

# Delivery models of pharmacy-led HIV pre-exposure prophylaxis (PrEP)

## Question

What are the best practices for pharmacy-led HIV PrEP delivery models in high-income settings?

## Key Take-Home Messages

- PrEP prescription by pharmacists is the most common intervention activity in pharmacy-led HIV PrEP delivery models (1).
- The scope of practice of pharmacists varies widely across local jurisdictions. Under some jurisdictional regulations (U.S. state level or federal) or under collaborative agreements, pharmacists may gain authorization to prescribe PrEP and take responsibility for ordering tests for monitoring and adherence (1–3).
- In some pharmacy-led HIV PrEP delivery models, pharmacists may provide PrEP services across the PrEP cascade which may include activities related to improved PrEP awareness, uptake (4, 5), adherence, and retention (1, 3).
- Funding models of pharmacy-led PrEP initiatives (e.g. assessment fees, testing fees) rely on a variety of sources, such as out-of-pocket (6), private and public insurance plans, and financial assistance programs (7).
- Accessibility (8, 9), convenience (10), and pharmacists' expertise are found to be common benefits (6), while lack of pharmacist training (11) or pharmacy resources, regulatory barriers (12), and concerns with compensation for services (13) could be common challenges in pharmacy-led PrEP delivery programs (10).

## Rapid Response: Evidence into Action

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- Common outcome measures reported by pharmacy-led PrEP programs include (but are not limited to) the number and age of individuals enrolled, the number of new HIV infections (HIV incidence), the number (incidence) of new sexually transmitted infections (STIs), adherence to PrEP medications, PrEP retention (14, 15), and drug tolerance (10, 16).
- Some pharmacy-led PrEP delivery models demonstrate similar, if not better, outcomes (e.g. PrEP adherence) compared to physician/nurse practitioner-led programs, indicating the value of this delivery model to increase access to PrEP (13) without compromising the quality of care (1, 16).
- There remains a gap in the literature on the associated costs (17) and cost-effectiveness of pharmacy-led PrEP delivery models across high-income countries (2, 7).

## The Issue and Why it's Important

PrEP is a highly effective medication taken to prevent HIV. PrEP consists of the use of antiretroviral drugs to lower the chance of HIV infection when taken by individuals at risk of acquiring (18, 19). PrEP reduces the risk of contracting HIV from sex by about 99% and from injection drug use by at least 74% (19). PrEP may be taken orally in a pill form (generally, as a combination of two antiretroviral drugs) daily or on-demand (on days before and after having sex), and in a long-acting injectable form (18). In Canada, two PrEP pills are approved for use (18), and as of 2024, the first long-acting injectable PrEP was approved (20). After an individual is assessed and prescribed PrEP by a licensed health care professional, individuals should have regular clinic visits with a health care provider (typically every 3 months) to test for HIV and STIs, and monitor for drug side effects and toxicity (18).

PrEP delivery systems are often a collaboration of clinical care and public health care models and can be described as a continuum of care, which outlines a framework for the steps needed for population health and prevention with PrEP (21). The continuum of PrEP care can be divided into three stages: awareness (program planning, educating populations and providers, identifying and engaging at-risk populations), uptake (linking to PrEP care, prescribing PrEP, and initiating PrEP), and adherence and retention (staying on PrEP) (21). A PrEP service delivery model can be divided into four key components: the target population, the delivery setting, the PrEP provider, and the delivery channel (22). A scoping review of 33 articles found that current PrEP service delivery models predominantly target high-risk individuals; namely, men who have sex with men (22). PrEP delivery models appear to be located in a clinical or hospital setting and delivered by clinically trained health professionals (22).

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Delivery of PrEP services is monitored to analyze trends and patterns associated with its use. A common method of tracking uptake of PrEP is by examining pharmacy dispensing data (23). Health Canada approval of new PrEP drugs ( $p=0.001$ ) and introducing generics/partial public drug coverage ( $p=0.002$ ) led to a significant increase of PrEP use over time in Ontario from 2015 to 2018 (23). An estimated 14,650 people were dispensed PrEP in Ontario in 2022—an increase of 2.3 times from 2018 ( $n=6,504$ ) (24). This data also revealed that the majority of people dispensed PrEP in Ontario in 2022 were men (97%), aged 20–39 years old (59%), prescribed PrEP by family and general practitioners (37%), and with the majority of prescriptions dispensed in Toronto and Ottawa (75%) (24). Despite the increase to 14,650 people being dispensed PrEP in Ontario in 2022, (which falls within the estimated 11,957 to 15,281 PrEP-eligible gay, bisexual men who have sex with men in Ontario) however only roughly 46.2–65.9% of eligible gay, bisexual men who have sex with men are estimated to be on PrEP (25).

A similar case of slow uptake and underutilization of PrEP delivery services is mirrored in other high-income settings, such as in the U.S.: from 2012 to 2021, PrEP use increased, but PrEP equity for Black and Hispanic Americans decreased (26). In 2022, the U.S. Centers for Disease Control and Prevention (CDC) reported that about one third of people in the U.S. who could benefit from PrEP had been prescribed it (27). Despite overall improvements in PrEP prescriptions in the U.S. from 2019 to 2022, significant disparities remain, with 94% of eligible White individuals receiving PrEP compared to only 13% of Black and 24% of Hispanic/Latino eligible individuals (27).

The reasons for low HIV PrEP uptake are multifactorial. PrEP uptake is affected by barriers in accessing PrEP (e.g. stigma, cost, health care access) (12, 28) and disparities in PrEP uptake among different population groups (29). A systematic review of 47 studies identified barriers to PrEP uptake and interventions to match those barriers (29). The review found that a key barrier to PrEP access was “the purview paradox”, which refers to the idea that primary care physicians consider PrEP to be beyond their purview, but HIV specialists typically do not treat people not living with HIV (29). Moreover, the review identified cognitive barriers such as knowledge, attitudes and beliefs about PrEP among both patients and providers (29). It also highlighted health care system barriers including poor communication about, funding for, and access to PrEP (29). Additionally, intersecting stigmas (e.g. HIV-stigma, PrEP-stigma, homophobia, transphobia) along with disparities across gender, racial and ethnic groups, remain largely unaddressed by existing interventions (29).

Alternative PrEP delivery models have emerged to increase PrEP access, uptake and adherence (9). In addition, these models may address disparities and circumvent access barriers (13) and, especially among population groups that are disproportionately at greater HIV

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risk (i.e. key populations) (6). The pharmacy-led PrEP delivery model is one such innovative strategy (6). Pharmacy-led PrEP delivery models position the pharmacy as the PrEP delivery setting, and in many cases, the pharmacist becomes the PrEP provider (9) and may integrate PrEP care duties related to PrEP awareness, uptake (30), and adherence (22), and retention (13). Pharmacy-led HIV PrEP delivery models may allow community pharmacists to provide PrEP to people at risk of HIV (e.g. when the clients are referred from an HIV/STI testing site) (6, 31). In 2018, a novel pharmacist-led PrEP delivery model in Saskatchewan demonstrated viability, efficacy, and retention in care for HIV prevention (32). Operating under a collaborative prescribing agreement with an infectious disease physician and working alongside a public health nurse, the protocol permitted the pharmacist to prescribe PrEP and order laboratory tests showcasing the potential of expanding the pharmacist's role in public health initiatives (32).

Community pharmacist-provided services take advantage of the medication expertise of a trusted medical professional (pharmacist), convenient location, extended hours of operation, and lower cost relative to other health care providers (12, 33). Research has highlighted positive support from both pharmacists and users for access to pharmacist-prescribed PrEP and PrEP care delivery services in pharmacies (34-40).

More than a dozen U.S. states have passed legislation allowing pharmacists to independently prescribe and dispense PrEP, each governed by a different set of laws and regulations (41). The scientific literature has highlighted the emergence of pharmacy-led PrEP programs in response to the evolving role of pharmacists as PrEP providers (3). As these pharmacy-led PrEP delivery models continue to be adopted or scaled-up, it is important to better understand how these delivery models are structured and the best practices recommended to obtain optimal quality HIV PrEP care. This review summarizes literature published from 2020 and onwards on pharmacy-led HIV PrEP models in high-income countries. It describes the scope of practice and roles of pharmacists, benefits and challenges, measured outcomes, costs and funding models of pharmacy-led PrEP delivery models.

## What We Found

### The scope of practice for pharmacists in pharmacy-led HIV PrEP delivery models

In pharmacy-led HIV PrEP delivery models, pharmacists may perform a variety of permitted activities in keeping with the terms of their professional license—often referred to as their scope of practice. The scope of practice for pharmacists in this delivery model is dictated and confined within the regulatory boundaries of laws and regulations governing their ability to provide HIV PrEP care services

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(2, 3). In Canada, the scope of practice varies at provincial level, with each province setting their own legislation and regulations on the ability of pharmacists to prescribe, dispense, administer medications as well as ordering, receiving, conducting and interpreting health tests (42). Likewise, in the U.S., the scope of practice for pharmacists is established at the state level and regulated by boards and agencies (3, 12). For example, states may experiment with different approaches to health services (e.g. adopting a pharmacy-led HIV PrEP delivery model) and often a trailblazing state may influence others states to follow suit (12).

In pharmacy-led HIV PrEP delivery models, pharmacists take on an expanded role in preventative HIV patient care (3). The scope of practice in this model typically includes assessing and counselling patients, prescribing and dispensing PrEP, ordering and interpreting laboratory tests for HIV and drug monitoring, and collaborating with health care providers (3). However, strategies to implement pharmacy-led HIV PrEP delivery vary widely by legislation, depending on jurisdictions and pharmacy type/setting (2). In turn, this influences the scope of practice of the pharmacist, especially with regards to the pharmacist's HIV PrEP prescribing authority—a common hallmark to this delivery model (17). A review of literature from 2018–2023 describing how pharmacist-led PrEP services in the U.S. initiated and managed PrEP for their clients found that the two most common models operating within community pharmacies were led by: 1) pharmacists who can independently prescribe HIV PrEP through established legislation, or 2) pharmacists who work collaboratively with an HIV PrEP-prescribing clinician (2). The second, dependent prescribing, is often initiated by formal agreements between pharmacists and licensed providers (2). One such agreement is called a collaborative drug therapy agreement (CDTA), allowing pharmacists to prescribe specific medications like PrEP under supervision (2). Another dependent PrEP-prescribing model at community pharmacies, which has become more common, is a collaborative practice agreement (CPA) (2). A CPA is a formal agreement between pharmacists and licensed providers where qualified pharmacists assume professional responsibility for patient care services (patient assessment, prescribing medications, ordering laboratory tests, administering drugs) (2, 3). For example, general internal medicine clinics in Ohio developed a CPA with pharmacists to assist with HIV PrEP prescribing and monitoring whereby the expanded responsibilities for pharmacists in this multidisciplinary setting included ordering pre-visit labs, assessing efficacy, safety and adherence of PrEP medications, refilling PrEP prescriptions and following up on abnormal laboratory results if needed (43). The expanded scope of practice of pharmacists was also highlighted in a study focused on increasing PrEP enrollment among veterans (5). A pharmacy-led HIV PrEP clinic utilized a dashboard to aid in screening patients (11.5% of eligible participants were initiated on PrEP) and one of three pharmacists in the study had a “scope of practice” for prescribing and monitoring PrEP medications, thus demonstrating the expanded role of pharmacists may play in all

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stages of the PrEP cascade (5).

McCree *et al.* (2020) summarized pharmacists' role in providing PrEP services within the "Prevent" strategy under the U.S. "Ending the HIV Epidemic" initiative (3). These PrEP services may include identifying patients at risk for HIV infection, initiating PrEP if appropriate and supported by regulations in their state, assisting patients with addressing barriers to adherence, ordering laboratory results and providing follow-up care (3).

A 2022 scoping review identified nine studies on the implementation of PrEP interventions within pharmacies and found the most common intervention activity was pharmacist prescription of PrEP (1). In addition, the review identified best practices of pharmacy-based PrEP interventions. Of 16 articles reviewed, ten highlighted the utility of pharmacists performing HIV screening in order to identify patient eligibility for PrEP; two studies suggested formation of CPAs to allow initiation and monitoring of PrEP by pharmacists, and two other studies suggested formation of CDTA to expand the pharmacist's scope to the prescription, modification or discontinuation of PrEP (1). Training pharmacists with PrEP adherence counseling, sexual health counseling and adverse effect screening was another common theme identified by this review (1).

A study evaluating acceptability of a PrEP-prescribing service by pharmacists in Nova Scotia found that eligible populations widely supported pharmacists' prescribing of PrEP (44). However, target users expressed concerns about the pharmacists' abilities to order and view lab results, pharmacists' knowledge and skills of sexual health, and the potential to experience stigma within the pharmacy setting (44). Another study from Nova Scotia found that pharmacists expressed mixed acceptance of a PrEP prescribing service (40). They expressed concerns about increased workload, time to provide service, PrEP delivery training, and laboratory test ordering and reimbursement (40). Findings from these two Nova Scotian studies have important implications on the pharmacists' scope of practice, especially in light of the recent news of The Nova Scotia College of Pharmacists enabling pharmacists to prescribe PrEP as of July 1, 2024 (40, 44, 45).

## Pharmacy-led HIV PrEP models in relation to the stages of PrEP care

In settings where pharmacists can provide PrEP services in pharmacy-led PrEP delivery models, they may participate in every stage of the PrEP care cascade, which includes PrEP awareness, uptake, adherence, and retention (3, 46). A qualitative systematic review identified two studies which examined the possibility of screening patients through pharmacies in Georgia (U.S.) for potential initiation of PrEP (4). Both of these studies presented with similar themes such as interest in patient screening, participants'

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desire to implement PrEP services into pharmacy practice and the need for training programs for pharmacy staff (4). PrEP uptake activities were mentioned in a scoping review reporting on integrating PrEP intervention within pharmacies (1). The authors identified four studies that were designed to initiate PrEP among eligible participants, achieving successful PrEP initiation among 54–100% of participants (1). Moreover, this review identified ten studies underscoring the utility of pharmacists performing HIV screening to identify at-risk individuals who may be eligible for PrEP initiation under the awareness PrEP stage (1). The review uncovered a common theme of training for PrEP adherence and retention, highlighting the need for additional training in areas such as adherence and sexual health counseling and adverse side effect screening (1).

Prior research has shown high willingness of PrEP users (mostly focused on men who have sex with men) to discuss, get screened for (47), and obtain PrEP in pharmacies, underscoring the potential role for pharmacists to engage with patients along the HIV PrEP care cascade (48, 49). In one study, pharmacists utilized a PrEP dashboard to review 94 patients, of which 26 were eligible for PrEP, and three of them were successfully enrolled (5). This study illustrates the valuable role pharmacists can play in enabling PrEP enrollment (5). Utilizing a health system specialty pharmacy (HSSP) model, a study within the Veterans Affairs Colorado Health Care System compared the effects of PrEP use over time (PrEP persistence) between the HSSP care model and external pharmacy services (50). Patients using a non-integrated HSSP were 2.7 times more likely to be non-persistent than HSSP patients (hazard ratio [HR] 2.7, 95% CI 1.6–4.7,  $p < 0.001$ ), demonstrating the value of integrating pharmacists as part of a multidisciplinary PrEP care team in enhanced continuity of PrEP care through the cascade and better persistence (50). It is important to note with the HSSP care model that the pharmacists were allowed to place lab orders and refill prescription under a CPPA, and as part of this multidisciplinary team they had access to patients' electronic health records (50). A telePrEP clinic run by two pharmacists (both have expanded scopes of practice approved by the infectious diseases service line, which includes prescribing PrEP medications, ordering of associated lab tests, STI screening and treatment) led and ensured access to PrEP (16). Researchers found adherence to PrEP and monitoring was similar between the pharmacist-led telePrEP clinic and an in-person PrEP clinic run by a physician or nurse practitioner (16). Similarly, a pharmacy-led, same-day PrEP program in Mississippi allowed pharmacists to serve as the PrEP navigator, and participate in various stages of the PrEP care cascade: awareness (educating eligible clients about PrEP effectiveness, adherence and side effects), uptake (provide a 90-day PrEP prescription), and adherence and retention (pharmacists scheduled a follow up clinical appointment within three months) (15). A study from Washington State, focusing on pharmacy interventions that may reduce HIV and hepatitis C virus (HCV) transmission and promote linkage to care among adults experiencing homelessness, expanded on the roles undertaken by pharmacists. The expanded

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roles undertaken by pharmacists included administration of HIV and HCV point of care testing (POCT), education about diseases, counselling to reduce risk, and referral to care (51). Among a total of 50 study participants, 44% (n=22) had a reactive HCV POCT, one participant had a reactive HIV POCT, 94% (n=47) reported illicit drug use and 76% (n=38) qualified for PrEP (51). Pharmacist referrals were made for 28 participants for follow-up HIV or HCV testing and/or evaluation for PrEP (51). Among those referred, 71% were confirmed to have established care. (51). These findings show that pharmacists may be in an optimal position to promote engagement and retention in care for vulnerable and difficult to treat populations (51).

## Funding framework for pharmacy-led PrEP delivery model

Pharmacy-led HIV PrEP initiatives may utilize several funding models to cover the costs of services like testing, medication, and assessment fees (7). Pharmacies may charge patients directly for assessments, counselling, or consultations related to PrEP, which is common in jurisdictions where pharmacy services are not fully covered (7); however, this may serve as a barrier in low income settings (6). In settings where pharmacists can provide PrEP services, private and public health insurances may reimburse for these assessments (7). In the U.S., most health insurance plans are required to cover the cost of PrEP medication and ancillary services; despite this, there are reports of private insurers not complying with this requirement (7, 52). Individuals without insurance may qualify for assistance programs, sponsored by the drug manufacturer (53), or state (54) or federal governments (55) that cover a portion or all of the cost (7). An affordability study among patients seen at a multidisciplinary specialty PrEP pharmacy model in Vanderbilt, Tennessee reported that 27% of patients required prior insurance authorization (all were approved), the median total out-of-pocket medication cost was zero, and most patients (86%) used manufacturer copay cards (56).

## Strengths/benefits and risks/challenges of pharmacy-led PrEP delivery models

Pharmacy-led PrEP delivery models have the potential to play a key role in enhancing access and uptake of PrEP; however, it is important to understand both the benefits and the challenges with this delivery model (2). According to the reviewed literature, the main benefits of pharmacy-led PrEP models could improve accessibility (8, 9), convenience (10) and confidentiality of the pharmacy setting, and the recognition of the pharmacists' expertise (11) in drug management (6). On the other hand, the literature identified some potential challenges of pharmacy-led PrEP models, such as training requirements for pharmacists (11), regulatory barriers affecting the scope of practice (12), reimbursement issues (13), patient awareness and follow-up, and resource limitations (6, 10).

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A 2024 literature review examined the advantages and disadvantages of three pharmacist prescribing models (12). Firstly, this review found that population-based CPA (also called non-patient-specific standing order) presented with less liability due to collaboration with a medical provider, however, finding a collaborator may be difficult and CPA terms can change or be terminated (12). The states of Illinois and New York provide examples of such population-based CPA approach (12). Second, pharmacists may be granted permission to prescribe PrEP under government protocol, such as in the case of Utah (12). Although government protocol prescribing models remove the need to find a willing medical provider collaborator, this model may not be adaptable to individual patient needs or reflect best practices (12). Thirdly, under a standard of care prescribing model, the broad framework is flexible and may accommodate unique practice settings, however, there is greater liability due to less specific legal guidance (12). Another 2024 review of relevant policies across U.S. states explored challenges that may impact access to PrEP for cisgender women in 20 U.S. states and found that four states allowed pharmacists to prescribe PrEP and six states have financial support programs to cover the cost of PrEP (57). Additionally, a limitation on pharmacist prescribing abilities was identified as a barrier to reproductive health services access for cisgender women (57). Importantly, this review includes policies in place as of July 2022 (57). A systematic review on private pharmacies as a delivery mode of HIV PrEP explored two pharmacy delivery models in the U.S.: a co-located model (at large retail pharmacy chains) and a full-task shifted model (private standalone pharmacies where pharmacists can prescribe PrEP) (7). The researchers reported that although both models enhance access to PrEP, there are challenges to long term feasibility because of resource limitation and reimbursements, especially with regards to pharmacists' lack of provider status at the federal level which prevents them from being able to bill the government for PrEP care services (7). One study described strategies to modify PrEP care to improve access in the U.S. South and rural communities (8). The authors highlighted the role of community pharmacies as an ideal setting for delivering PrEP services where primary care is limited because of their geographical accessibility and their familiarity and frequent use by clients/patients (8). In addition, the authors recognized the potential of pharmacist-led clinics to expand PrEP access in underserved areas (i.e. U.S. South and rural communities) by reducing the geographical barriers (8). Furthermore, pharmacy-based models could be conveniently integrated with other services (e.g. telemedicine) so that PrEP services could be co-delivered across the various stages of the PrEP care cascade (8). A 2023 systematic review found pharmacist-PrEP provider models to have promising potential to be successfully implemented and sustained in diverse real-world settings (13). A 2022 systematic review evaluated the evidence on distributing PrEP through pharmacies, identifying eight U.S. studies reporting the values and preferences of pharmacy staff and end users (10). The authors highlighted the benefits of pharmacy PrEP access such as convenience, accessibility, and alignment with

34. Crawford ND, Josma D, Morris J, Hopkins R, Young HN. Pharmacy-based pre-exposure prophylaxis support among pharmacists and men who have sex with men. *Journal of the American Pharmacists Association*. 2020;60(4):602-8.
35. Zhu V, Tran D, Banjo O, Onuegbu R, Seung H, Layson-Wolf C. Patient perception of community pharmacists prescribing pre-exposure prophylaxis for HIV prevention. *Journal of the American Pharmacists Association*. 2020;60(6):781-8. e2.
36. Lutz S, Heberling M, Goodlet KJ. Patient perspectives of pharmacists prescribing HIV pre-exposure prophylaxis: A survey of patients receiving antiretroviral therapy. *Journal of the American Pharmacists Association*. 2021;61(2):e75-e9.
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38. Wilby KJ, Smith AJ. A narrative review of continuing professional development needs for pharmacists with respect to pre-exposure prophylaxis (PrEP) for human immunodeficiency virus (HIV). *Pharmacy*. 2020;8(2):11.

scope of work; in contrast, concerns included inadequate time, compensation for services, privacy issues and training requirements (10). A review article exploring the PrEP implementation barriers and facilitators focused on the pharmacy delivery setting for PrEP (11). This study identified limited staff knowledge, capacity and experience with PrEP, counseling about sexual health and lack of incentives for pharmacists to prescribe PrEP as barriers (11). In contrast, long operating hours, frequent interactions with patients, perceived skills among pharmacists to counsel patients on PrEP were reported as positive attributes towards the pharmacy delivery settings (11). A qualitative study accessed pharmacists' and pharmacy technicians' perspectives regarding the implementation of PrEP screening and dispensing. Researchers found that both expressed strong willingness and support for screening and dispensing PrEP in pharmacies. However, both expressed concerns about time and the resources needed to perform these duties. Pharmacy technicians reported more barriers than pharmacists who largely fixated on practical issues, including logistics and workflow (58).

A recent review summarized novel platforms for biomedical HIV prevention delivery to key populations outside of the traditional health facilities environment, with one such platform being pharmacy-led PrEP delivery (6). The authors identified the extended operating hours of pharmacies, convenience of the pharmacy location, the perception of pharmacies as neutral and non-stigmatizing environments, high approachability of pharmacists as trusted medical professionals, and the ability to reach diverse populations as key benefits to pharmacy-led PrEP delivery models (6). This review describes pharmacy-led models as an efficient and highly accessible clinical setting to provide preventive services, and gives examples of pharmacy-led PrEP models in practice (6). For example, the convenience and accessibility of pharmacies are cited as advantages in California, where no external clinician is required to prescribe PrEP, and in Seattle, where a pharmacy-led clinic reported that most men who have sex with men who used PrEP did not have access to a primary care provider (6). In contrast, pharmacy-led models may be hindered by a need for lab-based tests and monitoring that requires clinician-based service delivery, or providers' hesitancy to prescribe PrEP without prior medical consultation (6). One study surveyed pharmacies to gauge PrEP access following a policy implementation authorizing pharmacies to prescribe and furnish the drug in the San Francisco Bay Area (59). "Furnish" is a California-specific term, meaning "to supply by any means, by sale or otherwise" (59, 60). Researchers found that although the California regulation allows pharmacies to furnish PrEP, only six of 209 pharmacies (2.9%) furnished the drug (59). Pharmacies cited competing demands related to COVID-19, a lack of patient awareness, difficulty obtaining laboratory tests from patients, lack of time, lack of staff, cost to pharmacy, vague wording of the policy, and difficulty in arranging follow-up care as barriers to implementation of furnishing (59). A systematic review of qualitative studies found that pharmacist-prescribed approaches to

39. Cernasev A, Barenie RE, Wofford BR, Golden J, Walker C. Empowering Tennessee pharmacists to initiate PrEP using collaborative pharmacy practice agreements. *Clinica Practica*. 2023;13(1):280-7.
40. Booker C, Murphy AL, Isenor JE, Ramsey TD, Smith AJ, Bishop A, et al. Community pharmacists' acceptance of prescribing pre-exposure prophylaxis (PrEP) for human immunodeficiency virus (HIV). *Canadian Pharmacists Journal*. 2023;156(3):137-49.
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42. Canadian Pharmacists Association. Practising to full scope. 2024. Available from: <https://www.pharmacists.ca/advocacy/scope-of-practice/practising-to-full-scope/> Accessed September 12, 2024.
43. Lee LC, Pollak BA, Coffey CP. Implementing a collaborative practice agreement for HIV pre-exposure prophylaxis in the primary care setting. *Journal of the American Pharmacists Association*. 2023;63(1):383-8.
44. MacDonald CB, Murphy AL, Isenor JE, Ramsey TD, Furlotte K, Smith AJ, et al. Target users' acceptance of a pharmacist-led prescribing service for pre-exposure prophylaxis (PrEP) for human immunodeficiency virus (HIV). *Canadian Pharmacists Journal*. 2023;156(4):194-203.

PrEP distribution may avoid some of the structural barriers relating to uptake and adherence for some men who have sex with men, but may not be enough for already underserved communities such as men who have sex with men of colour (9). A review providing recommendations on implementing a community pharmacy PrEP program suggested the need of pharmacists to receive additional training on HIV prevention to provide effective PrEP delivery to meet PrEP educational gaps for pharmacists and better accommodate workflow changes related to PrEP delivery, such as ordering and monitoring of lab tests (17). To address challenges related to pharmacy-led delivery models, the expansion of pharmacists and pharmacies in HIV PrEP delivery will require financial resources and human capital, training of pharmacists and pharmacy personnel, and supportive legislation to expand the scope of practice of pharmacists (3). The future of PrEP delivery for key populations will most likely favour a pharmacy-led model (6), however the path to pharmacy-based PrEP delivery will look different in each unique context (7). Therefore, identifying the best practices tailored to the unique local setting will be an ongoing challenge.

## Outcome measures of pharmacy-led HIV PrEP programs

Outcome measures can be used to evaluate the success or efficacy of PrEP programs in preventing HIV transmission (10). Outcome measures for PrEP vary widely among studies examining PrEP delivery programs (10). Common outcomes measures reported by PrEP programs include the number of individuals enrolled, age of individuals enrolled, number of new HIV infections, number of new STI infections (61, 62), adherence to PrEP medications, PrEP retention (14, 15, 63), and drug tolerance (16).

A 2022 systematic review examining the effectiveness of PrEP distribution in pharmacies reported six case studies of pharmacy-led PrEP programs in the U.S. and their corresponding outcome measures (10). Outcome measures presented in these case studies included data on the number of clients served, client demographics (e.g. race), adherence (measured as the percentage of clients filling their prescription), HIV test results, and PrEP continuation (measured as the drop-out rate and as the mean duration of PrEP use) (10). All six pharmacy-access PrEP sites were found to be a feasible service delivery model (10). A narrative review identified four pharmacy-based PrEP studies, of which three reported impact on adherence (64). The review classified “adherence” as to encompass three phases of adherence: uptake, executed adherence (i.e., day-to-day PrEP pill taking) and persistence (i.e., duration of ongoing PrEP use) (64, 65).

Two of these studies reported improved uptake, with a Seattle study reporting 74% initiation of PrEP on the same day and a Mississippi pharmacy reporting 77% of patients filled their prescription within a week (64). The third study, based out of Miami, reported improved

45. Riley A. Media release: Nova Scotia pharmacists among Canada's first to prescribe HIV prevention drug with help from Dalhousie pilot study. 2024. Available from: [https://www.dal.ca/news/media/media-releases/2024/07/26/media\\_release\\_\\_nova\\_scotia\\_pharmacists\\_among\\_canada\\_s\\_first\\_to\\_prescribe\\_hiv\\_prevention\\_drug\\_with\\_help\\_from\\_dalhousie\\_pilot\\_study.html](https://www.dal.ca/news/media/media-releases/2024/07/26/media_release__nova_scotia_pharmacists_among_canada_s_first_to_prescribe_hiv_prevention_drug_with_help_from_dalhousie_pilot_study.html) Accessed October 17, 2024.
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47. Crawford ND, Albarran T, Chamberlain A, Hopkins R, Josma D, Morris J, et al. Willingness to discuss and screen for pre-exposure prophylaxis in pharmacies among men who have sex with men. *Journal of Pharmacy Practice*. 2021;34(5):734–40.
48. Alohan DI, Evans G, Sanchez T, Harrington KRV, Quamina A, Young HN, et al. Examining pharmacies' ability to increase pre-exposure prophylaxis access for Black men who have sex with men in the United States. *Journal of the American Pharmacists Association*. 2023;63(2):547–54.

persistence with 41% receiving continuous PrEP for 12 months or more (64). A study in Dallas, Texas evaluated PrEP uptake and the care cascade before and after a Clinical Pharmacy Specialist (CPS) expanded HIV preventative services within a primary care setting for persons experiencing homelessness (66). Outcomes such as number of PrEP prescriptions, PrEP dispensations, PrEP discontinuations, patient retention in PrEP care and new HIV diagnoses were evaluated. (66). After incorporating a CPS into the primary care clinic, significantly more patients were appropriately enrolled in a patient assistance program (100% vs. 44%;  $p < 0.01$ ) and more patients picked up the first PrEP dispensation (80% vs 40%;  $p = 0.04$ ) (66).

## Comparison of outcomes between pharmacy-led HIV PrEP programs and programs led by physicians or nurse practitioners

A 2022 systematic review sought to address two questions: whether PrEP initiation should happen in pharmacies, and whether PrEP continuation should happen in pharmacies (10). While the authors identified 17 studies for inclusion, none met the criteria for inclusion related to PrEP effectiveness (for either PrEP initiation or continuation) (10). However, six of these 17 were case studies which demonstrated feasibility of PrEP pharmacy programmes in the U.S. (10). The authors highlight that this lack of effectiveness data/research indicates a scarcity of evidence investigating the comparative effectiveness of pharmacy-access versus provider-access to PrEP (10). A systematic review compared modified Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) scores between pharmacist-led and nurse-led PrEP care delivery models to assess potential applicability for implementation under real world conditions and measure public health impact. (13). A possible total score was -18 to 28 (13). A higher score means the intervention may be more applicable for implementation because of its ability to reach the focus population, positive impact on PrEP care delivery, appeal to implementation clients and staff, and less-challenging implementation procedures (13). Four pharmacists-led U.S. models scored 16, 16, 10 and 7, respectively, compared to two non-U.S. nurse-led (non-pharmacist-led) models which scored 13 and 11, from Australia and Canada, respectively (13). High RE-AIM scores demonstrate that some pharmacist-led models are applicable for implementation, and the use of alternative prescribers (pharmacists) may be acceptable and have a positive impact on PrEP care delivery but the efficacy remains unclear due to lack of studies with a comparison (13).

Another study compared differences in adherence outcomes between a physician- and nurse practitioner-led in-person setting and a pharmacist-led telehealth setting at a Colorado Veterans Affairs health centre over a span of eight years (16). Adherence to HIV PrEP medication and monitoring was similar between both

49. Josma D, Morris J, Hopkins R, Quamina A, Siegler AJ, Holland D, et al. Comparing open-ended question methods to vignette methods to explore willingness to obtain pre-exposure prophylaxis access in pharmacies among Black men who have sex with men. *AIDS Care*. 2023;35(12):1955-62.
50. Whelchel K, Zuckerman AD, DeClercq J, Choi L, Kelly SG. Optimizing HIV PrEP persistence: Does your pharmacy matter? *AIDS & Behavior*. 2023;27(11):3735-44.
51. Kherghehpoush S, McKeirnan KC. The role of community pharmacies in the HIV and HCV care continuum. *Exploratory Research in Clinical and Social Pharmacy*. 2023;9:100215.
52. Varney S. HIV preventive care is supposed to be free in the US. So, why are some patients still paying? Available from: <https://kffhealthnews.org/news/article/prep-hiv-prevention-costs-covered-problems-insurance/> Accessed October 23, 2024. *KFF Health News* March 3, 2022.
53. Gilead Sciences. Gilead patient support programs. Available from: <https://www.cahr-acrv.ca/wp-content/uploads/2019/04/CAHR-2019-Abstract-Book.pdf> Accessed October 23, 2024.
54. National Alliance of State & Territorial AIDS Directors. PrEP and PEP assistance programs. Available from: <https://nastad.org/prepcost-resources/prep-assistance-programs> Accessed October 23, 2024.

clinics (16). For example, the number of PrEP tablets filled per person-year was 324 (in-person) and 321 (telehealth); the number of serum creatinine tests per person-year was 3.51 (in person) and 3.37 (telehealth); and HIV screens per person-year was 3.55 (in person) and was 3.38 (telehealth) (16). However, there was higher patient retention in pharmacy-telehealth delivered model compared to models delivered by nurse practitioner or physician, though this was likely related to geographical factors (16). The authors claimed that this was the first study comparing pharmacist-prescribed PrEP with the model prescribed by physicians or nurse practitioners within the same health care system (16). Overall, one scoping review noted that studies that implemented pharmacy-based interventions lacked long-term data and comparison groups to adequately show the increased value of this novel delivery model, which could explain why this review found few studies comparing outcome measures between pharmacy-led and nurse/physician-led PrEP models (1).

As with other characteristics of pharmacy-led PrEP models, costs vary widely because of the inconsistent policy landscape of pharmacist's scope of practice, and reimbursement and payments schemes for PrEP services provided by pharmacists (2). A 2024 review found little published evidence on cost as an implementation outcome, with one exception being a Kenya-based pharmacy-led PrEP delivery model (7). However, the authors did discuss recommendations and gaps in financing pharmacy-based delivery models, so that countries during scale-up of pharmacy-led PrEP delivery models should finance at least the cost of PrEP drugs, even if clients pay a service fee (7). Additionally, the authors note that cost-effectiveness research is needed to understand workflow burden and costs of pharmacies to deliver PrEP (7).

A review examining the implementation science of integrating PrEP in pharmacist-led services in the U.S. reported costs associated with four pharmacist-led delivery models (2). Each of these studies reported costs associated with PrEP drug medications, laboratory tests, patient care services, STI screening, and point of care testing (2). A systematic review examining PrEP distribution in pharmacies identified two case studies from the U.S. which presented data focused on health sector costs and patient/family costs (10). No studies reported on other sector costs or productivity impacts (10). For health sector costs, one pharmacist-led clinic in Seattle recouped costs after nine months and financial sustainability depended on the ability of pharmacists to bill insurance plans for their services (10). Additionally, half (six of 12) of participants who completed a follow-up visit at a community pharmacy in Nebraska were willing to pay at least USD 20 quarterly for continued PrEP visits and half (six of 12) were willing to pay up to USD 60 (10). In another review, authors mentioned that the integration of telehealth into pharmacy-based PrEP delivery models (i.e. online pharmacies) may reduce additional costs; however, a new set of barriers is introduced, including access to technology and the Internet (64).

55. US Department of Health and Human Services. Ready, Set, PrEP Available from <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/prep-program> Accessed October 23, 2024.
56. Whelchel K, Zuckerman AD, DeClercq J, Choi L, Rashid S, Kelly SG. HIV PrEP access and affordability: A multidisciplinary specialty pharmacy model. *Journal of the American Pharmacists Association*. 2022;62(3):853-8.
57. Chory A, Bond K. Access to PrEP and other sexual health services for cisgender women in the United States: A review of state policy and Medicaid expansion. *Frontiers in Public Health*. 2024;12:1360349.
58. Hopkins R, Josma D, Morris J, Klepser DG, Young HN, Crawford ND. Support and perceived barriers to implementing pre-exposure prophylaxis screening and dispensing in pharmacies: Examining concordance between pharmacy technicians and pharmacists. *Journal of the American Pharmacists Association*. 2021;61(1):115-20.
59. Bellman R, Mohebbi S, Nobahar N, Parizher J, Apollonio DE. An observational survey assessing the extent of PrEP and PEP furnishing in San Francisco Bay Area pharmacies. *Journal of the American Pharmacists Association*. 2022;62(1):370-7. e3.

A study that surveyed pharmacies in the San Francisco Bay Area identified cost to the pharmacy as one barrier to implementing PrEP services (59). Pharmacists cited that the lack of provider status disallowed them from billing insurance companies and the high upfront costs of medication (ranging from USD 1,300 to USD 2,000 per individual month supply) was a deterrence to initial implementation, particularly for independent pharmacies with multiple patients on these medications (59).

A limiting factor related to cost and sustainability that was identified in multiple pharmacy-led PrEP delivery models was obtaining reimbursement to cover program costs (7, 17). This is a challenge because pharmacists are not recognized as providers at the national level in the U.S. (17). Washington State set the “gold standard” for pharmacist reimbursement when they passed a bill which requires insurance plans to reimburse and recognize pharmacists as providers, and similar reimbursement legislation has been passed in other states such as Texas and Tennessee (17, 67). Financial reimbursement is required for pharmacists and pharmacies to allocate time and resources to PrEP services, including focused counseling, confidential pharmacy space and laboratory testing (17). Moving towards implementing a pharmacy-led PrEP model by simply passing legislation that allows pharmacists to prescribe PrEP is insufficient; it is more critical that an appropriate payment model is attached to the policy that considers equity in reaching all populations at risk for HIV (2).

60. California Code Business and Professions Code § 4026. 1997. Available from: [https://leginfo.ca.gov/faces/codes\\_displayText.xhtml?lawCode=BPC&division=2.&title=&part=&chapter=9.&article=10](https://leginfo.ca.gov/faces/codes_displayText.xhtml?lawCode=BPC&division=2.&title=&part=&chapter=9.&article=10) Accessed October 25, 2024.
61. Schmidt D, Kollan C, Schewe K, Hanhoff N, Rusenberg R, Friebe M, et al. Evaluating the introduction of HIV pre-exposure prophylaxis as a benefit of statutory health insurance (EvE-PrEP): Highly effective protection against HIV without an increase in sexually transmitted infections. *Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz*. 2023;66(9):1008–18.
62. Schmidt MA, Dickerson JF, O’Keeffe-Rosetti MC, Salas SB, Donald JL, Tao G. Sexually transmitted infection testing, prevalence, and treatment among individuals receiving HIV preexposure prophylaxis within an integrated healthcare delivery system. *Sexually Transmitted Diseases*. 2022;49(9):616–21.
63. Pyra M, Rusie L, Castro M, Keglovitz Baker K, McNulty M, Bohm N, et al. A taxonomy of pragmatic measures of HIV preexposure prophylaxis use. *AIDS*. 2020;34(13):1951–7.
64. Garrison LE, Haberer JE. Pre-exposure prophylaxis uptake, adherence, and persistence: A narrative review of interventions in the U.S. *American Journal of Preventive Medicine*. 2021;61(5 Suppl 1):S73–S86.

## Factors That May Impact Local Applicability

This review is a synthesis of literature on studies focused the set-up and implementation of pharmacy-led HIV PrEP delivery models in high-income settings. Pharmacy-led PrEP delivery is a new and developing model in all jurisdictions (7). The main factor that may impact local applicability of implementing a pharmacy-led PrEP delivery model are the policy and legal environment. Local jurisdictions may limit the scope of practice of pharmacists and in turn, this may influence the roles and activities pharmacists engage with through the PrEP care cascade. Understanding the rules and regulations governing pharmacists' authority is extremely important as it helps guide the structuring process of the pharmacy-led PrEP delivery models and the implementation process. Additionally, the vast majority of studies and models reviewed were conducted in the U.S., and the uniquely different set up of the U.S. and Canadian health care systems may make it difficult to generalize the findings.

## What We Did

We searched Medline (including Epub Ahead of Print, In-Process & Other Non-Indexed Citations) using a combination of text term HIV and (MeSH term Pre-Exposure Prophylaxis/ or text terms PrEP or pre expos\* prophyla\* or preexpos\* prophyla\*) and text terms (pharmacy\* or pharmacies\* or pharmacist\* or drug store\* or drug-store\*). Searches were conducted on September 3, 2024 and results limited to articles published from 2020 to present in English. Studies from low- and middle-income countries were excluded. Reference lists of identified articles were also searched. Google (grey literature) searches using different combinations of these terms were also conducted. The searches yielded 250 references from which 67 were included.

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66. McElyea J, Bistransin K, Bana S, Alvarez KS, Brown LS, Persaud D, et al. Impact of a clinical pharmacist within an HIV PrEP program for patients experiencing homelessness. *Journal of the American Pharmacists Association*. 2023;63(1):324-9.
67. University of Washington School of Pharmacy. SB5557 expands patient care access in Washington. 2015. Available from: <https://sop.washington.edu/sb-5557-expands-patient-access-to-care-in-washington/> Accessed October 24, 2024.