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Analyzing the Safeguarding Our Communities Act: Patch for Patch Return Policy in Ontario

Soo-Min KIM, *University of Ottawa, Ottawa, Ontario, Canada*

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Abstract

Fentanyl is prescribed to patients suffering from severe chronic pain. Transdermal patches are the best mode of delivery for patients who have developed tolerance for opioids. However, used patches still contain fentanyl that can be extracted and misused, with potentially severe consequences. To address this issue, patients who are prescribed fentanyl patches in Ontario are now required to return previously dispensed patches to receive new patches under the *Safeguarding Our Communities Act: Patch for Patch (P4P) Return Policy*. The problem is significant in Ontario because the province has the largest annual dispense rate of high-dose prescription fentanyl (112 units per 1,000 population) in Canada even though the prevalence rate of chronic pain is lower than the national reported range (16.6% in Ontario versus 19.6 to 21.9% in other provinces, according to Gomes *et al.* 2014). The primary goal of this reform is to instil responsible use of fentanyl patches, and to improve safety for patients and the public by having a central disposal process. The reform was modelled after a community initiative that was pioneered in North Bay after receiving great support from health professional colleges and communities that voluntarily integrated the program prior to the introduction of Bill 33. Preliminary data suggest that the P4P policy is positively received by health professionals, although ongoing evaluation is needed to assess the effectiveness of the policy in reducing misuse and abuse of prescribed fentanyl patches.

Le fentanyl est prescrit aux patients souffrant de douleur chronique sévère. Le meilleur mode de délivrance pour les patients ayant développé une tolérance importante aux opioïdes est le timbre transdermique. Le problème est que les timbres usagés contiennent un résidu de fentanyl qui peut être extrait et réutilisé à mauvais escient, ce qui peut entraîner des conséquences graves. Pour y remédier, les patients à qui des timbres de fentanyl ont été prescrits en Ontario doivent rapporter les timbres utilisés pour recevoir les nouveaux, en vertu de la Loi pour protéger nos collectivités (politique d'échange de timbres, PET). Il s'agit d'un problème significatif en Ontario car cette province affiche le taux le plus élevé de prescription de fentanyl fortement dosé au Canada, avec 112 doses pour 1,000 habitants, alors pourtant que la prévalence de douleur chronique sévère est plus faible que dans les autres provinces (16,6% en Ontario contre 19,6 à 21,9%, d'après Gomes et al. 2014). L'objectif principal de la réforme est de rendre l'utilisation des timbres au fentanyl plus sûre et d'améliorer la sécurité pour les patients et la population en établissant un protocole d'élimination centralisé. La réforme s'inspire d'une initiative communautaire développée à North Bay, initiative approuvée par les collèges des professions de santé ainsi que par les communautés qui s'y sont volontairement associées avant même le vote de la Loi numéro 33. Les données préliminaires suggèrent que la politique PET est bien accueillie par les professionnels de santé, même si une évaluation est nécessaire pour mesurer l'efficacité de la politique en termes de réduction de la més-utilisation et de l'abus des timbres au fentanyl.

Key Messages

- The prevalence and abuse of prescription fentanyl is a growing national concern and has prompted a provincial strategy in Ontario for the distribution, collection and disposal of fentanyl patches.
- The recently enacted legislation, *Safeguarding our Communities Act: Patch for Patch (P4P) Return Policy*, is modelled after a “one in, one out” schedule whereby patients are required to return one fentanyl patch in exchange for every new patch dispensed.
- While this is a significant policy oriented towards safeguarding improper disposal and misuse of fentanyl, the policy should be closely monitored over time to assess its effectiveness.

Messages-clés

- *La prévalence et l’abus du fentanyl sur ordonnance sont des problèmes croissants au Canada et ont suscité une stratégie provinciale en Ontario pour la distribution, la collecte et l’élimination des timbres au fentanyl.*
- *La législation récente, Loi pour protéger nos communautés (politique d’échange de timbres, PET) s’inspire de la règle « un donné pour un rendu » selon laquelle les patients doivent rapporter un timbre au fentanyl usé pour en obtenir un nouveau.*
- *Il s’agit d’une initiative politique significative en vue de la sécurisation de l’élimination et de la réduction de l’abus du fentanyl, mais qui doit être évaluée sérieusement dans la durée pour en tester l’efficacité.*

1 BRIEF DESCRIPTION OF THE HEALTH POLICY REFORM

Fentanyl is a type of opioid and is prescribed to relieve severe pain. It works by binding to opioid receptors in the brain to provide an analgesic effect. Pharmaceutically produced fentanyl can come in various forms such as tablets, nasal sprays, liquids for intravenous injection and transdermal patches. While the advent of the transdermal delivery of fentanyl avoids the peaks and troughs that would normally be seen with other forms of fentanyl delivery (i.e., intravenous or oral), there is a risk for fentanyl in transdermal form to interact with other drugs as even when the patch is removed, the blood remains 50% saturated with fentanyl 17 hours post removal. As a result, management of patients who have been prescribed fentanyl patches is complex (Weaver 2014).

Because the patch form of fentanyl is designed to be slow release over a 72-hour period, used or discarded patches still contain substantial amounts of fentanyl which is sufficient to cause euphoric effects and overdose. A host of methods such as ingestion, intravenous injection, smoking and oral application to the gums are used by those addicted to extract the compound from the used patches. This potential misuse raises many public health and safety concerns for Canada, particularly the province of Ontario.

In response to the fentanyl crisis, Ontario implemented the *Safeguarding our Communities Act: Patch for Patch Return (P4P) Policy* to target patients in receipt of fentanyl patches. The purpose of this policy is to promote responsible use, collection, disposal and patient education by creating a streamlined transdermal fentanyl patch program involving patients, prescribers (typically physicians) and dispensers (typically pharmacists). Hence, this policy addresses only one aspect of the complicated fentanyl public health crisis—the use and misuse of prescription fentanyl. The P4P Policy does not address problems surrounding illicit fentanyl.

Physicians are required to notify and document the pharmacy where the patient will fill the prescription. They must also note if it is the first time the patient is on fentanyl and confirm that they have no reason to believe the patient has a prescription from a different prescriber. The policy recommends no more than a one-month supply (ten patches) be prescribed and dispensed. Patients are required to return their used patches prior to receiving new patches (Government of Ontario 2016). Used patches must be affixed to an Opioid Patch Exchange Disposal form, as developed by the Ontario Association of Chiefs of Police (OACP). During refills, pharmacists are expected to count the returned number of patches, inspect for any tampering and dispense new fentanyl patches in exchange for every patch returned by either the patient or the patient’s representative (Government of Ontario 2016). In the event the patient returns no or fewer patches, the contingency plan states that the: 1) pharmacist use clinical judgement to decide how many patches the patient receives; 2) physician is notified and; 3) law enforcement agency are contacted if there are reasons to believe the patches are counterfeit, tampered with or were misused. In circumstances

where the patient resides in a long-term care facility, hospital, or a correctional facility, an exemption may be made.

2 HISTORY AND CONTEXT

The prevalence of use, misuse of, and deaths associated with fentanyl is a growing national concern with consumption rates in Canada among some of the highest in the world (Fischer *et al.* 2015). Ontario has the highest annual rate of prescription fentanyl dispensing in Canada with 112 patches dispensed per 1,000 population even though the prevalence of chronic pain in the province is lower than the national average (Gomes *et al.* 2014).

Opioid related deaths are increasingly occurring among all ages, income brackets and sexes (CCENDU 2015). While prescription opioids are often necessitated for the relief of severe pain, their misuse is an on-going concern. This concern has set the scene for a public health crisis in many provinces across Canada along with an urgency for action. Between 2009 and 2013, 466 deaths were classified as fentanyl-implicated in Ontario, an increase from 69 in 2009 to 111 in 2013 (CCENDU 2015). Involvement of fentanyl in opioid-related death increased by 548% between 2006 and 2015, stressing the pervasiveness of this public health problem (ODPRN 2017). It must be noted that these data (usually from the Coroner's Office of Ontario and published by Public Health Ontario), do not separate deaths caused by prescribed fentanyl (including patches) from deaths caused by illicitly produced fentanyl (Public Health Ontario 2018).

It is important to keep in mind the difference between prescription and illicit fentanyl. Prescription fentanyl, such as the patch form, is given by prescribers as a pain killer. The risk of accidental overdose for prescription fentanyl is much higher compared to other prescription opioids due to its pharmacological properties, necessitating its use be controlled and monitored by prescribers. In contrast, illicit fentanyl is produced illegally and sold on the street for recreational purposes. Illicit fentanyl is often in a powder form and mixed with other drugs like cocaine, making it much more toxic than pharmaceutical opioids (Ottawa Public Health 2017).

Fentanyl enters the illicit drug market when: 1) pharmaceutical products, primarily transdermal patches, are diverted (number of patches that are diverted is unclear) and 2) illicit fentanyl produced from pharmaceutical grade fentanyl or fentanyl analogues is imported (CCENDU 2015). Due to high market prices of diverted fentanyl patches, the perceived issue when the legislation was developed was that patients who have a clinical prescription may be inclined to sell their patches (CCENDU 2015, OACP 2014). Perceived harms of this behaviour include supply route of fentanyl from prescribed users, individuals cutting diverted patches at time of use leading to inconsistent doses, and patches that could be sold to people who are not familiar with the drug (OACP 2014).

The P4P program was first developed in 2013 as a community-based initiative in North Bay, Ontario in response to voiced concerns about fentanyl overdoses (MOHLTC 2015).

North Bay credits this program for saving lives, reducing crime and a decline in fentanyl overdose in their municipality (Fedeli 2016). The North Bay City Police Crime Unit and the North Bay & Area Drug Strategy Committee, in consultation with local physicians and pharmacists, created a guidance document titled “Patch 4 Patch Initiative: Fentanyl Abuse Prevention—A Share Responsibility” to help other Ontario communities implement the program (MOHLTC 2015; OACP 2014). As a result, the P4P program was implemented in a number of communities across the province on a voluntary basis (MOHLTC 2015). On 22 October 2014, Progressive Conservative MPP for Nipissing, Vic Fedeli, introduced Bill 33 for consultation based on the successes and positive feedback from communities that implemented the P4P policy in Ontario. Feedback from the public was considered by posting the proposed regulations on the province’s Regulatory Registry website. The bill was supported by all parties and received royal assent on 10 December 2015.

The implementation of this initiative was based on the perception that diverted fentanyl patches are contributing to the opioid crisis (Government of Canada 2017). The purpose of this policy is to regulate the use, distribution, disposal and misuse of prescribed fentanyl patches. The policy is not intended to address the use and misuse of illicitly produced fentanyl.

3 GOALS OF THE REFORM

3.1 Stated

The explicit goal of the P4P policy is to address the devastating impact of prescription fentanyl patch misuse across Ontario. Through a systematic return and exchange program, the P4P policy seeks to address the opioid crisis by instilling responsible use of fentanyl patches, improving patient and public safety, and decreasing the diversion of patches by having prescribers, dispensers and patients follow a standardized protocol. Further, the P4P policy aims to reduce death rates and increase education about the dangers of fentanyl and the responsible use and proper disposal of fentanyl patches; this is a shared responsibility between the prescriber and the dispenser. The policy is not intended to create barriers or restrictions to fentanyl access for patients.

3.2 Implicit

Implicit goals include reducing criminal diversion of fentanyl patches as well as reducing drug dependency among individuals who misuse prescription fentanyl. Additional implicit goals include improving data collection about fentanyl patch use, improving communication between physicians and pharmacists, and improving environmental safety through a standard disposal procedure.

4 FACTORS INFLUENCING HOW AND WHY THE REFORM WAS ACHIEVED

Ontario is battling an opioid crisis that has received substantial media attention, and strategies to deal with the increase in fentanyl related fatalities have been on the public health agenda. As the fentanyl crisis is perceived to be critical among multiple stakeholders (physicians, patients, pharmacists, police officers, and the public), time from proposal to implementation occurred in a short period. This rapid implementation speaks to the government's desire to mobilize change.

Bill 33 was seen to be logistically and technically feasible because the community initiative from North Bay laid the groundwork for the program to be implemented. Scaling up to the provincial level was based on positive feedback from North Bay and other communities that voluntarily introduced the program. This allowed for smooth passage of Bill 33 without major setbacks or need for financial investment.

The political climate in Ontario helped push Bill 33 into legislation. Around the same time, the government was in the process of developing a provincial framework for opioid addiction and overdose. Minister of Health and Long-Term Care, Dr. Eric Hoskins, announced the Strategy to Prevent Opioid Addiction and Overdose on 12 October 2016. Objectives of this strategy include increasing access to holistic treatment for those with opioid disorder and increasing the safety and health of individuals who use opioids (Government of Ontario, 2017). The P4P initiative was observed as one possible means to address misuse of prescribed opioids, directly aligning with the goals of the opioid strategy (MOHLTC 2015). Furthermore, the P4P policy was strongly endorsed by The College of Physicians and Surgeons of Ontario and Ontario College of Pharmacists after regulations under the policy took effect on 1 October 2016 and fact sheets were made available for the colleges' members (MOHLTC 2015).

Another contributing factor that influenced the adoption of the policy surrounds the P4P policy target population. The policy was seen to be beneficial for a small but important group in individuals: patients who use fentanyl patches, as well as their prescribers and dispensers. Overall, the P4P policy was supported by all political parties, as well as the policy legacy of the *Narcotics Safety and Awareness Act* (which aims to promote appropriate prescribing and dispensing practices of narcotics and other monitored drugs outlined in the *Controlled Drugs and Substances Act*).

5 EVALUATION

Due to the policy's recent introduction, data attesting to its effectiveness and impact are unavailable. However, it is possible to draw some preliminary conclusions based on the experiences of those communities who voluntarily enacted the P4P program.

In an evaluation report prepared by representatives of the St. Thomas Police Services Drug Enforcement Unit and Elgin St. Thomas Public Health, the P4P program highlighted: 1) that the number of fentanyl prescriptions written did not decrease, but positive changes were noted in the dispensing process due to standardization; 2) better communication between physicians and pharmacists; 3) a substantial drop in the number of diverted patches; and 4) that surrounding communities contacted St. Thomas about how to implement the program (Allan and Boyes 2015). More recently, the Ontario Drug Policy Research Network released findings from a cross-sectional time-series study that analyzed the impact of the P4P return program in 21 counties that implemented the program between February 2013 and April 2016 (before the P4P policy went into effect) (ODPRN 2018). The assessment concludes that the P4P program “helped reduce the dispensing fentanyl patches that may have been diverted” and that the program should be part of a larger opioid reduction strategy, rather than a stand-alone solution (ODPRN 2018). However, the study did not find a significant difference in the number of fentanyl patch related police incidents between participating or non-participating P4P counties (ODPRN 2018).

Further evaluation research using post-policy implementation data must be conducted to assess outcomes regarding prescription fentanyl use before and after the P4P policy implementation. Ongoing surveillance of the impact on patient outcomes and the health care system is needed. Outcomes that would have to be monitored include number of times law enforcement was contacted for counterfeit patches, emergency department visits for fentanyl patch toxicity, fentanyl patch related deaths, and police incidents involving fentanyl patches (Gomes 2017). Impacts of this reform will be felt among physicians, pharmacists, patients and individuals who seek diverted fentanyl patches.

The evaluation will not be easy to conduct because the government enacted another change affecting opioid use and users in the same period: In January 2017, high-strength long-acting opioids (including fentanyl 75 mcg/hr and 100mcg/hr patches) were delisted from the Ontario Drug Benefit Program to raise awareness of the increased risk of overdose through the use of high opioid doses and to address inappropriate prescribing (MOHLTC 2017). High-strength long-acting opioids can still be prescribed, however, they are only reimbursed to patients 65 years old and older or enrolled in the following programs: Home care, Ontario Works, Ontario Disability Support Program, Trillium Drug Program and OHIP+ (MOHLTC 2017). Changes in outcomes such as those noted above may be attributable to the removal of high-dose fentanyl patches, although the lack of granular fentanyl patch-related data makes stratification of results difficult.

No unintended consequences of the P4P reform have been suggested or documented so far.

6 STRENGTHS, WEAKNESSES, OPPORTUNITIES AND THREATS

Strengths, weaknesses, opportunities and threats (SWOT) of the new *Safeguarding our Communities Act: Patch for Patch Return Policy* in Ontario are outlined in Table 1.

Table 1: SWOT Analysis of the P4P Policy

STRENGTHS	WEAKNESSES
<ul style="list-style-type: none"> ● Based on a well-established program in North Bay ● Standardizes procedures across the province ● Includes patient and public education about fentanyl patches as an explicit goal 	<ul style="list-style-type: none"> ● If Exchange Disposal Form is not securely stored, those looking to misuse could find ways to extract residual fentanyl from used patches ● Addicted individuals may resort to other toxic drugs ● Prescribers may cease fentanyl patch prescriptions without adequate tapering or patient support ● Addresses only one aspect of the complicated fentanyl public health crisis (i.e., does not address the illicit fentanyl problem nor the high rates of prescription).
OPPORTUNITIES	THREATS
<ul style="list-style-type: none"> ● Improved monitoring and evaluation ● Lessons learned could be used when developing regulatory measures for other drugs ● Potential to reduce a proportion of acute healthcare costs from overdose and unintended deaths for prescription fentanyl users, if effective 	<ul style="list-style-type: none"> ● If patients do not follow storage instructions, could increase risks/dangers posed to patients' family ● Some patients may feel ashamed or stigmatized when picking up prescription ● Possible health implications if patients are non-compliant ● Fake replicas of used patches may be returned ● Pharmacists' work environment may be negatively affected if individuals are denied patches

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