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Systematic Review of Alternative HIV Pre-Exposure Prophylaxis (PrEP) Care Delivery Models to Improve PrEP Services

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Abstract

Background: The US Food and Drug Administration approved the first daily oral HIV preexposure prophylaxis (PrEP) in 2012, yet only 25% of 1.2 million individuals eligible for PrEP were prescribed PrEP in 2020. To improve PrEP uptake, delivery of PrEP services outside of traditional care (i.e., alternative PrEP care delivery models) may be considered.

Objectives: To identify types, evidence, and study gaps of alternative PrEP care delivery models in the published literature.

Search Methods: We searched in the US Centers for Disease Control and Prevention (CDC) Prevention Research Synthesis (PRS) database through December 2022 (PROSPERO CRD42022311747)

Selection Criteria: We included studies published in English that reported implementation of alternative PrEP care delivery models via alternative prescribers or care settings.

Data Collection Analysis: Two reviewers independently reviewed the full text and extracted data by using standard forms. Risk of bias was assessed using the adapted Newcastle-Ottawa Quality Assessment Scale for observational studies. This review narratively synthesized the findings. Those that met our study criteria were evaluated for efficacy against CDC PRS PrEP Evidence-Based Intervention (EBI) or Evidence-Informed Intervention (EI) criteria or Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) Emergency Strategy (ES) criteria, or for applicability by using an assessment based on the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework.

Main Results: This review identified 16 studies published between 2018–2022 that implemented alternative prescriber (n=8), alternative setting for care (n=4), alternative setting for laboratory screening (n=1), or combination of alternative prescriber and setting for care with (n=1) or without alternative setting for laboratory screening (n=2). The majority of studies were US-based (n=12) with low risk of bias (n=11). None of the identified studies met EBI, EI, or ES criteria due to having no comparison group to evaluate efficacy. Promising applicability, per the RE-AIM

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framework, was found for pharmacists as alternative prescribers, telePrEP as an alternative care setting, and mail-in testing as an alternative approach to laboratory screening.

Author's Conclusions: Delivery of PrEP services outside of the traditional care system by expanding providers of PrEP care (e.g., pharmacist prescribers), as well as the settings of PrEP care (i.e., telePrEP) and laboratory screening (i.e., mail-in testing) may increase PrEP access and care delivery.

Public Health Implication: Increasing innovation and scope of practice for PrEP services may minimize HIV stigma, facilitate access to PrEP care, and contribute to ending the HIV epidemic.

Keywords

Pre-exposure prophylaxis; Telehealth; Self-collection; Collaborative Practice Agreement (CPA); Alternative Service; Effective Intervention; Systematic Review

Antiretroviral pre-exposure prophylaxis (PrEP) is effective in preventing HIV infection if persons who have risk factors take it as prescribed before HIV exposure.[1] It has now been more than 10 years since the US Food and Drug Administration approved the first daily oral PrEP in 2012, yet only 25% of 1.2 million individuals who were PrEP-eligible were prescribed PrEP in 2020.[1 2–4]One of the major barriers to PrEP uptake is the lack of access to healthcare providers who are knowledgeable about and willing to prescribe PrEP.[3,5] More than one in eight PrEP-eligible gay, bisexual, and other men who have sex with men (MSM thereafter) live in a "PrEP desert"[6] which is defined as requiring an hour or more round-trip drive to access PrEP services.

In 2020, the COVID-19 pandemic hit globally and created a serious problem with access to clinical services.[7,8] In response to the uncertain periods of restricted access to clinical services, healthcare delivery models were considerably altered with the use of technology and expanded workforce. Telehealth and mobile health were adopted to deliver care and communication from healthcare providers to patients in personal spaces to minimize COVID-19 exposure.[9] Self-testing and mail-in tests (i.e., self-collection kits) became more accessible and acceptable.[10] In response to the workforce shortage in the US, a Presidential Order was announced to expand the pool of legally authorized COVID-19 vaccinators to include dentists, veterinarians, pharmacists, respiratory therapists, emergency medical technicians, healthcare practitioners-in-training, and recently retired professionals.[11]

We may apply lessons learned from the COVID-19 pandemic to improve PrEP services. The US Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) encouraged telehealth for PrEP services (i.e., telePrEP) during the COVID-19 epidemic.[12,13] Such a non-traditional clinical model may help those in a PrEP desert to access PrEP services.[14] Mail-in tests and telePrEP not only improve access to services or reduce providers' becoming 'burned out' but also can reduce stigma for receiving PrEP services.[15,16] Workforce shortage is also a problem among providers of HIV services; the HIV service workforce is shrinking even though the number of people with HIV in the US has been increasing and aging.[17–19] To address this problem, the National HIV/AIDS Strategy for the United States 2022-2025 (NHAS) Implementation Plan now includes a proposal for the US Department of Justice to work with Boards of Pharmacy

to expand pharmacy clinical consultants' roles.[20] The expansion may enlist pharmacists to be involved to enable efficient and timely HIV care to improve retention and medication adherence, and increase the service workforce.

This review explored alternative PrEP care delivery models, defined as utilizing non-traditional healthcare settings (e.g., telePrEP) and/or expanded workforce (e.g., expansion of healthcare providers' roles) to provide PrEP services and to meet monitoring requirements (i.e., quarterly visits for oral PrEP, every two months for injectable PrEP) recommended by CDC.[21] The purposes of this review were to identify 1) types of alternative models for PrEP care delivery (i.e., non-traditional prescribers or methods/settings for care and lab screenings) in published studies, 2) evidence of alternative PrEP care delivery interventions, and 3) evidence gaps that can be explored by future studies.

METHODS

The study protocol for this review was registered in PROSPERO (CRD42022311747).[22] Our report followed the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRSIMA) Statement.[23]

Search

We searched the CDC's Prevention Research Synthesis (PRS) Project database. The PRS database is a collection of HIV prevention literature focused on behavioral risk reduction, medication adherence, linkage/retention/reengagement in HIV care, structural interventions, PrEP, and systematic reviews.[24] By March 2022, the PRS database had amassed ~111,000 citations collected by automated and supplementary searches developed by librarians with expertise in building and conducting systematic searches. The automated search is implemented annually using the following databases: MEDLINE (OVID), EMBASE (OVID), CINAHL (EBSCOhost), Global Health (OVID), PsycINFO (OVID), and Sociological Abstracts (ProQuest) (Appendix). The search was developed in the MEDLINE (OVID) database using indexing and keyword terms cross-referenced using Boolean logic with no language limits. The finalized search was tailored to other databases to adhere to each proprietary indexing system.[25] Supplementary searches include a manual search of journals (available from the PRS website), online non-indexed databases (e.g., Scopus), gray literature (e.g., Google Scholar), and reference lists from relevant HIV literature.

For this review, the PRS database was first searched on March 25, 2022 for literature published between 2000 and 2022. A librarian queried the PRS database of coded data applied by team members for interventions with PrEP behavioral or biological outcomes that evaluated structural (i.e., using approaches to alter the environment including access, capacity-building, community mobilization, mass media, physical structure, policy/procedure, and addressing social determinants of health), implementation, or technology-based components. We also searched for any newly published literature in PubMed, Scopus, and Google Scholar using the search terms "HIV and pre-exposure prophylaxis" and "telehealth or self-collection or mail-in or pharmacist" (searched December 2022). See Appendix for full PrEP annual searches, PRS database queries, and supplementary searches for this review.

Inclusion Criteria

This review included studies published in English that implemented alternative PrEP care delivery models, which involved structural and/or technology interventions utilizing non-traditional prescribers or setting for care or lab screening. We excluded studies that assessed traditional PrEP care delivery models in which care is delivered by traditional PrEP prescribers and lab screening at traditional lab settings. Traditional PrEP prescribers were defined as medical doctors or nurse practitioners for US-based studies while non-US-based studies included medical doctors only. Interventions using face-to-face encounters at initial and follow-up visits were excluded. We also excluded studies that did not include appropriate clinical follow-ups (e.g., lab review, behavioral risk assessment, sexually transmitted infection (STI) screening) and a study that used oral swab-based self-tests (i.e., rapid test) instead of blood-based tests.[26,27] Other excluded citations include commentaries, reviews, and non-peer-reviewed publications.

Selection and Data Extraction

Citations found in the PRS database were exported to DistillerSR (a systematic review software, Evidence Partners, Ottawa, Canada) for screening to identify eligible studies, data management, and data extraction. Two reviewers independently reviewed the full text, assessed studies, and extracted data on study, intervention and population characteristics and outcomes by using standard forms. Disagreements were resolved through discussions. Reviewers were trained, and data abstraction and screening forms were pilot tested and revised as necessary.

Quality Assessment

Risk of bias was assessed using the adapted Newcastle-Ottawa Quality Assessment Scale for observational studies.[28,29] We further adapted the scale to assess PrEP-related outcomes.[30,31] The scale consisted of five questions with “Yes” or “No” responses. A total score of five was possible, with three to five being considered as “low risk of bias.”

Data Synthesis

This review narratively synthesized characteristics and findings of the included studies. Evidence of intervention *efficacy* of included studies was evaluated using the CDC’s PRS PrEP Evidence-Based Intervention (EBI) or Evidence-Informed Intervention (EI) criteria [32] or HRSA’s HIV/AIDS Bureau (HAB) Emergency Strategies (ES) criteria.[33] Studies that did not meet EBI, EI, or ES criteria were evaluated for *applicability* (relevance and appropriateness) using a modified Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework.[34,35] The RE-AIM assessment assists in determining whether an intervention can be adopted, implemented, and evaluated under real-world conditions. The RE-AIM assessment provides information on whether an intervention developed under research conditions can be translated into prevention practice.[36–38] The RE-AIM assessment has five domains 1) *reach*: access to populations that can benefit most from PrEP, 2) *effectiveness*: impact on PrEP care delivery, consistency of the impact across subgroups; 3) *adoption*: acceptability to and appropriateness for PrEP clients and acceptability among implementers; 4) *implementation*: adaptability, generalizability, cost,

training and technical assistance to implementing staff, and feasibility/complexity; and 5) *maintenance*: sustainability, operationalized/became the standard of care. We used a modified RE-AIM assessment, which consisted of 29 questions with "Yes", "No", "Not Applicable" or/and "Nor Reported" responses.[39] A possible total score was −18 to 28. A higher score means the intervention may be more applicable for implementation due to its ability to reach the focus population, positive effects on PrEP care delivery, appeal to clients and implementation staff, and less-challenging implementation procedures.

We also planned to conduct sub-group analyses to investigate the variation across the HIV populations indicated in NHAS (e.g., MSM, people who inject drugs), type of PrEP dosing schedule (e.g., daily PrEP, on-demand [taking PrEP only when they are at risk for getting HIV]) and type of pharmacies (e.g., free-standing community commercial pharmacies, clinic-based pharmacies), and clinical services (e.g., gender-affirming care, family planning).[20]

RESULTS

Of the 7,198 PrEP citations screened for title and abstract in the PRS database,175 full reports were assessed for eligibility, and 16 studies with 15 unique interventions published between 2018-2022 were identified (Figure 1, Table 1). All interventions were completed before the COVID-19 era (before January 2020), except one in which registered nurses prescribed PrEP in Canada from August 2018 to March 2020.[40] Iowa TelePrEP started providing mail-in tests in addition to telePrEP and published the studies before[41] and after[15] mail-in implementation. Four interventions were non-US-based and 12 were US-based and implemented throughout different cities in the US. Most of the studies (n=11) had low risk of bias. Four types of alternative PrEP care delivery models were identified: alternative prescriber (n=8), alternative setting for care (n=4), alternative setting for laboratory screening (n=1), and combination of alternative prescriber and setting for care with (n=1) or without alternative setting for laboratory screening (n=2).

Types of Alternative PrEP Care Delivery

Alternative prescriber—Of eight studies with alternative PrEP prescribers, four were US-based and allowed community pharmacists to initiate PrEP. These studies were conducted in the West,[42,43] Midwest,[44] and South.[43] Sample sizes were from 53 to 695, and studies were done in 2015-2019. The four non-US-based studies implemented interventions in countries where only physicians were authorized to prescribe PrEP. Three studies (i.e., each in Australia,[45] Canada,[40] and Kenya[46]) allowed nurses to initiate PrEP. While nurses in community-based clinics initiated PrEP in high-income countries (i.e., Australia,[45] Canada[40]), those in maternal and child health clinics did so in Kenya.[46] The study in Thailand allowed lay health workers who were MSM or transgender women to initiate PrEP.[47]

Alternative setting for care—Four studies implemented telePrEP in lieu of in-person office visits.[48–51] These studies were implemented in US urban areas (i.e., New England; Charleston; San Francisco; Seattle). Sample sizes were from 25 to 105. All telePrEP interventions were implemented before the COVID-19 era (in 2016-2019). Telehealth in

WA[49] was accessed at a community-based clinic while other telePrEP services were accessed from home (or unspecific places). PrEPTech is the only included study which focused on young (18-25 years old) MSM.[48] One study focused on women involved in the criminal justice system and their network members.[50]

Alternative setting for laboratory screening—One study, PrEP@Home, implemented mail-in HIV, STI, and creatinine testing among 58 MSM.[52] The study was implemented in US urban areas (i.e., San Francisco, St. Louis, Boston). If laboratory and behavioral surveys that patients filled in electronically did not show any need for medical or behavioral interventions, PrEP prescriptions were renewed by their clinician without an in-person office visit (patients could skip 3 out of 4 quarterly visits).

Combination of alternative prescriber and setting for care with or without alternative setting for laboratory screening—Three US-based studies (two unique interventions) implemented combinations of alternative prescriber and clinic visits with or without lab visits. PrEP Model Incorporating Clinical Pharmacist Encounters and Antimicrobial Stewardship Program (ASP) implemented pharmacist-led telePrEP in a veterans affairs-based clinic in Miami, Florida.[53] Iowa TelePrEP implemented two phases of pharmacist-led telePrEP; the first phase was before implementing mail-in testing[41] then after.[15] Studies were done between 2013-2019. Sample sizes were from 77 to 127. In addition to prescribing PrEP, Iowa TelePrEP implemented PrEP home-delivery services and provided chlamydia trachomatis infection treatment by the pharmacist.

Implementation Science Assessment

None of the included studies met CDC's PRS PrEP EBI or EI[32] or HRSA's HAB ES criteria[33] as none of these studies had a comparison group to evaluate intervention *efficacy*. Thus, we evaluated the interventions using the RE-AIM framework to assess whether the intervention had high applicability in real-world situations. The RE-AIM total scores were from seven to 18 with a median of 13 and mode of 13 and 16 (Table 2). The intervention with the highest total score (18 points) was PrEP@Home which implemented mail-in testing.[52] Two studies received the second highest RE-AIM scores (17 points) and both were telePrEP.[48,51] Three studies received the third highest RE-AIM scores (16 points) and all were pharmacist PrEP providers.[41,42,44] Studies with the lowest scores (7 points) were Pharmacist-Led, Same-Day, PrEP Initiation Program[43] and Iowa TelePrEP with mail-in HIV test.[15] Both studies implemented pharmacist-led telehealth interventions plus some additional features (e.g., same-day PrEP for Pharmacist-Led, Same-Day, PrEP Initiation Program; STI treatment by pharmacists and PrEP medication home delivery for Iowa TelePrEP).

DISCUSSION

This review found 16 studies with alternative PrEP care delivery models. These included alternative PrEP prescriber (i.e., pharmacist in the US, nurse and lay heath worker in non-US countries), setting for care (i.e., telePrEP), and setting for lab screening (i.e., mail-in testing). High RE-AIM scores (indicating high potential applicability for implementation

under real-world conditions) did not cluster under any one approach for alternative PrEP care delivery models while the alternative PrEP care delivery model plus other strategy such as same-day PrEP[43] and STI treatment by pharmacists[15] received low scores.

Seven US-based studies with six unique interventions implemented a collaborative practice agreement (CPA) to expand a pharmacist's scope of practice to initiate PrEP. CPA is not new for drug therapy management. CDC has recommended team-based care through CPA and offers guidance on using CPA.[54] The Community Preventive Service Task Force found that pharmacy-based interventions including a pharmacist prescriber via CPA improve medication adherence for heart disease and stroke prevention.[55] CDC has also identified CPA as a Best Practice Strategy to improve drug therapy management.[56] Moreover, Indian Health Services has successfully implemented a pharmacist-led PrEP clinic to expand PrEP access in tribes and reduce the workload for providers.[57] Such innovative interventions seem to be acceptable and have positive impact on PrEP care delivery, but the efficacy is still unclear due to lack of studies with a comparison. Continued research with a comparison (e.g., randomized controlled trial, pre-post one group study) would help us to better understand the efficacy of CPA.[58]

In general, telePrEP has high applicability and thus would be appropriate for implementation under real-world conditions. However, the exception was the PrEP for Women Involved in Criminal Justice Systems and Risk Network Members intervention which focused on women with high medical, psychiatric, and social comorbidity.[50] TelePrEP accessed from home (i.e., PrEPTECH,[43] TelePrEP in South Carolina[46]) had higher effectiveness on how PrEP care is delivered compared to one accessed from a community-based clinic (i.e., Telehealth in WA).[49] TelePrEP may help clients who struggle to find time or transportation to travel to meet the monitoring requirements, especially those living in a PrEP desert.[59–61] The PrEP desert status is strongly associated with the Southern US and lower urbanicity.[5,6] TelePrEP in South Carolina, which showed the applicability of telePrEP services in a Southern urban area, is now expanding in Southern rural areas.[51] The upcoming study might inform how telePrEP would be appropriate for implementation in Southern and lower urbanicity areas. Moreover, this review only identified telePrEP as an alternative setting, yet there are many other potential alternative settings of PrEP services including web-based, mobile health, and home care. Siegler who was the primary investigator of PrEP@Home is currently conductinga randomized controlled trial called electronic PrEP (ePrEP) to test home-based care, a tailored mobile phone app, and interactive video consultations among nonurban young MSM.[62] These two upcoming telePrEP (i.e., telePrEP in South Carolina, ePrEP) interventions might further inform how we can help improve access to PrEP service with telePrEP.

The alternative setting for lab screening, PrEP@Home, received the highest RE-AIM score, meaning high potential applicability for implementation under real-world conditions. PrEP@Home only included MSM in urban areas as study participants. Mail-in testing may reduce HIV stigma experienced in laboratory sites.[15] Racism, sexism, and homophobia from healthcare providers may result in discomfort for receiving PrEP services, and PrEP users have reported that providers asked the purpose of laboratory orders in front of others or assumed they were HIV positive.[15,63,64] Continued study can explore applicability of this

model in other populations especially those that often report experiencing stigma (e.g., transgender persons, Black/African American [hereafter referred as Black] and Hispanic/Latina cisgender women) or other HIV priority populations indicated in NHAS.[65]

Iowa TelePrEP, which received the lowest RE-AIM score, also implemented mail-in testing along with pharmacist-led telePrEP but it was combined with PrEP medication home-delivery and chlamydia trachomatis infection treatment by pharmacist.[41] The acceptability of the mail-in test kits for Iowa TelePrEP was low (45.5%), and this may be due to the low self-efficacy among the participants to complete the kit including pricking their own fingers.[15] While the Iowa TelePrEP pharmacists described the kit process during videoconference or telephone/email correspondence with participants, PrEP@Home asked participants to view a brief instructional video with a 24-hour optional call line for assistance and had high acceptance of the kits. Thus, implementation of mail-in test kits could be enhanced if it includes detailed instructions and provides additional assistance to increase clients' self-efficacy related to self-collection of blood specimens. Also, some local public health and commercial laboratory sites may prohibit self-obtained swabs and may not be able to accept self-collected specimens for STI tests[15] and implications of these regulations and policies may warrant further exploration. In addition, a future study can explore the scope of practice for pharmacists and assess effectiveness and applicability for pharmacists to provide other PrEP-related services (e.g., STI treatment).

Another unique attribute of PrEP@Home was that PrEP prescriptions could be renewed by clinicians without in-person office visits (participants could skip 3 out of 4 quarterly visits) if laboratory and behavioral assessment (completed electronically) did not show any need for intervention. In fact, the majority (93%) of participants were able to have their prescriptions renewed without in-person office visits.[52] Nurx, a company whose work was not included in this review because none of their publications met our inclusion criteria, offers a 100% web- and app-based PrEP service.[66] This includes counseling via web or mobile app, mail-in testing, and PrEP home-delivery services without any in-person office or lab visits.[66,67] Such web-based PrEP services without in-person office or lab visits may allow individuals to receive PrEP services anywhere in the US from home or other private spaces. Users of Nurx reported initial skepticism but later reported satisfaction after they received the service; they mentioned that barriers to PrEP access were erased as embarrassment and discrimination were minimized.[67] Furthermore, TelePrEP in South Carolina found that more than half of participants (56.3%) preferred telemedicine only for obtaining PrEP compared with in-person only or the combination.[51]

In a separate study, Nurx users reported that the quarterly monitoring requirements were meaningful and might facilitate PrEP persistence.[68] Although monitoring requirements are important as indicated in CDC's PrEP clinical guideline, the delivery methods can be altered to facilitate access to PrEP services, minimize stigma and discrimination experienced among PrEP users, and reduce providers' becoming 'burned out'. CDC is committed to conduct implementation research on telehealth strategies to support those on PrEP during fiscal years 2022-2025 to meet the NHAS's goals.[20,65] Additional innovative telePrEP programs can help us determine whether these alternative approaches are deemed evidence-based and applicable for real world implementation.

Limitations

This review has several limitations. The majority of studies did not report the number of individuals who were approached but refused to participate in the study. Due to insufficient number of studies, we were unable to conduct subgroup analyses to examine whether the interventions reduced disparities in PrEP care among HIV priority populations indicated in NHAS such as Black, Hispanic/Latino and American Indian/Alaska Native men, Black women, transgender women, and people who inject drugs. We excluded studies that did not follow CDC's PrEP clinical practice guidelines such as those that replaced clinical follow-up assessments with negative mail-in HIV test or studies that substituted blood-based HIV tests with oral swab-based HIV self-tests.[26,27] However, these procedures may be the standard of care in non-US countries.[21]

CONCLUSION

This review found high applicability, per the modified RE-AIM framework, of alternative PrEP prescribers, telePrEP, and mail-in testing. The alternative PrEP care delivery model seems to have the ability to reach the focus population, positive effects on PrEP care delivery, appeal to clients and implementation staff, and less-challenging implementation procedures. Innovative models to deliver PrEP services outside of the traditional care system are needed to end the HIV epidemic, but each jurisdiction has different legislation and scope of practice policies. It is important to follow the local regulations and scope of practice policies, but it is also desirable to develop innovative PrEP services if possible. Using innovative/alternative PrEP delivery models can help the US achieve the federal Ending the HIV Epidemic in the US initiative's goals.[69]

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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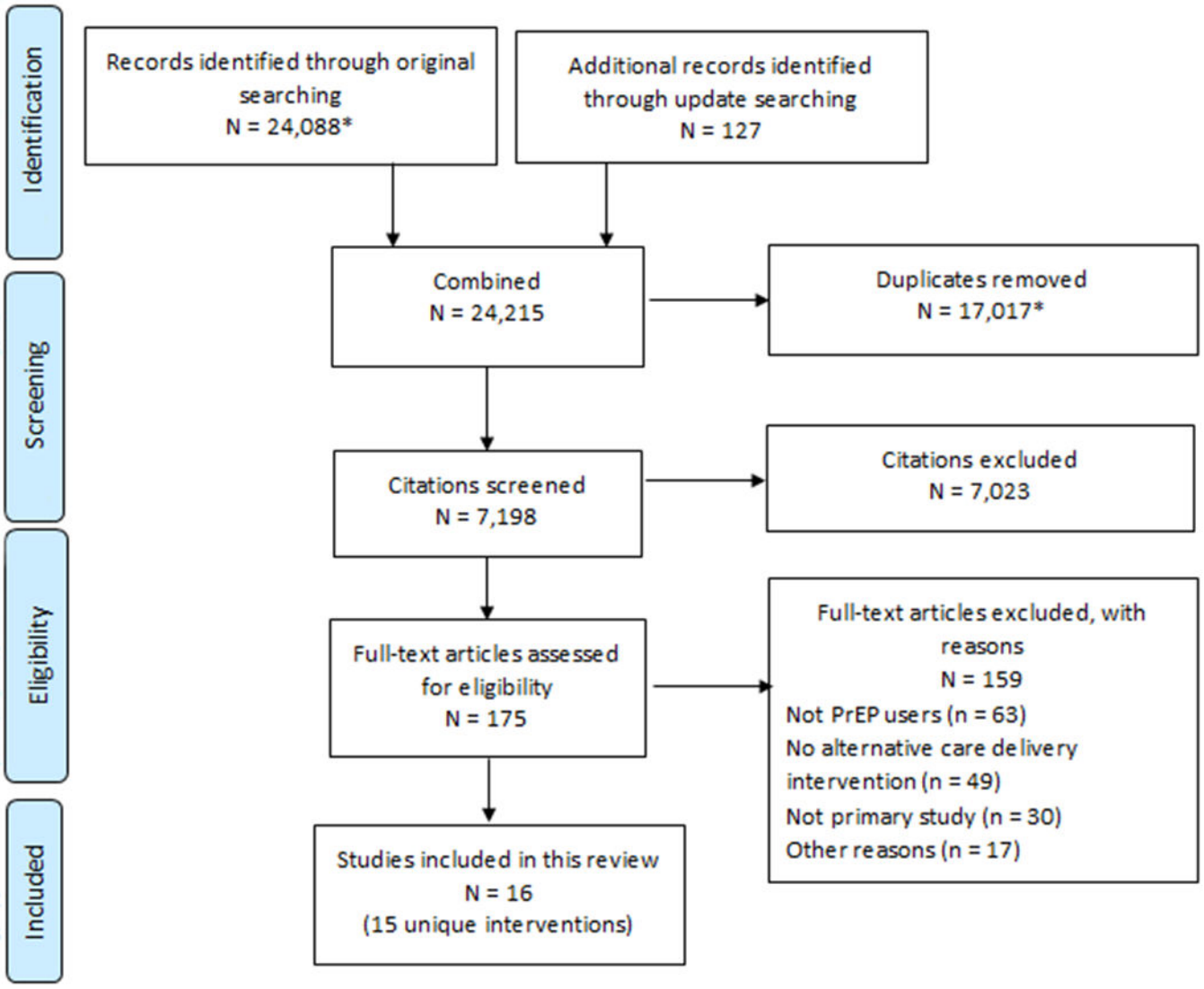

Figure 1:
Flow diagram of included studies
* Our search looked at multiple years, multiple times.

Table 1:

Characteristics of interventions and study participants (n=16)

Intervention name	Author (year)	Setting	Location	Sample size	Study year	Risk of Bias[3]
Alternative Prescriber (n=8)						
Pharmacist (n=4)						
Community Pharmacy-Initiated PrEP program[42]	Lopez (2020)	Community pharmacy	San Francisco, CA	53 patients	Apr 2018 – Mar 2019	High
One-Step PrEP[70]	Tung (2018)	Community pharmacy	Seattle, WA	695 patients	Mar 2015 – Feb 2018	Low
Pharmacist-Led PrEP Program (P-PrEP)[44]	Havens (2019)	University-based clinic, community pharmacy, community-based clinic	Omaha, NE	60 patients	Jan – Jun 2017	Low
Pharmacist-Led, Same-Day, PrEP Initiation Program43, *1, 2*	Khosropour (2020)	University-based clinic	Jackson, MS	69 patients	Nov 2018 – May 2019	High
Nurse [non-US-based] (n=3)						
Expanded PrEP Implementation in Communities in New South Wales (EPIC-NSW)[45]	Schmidt (2018)	Community-based clinic	Australia	More than 8,000 participants	Mar 2016 – Dec 2017	High
PrEP Implementation for Young Women and Adolescents (PrIYA)46, *1*	Kinuthia (2020)	Maternal and child health clinic	Kenya	9376 women	Nov 2017 – Aug 2018	Low
PrEP-Registered Nurse (RN)[40]	O'Byrne (2021)	Community-based clinic	Ottawa, Canada	347 patients	Aug 2018 –Mar 2020	Low
Non-medical care provider (n=1)						
Princess PrEP Program[47]	Phanuphak (2018)	Community-based clinic	Thailand	1467 MSM, 230 TGW	Jan 2016 – Dec 2017	Low
Alternative Setting for Care (n=4)						
Telehealth (n=4)						
PrEP for [50] Women Involved in Criminal Justice Systems (WICJ) and Risk Network (RN) Members[50]	Meyer (2022)	Home	New England, USA	38 WICJ, 67 RN members	Dec 2017 – May 2019	Low
PrEPTECH[48]	Refugio (2019)	Home	San Francisco, CA	25 YMSM (18-25)	Nov 2016 – May 2017	Low
TelePrEP in South Carolina[51]	Player (2022)	Home	North Charleston, SC	20 patients	Sep 2018 – Jun 2019	Low
Telehealth in WA[49]	Stekler (2018)	Community-based clinic	Seattle, WA	48 MSM/TGW	Jul 2016 – Mar 2017	High
Alternative Setting for Lab Screening(n=1)						
Mail-in test (n=1)						
PrEP@Home[52]	Siegler (2019)	Home	San Francisco CA, St. Louis, MO, Boston, MA	58 MSM	Not reported	Low

Intervention name		Author (year)	Setting	Location	Sample size	Study year	Risk of Bias[3]
Combination of Alternative Prescribers and Setting for Care with or without Laboratory Screenings (n=3)							
Pharmacist Prescriber Plus Telehealth with or without mail-in test(n=3)							
A PrEP Model Incorporating Clinical Pharmacist Encounters and Antimicrobial Stewardship Program (ASP)[53]		Gauthier (2019)	VA-based clinic	Miami, FL	79 patients	Jun 2013 – Feb 2018	High
Iowa Telehealth	Without mail-in HIV test[41]	Hoth (2019)	Home or other private community setting	Iowa	127 clients	Feb 2017 – Oct 2018	Low
	With mail-in HIV test[15]	Chasco (2021)			77 clients	JUL 2018 – May 2019	Low

MSM: men who have sex with men, PEP: post-exposure prophylaxis, RN: risk network members of WICJ; TGW: transgender women, VA: veterans affairs, WICJ: women involved in criminal justice systems YMSM: young men who have sex with men

[1] Same-day PrEP

[2] Assessment done by clinicians

[3] Risk of Bias was assessed by using the adapted Newcastle-Ottawa Quality Assessment Scale for observational studies. A total score of 5 was possible, with ≥ 3 considered as “low risk of bias.”

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Table 2:

Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) Scores (n=16)

Intervention name	Reach (−4 to 6)	Effectiveness (−6 to 7)	Adoption (−7 to 7)	Implementation (−1 to 7)	Maintenance (0 to 1)	Total[3] (−18 to 28)
Alternative Prescriber (n=8)						
Pharmacist (n=4)						
Community Pharmacy-Initiated PrEP program[42]	3	1	5	7	0	16
One-Step PrEP[70]	3	3	2	2	0	10
Pharmacist-Led PrEP Program (P-PrEP)[44]	3	4	5	4	0	16
Pharmacist-Led, Same-Day, PrEP Initiation Program43, *1, 2*	0	0	3	4	0	7
Nurse [non-US-based] (n=3)						
Expanded PrEP Implementation in Communities in New South Wales (EPIC-NSW)[45]	1	3	5	4	0	13
PrEP Implementation for Young Women and Adolescents (PrIYA)46, *1*	3	0	4	6	0	13
PrEP-Registered Nurse (RN)[40]	3	2	4	2	0	11
Non-Medical Care Provider (n=1)						
Princess PrEP Program[47]	3	2	3	3	0	11
Alternative Setting for Care (n=4)						
Telehealth (n=4)						
PrEP for Women Involved in Criminal Justice Systems (WICJ) and Risk Network (RN) Members[50]	2	1	3	3	0	9
PrEPTECH[48]	3	6	5	3	0	17
TelePrEP in South Carolina[51]	3	2	6	5	1	17
Telehealth in WA[49]	3	0	6	3	1	13
Alternative Setting for Laboratory Screening (n=1)						
Mail-in test (n=1)						
PrEP@Home[52]	3	4	6	5	0	18
Combination of Alternative Prescribers and Setting for Care with or without Laboratory Screening (n=3)						
Pharmacist Prescriber Plus Telehealth with or without mail-in test(n=3)						

Intervention name		Reach (−4 to 6)	Effectiveness (−6 to 7)	Adoption (−7 to 7)	Implementation (−1 to 7)	Maintenance (0 to 1)	Total[3] (−18 to 28)
A PrEP Model Incorporating Clinical Pharmacist Encounters and Antimicrobial Stewardship Program (ASP)[53]		0	3	6	2	1	12
Iowa TelePrEP	Without mail-in HIV test[41]	3	3	5	4	1	16
	With mail-in HIV test[15]	3	2	2	0	0	7

MSM: men who have sex with men, PEP: post-exposure prophylaxis, TGW: Transgender women, VA: Veterans Affairs, YMSM: Young men who have sex with men

[1] Same-day PrEP

[2] Assessment done by clinicians

[3] Higher score means the more applicable for implementation