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## Implementing a Nurse-led HIV Pre-exposure Prophylaxis Service (PrEP-RN) in a Public Health Unit STI Clinic: A Public Health Reform Analysis

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## Abstract

HIV pre-exposure prophylaxis (PrEP) is an efficacious pharmacologic HIV prevention strategy aimed at persons who are high-risk for HIV infection. Historically, PrEP uptake has been limited by systems-level barriers relating to the high cost of medications and few prescriber access points. In Ottawa, a team of researchers and clinicians sought to increase PrEP access to priority groups by implementing a fully nurse-led PrEP service, known as PrEP-RN, as part of the public health unit's sexual health clinic. This program was the first of its kind in Canada and required consideration from multiple stakeholders within the public health unit, and the Ottawa community. Patients at highest risk for HIV acquisition were offered a referral to PrEP-RN through a provider-driven, active-offer process by public health nurses, and medication coverage was provided to uninsured patients to ensure equal access to PrEP services. Preliminary results showed a 40% uptake of PrEP referrals among high-risk patients, demonstrating that this reform has been effective at reaching some priority groups; however, many persons continue to decline PrEP due to individual perceptions of risk (i.e., feeling they do not need this HIV prevention intervention).

*La prophylaxie pré-exposition au VIH (PrEP) est une stratégie pharmacologique efficace de prévention du VIH destinée aux personnes à haut risque d'infection par le VIH. Historiquement, l'adoption de la PrEP a été limitée par des obstacles au niveau des systèmes liés au coût élevé des médicaments et par le nombre réduit de points d'accès pour les prescripteurs. À Ottawa, une équipe de chercheurs et de cliniciens a cherché à améliorer l'accès de la PrEP aux groupes prioritaires en mettant en place un service de PrEP dirigé par une infirmière, appelé PrEP-RN, dans le cadre de la clinique de santé sexuelle du bureau de santé publique. Ce programme était le premier du genre au Canada et a nécessité l'attention de nombreux intervenants au sein du bureau de santé publique et de la communauté d'Ottawa. Les infirmières de la santé publique ont proposé aux patientes présentant le risque le plus élevé de contracter le VIH d'être dirigées vers une RNP-RN dans le cadre d'une offre active, et une couverture en médicaments a été fournie aux patients non assurés afin d'assurer un accès égal aux services de PrEP. Les résultats préliminaires ont montré une acceptation de 40% des références à la PrEP chez les patients à haut risque, qui démontre que cette réforme a été efficace à fournir des services à quelques groupes prioritaires, mais plusieurs personnes continuent de refuser la PrEP à cause de leur perception du risque (c'est-à-dire, ils pensent ne pas être à risque pour le VIH).*

### Key Messages

- In Ottawa, the first fully nurse-led pre-exposure prophylaxis clinic in Canada, PrEP-RN, was established as part of Ottawa Public Health's sexual health clinic in a novel program reform which focused on increasing PrEP access, enhancing the capacity of nurses to provide specialty HIV prevention services, and challenging the disciplinary role of public health units.
- Using a provider-driven, active-offer referral system, made by public health nurses, PrEP services were targeted at persons known to be at highest risk for HIV acquisition, which helped ensure equitable access of PrEP services to priority populations in the Ottawa region.
- A review of the initial findings from PrEP-RN found a 40% uptake among high-risk persons, demonstrating that this reform has been effective at reaching some priority groups; however, many persons continue to decline PrEP due to individual perceptions of risk (i.e., feeling they do not need this HIV prevention intervention).

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### Messages-clés

- *La première clinique de prophylaxie pré-exposition dirigée par des infirmière au Canada, la PrEP-IA, a été créée à Ottawa et fait partie intégrante de la clinique de santé-sexualité de Santé publique Ottawa. Ceci a été fait à l'occasion d'une réforme novatrice, axée sur l'amélioration de l'accès à la PrEP, permettant ainsi aux infirmières de fournir des services spécialisés de prévention du VIH et de remettre en question le rôle disciplinaire des bureaux de santé publique.*
- *À l'aide d'un système de demande de consultation axé sur l'offre active fait par des infirmières en santé publique, les services de PrEP étaient offerts aux personnes présentant le risque le plus élevé d'acquisition du VIH, ce qui garantissait un accès équitable des services de PrEP aux populations prioritaires de la région d'Ottawa.*
- *Les conclusions initiales de la PrEP-IA ont révélées une participation de 40% des personnes à haut risque, ce qui démontre que cette réforme a été efficace pour atteindre certains groupes prioritaires. Cependant, de nombreuses personnes continuent à décliner la PrEP en raison de perceptions individuelles du risque*

*(c'est-à-dire, le sentiment qu'elles n'ont pas besoin d'interventions de prévention du VIH).*

## 1 BRIEF DESCRIPTION OF THE REFORM

In response to local increases in HIV rates, researchers at the University of Ottawa collaborated with Ottawa Public Health to provide HIV pre-exposure prophylaxis (PrEP). This reform, known as PrEP-RN, sought to provide PrEP using: 1) a provider-driven, active-offer<sup>1</sup> referral process made by public health nurses and 2) nurse practitioners and registered nurses as the most responsible providers at the Ottawa sexually transmitted infection (STI) clinic. This program was unique because it differed from traditional models of physician-delivered care and because it challenged the role of public health units as being solely for STI surveillance, monitoring, and testing/treatment. This reform added a longer-term pharmacologic intervention to the spectrum of HIV prevention strategies health units provide.

## 2 HISTORY AND CONTEXT

PrEP involves the daily use of emtricitabine/tenofovir DF (FTC/TDF) by HIV-negative persons (Tan *et al.* 2017). PrEP is 96-99% effective in preventing HIV acquisition, when taken as prescribed and with condom use (Grant *et al.* 2010). Prior to 2016, FTC/TDF was only indicated for the treatment of HIV; however, in February 2016, Health Canada (2016) released a supplement for the use of FTC/TDF as PrEP, meaning that persons at high-risk for HIV infection could use this medication for prevention. This also enabled coverage through private drug plans. Because FTC/TDF was only indicated for HIV treatment on the Ontario drug formulary, patients without private insurance still had to pay \$1,200/month out-of-pocket. In July 2017, Health Canada approved generic formulations of FTC/TDF, which reduced the cost to \$250/month. In September 2017, the Ontario Ministry of Health and Long-Term Care (MOHLTC) changed its drug listing for FTC/TDF to include “HIV prevention” in the indications for use and removed the limited-use code. This revision meant that FTC/TDF was covered by publicly funded drug plans, reducing its cost to the user to \$50/month or less, depending on coverage.

Despite these changes, as practising nurses in our local public health unit STI clinic, we noted that cost remained a barrier for patients without drug coverage. Moreover, patients experienced difficulties accessing a prescriber for PrEP. Previously, only two infectious disease specialists in Ottawa offered PrEP, with 2-4 month wait times for consultation. Furthermore, uptake of PrEP delivery in primary care in Ottawa seemed slow to rise, likely related to providers' discomfort managing PrEP and low staffing resources to provide services. A pan-Canadian study found that, while PrEP is within the scope of family physicians, many felt they lacked resources, information, and training, and instead referred

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<sup>1</sup>In this context, the concept of “active offer” means that nurses offered referrals to patients who had not requested or considered PrEP. This contrasts with “passive offer” when referrals are provided to persons who present requesting this service.

patients to specialists (Sharma *et al.* 2014). An issue with these referrals is that, in Ontario, an infectious disease consultation (first PrEP visit) is billable for \$157.00, with subsequent visits costing \$38.05 (MOHLTC 2015, A76). Thus, in a fee-for-service structure, PrEP costs the health care system over \$365/patient in specialist billing fees in the first year, raising concerns about the long-term financial implications of this model when PrEP delivery is limited to specialists. Similarly, a case study analysis showed that the average cost of PrEP access with family physicians was over \$230 in the first year (O’Byrne, Orser, Jacob 2019). Thus, as more physicians begin to prescribe PrEP to more patients, the overall cost to the health care system will continue to increase (O’Byrne *et al.* 2019).

In comparison, in Ontario, nurse practitioners can autonomously provide PrEP, and do so at a reduced cost compared to specialists and family physicians. Nurse practitioners can also delegate the tasks for PrEP to registered nurses under medical directives, as we did in PrEP-RN. The costs of nurse-led PrEP are approximately \$150 in the first year, and less than \$100 each year thereafter (O’Byrne, Orser, *et al.* 2019).

PrEP provision by the health unit represented a departure from its typical population-level interventions. The PrEP-RN clinic adopted a medical model by providing patient services at the individual, not community, level. Instead of focusing on strategies such as counselling and condom use, with PrEP, the health unit provided a longer-term clinical intervention. While some Ontario health units operate STI clinics, PrEP-RN changed the focus from episodic to ongoing care. PrEP delivery by public health nurses, thus constituted a change in focus for health units.

Lastly, the medical model of health care delivery has historically emphasized physicians as the “experts” in patient assessments, consultations and follow-up. In this model, nurses are “assistants”—with permissions to provide services allowed when authorized by prescribers. The implementation of a nurse-led PrEP program, such as PrEP-RN, thus shifted care delivery in that nurses acquired a more active role in providing PrEP assessments, interpreting laboratory results, and providing HIV prevention medications for ongoing use.

### 3 GOALS OF THE PROGRAM

Recognizing there were few clinical access points for PrEP in Ottawa, we set-out to establish PrEP-RN. Our aims were to: 1) establish a nurse-led PrEP clinic, 2) offer PrEP to those at highest risk for HIV using active-offer referrals from public health nurses during STI follow-up and 3) build capacity in primary care for PrEP delivery by initiating patients in the PrEP-RN clinic and referring these patients to their primary care providers for ongoing care. The overarching goals of this program reform were to reduce HIV transmission and increase PrEP access in Ottawa. Some of the research funds provided by the Ontario HIV Treatment Network for the study were allocated to provide PrEP to persons without medication insurance until they could secure alternate forms of coverage.

## 4 FACTORS THAT INFLUENCED THE DECISION TO IMPLEMENT THE PROGRAM

The decision to implement an active-offer PrEP-RN clinic required consultation with multiple stakeholders, including Ottawa Public Health (e.g., administrators and clinical staff), and community members (e.g., infectious disease specialists and HIV/AIDS organizations). Considerations are detailed below using the 3I framework of interests, ideas, and institutions (Lavis *et al.* 2012).

While stakeholders were united in their interest to reduce HIV transmission and agreed that PrEP was important, differences arose regarding institutional beliefs for the reform. All groups felt PrEP should be available, but public health administrators were appropriately reluctant to replicate infectious disease and primary care services in the STI clinic; they felt their focus should be to enhance primary care capacity. Moreover, consideration needed to be made for the shift from episodic STI management to continuous care for PrEP, which required training the STI clinic nurses and protocol development (e.g., interpretation and management of kidney test results). This change raised concern about how the STI clinic could offer PrEP.

The physicians in our local context had discordant interests in the reform as well. Infectious disease physicians noted that their clinics were busy and could not sustain PrEP at the rate it was being requested. Their clinical hours were increasingly devoted to PrEP, as opposed to care for complex health issues requiring specialist consultation. These specialists supported PrEP delivery by the health unit. Family physicians also supported the shift in PrEP delivery, as, in our local context, the majority did not feel comfortable providing PrEP, thus limiting patient access. Moreover, the small number of family physicians prescribing PrEP only did so for their rostered patients. Finally, some local HIV/AIDS organizations also began to pressure the local health unit, arguing that more “needed to be done” to address HIV transmission and PrEP access in Ottawa. Importantly, the idea that PrEP-RN would be more cost-effective, did not factor into initial discussions. This was because, at the outset, we did not know what the actual costs and outcomes would be. Moving forward, this idea of cost will likely be influential for decision-makers in other health units who consider this approach and for those at the provincial level who inform health systems care delivery more broadly.

To summarize, while all stakeholders felt PrEP should be available, each group felt the others might be better suited to provide it, creating a “purview paradox” (Krakower *et al.* 2014). In this case, public health administrators felt primary care should provide PrEP, while primary care felt this should be done by specialists, and specialists looked to the public health STI clinic. There are two important policy development points here. First, while the idea that access should be increased was shared among the stakeholders, their interest in leading this initiative varied. This led to the second point, which is that stakeholders were willing to meet and discuss PrEP with the health unit. While specific views on

implementation varied, the functional capacity of these relationships fostered collaborative decision-making, and likely influenced the outcome.

To mitigate the incongruity in PrEP delivery, this stakeholder consultation led to the idea that PrEP services in the STI clinic should target those at highest risk for HIV, so that services were not replicated, but augmented for those in greatest need. In agreement with public health administrators' sentiments to enhance capacity for PrEP delivery in primary care, it was decided that PrEP-RN patients would be initiated and followed for less than one year and referred back to primary care with instructions for PrEP maintenance. Patients at highest risk could thus receive rapid access to PrEP in the public health STI clinic, while capacity was simultaneously built in primary care. To operationalize this targeted approach, we developed risk stratification criteria to determine patient eligibility (Table 1). Persons with a known HIV exposure(s), objective risk indicators, and/or who were from groups with elevated HIV prevalence could be referred to PrEP-RN. While the groups included in this list only account for a small portion of the Canadian population, they make up 90% of all HIV diagnoses in Canada (PHAC 2018). Those who did not meet the criteria could be referred to alternate clinics, ensuring no patient was denied access.

Table 1: HIV risk stratification

HIERARCHY OF RISK	INCLUDES
<b>1</b> <i>HIV contacts</i>	<ul style="list-style-type: none"> <li>• Sexual partners of HIV case with detectable viral load</li> </ul>
<b>2</b> <i>Objective risk indicators</i>	<ul style="list-style-type: none"> <li>• Infectious syphilis</li> <li>• Two or more rectal bacterial STI diagnoses in past year</li> <li>• Post-exposure prophylaxis use</li> <li>• High-risk based on nurses' clinical judgment</li> </ul>
<b>3</b> <i>Groups with elevated HIV prevalence</i>	<ul style="list-style-type: none"> <li>• Men who have sex with men</li> <li>• People who inject drugs</li> <li>• African, Caribbean, Black persons</li> <li>• Indigenous persons</li> </ul>
<b>4</b> <i>General public</i>	



## 5 HOW THE PROGRAM WAS IMPLEMENTED

To implement this program, we developed documents to detail clinical pathways in two domains: PrEP referrals by public health nurses and PrEP-RN procedures. We developed these items with input and feedback from the nurses who were to make these referrals and run PrEP-RN.

For referrals, public health nurses completing STI follow-up would assess patients’ risk factors and offer PrEP to those who met our criteria. Public health nurses were selected because they have expert STI knowledge and access to patient’s STI history. Because STI diagnoses are reportable to health units in Ontario, these nurses knew which patients were previously positive, even when their primary care providers did not. This meant that public health nurses determine where patients fell on the risk stratification criteria and whom to target for PrEP.

To ensure appropriate triaging, we worked with these nurses to develop a clinical pathway detailing steps to determine eligibility, counselling, and referral options (e.g., PrEP-RN or alternate clinic). We then had these nurses document whether patients accepted a PrEP referral (and to which clinic), declined a referral (with rationale), or if patients were ineligible (e.g., medical or insurance reasons).

Using the Canadian Guidelines for PrEP (Tan *et al.* 2017), the principal investigator (O’Byrne), along with nurse practitioners and registered nurses at the STI clinic and a local infectious disease specialist, developed the PrEP-RN clinical procedures (see O’Byrne, MacPherson, *et al.*, 2019). Medical directives for registered nurses were developed and authorized by the lead nurse practitioner.

## 6 EVALUATION

Within four months of program initiation, public health nurses offered referrals to 103 patients who met our criteria; 40% accepted, 50% declined, and 10% were ineligible. Ineligible patients were already HIV-positive, had kidney impairment, or did not have provincial health insurance. Of patients who accepted a referral, five had sexual contact with someone diagnosed with HIV within one year, 25 had more than one objective risk factor, and six were deemed high-risk by clinical judgment. Almost all of the patients offered PrEP were men who have sex with men, which may have related to higher rates of sexually transmitted infections and/or testing for these infections within this group (meaning that these persons were more likely to meet the objective risk indicator criteria).

These findings demonstrate that public health nurses identified at-risk persons who may not have self-selected for PrEP based on their perceptions of HIV risk. While over 50% of our patients declined referral, the active-offering of this intervention meant that higher risk individuals received more education about HIV prevention and had an access point to receive PrEP in the future should they wish. That being said, many of the patients who declined referrals felt they were not sufficiently “at risk” to warrant PrEP, while others had

concerns about the health outcomes of antiretroviral use (although FTC/TDF is generally without long-term adverse effects).

A limitation of our referral system is that it unintentionally restricted referrals to other groups with elevated HIV rates compared to the general population, but lower STI rates before HIV diagnosis (e.g., persons using injection drugs). This is because, in Ottawa, the majority of the STIs we focused on were diagnosed in men who have sex with men, as this group more regularly accesses STI testing/screening compared to other groups who might have social, behavioural, and geographical barriers to health care access. Extending referrals based on nurses’ clinical judgment partially addresses this issue (O’Byrne, MacPherson, *et al.* 2019).

As part of our knowledge dissemination strategy, we published various research articles about PrEP-RN, including clinical protocols, indications for PrEP among populations at higher risk for HIV, and a cost analysis comparing specialists, physicians, and nurses. Additionally, our principal investigator has advised other health units in Ontario regarding PrEP-RN implementation and has provided presentations locally as well.

## 7 STRENGTHS, WEAKNESSES, OPPORTUNITIES AND THREATS

Table 2 provides a summary of factors that strengthened and weakened our implementation of PrEP-RN, while also highlighting threats and future opportunities.

Table 2: SWOT Analysis of PrEP-RN

STRENGTHS	WEAKNESSES
<ul style="list-style-type: none"> <li>● Lower cost service with nurses</li> <li>● Community-based access point: more accessible environment for patients compared to specialist offices or hospital-based clinics</li> <li>● Equity of services by subsidizing PrEP for uninsured patients</li> <li>● Stigma-free HIV prevention services</li> </ul>	<ul style="list-style-type: none"> <li>● Inclusion criteria may restrict access to low-risk patients or high-risk patients without STI diagnosis</li> <li>● Reliance on certain health care providers to identify high-risk patients and make referrals</li> <li>● Lack of consensus on how much to pursue PrEP referrals for high-risk patients</li> <li>● Addressing issue of high-risk patients who decline a PrEP referral</li> </ul>

OPPORTUNITIES	THREATS
<ul style="list-style-type: none"> <li>● Expand PrEP services at Ottawa Public Health (increase number of service days/clinic staff)</li> <li>● Develop a provincial PrEP service running in all health units (based on PrEP-RN model)</li> <li>● Have the MOHLTC fund PrEP for all persons who request it</li> </ul>	<ul style="list-style-type: none"> <li>● Nurses role in providing specialist services could be challenged by other health care providers</li> <li>● Ethical dilemmas faced by nurses when discontinuing services to high-risk patients (e.g., who miss follow-up appointments)</li> <li>● Limited focus of health in PrEP clinic: other health issues have to be referred to primary care</li> </ul>

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