil with the mixture to smoke. Because the patch is made for a 72-hour slow release, scraping off the medication and smoking or sucking the drug out of the patch can make a single patch lethal.

Symptoms
Users may experience slowed breathing, nausea, constipation, drowsiness, unconsciousness, coma and potentially death.

Street Prices (per patch)

Growing Concern
In March 2012 Purdue Pharma replaced OxyContin with OxyNEO which is more difficult to misuse. Since that time many people who are addicted to opioids have migrated to using other opioids including fentanyl and heroin. Fentanyl is obtained in a number of ways including the sale of legitimate prescriptions, theft of prescriptions, theft from institutions with drug inventories and fraudulent prescriptions.

Prevention of Fentanyl Diversion
Various Law Enforcement Agencies in Ontario have taken a leadership role in bringing together key professionals who were also concerned with the dangerous trend of fentanyl misuse and abuse. They have identified that fentanyl is a prescribed medication which is being diverted to individuals within the drug subculture. These agencies have clearly identified their ‘ownership’ of enforcement and then turned their focus to provide leadership by bringing together the other disciplines namely, pharmacists, physicians, addiction counsellors and health care workers to adopt the “Patch 4 Patch” initiative.

The importance of additional communities within Ontario adopting a similar initiative and taking on a shared responsibility to prevent individuals from becoming addicted to fentanyl is paramount.

Saving lives and preventing new users from becoming addicted to this powerful painkiller cannot be accomplished independently through traditional police methods such as investigation and prosecution. The continual misuse and abuse of fentanyl has to be recognized as a shared responsibility between many community stakeholders. The police are able to share their observations through Confidential Informant information, first hand experiences and the identification of drug enforcement trends. The key is to bring this information to core groups of professionals who are often concerned about the same issue, understanding however that each stakeholder may possess a different point of reference.

When organizing or speaking to those concerned with prescription drug misuse, notably the misuse of fentanyl patches, it is important to spend some time educating them about what is occurring from the law enforcement perspective at the street level.

For each of the identified “Patch 4 Patch” initiatives that are currently operating in Ontario, Law Enforcement facilitators found that medical professionals, once they were presented with the street situation, were extremely supportive of the initiative. A quote from a physician at an initial meeting hosted by North Bay Police was once the street picture had been painted, the need for a protocol was evident. Specifics relating to the misuse of fentanyl were vague to some of the medical professionals based on lack of exposure to the issue. Police, through their front line experiences were able to provide insight into the following:

METHOD OF INGESTION

- Some medical professionals assumed their patients were using the patch as prescribed in a transdermal manner as opposed to smoking, chewing or injecting;
- Fentanyl patches are being supplied illicitly by individuals possessing valid prescription for the medication who then divert all or a portion of their prescription. A cottage industry to supply people who are addicted to opioids as opposed to organized crime groups has grown up across the province. Any gang involvement still sees the supply route as being from prescribed users selling patches;
- Prices for these patches on the street range from $200-$300 in southern Ontario and upwards of $500/patch in First Nations communities in the north;
- Patches are being cut up for use resulting in inconsistent doses being consumed by users which increases the risk of overdose;
- Patches that are properly used may retain 60% to 80% of the original dosage;
- Because of the high street price in some communities, patients who are receiving the patch for appropriate clinical reasons may sell some of their patches, or be pressured to sell some or all of their patches, for additional income. If the patches are sold to people not familiar with the drug, significant harm or death can result.
**Prevention (continued)**

**ADDITION**

- Younger people are becoming addicted due to the strength of the high;
- People administering immediately when patches are acquired;
- Experienced and long term heroin users are alarmed at friends using fentanyl due to the dangers;
- Police Confidential Informants reporting that it is usual for users of fentanyl to experience the nod, so much so, that many users will not use alone due to the high risk of overdosing.

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**Law Enforcement Agencies Supporting a “Patch 4 Patch” Initiative:**

ONTARIO PROVINCIAL POLICE – D/Sgt Don Eastop, Operations Support Manager, OPP Drug Enforcement Unit – Donald.Eastop@ontario.ca

DURHAM REGIONAL POLICE – S/Sgt James Stewart-Haas, Patrol Services Leader, North Division, Durham Regional Police - JSTEWART-HAASS@drps.ca

NORTH BAY POLICE - Detective Jim Warren, Supervisor, Investigative Support Section, North Bay Police Service - jwarren@northbaypolice.on.ca

PETERBOROUGH LAKEFIELD COMMUNITY POLICE - D/Sgt Laine Schubert, Drug Unit - lshubert@Peterborough.ca

GUELPH POLICE SERVICE – D/Sgt Ben Bair – BBair@guelphpolice.ca

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**Media Reference to the “Patch 4 Patch” Initiative**

- Comments on the concept from concerned Ottawa Pharmasave Owner Pharmacist Mark Barnes:
  

- Fentanyl Patch for Patch Return Private Member’s Bill put forward by Nipissing MPP Vic Fedeli:
  
FAQ
FOR HEALTH CARE PROFESSIONAL
Patch 4 Patch - Fentanyl Patch Return Initiative

What is the Patch 4 Patch Initiative?
This initiative is a collaboration between physicians, pharmacists, and patients to promote the safe, effective, and responsible use of fentanyl patches. Patients are asked to return any patches previously dispensed to them back to the pharmacy before they are able to receive more.

How can physicians help ensure fentanyl is taken appropriately by their patients?
Physicians should write prescriptions for fentanyl that direct the pharmacist to collect used or unused patches before dispensing the next set of patches. See attached sample prescription for an example.

Physicians are reminded the NOUGG Opioid Guidelines are available as a reference tool: http://nationalpaincentre.mcmaster.ca/opioid/

Physicians can also reference to the CPSO’s prescribing policy at: http://www.cpsso.on.ca/Policies:Publications/Policies:Prescribing-Drugs

What is the role of the pharmacist?
A prescription is essentially a direction for a particular product to be dispensed to a patient. When a prescriber writes specific instructions for the pharmacist, such as those provided in the example, the pharmacist is expected to follow or adhere to those specific instructions if, in the professional opinion of the pharmacist, it is in the best interest of the patient to do so.

When a pharmacist is unable to follow the instructions of the prescriber for any reason, that decision should be discussed with the patient, the decision should be documented, and the prescriber should be consulted to discuss the reasons and any action that the pharmacist intends to take.

Will the Ontario College of Pharmacist (OCP) support me on this?
The College supports professional activities that improve patient care, and which protect the public interest. Because the intent of a Fentanyl Patch 4 Patch Initiative is to encourage the safe disposal of a potentially dangerous medication after its therapeutic use has finished, the College supports this initiative and participating pharmacists.

The OCP does not currently have a “Best Practice” recommendation on this matter, but there are parallels to some of the policies and guidelines that pharmacies must adhere to when dispensing methadone. Pharmacists are encouraged to contact the OCP Practice Department with any questions specific to the P4P Initiative.

The OCP is also supportive of three-way Narcotic Contracts between the physician, patient, and pharmacy, and encourages physicians to incorporate a Fentanyl Patch 4 Patch Initiative clause in their Narcotic Contracts.

Why don’t the physicians just issue single-dispense prescriptions (i.e. do not prescribe fentanyl as part-fills®) and have the patches returned to them before issuing the next prescription? Then they become aware of any concerns and the pharmacist is not “policing”.
Physicians generally do not have a mechanism for the safe disposal of hazardous wastes such as medications. Pharmacists have a system for drug disposal available to them through the Health Products Stewardship Association. In addition, pharmacists are in a unique position as they see patients more often and are involved in handling new and discarded medications on a daily basis.

This initiative is intended to be a shared responsibility between the physicians and the pharmacists. The physicians are being asked to discuss this initiative with their patients and add it to their Narcotics Contracts.

Has patient education regarding disposal and the handing out of disposal containers being considered instead of this P4P Initiative?
A cornerstone of the Fentanyl Patch 4 Patch Initiative will be the need for patients to be educated about the dangers of used patches and the need for their safe disposal at pharmacies.

A home disposal container for fentanyl patches could potentially be viewed as more attractive to drug seekers. This would not adequately deal with the issue of diversion, and may facilitate crime in the form of home invasions. Also we cannot count dispose d patches and verify 1:1 disposal.

How is a situation handled when a patient brings back 8 out of 10 patches?
Then they are only entitled to receive 8 patches in the next prescription and must return those before they receive the next prescription. It is suggested that if this happens once, that they be reminded of the need to return the patches; and if it happens again, they must see their physician for him/her to determine if it is appropriate to continue the treatment with fentanyl patches.

For the first prescription there will be only 9 out of 10 patches returned.
Yes, that is expected as the last patch technically should be on the patient’s skin. This will be a one-time occurrence and should be documented.
FAQ (continued)
FOR HEALTH CARE PROFESSIONAL
Patch 4 Patch - Fentanyl Patch Return Initiative

How should the used patches be stored?
It is recommended that patients stick the used patches onto a sheet of paper, in a non-overlapping sequential order, so that each patch can easily be recognized and accounted for. These sheets can be made available through public health.

Patients should store the sheet with used patches out of sight and out of the reach of children and/or pets. It should be treated with the same care and concern as other medications.

Once returned to the pharmacies, the returned sheets with used patches should be placed into the pharmacy’s drug disposal bin to be removed and destroyed on a regular basis.

How do we handle a vacation supply (larger quantity than patient has returns for)?
The patient must return the quantity of patches received in their last order. If they are prescribed a larger quantity than usual, they must return the same number in order to receive the next lot, even if the next prescription is for a smaller quantity than the current prescription. It is important to document the changes for appropriate record keeping.

What if there is a new prescription at our pharmacy but the patient has previously received fentanyl patches from another pharmacy?
Participating pharmacists may contact the patient’s previous pharmacy to confirm information regarding the last prescription dispensed and any information regarding patches returned.

What if the patient says she/he has returned her/his patches to the doctor’s office and you can’t reach office to verify?
As indicated above, physicians are not equipped to handle the return and disposal of used patches. Thus, this is not likely to happen. On the off-chance that a patient does give their patches to their physician, physicians have been asked to document this fact on the prescription. If the pharmacist is unable to confirm that a patient has returned patches to their physician, they can use their professional judgement to determine the appropriate course of action and should document accordingly.

How do I handle the delivery situation?
Pharmacy delivery personnel are considered agents of the pharmacy, and should be advised of the need to collect used patches from patients. In a similar way in which they collect money, drug cards, expired medications, and other items such as signatures under the Narcotics Safety and Awareness Act 2010 (NSAA), they can also be entrusted to collect and return used patches to the pharmacy.

As a best practice when delivering a fentanyl patch prescription to a patient, it would be advisable for both the patient and delivery personnel to sign the NSAA delivery record to indicate that they picked up used patches from the patient.

Who do I notify if I feel there is an issue with diversion?
The medication should not be dispensed and the prescribing doctor must be notified.

What do I do if I encounter what I suspect to be a counterfeit patch?
Advise the patient that it is a criminal offense to unlawfully obtain narcotics and that they must bring in all the used patches before you can dispense more. If the pharmacist suspects the patient is involved in any type of fraudulent or drug diversion activity, he/she may consider notifying local law enforcement authorities.
FAQ
FOR PATIENTS
Patch 4 Patch - Fentanyl Patch Return Initiative

What is the Patch 4 Patch - Fentanyl Patch Return Initiative?
This initiative is a collaboration between physicians, pharmacists, and patients to promote the safe, effective, and responsible use of fentanyl patches. In general, it applies a ‘one in, one out’ model, where patients are asked to return any patches previously dispensed to them back to the pharmacy before they are able to receive more.

Why are these changes being made?
Patch 4 Patch promotes safety for patients and the community. In returning these patches, you are contributing to reducing harm as a used patch poses many dangers to children and pets, and contain enough medication to be harmful or fatal to someone who is not prescribed the medication.

How should the used patches be stored?
It is recommended that you place the used patches onto the patch disposal sheet, in a non-overlapping sequential order, so that each patch can easily be recognized and accounted for. These sheets are available from your pharmacist and will be given at the time your medication is dispensed.

What if I am prescribed a different quantity of patches than usual (vacation supply)?
In order to fill a new prescription, you must return the exact quantity of patches from the previous prescription. If you are prescribed a larger quantity than usual, you must return the same number in order to receive the next lot, even if the next prescription is for a smaller quantity than the current prescription.

Can I return patches to the doctor’s office or another pharmacy?
No, the patches are to be returned to the pharmacy where the prescription was originally filled. Physicians are not equipped to handle the return and disposal of used patches. Prior to dispensing any new prescription, the pharmacist needs to document the return of the patches from the previous prescriptions.

What happens if I lose a patch?
Participating in the P4P initiative involves a narcotic contract between the patient and physicians. If you lose a patch, the pharmacist will need to contact your doctor and you will be given fewer patches. For example, if you return only 8 out of 10 patches, you will only receive 8 with your next prescription. These must be returned before you receive the next prescription.

What do I do if I am being pressured to sell my medication?
Fentanyl is a very strong drug and it can be very easy for people who have not taken it before to overdose. People have died as a result of taking fentanyl that was not prescribed to them. Selling this medication is illegal. Talk to your physician and or law enforcement if this situation occurs.

What do I do if I feel my use is getting out of control?
Be up front with your health care professional and seek help early, as this is a potent medication, with potential serious side effects.

If you need someone to talk to you can contact ConnexOntario for help at the following numbers:

Drug & Alcohol Helpline: 1-800-565-8603
Mental Health Helpline: 1-866-531-2600

Services are also available online through www.connexontario.ca
Suggested Guidelines
Fentanyl Patch 4 Patch Return Initiative

The Fentanyl Patch 4 Patch Return Initiative has been established for the purpose of public education and awareness regarding the risks of fentanyl misuse and abuse. The initiative is not meant to restrict or limit the appropriate treatment of pain for patients that require it, but is meant to facilitate the responsible provision of fentanyl patches. It is important to address the issue of disposal of fentanyl patches properly to avoid harm to others.

(1) PHYSICIAN’S RESPONSIBILITIES:

(a) Patient Education: Accurate and thorough patient/family education is essential in promoting safe use of fentanyl patches. The physician will also caution the patient/family to store the patches in a secure place, and to follow the procedure to keep track of the number of patches they have, to decrease the risk of accidental misuse by others.

(b) Prescriptions: Physicians are cautioned not to write prescriptions for large numbers of fentanyl patches. It is recommended that no more than “10 fentanyl patches be dispensed” at one time. (one patch every 72 hour x10 patches = 30 days).

Physicians will determine from their patients which pharmacy they utilize for their medication management. The physician should write on the prescription the actual pharmacy and location in which the prescription will be dispensed. Whenever, possible the prescription will be faxed to that pharmacy.

(c) When patches are not returned the pharmacist will implement an agreed upon protocol such as dispensing one patch every third day until the pharmacist is able to contact the physician or the physician contacts the pharmacy.

(2) PHARMACIST’S RESPONSIBILITIES:

(a) Patient Education: Accurate and thorough patient/family education is essential in promoting safe use of fentanyl patches. The pharmacy will caution the patient/family to store the patches in a secure place, and to follow the procedure to keep track of the number of patches they have, to decrease the risk of accidental misuse by others.

(b) Counselling Patient/Family on Fentanyl:

- Attach a provided “Opioid Patch Exchange Disposal Sheet” to the fentanyl prescription
- Remind the patient/family to keep the used patch when applying a new patch.
- Tape the patch to the “Opioid Patch Exchange Disposal Sheet”, sign below, place the time and the date below.
- Explain to the patient/family that they may not be able to receive more patches if the current patches are not returned to the pharmacy.
- Educate on the importance of the fentanyl return policy and the need for such a policy.

(c) Count the fentanyl patches returned and inspect them for any damage or tampering.

(d) Report any suspected patch damaged or tampering to the physician and communicate this to the patient/family.

(e) At any point if the pharmacist believes that a Criminal offense i.e.: illegal diversion of fentanyl patches has occurred, he/she is encouraged to report to the local police agency.

(f) When a patient does not return all their patches the pharmacist will initiate a contingent dispensing protocol such as providing one patch every third day until the pharmacist is able to contact the physician.

(3) PHARMACY TECHNICIANS RESPONSIBILITIES:

- When filling a fentanyl prescription, place the comment “return all patches to pharmacy, once used” at the end of the direction line.
- When filling a fentanyl patch prescription, place an opioid patch exchange disposal sheet with the filled prescription to be attached by the pharmacist.
- For any questions regarding the fentanyl return policy refer the patient/family to the pharmacist.
- Destroy the returned patches daily using gloves and scissors. Place in environmental disposal bins.

(4) OTHER

- Refer all patients unaware of the fentanyl return policy to the pharmacist for counselling.
- For any questions regarding the fentanyl return policy refer the patient to the pharmacist.
- Patients that die at home under the care of Allied Home Care such as CCAC, the Home Care staff are encouraged to return the fentanyl patches and attached form to a pharmacy.
- Sudden death cases when police attended the scene and secure the medications, the procedure of disposal of fentanyl will be reviewed with the police agencies.
- Evaluation of the process will be done in three months and any issues are to be discussed at the Drug Strategy Committee or the Patch 4 Patch organizing group for follow-up and action.
Sample of Prescription
Written By Doctors

Dr. Sample, MD CCFOP (EM) FCFP
CPSO # XXXXX
Any Town Family Health Team
127 North Rd
Any Town, ON (Postal Code)
Phone: XXX-XXX-XXXX
Fax: XXX-XXX-XXXX

Prescription for: Patient name: date of prescription:
Full address:
ID: # HC # XXXX XXXX XX CT
D.O.B. of patient:
(Female / Male)

Fentanyl
75mcg./hr patch change Q72H
Quantity: (15)- dispense 5 every two weeks

Note to pharmacist and patient: must return (non-sticking) patches with Opioid Patch Exchange Disposal Sheet prior to any subsequent dispensing

Patient name: Fentanyl
D.O.B.: Dr. Sample, MD CCFOP (EM) FCFP
Rx date: 75mcg.hr patch Change Q72H Quality : ten

Professional ID:
Dr. Sample, MD CCFOP (EM) FCFP
A patch exchange system is one way to promote the safe, effective and responsible use of opioid patches. While receiving prescriptions for the patch, you will be asked to return all used patches on a piece of paper like this: to use:

1. Stick the used patch on this sheet in the numbered boxes
2. Store this sheet out of sight and out of reach of children/pets
3. After applying your last patch, return this sheet with the used patches to the pharmacy in order to pick up your next supply
4. In the future, you may use a blank sheet of paper making sure all used patches are affixed.

Patient Name ___________________________  # of patches returned _____
Fentanyl Patch 4 Patch Partnership Agreement
LOCATION – A Community Safety Initiative

WHEREAS the various communities in the Location Area have identified misuse and abuse and trafficking of fentanyl patches creates a health issue; and

WHEREAS the medical professionals in the Location Area acknowledge their role in ensuring the safe and lawful use of medications; and

WHEREAS the establishment of procedures for the dispensing and return of fentanyl patches can reduce the harm to the community.

THEREFORE the undersigned, representing Physicians and Pharmacists in the Location Area hereby endorse and adopt the “Patch 4Patch” Protocols attached hereto.

Dated this Date at the Location in the Province of Ontario.

_________________________________  ____________________________________________
Signature and Agency               Signature and Agency

_________________________________  ____________________________________________
Signature and Agency               Signature and Agency

_________________________________  ____________________________________________
Signature and Agency               Signature and Agency
"Drug Strategy Committee" or “Patch 4 Patch Organizing Group” Evaluation
“Fentanyl Patch 4 Patch Evaluation”

Evaluation From (recommended 6 months after implementation):
(1) Date
(2) Month of xxxx, 2014
to
(3) Month of xxxx, 2014

Please send evaluation forms once completed to Contact Person at email or Fax xxx-xxxx-
xxxx

1. Since the implementation of the Patch 4 Patch Initiative..

a) Are the patients returning the pharmacy medication disposal sheet? Yes _ No _

If no, what are the issues?

b) Are physicians writing fentanyl prescriptions properly i.e is the dose correct and are they writing P4P on the prescription?

Yes __ No __

If no, what are the issues?

c) With reference to the pharmacy, has the number of fentanyl patches dispensed decreased since the policy was implemented or has it stayed the same?

Increased [ ]
Decreased [ ]

Period Between __________ (DATE) and ___________DATE

2. Have you had any complaints from your patients? If yes what?

3. Do you have any suggestions for improvement of this initiative?
Acknowledgements:

The OACP Substance Abuse Committee is grateful to members of the “Stakeholder Working Group” who provided detailed review of this document.

Tom Andreopoulos – Deputy Chief Federal Prosecutor, Public Prosecution Service of Canada

Maureen Boon – Senior Advisor, College of Physicians and Surgeons of Ontario

Anne Bowlby – Manager, Mental Health Addiction Unit, Ontario Ministry of Health and Long Term Care

Rob Crews – Senior Pharmacist, Ontario Ministry of Health and Long Term Care

Barb LeBlanc – Executive Director, Ontario Medical Association

Allan Malek – Senior Vice President, Ontario Pharmacists Association

Anne Resnick – Deputy Registrar, Ontario College of Pharmacists

Dr. Roger P. Skinner – Regional Supervising Coroner, Office of the Chief Coroner of Ontario

Additionally the committee wishes to acknowledge those agencies and stakeholder groups and their representatives that have identified, promoted and implemented this important initiative in their respective communities. It is their effort that has resulted in the creation of this Patch 4 Patch document to be further utilized by all interested participants throughout Ontario.

*The contents contained within this document are not meant to replace any existing guidelines or policies that currently exist within any of the “Stakeholder Working Group” organizations.