



# Implementation Science of Integrating Pre-Exposure Prophylaxis in Pharmacist-Led Services in the United States

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## Abstract

**Background** Racial inequities in HIV in the United States (US) are pervasive. Pre-exposure prophylaxis (PrEP) is one of the most effective yet underutilized HIV prevention strategies, and stark inequities in PrEP uptake exist. Lack of access to PrEP clinics is a major barrier to access that could be overcome by integrating pharmacists into the provision of PrEP services including prescribing and dispensing.

**Methods** A number of reviews have shown promise in folding pharmacies into the expansion of PrEP services, but this review extends those by examining the implementation science evidence of pharmacist-led PrEP services in the US. We reviewed literature over the past five years of the implementation science of pharmacist PrEP services (2018–2023) and present seminal findings in this area.

**Results** Only two studies are anchored within an implementation science framework despite all studies assessing common implementation science constructs. Overwhelming evidence supports feasibility and adoption of PrEP services in pharmacies yet gaps in workflow integration, scalability and sustainability exist.

**Conclusion** Continuing to build the implementation science evidence of pharmacy-based PrEP services is critical to standardize our measures across varying contexts and inform policy efforts that support pharmacy-based PrEP services.

**Keywords** HIV · Pre-exposure Prophylaxis (PrEP) · Implementation Science · Pharmacy-based services

Racial inequities in HIV in the United States (US) are pervasive. The Centers for Disease Control and Prevention (CDC) estimates that of more than 32,000 new HIV infections in 2021, 40% were among Black Americans, who only make up 12% of the US population [1]. One of the main drivers of these inequities is that the HIV prevention resources that we need to reach people are failing to do so. In particular, the uptake of HIV pre-exposure prophylaxis (PrEP) is an underutilized HIV prevention strategy [2]. Despite PrEP preventing up to 99% of HIV transmissions when taken daily [3], only 30% of those indicated for

PrEP were given prescriptions, and stark racial inequities exist [2]. For instance, of those on PrEP in 2020, 66% were White Americans compared to only 9% of Black Americans, which creates a continued expectation of racial inequities in HIV transmission [3]. Inequitable access and uptake of this highly effective HIV prevention resource is underscored by recent work from Harrington et al., showing a mismatch between PrEP clinic locations and the highest HIV incidence areas in US Southeastern states [4•]. Put simply, HIV prevention resources are not located at mass in the areas where they are most needed. When considering how to remedy this structural disadvantage, Harrington et al. showed that if pharmacies were able to provide HIV prevention resources, they could increase the accessibility of facilities with PrEP linkage by 80-fold in the areas with the highest need for HIV resources [4•].

Integrating pharmacists into the provision of PrEP services holds tremendous scientific premise to contribute to the reduction of HIV transmission by providing accessible and culturally competent care. Pharmacists have a good reputation with community members who view them as

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a trusted source of healthcare [5, 6]. Data also show that pharmacists can engage with racially minoritized and substance-using populations who are the most affected by HIV to effectively provide HIV prevention services [6–13], even when HIV-related stigma is high [6]. Moreover, pharmacists and pharmacy technicians who work in communities with high HIV risk report a high willingness to provide HIV prevention screenings [14•, 15, 16]. In addition, pharmacies are generally located in the neighborhoods experiencing the highest HIV burden which also are more likely to be Black and lower-income neighborhoods [17]. Finally, pharmacy accessibility is high. About 95% of Americans live within 5 miles of a pharmacy [18]; patients are estimated to visit pharmacies about three times per month [19]; and most pharmacies are open beyond the standard work day and on weekends [18]. Thus, the implementation of PrEP in pharmacies has the potential to address several barriers to access.

There have been a growing number of systematic literature reviews examining the collective evidence of HIV prevention resource integration, namely PrEP, by pharmacists [20••, 21, 22••, 23]. As the positive evidence base continues to build, it is also necessary to understand the implementation science, or the processes and approaches that enable the integration and uptake of these services in pharmacies across multiple levels – the pharmacist, pharmacy technician, and pharmacy client. The purpose of this manuscript is to explore the implementation science of pharmacist-led PrEP services in the US and discuss the strategies, challenges, and successes in integration, as well as the gaps in the implementation science evidence. By examining the existing literature, this study aims to identify best practices, assess the feasibility of implementation, and highlight potential barriers that must be addressed to ensure the successful integration of HIV prevention services in pharmacies.

## Implementation of Pharmacists' PrEP services

In recent years, pharmacists and public health researchers have demonstrated that pharmacists can successfully initiate and manage PrEP for their clients [24–27]. However, strategies to implement PrEP in pharmacies vary widely by the state legislation where the pharmacy is located and the pharmacy type/setting (e.g., independent, chain, hospital, ambulatory care) implementing these activities. Despite growing evidence of the success of pharmacist PrEP provision across varied contexts, there is limited knowledge of the implementation science of these activities. Although many of these studies assess key implementation science outcomes such as acceptability and willingness, there is a chasm of studies applying implementation science frameworks to guide the evaluation of pharmacy-based PrEP implementation. After

reviewing the literature over the past five years of the implementation science of pharmacist PrEP services (2018–2023), we only identified two studies utilizing an implementation science framework to evaluate PrEP integration in pharmacies [14•, 28•] (Table 1). Regardless of whether most studies are steeped in implementation science frameworks, the literature strongly suggests that pharmacists can play a larger role in PrEP provision. The ways in which they are able to do so depends on their practice settings. Herein, we describe the landmark studies and current evidence of pharmacist PrEP services among studies anchored in implementation as well as non-theoretical evaluation models across three settings: community, ambulatory care and health systems and telehealth.

### Community Pharmacy Models

Within community pharmacies, the two most commonly applied models are those led by pharmacists who are able to prescribe PrEP and those led by pharmacists who work collaboratively with a PrEP-prescribing clinician. In a seminal study, Kelley-Ross Pharmacy in Seattle showed that pharmacists successfully initiated PrEP prescriptions and managed daily oral PrEP [24, 25]. While the model is entirely pharmacist-led, and legislation in Seattle allows pharmacists' prescribing authority, this model was still under the supervision of a physician via a collaborative drug therapy agreement (CDTA). The Kelley-Ross Pharmacy model was also one of the earliest demonstrations for feasibility of pharmacist-managed PrEP care, in which Tung et al. showed that over three years, 97% of clients evaluated initiated PrEP, with nearly three-quarters initiating PrEP the same day as their initial appointment [24, 25]. Furthermore, the researchers observed high adherence among those filling PrEP prescriptions at the pharmacy, and only a quarter were either lost to follow-up or discontinued PrEP [25].

Other PrEP models at community pharmacies have followed in the footsteps of the Kelley-Ross Pharmacy model by using collaborative practice agreements (CPA), which are similar to CDTAs. A CPA is a formal agreement between pharmacists and licensed providers where pharmacists can offer patient care services (e.g., prescribing medicine and ordering laboratory tests) under the supervision of the provider, and state regulations on CPAs can vary drastically. In 2017, a CPA was established between HIV medical providers at the University of Nebraska Medical Center and participating pharmacists, which included pharmacists from the University-based HIV clinic, a community pharmacy, and community-based clinics [27]. Havens et al. found that of 60 participants who were enrolled in the program, nearly half chose the community pharmacy as their preferred follow-up site, 58% were retained in the program after 6 months (similar to what is found in other PrEP implementation studies),

**Table 1** Examples of implementation science findings that have been reported in key studies evaluating PrEP integration in pharmacies 2017–2023

Study	Implementation Science Framework Used	Implementation Science Findings <sup>a</sup>	
Community pharmacy models			
Tung et al. (2017) [24]	No	Cost	96% (235/245) of clients who initiated PrEP paid \$0 per month for their PrEP medication
		Cost/Sustainability	Initial startup costs were recouped after 9 months of clinic operations, showing a return on investment in less than a year of clinic operation
		Feasibility	Tung et al. report that a collaborative drug therapy agreement (CDTA) made the pharmacist-run PrEP clinic feasible
		Adoption/Uptake	98% (245/251) of pharmacy clients who were evaluated for PrEP in the pharmacy-initiated PrEP
Tung et al. (2018) [25]	No	Cost	98% of clients who filled PrEP prescriptions (n = 646) in the pharmacy had a zero-dollar patient responsibility per month, including among those who were uninsured
		Cost/Sustainability	As a result of Washington State passing legislation recognizing pharmacists as healthcare providers in 2015, the pharmacists were able to bill for patient care services, which were then paid for by the client's medical insurance The pharmacy installed and used software to run claims and receive electronic explanations of benefits
		Feasibility	Support from ancillary staff, such as pharmacy technicians, allowed pharmacists to focus on reimbursable patient care services. Pharmacy technicians supported with prior authorization, prescription processing, identifying gaps in medication refills, and notifying pharmacists when there was a potential non-adherence issue
		Adoption/Uptake	97% (695/714) of pharmacy clients who were evaluated for PrEP in the pharmacy-initiated PrEP
Havens et al. (2019) [27]	No	Acceptability	Of 29 participants completing a satisfaction questionnaire, all reported that they would recommend the pharmacist-led PrEP program. These participants noted that quick service, extended hours for follow-up visits, and friendly and honest pharmacists were strengths of the program. However, they also noted areas of improvement included medication access, collection of rectal and pharyngeal STI swabs, and communication between pharmacists and medical providers Seven pharmacists participated in the program, and all of them reported being comfortable performing point-of-care testing. One community pharmacist felt uncomfortable on 3 occasions of collecting sexual histories during client follow-up visits
		Fidelity	There was only one occasion where pharmacists reported workflow disruption during the study period
		Feasibility	Havens et al. note that the community pharmacy site in this study was small and independent with substantial buy-in by the pharmacists and the pharmacy owner At the community pharmacy site, laboratory management and STI screening were logistical challenges since some tests require venipuncture and processing at a clinical laboratory
		Cost	Participants in the community pharmacy program received PrEP care, point-of-care testing, and sexually transmitted infection screening at no cost. These participants noted that they were willing to pay \$20 to \$60 quarterly for the services
Lopez et al. (2020) [28•]	Yes (Active implementation framework for implementation drivers)	Leadership Drivers	Leadership drivers for the program included creation of partnerships, identification of program leaders, and development of a collaborative practice agreement. The program was staffed by employees of the San Francisco Department of Public Health and the health departments city clinic PrEP protocol was adapted for the collaborative practice agreement

**Table 1** (continued)

Study	Implementation Science Framework Used	Implementation Science Findings <sup>a</sup>	
Crawford (2022) [14•]	Yes (Systems Engineering Initiative for Patient Safety [SEIPS])	Competency Drivers	The pharmacists involved in the program had HIV-specific training and underwent training that included education on PrEP, HIV, and STID testing and counseling and interviewing, discussing sexual health history, and training in phlebotomy skills. The total time in training conducted by the San Francisco Department of Public Health was approximately 23 h
		Organization Drivers	Organization drivers included the creation of workflow systems and environments to facilitate the PrEP program in the pharmacy. This included constructing three private visit rooms for PrEP visits and developing a pharmacy-based PrEP workflow to complement usual business in the pharmacy during operating hours
		Cost/Feasibility	Funding and support from the San Francisco Department of Health made the program possible since pharmacists were unable to be reimbursed for point-of-care testing or PrEP services at the time of program implementation
		Feasibility	California's requirement that pharmacy-based testing for tests like rapid HIV tests require the supervision of a physician, phlebotomist, or nurse created challenges for pharmacists
		Adoption/Uptake	96% (51/53) of clients that completed a PrEP initiation visit filled their PrEP prescription
		Acceptability	Formative work showed strong support of a pharmacy PrEP delivery model from pharmacists, Black men who have sex with men, and pharmacy technicians Some Black men who have sex with had pre-existing relationships with and trust for pharmacy staff
		Appropriateness	Black men who have sex with men noted that pharmacies were conveniently located and more accessible in their neighborhoods
		Feasibility	Pharmacists showed high levels of comfort provided HIV prevention services and high willingness to make structural changes to promote PrEP delivery. However, they noted that additional training was needed to counsel clients Existing infrastructure, including relationships between physicians and local HIV organizations and use of payment programs for PrEP, would support PrEP delivery in the pharmacy
Ambulatory care and health systems models		Safety & Sustainability	These outcomes will be reported as well after the implementation phase of the study is complete
Khosropour et al. (2020)	No	Adoption/Uptake	100% of pharmacy clients referred for same-day PrEP received a prescription, 77% of whom filled their prescription. However, only 33% of those who were prescribed and filled their prescription were linked to PrEP care within six weeks
Khosropour et al. (2023)	No	Sustainability	18% of pharmacy clients initiated and linked to ongoing PrEP care over 3 months and 7.4% continued PrEP Qualitative interviews revealed that sustainability was influenced by perceived HIV risk, ease and convenience of same-day PrEP program, perception of and experiences with side effects and perceived PrEP adherence self-efficacy
Maier et al. (2019)	No	Adoption/Uptake Penetration	There are 1600 PrEP patients across a comprehensive VHA database. The average rate of initiation of patients across all sites was 20 per 100,000 There was substantial variation in PrEP initiation across health facilities. Facility-wide characteristics related to PrEP initiation include higher percentages of people age 45 or younger, urban dwellers, tertiary care status and Western geographic location
Gauthier et al. (2019)	No	Sustainability	87% of patients who initiated PrEP had a follow appointment. Of those 46% received PrEP for at least 12 months once adding pharmacists to efforts to improve retention in care

**Table 1** (continued)

Study	Implementation Science Framework Used	Implementation Science Findings <sup>a</sup>
Coleman et al. (2020)	No	Adoption/Uptake 83% of individuals in the intervention group versus 75% in the standard or care group ( $p=0.085$ ) picked up their PrEP prescription less than 7 days
Telehealth models		
Hoth et al. (2019) [29]	No	Feasibility Iowa TelePrEP illustrates the feasibility of using telehealth to regionalize pharmacist-based PrEP to serve small urban and rural communities The delivery model was feasible due to Iowa law permitting pharmacist practice within CPAs and telehealth visits with clients in the community Implementation of screening for <i>N. gonorrhoeae</i> (NG) and <i>C. trachomatis</i> (CT) infections using self-collected swabs was feasible in public health-affiliated laboratory sites but was difficult to implement in commercial and clinical laboratory sites in rural and small urban areas of Eastern Iowa because of local laboratory policies prohibiting the submission of self-collected swabs Cost Iowa Department of Public Health provided initial financial support for pharmacists when developing the program in 2017, with subsequent pharmacist efforts supported through cost savings on FTC/TDF under the 340B drug-pricing program. Medication and laboratory costs were covered by client insurance. Iowa is a Medicaid expansion state, including coverage for PrEP laboratory studies and medications. Applications to industry assistance programs for FTC/TDF were submitted as appropriate Fidelity/Adherence Adherence to guideline-indicated laboratory monitoring was high in Iowa TelePrEP; clients received 96% of all indicated laboratory-monitoring tests, 100% of indicated HIV tests, and 98% of creatinine tests
Smith et al. (2019) [30]	No	Feasibility, Adoption/Uptake The use of a pharmacy-based PrEP program to train and support clinical providers in hospital systems can facilitate PrEP uptake and retention in primary care

<sup>a</sup> We used the implementation outcomes described in Proctor et al. (2011) [31], or specific implementation science frameworks described in the study, to guide our extraction of implementation science-specific findings from these studies

and those retained in the program achieved high adherence to PrEP with a mean medication possession ratio of 93%, which is above the gold standard of 80% [27]. Moreover, the pharmacists reported being comfortable providing point-of-care testing for HIV, chlamydia, and gonorrhea.

Another example is the community pharmacist-led HIV PrEP clinic in San Francisco's Mission Wellness Pharmacy, which is a community pharmacy located in a historically Hispanic neighborhood. Pharmacists at Mission Wellness Pharmacy operate under a CPA in collaboration with the San Francisco Department of Public Health and was the first CPA for PrEP in an independent pharmacy in California. Pharmacists are authorized to prescribe both PrEP and post-exposure prophylaxis (PEP) if the client asks and they deem it appropriate and conduct all of the screening and testing required for PrEP care. Between 2018–2019, Lopez et al. reported that 53 clients completed a PrEP initiation visit and 96% filled their prescription [28•]. Given the recency

of some of their potential exposures, six clients were identified for and prescribed PEP, which may be considered a secondary benefit of pharmacy-based PrEP provision. To our knowledge, this was only one of two studies applying an implementation science framework for pharmacy-based PrEP. Lopez et al. applied the active framework for implementation drivers, which allowed the authors to map out and describe leadership drivers, competency drivers, and organization drivers to support PrEP implementation at the pharmacy [28•]. Notably, over half of these pharmacy clients were Hispanic or Black, two racially minoritized groups that are disproportionately affected by HIV. The implementation process used by Lopez et al. can support other pharmacies who hope to prescribe PrEP in their pharmacies by adapting the specific implementation science frameworks to their context. For example, the authors identified several regulatory barriers for HIV testing that were able to be integrated into their protocols and workflows for PrEP initiation.



These implementation lessons learned can be adapted to other contexts.

Finally, and importantly, the PrEP Up Pharmacies study is one of few to apply an implementation sciences framework to examine acceptability, appropriateness, feasibility, safety, and sustainability pharmacy-based PrEP implementation without a CPA model [14•, 15]. Utilizing the Systems Engineering Initiative for Patient Safety (SEIPS) implementation science framework to guide measures included in the study, PrEP Up Pharmacies showed that pharmacists', pharmacy technicians and Black men who have sex with men strongly support pharmacist-led PrEP services and view them as highly appropriate and feasible [14•, 15]. Additionally, a brief transitional pilot phase period identified 81 pharmacy clients, who mostly identified as racially minoritized and who would have been eligible for the next phase of the study, emphasizing the potential of pharmacist-led PrEP to address inequitable access to PrEP. However, collection of quantitative data on adoption, uptake, safety, and sustainability are still underway.

### Ambulatory Care And Health Systems Models

Pharmacist-led PrEP programs, including those enabled by CPAs, have also been implemented in non-community pharmacy settings. For example, in Mississippi, a walk-in HIV/STI testing center affiliated with the University of Mississippi Medical Center implemented a rapid PrEP initiation program to offer same-day PrEP prescriptions involving the center's clinical pharmacists. Under a CPA, the pharmacists were able to counsel a client on PrEP (e.g., effectiveness, side effects, etc.), obtain the client's medical history, evaluate the client for signs and symptoms of acute HIV, complete insurance or medication assistance paperwork, send a 90-day PrEP prescription to the client's preferred pharmacy, and schedule the clients' first clinical PrEP appointment with a PrEP provider within 12 weeks to receive recommended laboratory testing [32, 33]. Studies resulting from this program found that about three-quarters of participants filled their PrEP prescriptions but only 18% were linked to care within 3 months, and 12% were linked to care after 3 months. These stark drop-offs after onboarding to PrEP could suggest large gaps in the PrEP continuum of care and highlight critical areas to strengthen interventions that link patients to PrEP via pharmacist-led programs. Alternatively, patients may have shifts in their risk perceptions after onboarding onto PrEP that change their desired uptake [34, 35].

Another example of a pharmacist-led, non-pharmacy based PrEP program is within the Veterans Affairs Healthcare System where some clinical pharmacists have the ability to authorize PrEP prescriptions, order labs or consults, screen for PrEP eligibility, and manage medication adherence.

within their scope of practice [36, 37]. A large federally qualified health center in Washington, DC specializing in health care for sexual and gender minorities implemented PrEP navigation services that involved a pharmacy liaison to its on-site pharmacy to support initial filling of PrEP prescriptions, meetings between pharmacy staff and care teams to discuss PrEP clients, and retraining of pharmacy technicians to ask clients if they want to enroll in a copay assistance program [38]. The intervention increased the proportion of clients prescribed PrEP who filled their prescription while also reducing the time to first prescription fill.

### Telehealth Models

Pharmacist-led PrEP delivery has also been combined with innovative service delivery methods such as telemedicine. The most notable is the Iowa TelePrEP program led by the Iowa Department of Public Health and the University of Iowa [29]. In this hybrid model, potential PrEP clients are directed to TelePrEP through local health departments, the university's HIV specialty clinic, or self-referral. Then, pharmacists conduct videoconferencing visits with clients in their home or in a private community setting that includes a clinical assessment, PrEP education, and HIV risk reduction and medication adherence counseling. Pharmacists assess clients for PrEP indications and can prescribe PrEP and manage their PrEP care. Out of 186 referrals between 2017–2018, 68% completed initial video visits with pharmacists, and of these, 91% started PrEP. Another pharmacy-based tele-PrEP program was implemented in a large hospital system in Atlanta, and the program aimed to improve physician referrals for PrEP and manage PrEP initiation and retention. During a pilot phase of 9 months, this program received 95 referrals, 59% of whom started PrEP, and of those, 81% remained on PrEP at the time the analysis was conducted [30]. Pharmacist-led tele-PrEP programs have the potential to reduce HIV inequities by increasing the reach of PrEP services to rural areas, and areas that have fewer healthcare facilities, or to people who face barriers to access such as transportation.

Of note, the pharmacist-led PrEP programs at Mission Wellness Pharmacy and at the University of Mississippi Medical Center showcase the ability of pharmacist-led PrEP services to reach Hispanic and Black populations who can benefit from PrEP. This is especially important given that one study found that out of an estimated 1.1 million people in the US indicated for PrEP, 44% were Black and 25% were Hispanic; yet, only 11% of PrEP users in the study were Black and 13% were Hispanic [39]. However, most studies have not specifically directed pharmacy PrEP programs to these populations.

## Gaps in the Implementation Science Evidence of Prep in Pharmacies

While the existing evidence on pharmacy-based PrEP has tackled implementation science outcomes such as acceptability and adoption, few studies have been specifically organized around an implementation science framework. Important gaps in understanding other critically important implementation science outcomes such as reach, fidelity, cost, and sustainment exist. In a systematic review of implementation determinants of PrEP based on Consolidated Framework for Implementation Research (CFIR), constructs for a variety of medical settings including pharmacies showed that only 61 CFIR constructs were measured in pharmacy-based settings compared to 582 constructs in specialty and primary care clinics and 612 in non-primary clinics [40••]. These studies focused mostly on individual provider characteristics, inner setting, and providers' perspectives about PrEP. However, existing evidence has shown strong data for many outer setting characteristics including individual pharmacy client perceptions, willingness, and uptake of pharmacy-based PrEP [40••]. It is likely that many of these studies were not included in this review because they either employed a different implementation science framework (e.g., RE-AIM) or used language that was not in line with existing implementation science frameworks. Therefore, we argue that pharmacy-based PrEP studies should be anchored by an implementation science framework, particularly those that address and measure sustainability.

Evaluation of pharmacy-based PrEP services organized within an implementation science framework has a number of advantages. First, given the inconsistent policy landscape of pharmacists' scope of practice across the US, as described above, there are widely varying models for implementing PrEP in pharmacies. Several states have recently passed legislation allowing pharmacists to independently prescribe and dispense PrEP under a statewide protocol or under specific conditions [41], but many models of pharmacist PrEP services still operate under the supervision of a collaborating physician. While there is growing momentum to expand pharmacists' prescriptive authority broadly so that communities historically marginalized from and stigmatized within the healthcare system are able to more easily access a number of medication therapies (e.g., opioid replacement therapy, birth control), these policies face a number of challenges that are similar to those faced by expanding pharmacist ability to prescribe PrEP [42–44]. For example, there are patient safety concerns including breakdowns in client-pharmacist communication and potential for over-prescribing. Most of the efforts to expand pharmacists' prescriptive authority are occurring individually for each drug, which limits the impact that pharmacists could have across

a number of health conditions. However, research needs to better understand how some states have passed pharmacy-based legislation for PrEP as well as other medications to inform future policy efforts. Consistent data collection across all of these policies within an implementation science framework could allow effective comparisons across the range of policies enacted, and help us understand which policies are the most effective, and how to better fill gaps where data are lacking.

The exploration, preparation, implementation and sustainment (EPIS) framework is a strong guiding implementation science framework [45]. However, given the breadth and development of specific measures, many studies may also use the CFIR [46]. While an implementation science framework is essential, it is also critical that studies consider the unique role of pharmacists in patient care and business and workforce development. Thus, implementation science frameworks such as the Systems Engineering Initiative for Patient Safety (SEIPS) may be employed or integrated with more frequently used implementation science frameworks to ensure that implementation of PrEP in pharmacies equally values patient safety, cost, and workflow models [47].

Yet, research on the impact of statewide protocols and legislation to allow pharmacist PrEP prescribing is still nascent. For example, in California, under Senate Bill 159 (SB-159) passed in 2019, pharmacists are authorized to dispense 30–60 days of PrEP and PEP without a prescription after testing and counseling under the conditions that the pharmacists complete a training program [48]. Furthermore, this bill mandates that pharmacists are reimbursed for their services at 85% of the physician rate, which may reduce overall healthcare costs. One study found that among 209 independent community and mail-order pharmacies in the San Francisco Bay area, only 6 (3%) furnished PrEP under SB-159, two were in the process of furnishing PrEP under SB-159, and one furnished PrEP under a CPA [49]. Barriers to offering PrEP in pharmacies under SB-159 included additional burdens on pharmacies during the COVID-19 pandemic, including difficulty ordering laboratory tests, overall lack of time and staffing, and potential costs to the pharmacy. There are 11 other states that have passed legislation to give pharmacists PrEP-prescribing authority, and it is unclear what factors influence whether a policy is implemented, how it is implemented, enforced, and sustained over time, and these factors should be explored [49–55].

There are a number of important considerations for understanding “on the ground” implementation of a policy. As noted above, payment and reimbursement models are critical. So, developing and passing legislation that simply allows pharmacies to prescribe PrEP will not be successful if appropriate payment models are not attached to the policy. Payment models should consider equity in reaching

all populations at risk for HIV so that inequities in PrEP access do not increase.

Payment models alone, however, will not ensure that PrEP is integrated into the pharmacy work system. Research should explore pharmacy staff motivations, and barriers and facilitators of integrating PrEP. While some pharmacies have noted training as a barrier [14•], some pharmacies located in neighborhoods with low HIV prevalence will not include these services since their catchment population has low need. Given this, policy implementation should be followed by prioritizing training among pharmacy staff in areas where PrEP access is low and HIV is high. Likewise, the pharmacy client experience could also dictate which pharmacies are more amenable to PrEP integration. For example, previous research shows that HIV prevention uptake is higher for pharmacy clients when packaged with non-stigmatized health screenings in pharmacies [6]. Therefore, pharmacies with infrastructure to provide screenings may be viewed as more welcoming to clients. These factors, as well as other pharmacy neighborhood, organizational, and staff factors should be explored.

Moreover, the HIV epidemics within these contexts are drastically different and may affect PrEP implementation. Only two states (Virginia and Arkansas) in the US South, where HIV burden is highest [56] have passed legislation to authorize pharmacists to prescribe PrEP. It is possible that the demand in these areas is met with different levels of interest, and therefore, outer context may have an important influence on several pharmacy-based PrEP implementation science outcomes. Until legislation that expands the pharmacist scope of practice to include PrEP services and recognize pharmacists as providers on a national level, it is critical to examine state-level variation and policy on pharmacy-based PrEP implementation [57–59].

Indeed, much of the lack of evidence of pharmacy-based PrEP programs lies in our lack of understanding about adequate workflow integration for a cost-effective model that can be applied across various pharmacy types/settings. Moreover, most studies have also been evaluated in a handful of pharmacies [6–8, 27, 60, 61]. And although these small-scale intervention studies have shown success, it remains unclear how these programs can be maximized to reach their greatest potential, which is undoubtedly reaching populations at the highest risk of HIV. Thus, more implementation science-based research is needed to support widespread scale up of pharmacist-led PrEP. As stronger evidence on the effectiveness of these interventions is built, we can also assess and understand the mechanisms that various policies and integration models in the pharmacy work system impact pharmacy client outcomes.

Most studies have also been conducted in lower transmission areas, which limits our understanding of the true reach and impact on the reducing HIV transmission. Thus,

one of the most pressing questions remains: if these services are implemented in pharmacies, will the populations experiencing the highest levels of transmission successfully progress through the continuum of PrEP care? This is especially critical to achieving our goal of reducing the HIV burden among gay, bisexual, and other men who have sex with men and transgender individuals [62]. Recent cross-sectional data from the American Men's Internet Survey indicates that over 70% of men who have sex with men are willing to obtain PrEP services in pharmacies [63]. But we need more data on how acceptable PrEP services are for these sexual minority populations when these services are integrated in their community pharmacies.

Cost-effectiveness models must also consider what is gained to the medical system if pharmacist PrEP provision is able to fold populations currently experiencing inequitable access to HIV services into the HIV prevention and care continua. For example, there are an estimated 27.5 million people without health insurance in the US [64], and over 100 million lack a primary care doctor [65]. These individuals are likely relying on non-traditional healthcare sources, oftentimes pharmacies. It is possible that reaching those individuals with unmet medical needs through pharmacies will create a pathway for medical service integration that has not previously existed. This integration of services will not only benefit the community and pharmacies, but it may also increase patient population of medical systems that were previously unable to reach certain individuals undiagnosed with HIV or eligible for PrEP.

Finally, the long-term fidelity of pharmacy-based PrEP services is also unclear, although these data likely exist. Initial pharmacy-based PrEP studies began in 2015. While many of these studies are ongoing, it is unclear how their initial protocols have been changed to meet competing workflow obligations or the dynamic needs of the client population. Updated data on these findings should be published to highlight not only fidelity to the program but also sustainability of the program.

## Conclusions

In this review, we discuss the implementation science evidence of pharmacy-based PrEP and note that while many studies in this area have explored common implementation outcomes, there is a large gap in studies that explicitly employ an implementation science framework. While most studies have provided strong data suggesting that PrEP can be implemented in pharmacies with strong acceptability from pharmacy staff and pharmacy clients, including those in Black, Hispanic, and low-income communities, it is important that the field continues to explore these within an overarching implementation science



framework. Although pharmacists leading and guiding these efforts may perform varying study designs to evaluate PrEP services in pharmacies, efforts that continue to pool these studies are needed to ensure that assessment of the multi-level challenges that pharmacists, pharmacy technicians, and pharmacy clients may encounter via PrEP integration and dissemination occurs and appropriate recommendations are being made to fill the critical gaps in our knowledge [22]. These reviews should encourage some standardization of measures within implementation science constructs, where publicly available measures exist. Understanding whether adequate assessment across implementation science constructs has occurred will also highlight where measures need to be developed. Ultimately, the organization of these studies within implementation science will support the comparability of our understanding of pharmacy-based PrEP across contexts and make it clearer where we need to further develop the evidence base. In our review, we highlight that future studies are needed on a larger scale and in higher HIV transmission contexts to support evidence of scalability, sustainability, and impact of pharmacist-led PrEP on the HIV epidemic and racial inequities in HIV burden. These data should inform national policy efforts that have currently limited the scale of pharmacy-based PrEP programs to local and state efforts that have limited their generalizability and impact.

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**Data Availability** The authors confirm that the data supporting the findings of this study are available within the article.

## Declarations

**Competing Interests** The authors confirm that the data supporting the findings of this study are available within the article.

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