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Person-centred HIV prevention: supporting people vulnerable to HIV acquisition through tailored programming, service delivery and prevention products

Guest Editors: Andrew Mujugira, Iskandar Azwa, Marie-Claude Lavoie
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EDITORIAL

Person-centred HIV prevention in an era of innovation and uncertainties

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Person-centred care (PCC) is a healthcare approach that focuses on understanding and respecting clients' preferences, values and beliefs. It aims to empower clients by actively involving them in their own care and highlighting the importance of effective communication and relationships between providers and clients [1–3]. Person-centred health systems are widely endorsed in political and policy statements as essential for addressing health system challenges, promoting equity in access, delivering quality and effective care, and ensuring that no one is left behind [4]. Despite widespread recognition of these PCC principles, current healthcare delivery models often fall short of these ideals because they tend to be disease-focused, fragmented and siloed, emphasising specific programmatic outputs, putting pressure on health workers and jeopardising client-centred care delivery [5]. There is an urgent need to transition from disease-focused health systems to those centred on individuals because nearly half of the global population lacks equitable access to essential healthcare services.

This transformation requires innovative solutions that meet client needs while maintaining accessibility and continuity of care. Recent advances in HIV prevention, including long-acting injectables for pre-exposure prophylaxis (LAI-PrEP), create unprecedented opportunities for PCC. In 2024, the ground-breaking PURPOSE 1 trial reported 100% efficacy among young women receiving twice-yearly lenacapavir [6]. Similarly, the PURPOSE 2 trial demonstrated that HIV incidence was 96% lower with lenacapavir compared to the background incidence [7]. For the first time, individuals can choose from multiple PrEP options—pills, rings or injectables—that align with their sexual behaviours, needs, preferences and life circumstances. Health providers need to educate and counsel individuals about these options, providing evidence-based information about their effectiveness, side effects and requirements (such as adherence to daily dosing or injection schedule) to facilitate autonomous and informed decision-making.

HIV self-testing (HIVST) utilisation can be improved through PCC approaches and complement PrEP. A meta-analysis of 33 studies from around the globe found that HIVST kit distribution by sexual partners, peers or through online platforms achieved higher testing rates than facility-based testing [8]. Significantly, it expanded testing coverage in key populations without reducing test accuracy or safety. Recent evidence suggests that HIVST streamlines HIV screening for people on PrEP and promotes PrEP uptake by individuals not accessing care. It can be leveraged to support PrEP initiation, continuation and re-engagement in care [9]. Technological innovations, such as LAI-PrEP and HIVST, represent only one component of effective prevention. To maximise their effectiveness, it is crucial to adopt comprehensive policies that integrate biomedical strategies with behavioural and structural interventions, implement multi-sectoral programmatic approaches and develop community-responsive service delivery models. This supplement synthesises evidence from PCC intervention research conducted across Africa, Asia, the Caribbean and North America. It includes four research articles, two short reports, a systematic review, a viewpoint and a debate article. Three main themes emerged from the research included in this supplement.

The first theme centres on strategies designed to overcome structural and health system barriers that impede access to HIV prevention services. Australia's approach highlights the importance of person-centred HIV prevention at a national level, driven by partnerships among community organisations, policymakers and researchers that reflect the experiences of local communities, as illustrated in the Viewpoint by Bavinton et al [10]. Despite progress in eliminating HIV among gay and bisexual men who have sex with men, there was a 55% rise in HIV cases among overseas-born individuals from 2010 to 2023. Addressing these disparities requires principles like accessibility and cultural responsiveness, along with enabling access and choices for PrEP. Efforts to expand PrEP options, integrate services into primary healthcare and expand multicultural peer navigation services demonstrate how prioritising dignity and autonomy can improve reach and retention in HIV prevention programmes. McLemore and Amon present the experience of the Global Fund's Breaking Down Barriers initiative, which targeted structural and health system barriers affecting key populations, who account for 70% of new HIV acquisitions worldwide [11]. The authors highlight the experience of Jamaica, Mozambique and Indonesia, which all incorporated a human rights-based approach to improve access to health services. In Indonesia, nearly

900 transgender individuals obtained their national ID cards to enhance access to healthcare and social services. Meanwhile, in Mozambique, community members received support from legal professionals and peers to address human rights issues related to HIV services, successfully resolving 90% of the 6018 cases reported. In Jamaica, civil society organisations have improved legal literacy initiatives, known as "Know your rights," and formed multi-institutional coalitions to tackle stigma and discrimination. Thus, combining community-led human rights efforts with person-centred HIV prevention and treatment has the potential to overcome structural barriers to care.

The second theme focuses on delivering integrated services beyond conventional health models to reach populations who infrequently seek HIV preventive services due to multi-level barriers, including stigma and discrimination, such as key populations and youth. In India, the Mitr clinics provide a comprehensive approach for transgender women, combining gender-affirming services with HIV testing and PrEP. Services such as laser hair removal and hormone therapy attract clients, facilitating access to HIV prevention services (Shaikh et al.) [12]. As a result, 62% of eligible clients received HIV testing, and among 585 clients interested in PrEP, nearly all (98%) took it. These interventions demonstrate the value of integrated, client-centred care for underserved populations. A qualitative study in Canada examined the experiences of both service providers and care recipients regarding integrated HIV/HCV care and the safer supply programme for people who use drugs (Guta et al.) [13]. This programme, managed by healthcare professionals, focused on providing services in a person-centred, non-punitive and trauma-informed manner.

Providers noted that the safer supply model facilitated discussions with people who use drugs about preventing HIV, HCV, and other sexually transmitted and bloodborne infections. In South Africa, community-based peer navigation reached 75% of youth enrolled in a stepped-wedge, cluster-randomised trial, with high acceptability for support; 93% tested for HIV, while 63% tested for curable sexually transmitted infections (STIs), revealing an STI prevalence of 29%, with 85% linked to treatment (Busang et al.) [14]. Males were more likely than females to be offered PrEP, indicating that tailored interventions addressing men's specific PrEP needs and preferences can improve uptake. These diverse examples demonstrate how the discourse can shift from labelling populations as "hard-to-reach" to focusing on what comprehensive services can be offered to them alongside HIV preventive services.

The third theme includes papers focusing on new technologies, including digital health solutions, data health systems, and point-of-care (POC) testing. At the global level, the World Health Organisation has proposed guidelines on person-centred HIV strategic information, with an emphasis on strengthening digital data systems to harmonise and increase the use of essential data elements for national health information systems, thereby improving the HIV response, including HIV prevention [15]. Dalal et al. surveyed 21 countries to gather data on the implementation of these guidelines at the national level. Among the 18 participating countries (82%), all of them included the recommended HIV testing data elements, and nearly all addressed vertical transmission [16]. However, only half provided the necessary data to calculate PrEP coverage. Harm reduction services, such as opioid-agonist maintenance therapy (OAMT), were available in only eight countries due to legal barriers; of these, 75% collected the required OAMT data elements. These findings highlight significant gaps in global implementation of WHO digital health guidelines, particularly in PrEP monitoring and harm reduction data collection, underscoring the importance of ongoing technical support in strengthening HIV surveillance systems. In a similar vein, technology is being utilised to improve oral PrEP use. Recent research has focused on identifying evidence-based interventions to improve adherence and retention in PrEP programmes. A systematic review conducted by Rotsaert et al. found that two-way text reminders or POC tenofovir testing combined with HIV biofeedback counselling improved oral PrEP continuation rates among pregnant and postpartum women [17]. While POC STI testing did not influence PrEP initiation or continuation rates, STI diagnosis was a predictor for PrEP uptake. Future research on PCC interventions should explore the interplay between risk perception, STI diagnosis, PrEP usage and drug-level feedback.

Two papers from Asia demonstrate how digital interventions can be incorporated to deliver real-time individualised HIV prevention messaging and identify predictive attributes for PrEP adherence. Mobile health (mHealth) applications designed to support adherence or self-care can tailor information, advice, and reminders based on user-provided data and preferences. mHealth apps that include self-monitoring and visual feedback have the potential to increase PrEP use. The "Stand by You" initiative in Thailand used a mobile app to provide person-centred support for young people, especially sexual and gender minorities, by ensuring privacy while delivering HIVST kits and non-judgemental text-based real-time counselling (Sripanidkulchai et al.) [18]. The programme's effectiveness was demonstrated through high engagement: 56% were first-time testers, the prevalence of undiagnosed HIV was 3.6%, and among them, 60.2% were linked to care. This success highlights how digital tools, community involvement, TikTok influencers and tailored messaging can effectively overcome barriers such as stigma and limited access to healthcare. Building on this evidence of mHealth engagement strategies, researchers have also leveraged machine learning techniques to better understand and predict user behaviour patterns within digital health platforms. A machine learning study of a mobile health app found that age, cumulative PrEP use, condom use and anal sex events with HIV-negative partners not on PrEP predicted PrEP utilisation among men in Taiwan (Liao et al.) [19]. The use of digital health person-centred interventions is rapidly evolving, and new scientific research questions will emerge on how to incorporate them into routine clinical care and assess their sustained effects on PrEP persistence.

The year 2025 has been marked by extraordinary changes in the HIV response globally following the unprecedented funding cuts and reorganisation of the US global health programme. This disruption will significantly impact PCC, leading to service cuts, lower quality, increased client burden and weakened healthcare system capacity. Evidence from low- and middle-income countries shows worsened client experiences, higher out-of-pocket costs and disrupted care

continuity [20]. UNAIDS projects that the permanent discontinuation of HIV programmes currently supported by PEPFAR will lead to 6.6 million new HIV acquisitions between 2025 and 2029 [21]. Within this environment, advocacy for increased resources, global and domestic support, funding for HIV prevention efforts and alignment of donor resources with local requirements is critical [22]. Striking a balance between the demand for comprehensive care and fiscal constraints necessitates innovative strategies and collaborative partnerships. Prioritising high-impact, cost-efficient and community-led interventions is key to sustainability for PCC [23].

Bringing people-centred HIV prevention interventions to scale requires a comprehensive strategy that integrates biomedical, behavioural and social interventions into existing healthcare systems [22, 24], while actively involving communities in the design and delivery of services. Additionally, implementing a combination of evidence-based HIV prevention strategies at the individual, community and policy levels—such as integrating PrEP, antiretroviral treatment and behavioural support to improve uptake and adherence—is essential for improving population-level impact [25]. It is also important to address stigma and discrimination that hinder access to care [26]. Advocacy for increased resources, support for HIV prevention efforts, increasing domestic funding sources and ensuring that donor resources align with local requirements can help secure the sustainability of PCC interventions. Despite these strategies for sustaining person-centred HIV interventions, such as mHealth apps, peer navigation, two-way texting and POC testing, challenges such as chronic underfunding, drastic funding reductions, and pervasive multi-level stigma continue to pose significant barriers to care.

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COMPETING INTERESTS

AM, IA and M-CL have no competing interests to report.

AUTHORS' CONTRIBUTIONS

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VIEWPOINT ARTICLE

Sustaining HIV prevention success in Australia through person-centred approaches

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Person-centred care is a critical element of HIV care. Global and country-level consensus statements, including from Australia, have emphasized holistic, rights-based approaches centring the autonomy, dignity, experiences, diverse needs, preferences and wellbeing of people living with HIV (PLHIV) [1]. However, the focus has been on HIV care with less focus on person-centred prevention, despite its recent integration into the Joint United Nations Programme on HIV/AIDS (UNAIDS) goal that 95% of individuals at risk of HIV will utilize "appropriate, person-centred, prioritised, and effective combination prevention options" by 2025 [2].

Drawing on the concept of person-centred care, person-centred HIV prevention [3] prioritizes individuals – their autonomy, dignity, rights, decisions and experiences – over interventions or risk categories. It recognizes that individuals are best placed to determine suitable prevention methods, respecting their personal choice and agency. This approach acknowledges the dynamic nature of needs and choices, shaped by personal, contextual and structural factors, such as stigma, discrimination, criminalization and socio-economic conditions. It requires services to be appropriate, responsive and accessible, particularly for marginalized communities facing barriers to care.

Australia has achieved considerable success in HIV prevention, and has an ambitious goal to virtually eliminate HIV transmission by 2030 [4]. In gay, bisexual and other men who have sex with men (GBMSM) in certain urban areas, reductions in HIV diagnoses are approaching the UNAIDS 2030 goal of a 90% reduction from a 2010 baseline [5]. Nonetheless, disparities are evident, particularly among overseas-born GBMSM and those residing outside inner-city suburbs. While nationwide HIV diagnoses decreased by 54% in Australian-born GBMSM between 2010 and 2023, there was a 55% increase in migrant GBMSM, and by 2023, 59% of all GBMSM diagnoses were in migrants [6]. Diagnoses among sex workers and people who use drugs are very low, and HIV rates are also very low among heterosexuals, though those born overseas are at higher risk [6].

Community and community-based organizations (CBOs) have long been integral to HIV prevention, and play an essential role in understanding, articulating and advocating for the needs and preferences of communities affected by HIV [7]. Referred to in Australia as the "partnership approach" [8], collaboration between community, government, policymakers, clinicians and researchers has ensured that communities affected by HIV are key players in decision-making. Despite occasional fluctuations, there has been sustained investment in Australia's HIV-focused CBOs, including support to diversify their remit to encompass broader elements of LGBTQ+ health, other blood-borne viruses and/or sexually transmitted infections (STIs).

Australian CBOs have been instrumental in delivering peer-led, sex-positive, inclusive and pragmatic HIV prevention health promotion, peer education and social marketing. Indeed, the first condom use campaign in Australia was produced and delivered by and for gay men within the community, even before many of the CBOs were formally established [9]. Government-led HIV prevention social marketing is minimal in Australia, and CBOs predominantly deliver these campaigns. CBOs representing key populations such as GBMSM, sex workers and people who use drugs can be more responsive to community needs, have a greater understanding of effective messaging and can be more explicit in community-centred, sex-positive messaging than government agencies [7].

CBOs have also played a crucial role in service delivery, such as condom distribution, needle and syringe programmes, running community-based HIV/STI testing sites (some of which were successful in delivering pre-exposure prophylaxis [PrEP]) [10, 11] and scaling up HIV self-testing via online platforms or vending machines. Peer navigation – often mentioned as a quintessential example of person-centred care [1] – has been a vital component of supporting PLHIV. It has recently been recognized by the Australian Government as a potentially high-impact tool to address barriers faced by migrants in HIV testing and prevention, with funding for a new national multicultural peer navigation project to be led by a CBO.

Australia has a publicly funded universal healthcare system providing free or subsidized primary healthcare. Integration of HIV testing and prevention into primary care exemplifies person-centred principles and offers two major benefits: holistic care and patient choice. In many countries, HIV

testing and PrEP are primarily offered in specialist HIV services and hospitals – a setup that may be effective for HIV care but is less likely to succeed in reaching the much larger populations needing access to prevention [12]. For prevention to be effective, it must be genuinely accessible, everywhere. From the inception of PrEP in Australia, any medical practitioner could prescribe it. This approach means that when a patient seeks HIV testing, STI testing or PrEP, they are attended to by a clinician capable of addressing more general health issues, such as mental health, sexual wellbeing and physical health. Specialist sexual health centres provide another choice for people's HIV prevention needs, with many centres having counselling teams and referral pathways to other specialist services.

However, further progress is necessary, and Australia must continue its long history of innovating and implementing person-centred approaches. One example is the limited choice of PrEP options in Australia. Oral PrEP scale-up led to rapid declines in HIV diagnoses and one of the highest per-capita uptake rates globally [5, 12, 13], with community-based surveys suggesting over three-quarters of GBMSM at risk of HIV are taking PrEP [14]. However, essentially, only one PrEP product is widely available (oral tenofovir disoproxil* and emtricitabine [TD*/FTC]; although emtricitabine/tenofovir alafenamide can be legally ordered online and personally imported). Oral TD*/FTC is not suitable for everyone: some individuals have medical contraindications, while others experience side effects, dislike taking tablets, or struggle with adherence [15]. Decisions on government subsidy for new medicines in Australia are based on efficacy and cost-effectiveness compared to current practice [16], meaning that the success of generic oral TD*/FTC PrEP – and its low cost – poses a challenge for the introduction of new PrEP products [17]. Despite long-acting injectable Cabotegravir receiving early regulatory approval, a positive recommendation for government subsidy and ongoing advocacy from community organizations, price negotiations were unsuccessful, and this product is unavailable. In the meantime, choice is paramount in person-centred care, and it is essential to enhance oral PrEP accessibility and affordability, especially for marginalized populations. Options being explored include nurse-led PrEP provision at publicly funded sexual health centres, PrEP delivered by community pharmacists, extending the duration of PrEP prescriptions, telehealth PrEP services and research into peer-provided PrEP [16].

To achieve national and global goals, Australia must build on its successes in prevention with a commitment to person-centred principles – an approach that has long been embedded in the Australian response, even before the concept was formally articulated. Despite being in a context of universal healthcare and legal protections for sexual and gender minorities, disparities have emerged in the HIV epidemic. We must continue to innovate and implement person-centred approaches to ensure all individuals have access to the prevention methods that are right for them.

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DEBATE

Put rights at the centre of person- and people-centred HIV prevention

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Abstract

Introduction: "Person-centred" and "people-centred" HIV prevention programmes both seek to scale up access to HIV prevention services. A "person-centred" approach presents a vision of a client with agency in decision-making, engaged and empowered, working with providers in a process that is not disease-centric but focused on addressing, holistically, a client's needs. A "people-centred" approach recognizes the broader role of family and community, as well as the influence of the political and legal environment as barriers or facilitators to HIV services. In both cases, human rights are a critical determinant of positive or negative outcomes.

Discussion: In 2017, the Global Fund's *Breaking Down Barriers* initiative funded baseline assessments in 20 countries examining key human rights barriers to HIV services. Subsequent evaluations in 2019–2021 and 2022–2024 focused on the scale-up of community-led human rights interventions and the impact of these programmes on access to HIV prevention and care. Results from the latest assessment describe a range of strategies and impact across diverse countries, settings and populations. For example, in Indonesia, transgender-led organizations catalysed a national drive to allow transgender persons to receive gender-matched identity cards, allowing thousands of individuals to access HIV prevention and treatment and broader social benefits. In Mozambique, peer-led paralegals and community advocates promoted legal literacy and assisted clients with claims of human rights violations, preventing access to HIV services. In Jamaica, lesbian, gay, bisexual and transgender led organizations sponsored trainings that advanced community activism for HIV prevention, education and advocacy. Despite facing stigma and challenging legal environments, in each case, human rights-based programmes removed structural and legal barriers to HIV prevention services, strengthening accountability and increasing uptake and retention in HIV services, especially among marginalized and criminalized populations.

Conclusions: Community mobilization led by key populations is a long-term undertaking that requires partnership and support from a wide range of stakeholders to ensure sustainability. A growing body of evidence across a range of diverse countries and settings demonstrates the impact of rights-based and people-centred programmes on access to, and retention in, HIV prevention and treatment.

Keywords: HIV; human rights; people-centred care; Jamaica; Indonesia; Mozambique

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1 | INTRODUCTION

The past decade has seen the global HIV response move towards a model of "person-centred" services for prevention and treatment [1]. At the heart of this approach is a vision of a client with agency in decision-making, engaged and empowered, working with providers in a process that is not disease-centric but focused on holistically addressing a client's needs [2]. Increasingly, however, there is recognition that a broader "people-centred" approach, that emphasizes the role of family, community, environment and other factors, such as the human rights environment in which HIV services are delivered, is critical to ensuring access to HIV prevention and treatment [3–5].

For many decades, the HIV response has pioneered aspects of this broader people-centred approach – engaging communities and underlining the importance of addressing and overcoming barriers that limit access to prevention and care, including human rights abuses which disproportionately affect adolescent girls and young women, sex workers, lesbian, gay, bisexual, transgender, queer and intersex (LGBTQI) individuals and people who inject drugs (PWID). Collectively, these key populations (KPs) account for at least 70% of new HIV acquisition worldwide and human rights abuses represent a major driver of HIV risk, as a result of discrimination in healthcare and community settings; the criminalization of these populations; and the experience of violence—from police, clients and community members [6].

Box. Breaking Down Barriers initiative: programmes to remove human rights-related barriers to HIV services

- Eliminating stigma and discrimination in all settings
- Ensuring non-discriminatory provision of healthcare
- Ensuring rights-based law enforcement practices
- Legal literacy ("know your rights")
- Increasing access to justice
- Improving laws, regulations and polices relating to HIV
- Reducing gender discrimination, harmful gender norms and violence against women and girls in all their diversity
- Community mobilization and advocacy for human rights

To address this, there needs to be at the core of people-centred approaches evidence-based human rights interventions operating at scale and working at multiple levels: addressing individual rights violations, community-level stigma and discrimination, and punitive laws that target KPs and drive individuals away from prevention and treatment. These laws, as currently proposed and implemented, for example, in Uganda, Ghana and Kenya, can also target HIV organizations by outlawing the "promotion" or "normalization" of homosexuality [7]. In other countries, prevention approaches such as the distribution and possession of condoms or sterile syringes can be used as evidence of crimes such as solicitation, prostitution or illicit drug use [8, 9].

Since 2017, the Global Fund's *Breaking Down Barriers* (BDB) initiative has supported community-led programming in more than 20 countries seeking to reduce human rights-related barriers to HIV, tuberculosis (TB) and malaria prevention and treatment [10]. These programmes seek to mobilize communities and ensure accountability and access to justice in the face of rights violations. More specifically, programmes aim to eliminate stigma and discrimination; ensure rights-based law enforcement practices; promote legal literacy; increase access to justice; and improve laws, regulations and polices relating to HIV (see Box).

By design, none of these interventions can be undertaken without engaging multiple stakeholders, including national health ministries and other government actors, civil society and non-governmental organizations (NGOs), the Joint United Nations Programme on HIV/AIDS (UNAIDS), international donors and technical partners. Community and peer leadership is prioritized in programme design and implementation, reflecting the Global Fund definition of "people-centred" care that puts "people *and communities* (emphasis added) at the centre of services" [11].

Without addressing structural and legal barriers to HIV services, violence, discrimination, lack of access to prevention and denial of care and treatment will continue to impact marginalized and criminalized populations [12]. Human rights-based interventions which seek to create an enabling environment for HIV programmes can expand access to both biological (e.g. pre-exposure prophylaxis or PrEP) and behavioural HIV prevention strategies and reduce loss to follow-up and ensure ongoing use of HIV prevention methods.

To illustrate the importance of integrating human rights-based interventions into people-centred HIV programmes, we highlight results from three country assessments conducted in Indonesia, Mozambique and Jamaica, and describe in each case: (1) how community-based organizations led rights-based campaigns to address issues that they identified as posing critical barriers to HIV prevention; (2) the challenges they faced and the strategies used to overcome those challenges; and (3) the direct and indirect outcomes resulting from the campaigns.

2 | DISCUSSION

Between 2022 and 2024, an evaluation of the *Breaking Down Barriers* initiative was conducted to examine community-led, and people-centred, human rights-based HIV programmes in 20 countries [13]. The evaluation used an implementation learning approach including a document review of programme monitoring and budget documents (such as grant agreements and related documents); financial and programmatic reports; programme outputs (activity reports, tools, training manuals, guidelines, policies, etc.); documentation on human rights-related barriers (violations reports, press statements, etc.); and other documents related to national strategies and programmes to reduce or remove human rights barriers.

Key informant interviews were conducted with implementers, government officials, human rights experts and beneficiaries, and sought to understand challenges faced in the implementation and scale-up of rights-based initiatives, as well as key outputs, outcomes and impact. Interviewers probed strategies to advance HIV programmes in the face of challenging legal and political environments and to assess different perspectives on priorities for future investment. In all countries, stakeholder validation meetings were held to share preliminary results and receive feedback.

2.1 | Indonesia

In Indonesia, the Breaking Down Barriers assessment was conducted between December 2022 and February 2023 and included interviews with 190 individuals, including programme implementers, representatives from government agencies, and community and technical partners. Site visits were conducted in Bandung, Bogor, Jakarta (Java) and Medan (Sumatra). Follow-up interviews were conducted in March 2023, and stakeholder validation meetings were held in April 2023 [14].

One programme the evaluation highlighted was the collaborative work of the transgender-led network "Our Voice," the Indonesia AIDS Coalition (a community-based organization focused on promoting the rights of people living with HIV and KPs), and the Indonesian government to address the challenges KPs face if they did not have a national identity card (Kartu Tanda Penduduk or KTP).

The KTP card gives Indonesians access to HIV prevention and treatment services, as well as critical health and social welfare programmes [15–18]. Having a KTP card ensures

affordable access to HIV testing, PrEP and syringe access programmes, yet transgender individuals face specific obstacles to obtaining the ID cards, as many leave their families and hometowns before obtaining a card, or the card they hold no longer matches their gender identity, resulting in stigma and denial of access to HIV services.

Initially, HIV and LGBT organizations worked with local government officials to facilitate access to the KTP for individuals. However, all groups recognized that a more durable solution was needed, and together they conducted advocacy with the Ministry of Home Affairs, which issued new guidance that loosened restrictions on eligibility for national ID cards for transgender people. This guidance then became the basis of a letter to civil registration agencies around the country.

What was needed next was community mobilization to take advantage of the changing requirements. Supported by multiple donors, a coalition led by Our Voice obtained 897 national identity cards for transgender people in 29 districts in the first year following the regulatory change [14]. Key participants in the coalition were advocacy officers and paralegals from "District Task Forces" established as part of the BDB initiative in 23 high-burden districts for HIV. In some cases, District Task Forces also included community leaders, government officials and other local stakeholders. Advocacy Officers, who were members of the KPs they served, worked with peer advocates to inform the community of the new eligibility rules, to collect and develop necessary documentation, and help individuals submit the documents to the appropriate civil agencies.

District Task Force teams also successfully campaigned for increased access to ID cards for female sex workers. A 2021 study indicated that having a KTP was a key factor in the ability of female sex workers in Indonesia to access HIV and viral load testing and that having a KTP correlated with adherence to treatment regimens [18]. As of December 2022, at least 100 KP members had enrolled in the health insurance programme as a result of obtaining national ID cards, and community advocacy on this issue was ongoing [14].

Of course, challenges and barriers to HIV prevention for KPs in Indonesia remain. The evaluation found widespread concern among implementers about the impact of a newly proposed Criminal Code on the rights of women, LGBT persons, and on HIV prevention and treatment services [14]. Among other things, the law criminalizes consensual extramarital sex and distributing information about contraception to minors [19]. As same-sex couples cannot marry in the country, all same-sex conduct would be against the law. People who use drugs also face severe treatment, especially women, by Indonesia's drug laws. One study found that among women in Indonesia who have come into contact with the police because of injection drug use, 90% also have experienced extortion, physical and/or sexual violence [20].

2.2 | Mozambique

In Mozambique, the BDB assessment was conducted between January and April 2023 and included 26 key informant interviews and group discussions with representatives of KPs, including sex workers, people who use or inject drugs (PWUD/PWID), gay men and other men who have sex with men (MSM) and transgender people. Preliminary results and stakeholder validation meetings were held in November 2023 [21].

A key component of the Mozambique programme was the development of an integrated structure of support for people experiencing stigma and discrimination in access to HIV programmes and health services. The initiative was championed by the Fundação para o Desenvolvimento da Comunidade (Foundation for Community Development, or FDC), a non-profit organization that promotes social justice and works to empower communities to overcome poverty.

To address these challenges, FDC, the Centro de Colaboracao em Saude (CSS) and other NGOs worked with local government officials, police and community health committees, to resolve barriers to HIV services through the training and engagement of KP members as *activistas* and paralegals who could conduct legal literacy trainings and educate KPs and affected communities in their rights to HIV prevention. When necessary, *activistas* and paralegals also worked closely with district supervisors or provincial human rights officials to escalate concerns, such as denial of care and discriminatory or abusive treatment, to the Mozambique government's legal aid institute or directly to prosecutors [21].

Although time-consuming and requiring sustained engagement, the organizations participating reported positive results in reconnecting people to HIV prevention and treatment programmes. For example, the Centro de Colaboracao em Saude (CSS), a leading implementer alongside FDC, reported that from January to March 2020, 696 of 875 patients (79%) were reintegrated into HIV care by health advocates, including paralegals who provided assistance in cases involving violations of human rights. Between July and October of 2021, 591 people living with HIV returned to treatment following interventions from *activistas* and paralegals [22].

FDC reported a total of 7381 human rights-related claims were handled by its team of 10 lawyers, 300 paralegals and 15,000 *activistas* between July 2022 and January 2023. Nearly a third of all claims (2369) were related to human rights violations experienced in health facilities. Stigma and discrimination represented the single largest number of complaints, followed by lack of informed consent and lack of access to care. Other complaints included violations of the right to privacy, extortion, corruption and police harassment, which impact both HIV prevention and care (see Figure 1) [23].

According to reports by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), assistance by *activistas* and paralegal advocates encouraged clients to seek redress for inappropriate or discriminatory treatment and increased accountability from both clinic staff and the health system more generally [24].

2.3 | Jamaica

In Jamaica, the BDB assessment was conducted between August and November 2023, with interviews conducted remotely and during a country visit in October 2023. The research team interviewed 24 key implementers, government agency representatives, technical partners and beneficiaries.

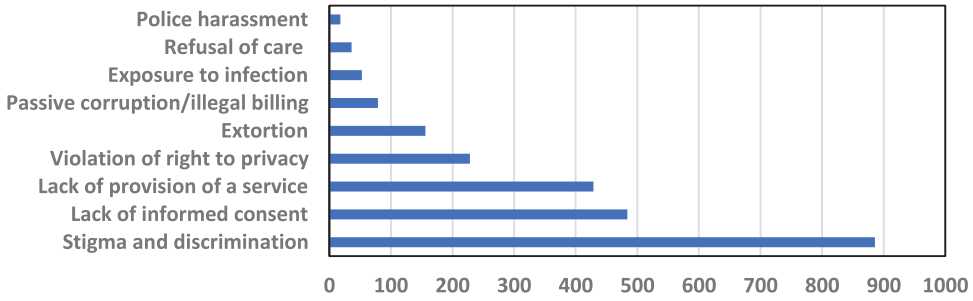

Figure 1. Human rights claims related to access to HIV services reported to Fundação para o Desenvolvimento da Comunidade, Mozambique (July 2022–January 2023).

Stakeholders were given preliminary findings and recommendations for review and comment in October 2023, prior to finalization of the report [25].

Since the start of the HIV epidemic in Jamaica, the criminalization of same-sex sexual relations and a culture of pervasive homophobia have undermined the national HIV response [26, 27]. Previous studies have found that Jamaica's Offenses Against Person Act, which was enacted in 1864, and which the Jamaican Supreme Court declined to overturn in 2023, and widespread police harassment of MSM and transgender women, have resulted in barriers to accessing HIV prevention and treatment services [28, 29]. A 2016 report commissioned by J-FLAG found that more than half (51.3%) of LGBTQI individuals surveyed who had experienced physical or sexual assault did not report it to the police. Forty-one percent did not report it because they did not believe the police would take any action [30].

In response to these challenges, the Enabling Environment and Human Rights (EEHR) unit of the Jamaican Ministry of Health and Wellness and civil society organizations (CSOs) such as JASL, JFJ, JN+, Eve for Life, J-FLAG, Equality for All and Transwave have participated in intensive efforts to present hundreds of legal literacy and "Know Your Rights" sessions for community members throughout the country. Results from the campaign show that people living with HIV have high levels of understanding of their rights and ways to seek redress in the face of discrimination in healthcare, employment and other sectors [25]. In addition, the EEHR unit and CSOs trained more than 1000 police officers in regions across Jamaica on the human rights of people living with HIV and KPs, including pre-service recruits at the national police academy and in-service trainings that reached regional and divisional leaders in addition to rank and file officers. Post-training surveys indicated changed attitudes among police and KPs reported improved treatment [25].

Nonetheless, the organizations leading these programmes noted a gap in national coverage and challenges faced by new organizations seeking to expand knowledge of human rights and HIV. In response, and with the goal to ensure that lessons learned from more established organizations were passed from one generation of activists to the next, J-FLAG created a series of workshops designed to build visibility and capacity for LGBTQI activists in several regions in Jamaica to fight against stigma and discrimination, complementing training of police with building confidence among LGBTQI communities.

One aspect of the training focused on teaching the history of HIV and the human rights movement. The initiative was designed around a theory of change that learning about the history of the human rights movement in Jamaica could strengthen the sense of solidarity and build collaboration among groups working on HIV despite diversity in terms of generation and geography. The director of a newly founded organization named Queertego, based in Montego Bay, attended one workshop and described the experience of being in a safe, open space where queer people could freely express themselves as profoundly changing his perception of himself and his place in the world [25].

Building on the relationship established in the workshop, and with the backing of a partnership with J-FLAG and Jamaica AIDS Services for Life (JASL), Queertego was able to significantly expand their community presence by hosting LGBTQI health fairs, town hall events and workshops focused on issues central to LGBTQI people in Montego Bay, including HIV prevention, access to PrEP, substance use and mental health challenges.

The *Breaking Down Barriers* assessment found that Queertego's partnership with J-FLAG and JASL had improved access to HIV education, prevention and care in Montego Bay while also opening an important connection with JASL's extensive legal network and resources, which includes peer HIV advocates trained as legal "focal points" as well as paralegals and lawyers offering services to people living with HIV in three regions of the country. Expanding the network geographically also strengthened the Jamaican Anti-Discrimination System and Shared Incidents Database (JADS), a platform for reporting and resolving complaints related to discrimination and human rights violations used by civil society and Jamaican government agencies, including the Ministry of Health and Wellness and key social service and child welfare agencies. More complete coverage and stronger collaboration promoted faster resolution of issues related to HIV prevention and treatment access and offered an opportunity for greater understanding of linkages between human rights programming and health and HIV outcomes [31].

3 | CONCLUSIONS

Addressing human rights challenges that reduce access to prevention and treatment are critically important to the implementation of successful people-centred HIV prevention approaches. Integrating programmes targeting stigma and discrimination, improving laws and ensuring rights-based law enforcement practices, expanding legal literacy and access to justice, reducing gender discrimination and harmful gender norms and mobilizing communities to demand respect for human rights for LGBTQI communities, women, sex workers and others acutely impacted by HIV helps to close the gap to achieve global goals to "end AIDS" by 2030. Especially as human rights environments for KPs deteriorate in many countries, targeted rights-based programmes to reduce barriers to HIV services and mitigate harm from punitive laws and policies become increasingly urgent.

However, human rights-related interventions should not be expected to reduce barriers to HIV prevention and treatment overnight, especially in a moment where funds for global health research and implementation, generally and for marginalized populations in particular, have been drastically cut. In March 2025, USAID's staff was cut from about 10,000 employees to 15, before being closed completely on 1 July 2025 [32]. In the next 5 years, cuts to foreign assistance could cause an additional 4–10 million new HIV acquisitions and 1–3 million HIV-related deaths [33]. It is especially at these times when rights-based programmes that combat discrimination and criminalization – which cost governments little – are essential to sustaining HIV prevention and treatment gains. While historically rights-based approaches were supported primarily by external donors, the Breaking Down Barriers initiative required countries to commit matching funds and integrate rights into national strategic plans, fostering sustainability.

A growing body of evidence across a range of diverse countries and settings demonstrates the potential of a model of people-centred services that recognizes the impact of family, community and the social and political environment on access to HIV services and aims to strengthen advocacy and respect for human rights. Community-led initiatives can increase access to prevention and treatment services by reducing structural and legal barriers for people disproportionately affected by HIV, particularly criminalized and marginalized populations.

Nearly all of the rights-based interventions supported by the Global Fund's BDB initiative, as identified in the Box above, address traditional core responsibilities of government: enforcing non-discrimination; ensuring law enforcement is just and fair; educating the public on rights and ensuring access to justice for all. Recognizing this, government officials have increasingly spoken out about the importance of rights-based approaches, especially in countries where the HIV response has been most successful.

For example, in Botswana on World AIDS Day 2024, the country's Vice President emphasized the importance of human rights interventions, saying that "…collaboration between stakeholders such as lawmakers, the judiciary, the police, traditional leaders and private legal practitioners must be strengthened with a view to removing human rights barriers" [34]. The Vice President went on to note that the government had established a human rights unit within the National AIDS and Health Promotion Agency (NAHPA).

In 2020, Jamaica became one of the first countries to join the Global Partnership for Action to Eliminate all Forms of HIV-Related Stigma and Discrimination. The initiative brings together government, civil society, donors and others to address rights-related issues across sectors, including the workplace, justice system, families and communities. In launching the initiative's first report in June 2021, the Minister for Health and Wellness, Juliet Cuthbert Flynn, reiterated the government's commitment to addressing the social and legal issues that are barriers to an effective HIV response and called for political leadership across party lines to recognize their role in helping to create an enabling environment [35].

Similarly, South Africa's 2023–2028 National Strategic Plan for HIV, TB and STIs mentions "human rights" throughout [36]. Protecting and promoting human rights and advancing access to justice is specifically identified as a key objective, and "reducing inequalities through human rights-based, people- and community-centred approaches" and removing "all societal and legal barriers" are identified as essential to achieving global HIV targets.

Of course, what is written in plans and said on World AIDS Day is not always what is delivered, and the politics of criminalizing KPs can be more appealing to governments than implementing effective HIV programmes. However, since 2017, the Global Fund's Breaking Down Barriers project has invested more than US$200 million in rights-based programmes involving both non-governmental organizations and government agencies in the response, and countries have made matching contributions from their own treasuries [13].

In each of the case studies above, impact and sustainability were fostered by partnerships between community-based organizations, Ministries of Health and legal professionals. Organizations often prioritized mediation strategies and working outside of formal judicial systems to address and overcome barriers to HIV services, while maintaining the option of seeking accountability through the courts or direct appeals to the government as needed.

In order to achieve AIDS 2030 goals, rights-based interventions such as those that promote community mobilization, access to justice, and that combat stigma and discrimination are essential, both for KPs and to ensure that people-centred services are equitable and available to everyone. Donors and governments should recognize their value and expand support for evidence-based approaches that place people and human rights at the centre of person-centred HIV prevention and treatment.

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COMPETING INTERESTS

The authors report no competing interests.

AUTHORS' CONTRIBUTIONS

MM and JJA conceptualized the article. MM wrote the first draft, and MM and JJA contributed to subsequent revisions.

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RESEARCH ARTICLE

Laser hair removal to antiretrovirals: findings from a person-centred care model for transgender people in India

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Abstract

Introduction: Transgender women (TGW) in India continue to bear disproportionate HIV burden and face persistent social, legal and structural barriers to receive gender-affirming care.

Methods: Since 2021, we established three "*Mitr*" (meaning: friend) clinics in Hyderabad, Pune and Thane, India, for transgender people with staffing primarily from the community. *Mitr* clinics provide free HIV testing and pre-exposure prophylaxis (PrEP) on site with linkage to government antiretroviral therapy (ART) centres. They also provide free consultation for gender-affirming hormone therapy (GAHT), subsidized laser hair removal and legal assistance. Client service utilization data were analysed using summary statistics to evaluate uptake of HIV and gender-affirming services; correlates of HIV testing were examined using logistic regression. Semi-structured interviews conducted at one site were used to understand barriers/facilitators of HIV testing.

Results: A total of 5223 unique clients registered between March 2021 and September 2024; median age was 26 years. Most (86%) self-identified as TGW, and 35% reported transactional sex. Most clients (70%) had not previously accessed public sector HIV services. The majority (75%) accessed *Mitr* clinics for gender-affirming care, including laser hair removal (53%), GAHT consultations (34%) and surgical referral (26%). Over half (62%) of clients eligible for HIV testing underwent screening, of whom 6% were newly diagnosed. Accessing *Mitr* clinics for gender-affirming surgical services was significantly associated with HIV testing receipt (aOR: 1.51; 95% CI: 1.02, 2.25). Services provided by staff from the community were a prominent facilitator for HIV testing, while stigma and disclosure concerns were notable barriers. Among 585 clients interested in and eligible for PrEP, 576 (98%) initiated PrEP, and 378 (66%) were PrEP persistent at 3 months. Of 454 clients with HIV (newly diagnosed or previously known), 392 (86%) initiated ART. As of 30 September 2024, 233 (59%) were still receiving *Mitr* clinic services and retained in HIV care; viral suppression was 98% among the 156 clients with data.

Conclusions: The *Mitr* model highlights the importance of aligning programme and community priorities. The provision of gender-affirming care attracted many clients who might not otherwise have accessed HIV services; indeed, laser hair removal served as the key entry point to HIV testing, PrEP and ART.

Keywords: comprehensive services; gender-affirming care; HIV; low- and middle-income country; person-centred; transgender people

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1 | INTRODUCTION

Globally, transgender people experience significant disparities in access to health services, shaped by structural and psychosocial factors including stigma, discrimination, violence and legal barriers [1–3]. These inequities extend to receipt of HIV services [4–7], with global estimates indicating a high burden of HIV among transgender people [8–10] and unequal outcomes across the HIV care continuum compared to the general population [11–14].

Transgender communities in India [15, 16] are highly diverse and include organized groups such as Hijra communities that have evolved social structures built on systems of kinship [17]. However, laws criminalizing gender and sexual minority individuals [18] have perpetuated intersectional stigma [19–22] and contributed to the marginalization

of transgender people. Consistent with global findings [23–28], transgender people in India experience minority stress and syndemics that influence health outcomes [29–38]. Hijra/transgender women (TGW) in India have a HIV prevalence of 3.8% [39], nearly 19 times higher than the general population.

Following long-standing advocacy, the Transgender Persons (Protection of Rights) Act was passed in 2019, recognizing equal rights of transgender people to education, employment and healthcare [40]. The Act prohibits discrimination in healthcare services, and mandates that medical facilities include gender-affirming services to support a person's process of living and being perceived in alignment with their gender identity [40]. Despite this act, the implementation of gender-affirming care models is rare. The delivery of public sector health services to transgender people has largely focused on HIV prevention and treatment without the integration of gender-affirming care; prevention services are primarily delivered through the Targeted Intervention (TI) programme, while antiretroviral therapy (ART) is provided at over 700 government ART centres. HIV pre-exposure prophylaxis (PrEP) is not available in the public sector free of charge. While medical and surgical gender-affirming services are available in the private sector, cost limits accessibility [41–43]. Further, state-level variability and bureaucracy limit accessibility to social welfare schemes [41, 44–46].

Multiple service delivery models globally for transgender people have paved the way for the provision of person-centred care [47–53] (i.e. a care approach that prioritizes the values, goals and preferences of transgender people over a particular disease/diseases outcome(s)). These models are built on the principle that provision of integral services encompassing gender-affirming care can facilitate receipt of other health services and are paramount to shaping health outcomes among transgender people [54–60]. Despite this evidence, few such models exist in India.

To address this implementation gap and to intervene on the inequities experienced in health services by transgender people, starting in February 2021, we established three comprehensive person-centred clinics, known as "*Mitr*" clinics, in the Indian cities of Hyderabad (Telangana State), Pune and Thane (Maharashtra State). We detail the implementation of these clinics and provide evaluation insights on (1) the delivery and uptake of HIV and gender-affirming services; (2) the association of receiving gender-affirming services and other factors such as socio-demographic characteristics and risk behaviours with HIV testing receipt; and (3) the HIV prevention and treatment cascades among clients.

2 | METHODS

2.1 | Implementation of *Mitr* clinics

Mitr clinics were established on foundational principles: (1) gender-affirming person-centred care as a fundamental right; (2) integration of medical, psychosocial and legal services to minimize barriers; (3) ownership of the clinic by members of the community in the cities where they were established.

Initial implementation processes included multiple rounds of consultations with community members and stakeholders in each city on service delivery priorities across the spectrum of person-centred care, including health, psychosocial, legal and advocacy needs. A discussion guide was developed to elicit stakeholders' perspectives. Key service priorities recommended included: (1) integration of HIV care, gender-affirming services and support to access legal services and social protection schemes in decentralized community-based, "one-stop" venues; (2) expansion of counselling services beyond HIV; and (3) enhancement of peer navigation. Consensus regarding which of the service delivery priorities could be implemented across *Mitr* clinics was achieved through discussions between our team and community leaders. Clinics ensured that transgender personnel were represented at multiple staffing levels, offering a credible and comfortable community-led environment while providing a pathway for professional development for staff. Each *Mitr* clinic includes a physician, clinic manager, nurse, a peer counsellor and two community outreach workers.

Gender-affirming services at *Mitr* clinics include consultations and prescriptions for gender-affirming hormone therapy (GAHT), laser hair removal services, mental health services (including individual and family counselling, substance use counselling, referrals to psychiatrists and other mental health professionals), counselling on surgical services (top surgery, breast implants and other gender-affirming surgery), and social and legal gender identity services (i.e. assistance with transgender certificate applications and accessing state welfare benefits). HIV and sexual health services include rapid on-site HIV screening with linkage to government integrated counselling and testing centres to receive confirmatory testing, provision of PrEP (which was initiated across *Mitr* clinics in October 2022), testing for syphilis (as per local guidelines) [61], and provision of lubricants and condoms. Syndromic management of sexually transmitted infections (STIs) is the standard in the public sector in India, with syphilis being the only STI with an on-site rapid test [61]. While all the aforementioned services are provided on site either free of cost or at subsidized rates (i.e., laser hair removal services), ART and surgical services are facilitated through referrals to government ART centres and surgical programmes at government or private hospitals. Clients paid out-of-pocket for surgical services and GAHT.

2.2 | Evaluation of uptake of services at *Mitr* clinics

2.2.1 | *Data collection*

Evaluation of *Mitr* clinics included both programmatic data routinely collected at all *Mitr* clinics as well as a one-time semi-structured survey collected at one site. Programmatic data were collected between 1 March 2021, and 30 September 2024 (n = 5226 clients registered during this time). All programmatic data were stored in electronic medical records. Variables pertaining to socio-demographics, reported risk behaviours, services provided, HIV and syphilis testing history, PrEP delivery, ART and viral load testing were retained for analysis. Of note, during registration, clients were queried on substance use, and the Alcohol Use Disorders Identification Tool (AUDIT-C) was administered. Semi-structured interviews were conducted between 28 June 2022, and 28 July 2022,

in Hyderabad as part of continuous quality improvement. In-person interviews were conducted with 52 clients and 7 staff. The Hyderabad *Mitr* clinic was selected as it had been operational for over a year at the time. Clients invited to participate in the interviews were selected from those visiting Hyderabad's clinic in June–July 2022. To understand barriers and facilitators of HIV testing, clients were purposively invited by HIV testing uptake, with about half having received a test at the clinic. The interview guide included close-ended and open-ended questions and explored (1) reasons for interest in *Mitr* clinics and services broadly, and (2) barriers and facilitators of HIV testing. Interviews were conducted in a private room at the clinic and lasted 30 minutes. No compensation was provided.

2.2.2 | *Definitions*

Eligibility for HIV testing: Clients were deemed eligible to receive HIV testing if they had never received HIV testing, had previously tested negative or did not know their HIV status.

Eligibility for PrEP: Eligibility for PrEP was defined per national guidelines [62], namely a negative HIV rapid antibody test on the day of PrEP initiation, substantial risk for HIV acquisition by self-report, no contraindication to PrEP, assessed as ready to initiate PrEP and willing to attend follow-up evaluations.

PrEP persistence: PrEP persistence was defined as obtaining medication refills, without an interruption for > 30 days for ≥ 3 consecutive months, consistent with other literature [63].

Retention in HIV care: Retention in HIV care was defined as receipt of ART refills without interruptions and within 28 days of the expected refill date per national guidelines [64].

2.2.3 | *Data analysis*

We used summary statistics to describe socio-demographic characteristics, service utilization, and HIV prevention and treatment continuum measures across all three *Mitr* clinics. To evaluate the association between receipt of gender-affirming services, socio-demographic characteristics and risk behaviours with HIV testing, we utilized multivariable logistic regression models among clients eligible for HIV testing. Covariates included socio-demographic characteristics such as age, gender identity, marital status, education, prior history of HIV testing, behavioural factors (e.g. recent drug use, alcohol use, recent sexual intercourse) and receipt of one or more gender-affirming services at *Mitr* clinics. Factors significantly associated with HIV testing in univariable analysis were considered for inclusion in multivariable analysis. Covariates that retained statistical significance ($p < 0.05$) were included in the final model. Multicollinearity was assessed using the variance inflation factor, and a clustered sandwich estimator was used to account for clustering within clinics. All quantitative analyses were conducted using Stata version 17 (StataCorp, 2021). To categorize open-ended responses from semi-structured interviews, we employed principles of text analysis [65] and manually collated responses using Microsoft Excel 2021 (Microsoft Corporation, 2021).

2.3 | Ethical clearances

Interviewers administered informed oral consent in the local language of participants prior to asking questions for the semi-structured interviews, explaining the voluntary nature of the interviews. No identifying information was collected during the interviews. The use of programmatic data at the *Mitr* clinics is approved by the Johns Hopkins University IRB as public health surveillance.

3 | RESULTS

3.1 | Socio-demographic characteristics and self-reported risk behaviours among clients

Among the 5226 unique clients who registered between 1 March 2021, and 30 September 2024 (Table 1), the median age of clients was 26 years (interquartile range [IQR] 22–30 years). Ninety-six percent of clients were assigned male sex at birth. The majority of clients (86%) self-identified as TGW, while 5% as transgender men (TGM), and 7% as "other gender." Most clients (71%) had high school or lower education and were unmarried (89%). A quarter (25%) reported earning wages through begging, while 21% earned wages through performing "badhai" (a cultural practice of providing blessings at weddings or when a child is born), and 20% reported being unemployed. Although only 16% of clients identified sex work as their current occupation, over a third (35%) reported a history of transactional sex.

Three-quarters of clients (77%) reported recent sexual intercourse in the prior 12 months. Among those who reported recent sexual intercourse, the median number of sexual partners was 3 (IQR: 1–15 partners). Among those who reported a history of transactional sex in the prior 12 months, the median number of sex partners was 24 (IQR: 3–350). Over a third of clients (40%) reported alcohol use, with 15% being classified at high or severe risk for alcohol use disorders based on the AUDIT-C [66]. Only 2% of clients reported any history of substance use other than alcohol. City-specific data on socio-demographic characteristics and self-reported behaviours are presented in Table 1.

3.2 | Service utilization at *Mitr* clinics

Seventy percent of clients who registered at *Mitr* clinics had never been registered in the public sector TI programme by self-report. At registration, only 10% of clients were currently on or reported prior receipt of GAHT. Most clients (75%) received gender-affirming care services, with the majority (53%) accessing laser hair removal services (Table 2). While 34% received consultations and prescriptions for GAHT, 26% received referrals to surgical services, and 15% received social and legal gender identity services. Most clients who received counselling services primarily received HIV pre- and post-test and risk reduction counselling (78%). Additionally, 8% of clients also received individual mental health, substance use and family counselling services. Clients also accessed other HIV prevention services, with 38% receiving condoms.

Table 1. Client demographics and sexual/substance use behaviours at registration among 5226 clients receiving services at *Mitr* clinics across three cities in India from 1 March 2021 to 30 September 2024

Clients registered	Total		Hyderabad		Pune		Thane	
N	5226		2082		1511		1633	
Age, years								
Median (IQR)	26 (22–30)		25 (22–30)		26 (23–30)		26 (22–31)	
Gender[a]	*n*	%	*n*	%	*n*	%	*n*	%
Man	126	2	74	4	41	3	11	1
Woman	7	0.1	6	0.3	0		0	
TGM	239	5	88	4	86	6	65	4
TGW	4472	86	1889	91	1114	74	1472	90
Other	377	7	23	1	269	18	85	5
Unknown	2	0.04	2	0.1	0		0	
Sex-assigned at birth								
Male	5001	96	1985	95	1430	95	1586	97
Female	217	4	92	4	78	5	47	3
Intersex	7	0.1	5	0.2	2	0.1	0	
Refused	1	0.02	0		1	0.1	0	
Registered at a TI programme								
No	3641	70	1363	65	1117	74	1161	71
Yes	872	17	215	10	191	13	466	29
Unknown	713	14	504	24	203	13	6	0.4
Primary occupation								
Unemployed	1055	20	299	14	425	28	331	20
Employed	276	5	66	3	114	8	96	6
Sex work	829	16	398	19	329	22	102	6
Badhai	1086	21	711	34	96	6	279	17
Begging	1332	25	301	14	383	25	648	40
Dancing	79	2	24	1	17	1	38	2
Other	373	7	206	10	96	6	71	4
Unknown	196	4	77	4	51	3	68	4
Education level								
No school	812	16	310	15	257	17	245	15
Primary education	463	9	172	8	85	6	206	13
Middle education	703	13	230	11	134	9	339	21
Higher secondary	1745	33	695	33	515	34	535	33
Graduate	1334	26	585	28	489	32	280	17
Other	15	0.3	4	0.2	7	0.5	4	0.2
Unknown	154	3	86	4	44	3	24	1
Marital status								
Unmarried	4629	89	1708	82	1366	90	1555	95
Married	367	7	262	13	70	5	35	2
Divorced/separated/widowed	63	1	32	1.5	6	0.4	25	2
Live in partner	3	0.1	1	0.05	1	0.1	1	0.1
Unknown	164	3	79	4	68	5	17	1
Sexually active in the past 12 months								
No	1097	21	371	18	98	6	628	38
Yes	3999	77	1658	80	1361	90	980	60
Unknown	130	2	53	3	52	3	25	2

(*Continued*)

Table 1. (Continued)

Clients registered	Total		Hyderabad		Pune		Thane	
Number of sexual partners in the past 12 months (among those sexually active, *n* = 3999)								
Median (IQR)	3 (1–15)		4 (1–100)		2 (1–5)		4 (1–13)	
Engaged in sex work currently								
No	2236	56	893	54	695	51	648	66
Yes	1385	35	731	44	426	31	228	23
Unknown	378	9	34	2	240	18	104	11
Years in sex work (*n* = 1385)								
Median (IQR)	3 (2–6)		4 (2–8)		3 (2–5)		2 (1–5)	
Sex acts per day in the last week (among those in sex work, *n* = 1385)								
Median (IQR)	5 (2–10)		4 (2–10)		5 (3–10)		7 (4–12)	
Current alcohol use								
No	2872	55	966	46	787	52	1119	69
Yes	2077	40	1043	50	655	43	379	23
Unknown	277	5	73	4	69	5	135	8
AUDIT-C Score (*n* = 2077)								
Moderate/low risk	1772	85	998	96	517	79	257	68
Severe/high risk	305	15	45	4	138	21	122	32
Injection drug use								
Never	4637	89	1974	95	1238	82	1435	88
In the last 6 months	12	0.2	5	0.2	3	0.2	4	0.2
Over 6 months ago	6	0.1	2	0.1	3	0.2	1	0.1
Unknown	561	11	101	5	267	18	193	12
Non-injection drug use in the last 6 months								
No	3399	65	1861	89	564	37	974	60
Yes	117	2	102	5	15	1	0	
Unknown	1710	33	119	6	932	62	659	40
On GAHT								
Yes, currently	189	4	74	4	19	1	96	6
No, but have in the past	351	7	169	8	73	5	109	7
No	3995	76	1620	78	993	66	1382	85
Unknown	691	13	219	11	426	28	46	3
Ever shared needles for GAHT (*n* = 540)								
No	169	31	145	60	11	12	13	6
Yes	6	1	3	1	1	1	2	1
Unknown	365	68	95	39	80	87	190	93
HIV status at registration								
Positive	331	6	202	10	100	7	29	2
Tested in the last 6 months	2222	43	888	43	683	45	651	40
Tested over 6 months ago	849	16	390	19	287	19	172	11
Never tested	1401	27	496	24	239	16	666	41
Unknown	423	8	106	5	202	13	115	7

Abbreviations: AUDIT-C, Alcohol Use Disorders Identification Test; GAHT, gender-affirming hormone therapy; TGM, transgender men; TGW, transgender women; TI, Targeted Intervention.
[a]Gender is reported as self-identified by the client.

Table 2. Utilization of services at *Mitr* clinics across three Indian cities from 1 March 2021 to 30 September 2024 (*N* = 5226)

Services	Total		Hyderabad		Pune		Thane	
	n	%	*n*	%	*n*	%	*n*	%
Screened for syphilis	1059	20	755	36	158	10	146	9
Risk reduction counselling services	1413	27	699	34	562	37	152	9
HIV testing and/or HIV counselling services	4071	78	1580	76	1308	87	1183	72
HIV motivational counselling	2387	46	467	22	848	56	1072	66
Mental health services	375	7	295	14	30	2	50	3
Gender-affirming hormone therapy services	1790	34	727	35	784	52	279	17
Family counselling services	156	3	152	7	0		4	0.2
Gender-affirming surgery services	943	18	293	14	401	27	249	15
Breast implant services	735	14	133	6	388	26	214	13
Reproductive health services	22	0.4	5	0.2	17	1	0	
Sexual health services	48	1	1	0.5	44	3	3	0.2
Laser hair removal services	2794	53	893	43	647	43	1254	77
Gender identity services (i.e. transgender identity cards)	758	15	198	10	373	25	187	11
Condoms	1996	38	894	43	138	9	964	59
Lube	232	4	231	11	0		1	0.1
General PrEP counselling	1332	25	520	25	191	13	621	38
PEP counselling	65	1	58	3	2	0.3	5	0.3
Top surgery counselling	71	1	14	1	31	2	26	2
Substance use counselling	186	4	160	8	26	2	0	
Other services	1946	37	1093	52	495	33	358	22

Abbreviations: PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis.

3.3 | HIV testing cascade and correlates of HIV testing

Among the 5226 clients who registered at *Mitr* clinics, 4895 were eligible to receive HIV testing. Among eligible clients, 3036 (62%) were screened for HIV using rapid test kits, of whom 178 (6%) had screened positive (Figure 1). Among the 178 clients who had a positive HIV screening test, 124 (70%) completed confirmatory testing at government integrated counselling and testing centres, of whom 119 (96%) were confirmed as being HIV positive (Figure 1). Thus, 3.92% of all eligible clients screened for HIV were confirmed as being HIV positive.

In multivariable analysis, recent sexual activity (aOR 1.60, 95% CI 1.06–2.40), high/severe risk for alcohol use disorders (aOR 1.37, 95% CI 1.22–1.53), having a long-term partner (aOR 2.96, 95% CI 1.22–7.22) and seeking referrals for surgical services (aOR 1.51, 95% CI 1.02–2.25) were significantly associated with greater odds of HIV testing. Conversely, age > 25 years, gender self-identified as man, low/moderate risk of alcohol use disorders and being married were significantly associated with lower odds of HIV testing (all $p < 0.05$; Table 3). No multicollinearity was identified among variables included in the multivariable model.

3.4 | HIV prevention and treatment cascades

Among 607 *Mitr* clinic clients interested in PrEP, 591 (97%) completed a consultation with the physician; 585 (99%) were eligible per national guidelines [62]. Of these, 576 clients (98%) initiated PrEP, of whom 378 (66%) were PrEP persistent (Figure 2). One seroconversion was observed among clients initiating PrEP. The most common reasons for PrEP discontinuation reported were perception of being at low risk (51%) or being no longer interested (19%).

For ART initiation and viral suppression, we report available data from clients *newly* diagnosed with HIV through initial screening at *Mitr* clinics, as well as clients known to be living with HIV at registration. Among 119 clients newly diagnosed with HIV after registration, 115 (97%) initiated ART within 30 days (Figure 1). Among 454 HIV clients with HIV (including those previously diagnosed with HIV), 392 (86%) had initiated ART. As of 30 September 2024, 233 of these clients (59%) were still engaged in *Mitr* clinic services and retained in HIV care; data on HIV care engagement for the remainder of the clients were not systematically available at the *Mitr* clinics. Among those ascertained to still be engaged in HIV care, 213 were eligible for a viral load (i.e. those who initiated ART over 6 months ago), of whom 156 (73%) had ever received a viral load test, and 153 (98%) were virally suppressed (viral load <1000 copies/ml).

3.5 | Perspectives from clients and providers at Hyderbad's *Mitr* clinic Among 52 clients who completed the semi-structured survey in Hyderabad's *Mitr* clinic, most (83%) had first heard about the clinic from their friends and/or clinic providers themselves, while 17% had learned about the clinic from social media. Accessibility to a variety of gender-affirming services and receiving services from providers from

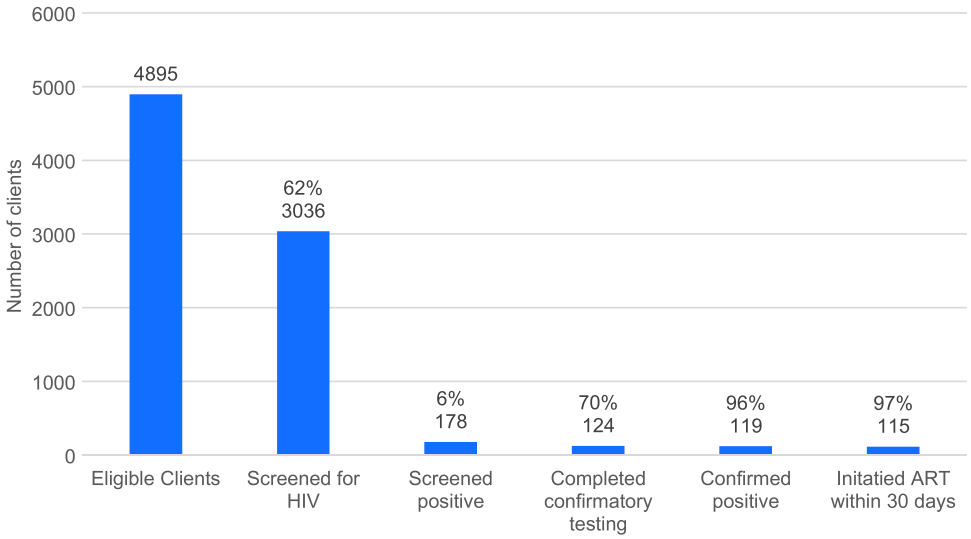

Figure 1. HIV testing cascade at the three *Mitr* clinics across India (Hyderabad, Pune and Thane) between 1 March 2021 and 30 September 2024. *Note*: Denominator for percentages are the number satisfying prior indicator; for example 3036 (62%) out of the 4895 eligible clients were screened for HIV. Abbreviation: ART, antiretroviral therapy.

the community were cited as the main reasons for interest in the clinic.

Specific to HIV testing, clinic providers reported conducive workflows with opportunities to offer HIV testing to clients at registration as well as when clients presented to receive other non-HIV services. Providers and clients identified trust fostered by service provision by members of the community as a key facilitator of HIV testing uptake. At the same time, both groups identified barriers encountered by the subset of clients who declined HIV testing despite being eligible. Providers perceived lack of knowledge, HIV stigma and fear of HIV status disclosure, especially to older members of the community (also known as "gurus") as the main reasons for declining HIV testing. Half of the eligible clients who declined HIV testing perceived themselves at low risk for HIV acquisition.

With regard to the HIV testing cascade and linkage to government ART centres, clients identified fragmented services as a main barrier. Specifically, clients reported the need to receive confirmatory HIV testing at a different venue (i.e. government integrated testing and counselling centres) after initial HIV screening at *Mitr* clinics, and unfriendly staff at those centres as hampering their enthusiasm. Providers additionally reported challenges in obtaining reliable contact information from clients with HIV to facilitate linkage to government ART centres due to clients' disclosure fears.

4 | DISCUSSION

The *Mitr* clinics represent one of the first community-based, person-centred service delivery models integrating gender-affirming services with HIV services for transgender people in India. Key findings include the notable role that gender-affirming services delivered by transgender providers played in providing an entry portal for HIV services among clients. We also observed high uptake of PrEP among interested clients and retention in HIV care among clients with HIV. One of the key challenges observed was the fragmented service delivery with respect to ART and confirmatory testing, which, if addressed, could further improve HIV outcomes.

The low engagement of transgender people in HIV services is consistent with other Indian studies [38, 67–69]. In a recent nationwide survey among sexually active transgender and gender diverse individuals, nearly 50% had never accessed HIV testing [67]. The *Mitr* clinics highlight that co-locating gender-affirming services can significantly enhance this reach. Most notably, the majority of clients who registered at *Mitr* clinics had never engaged with TI programmes; about 75% of clients who accessed *Mitr* clinics did so to receive gender-affirming care. Co-locating gender-affirming care with HIV services not only promoted initial engagement but also presented multiple contact points to offer HIV testing and PrEP. Additionally, staffing from the community was equally integral. These factors likely led to a majority of eligible clients receiving an HIV test, and almost all clients interested in PrEP initiating PrEP. In fact, receipt of gender-affirming services was associated with a higher likelihood of receiving an HIV test. We did not observe a similar uptake with STI testing, suggesting a potential use case for HIV/syphilis dual kits. Collectively, these findings suggest that person-centred care models can be compelling entry points for the receipt of HIV services among transgender people in India.

Findings from *Mitr* clinics are also consistent with findings from the evaluation of care models in other low- and middle-income countries (LMICs) delivering HIV services to transgender people. In South Africa, receipt of GAHT was associated with viral suppression [70]. In Vietnam, integrating gender-affirming services delivered by transgender providers increased PrEP uptake and persistence [71]. In Thailand, "The

Table 3. Correlates of receiving an HIV test at the three *Mitr* clinics across India (*N* = 4786)

	Univariable			Multivariable		
HIV screening test	**Coef.**	**[95% Conf. Interval]**		**Coef.**	**[95% Conf. Interval]**	
Gender						
Man	0.67**	0.50	0.90	0.55**	0.39	0.78
Woman	0.26	0.05	1.29	0.17	0.03	1.18
TGM	1.09	0.47	2.53	0.74	0.51	1.08
TGW	*ref.*					
Other/unknown	1.90**	1.30	2.78	1.51**	1.12	2.05
Sex						
Male	*ref.*					
Female	0.90	0.43	1.96			
Intersex	0.95	0.45	2.61			
Age group						
25 or less	*ref.*					
26 or older	0.69***	0.61	0.79	0.73***	0.65	0.81
Unknown	0.85	0.71	1.02	1.43	0.97	2.10
Job						
Unemployed	*ref.*					
Employed	1.25***	1.14	1.37	1.57***	1.35	1.82
Sex work	0.95	0.47	1.91	1.09	0.69	1.70
Badhai	0.54	0.29	1.01	0.72	0.50	1.04
Begging	0.79	0.47	1.32	0.91	0.60	1.37
Dancing	1.00	0.71	1.40	1.13	0.88	1.45
Other	0.60**	0.44	0.81	0.74	0.53	1.03
Education level						
Secondary school or below	*ref.*					
Above secondary schooling	1.29**	1.07	1.54			
Other	0.62	0.32	1.21			
Marital status						
Unmarried	*ref.*					
Married	0.52***	0.44	0.61	0.60	0.50***	0.71
Divorced/separated/widow	0.68***	0.65	0.72	0.99	0.91	1.08
Live in partner	2.90***	1.85	4.56	2.96	1.22*	7.22
Unknown/refused	0.48*	0.26	0.90	0.74	0.21	2.59
HIV testing history at registration						
Tested negative in the last 6 months	*ref.*					
Tested negative over 6 months ago	1.49**	1.14	1.96	1.46***	1.17	1.83
Never tested	2.52	0.66	9.62	2.54	0.80	8.11
Unknown/refused	0.91	0.29	2.87	1.08	0.30	3.90
Sexually active						
No	*ref.*					
Yes	1.62**	1.23	2.13	1.60*	1.06	2.40
Unknown	0.65*	0.42	0.99	0.62***	0.51	0.77
Sex work						
No	*ref.*					
Yes	0.97	0.59	1.59			
AUDIT-C rating						
No alcohol use	*ref.*					
Low/moderate risk	0.86*	0.76	0.97	0.84***	0.76	0.92
Severe/high risk	1.44**	1.10	1.87	1.37***	1.22	1.53
Unknown	0.96	0.74	1.26	1.62**	1.14	2.29

(*Continued*)

Table 3. (Continued)

HIV screening test	Univariable			Multivariable		
	Coef.	[95% Conf. Interval]		Coef.	[95% Conf. Interval]	
Any drug use						
No	*ref.*					
Yes	1.00	0.55	1.83			
Gender-affirming surgery services[a]						
No	*ref.*					
Yes	1.56*	1.02	2.40	1.51*	1.02	2.25
Gender identity services (i.e. transgender identity cards)						
No	*ref.*					
Yes	0.98	0.83	1.16			
Gender-affirming hormone therapy						
No	*ref.*					
Yes	1.27	0.69	2.35			
Laser hair removal services						
No	*ref.*					
Yes	0.99	0.96	1.02			

Abbreviations: AUDIT-C, Alcohol Use Disorders Identification Test; TGM, transgender men; TGW, transgender women.
[a]Gender-affirming surgery services include services related to gender-affirming surgery, top surgery and breast implants.
***indicates a *p*-value < 0.001.
**indicates a *p*-value < 0.01.
*indicates a *p*-value < 0.05.

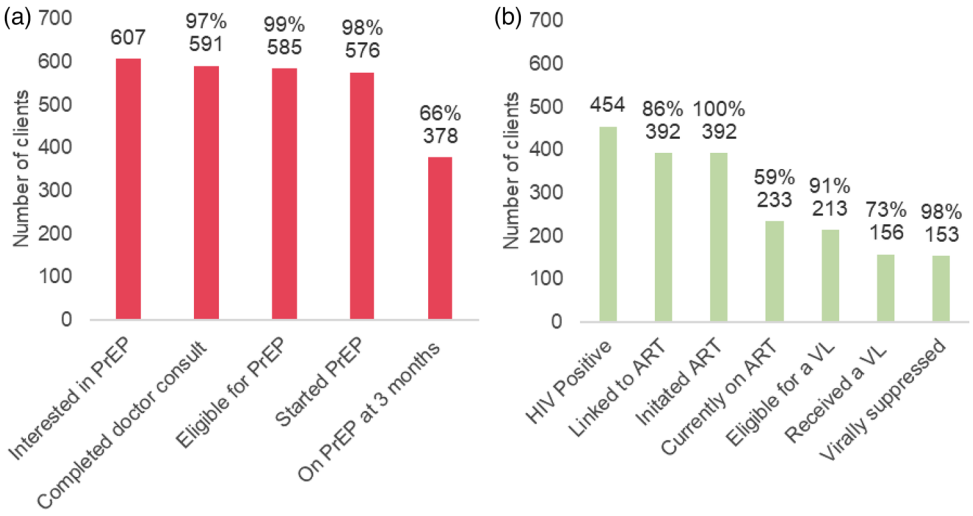

Figure 2. Pre-exposure prophylaxis (PrEP) (Panel A) and HIV care cascade (Panel B) among clients at the three *Mitr* clinics across India from 1 March 2021 to 30 September 2024. *Note*: Denominator for percentages are the number satisfying prior indicator; for example 591 (97%) out of the 607 clients interested in PrEP completed a doctor consultation. Abbreviations: ART, antiretroviral therapy; PrEP, pre-exposure prophylaxis; VL, viral load.

Integrated Trans Model" clinics, providing primary care, HIV and gender-affirming services, have demonstrated low HIV incidence [72]. Dissemination of The Integrated Trans Model to other Asian countries has led to increased HIV and PrEP services access among TGW [73]. Contrastingly, a randomized trial in the United States and Brazil [74] found high rates of PrEP acceptance and persistence regardless of the co-location of gender-affirming services. However, participants in the trial were referred to pre-identified centres with well-established gender-affirming services, and had access to experienced peer navigators. Unlike these sites, in the *Mitr* clinic cities, there were no other alternative venues for the receipt of comprehensive gender-affirming care. Our findings emphasize that in settings with with limited access to gender-affirming

services, co-locating gender-affirming services with HIV services and reducing barriers to integrated care is paramount to engaging transgender people.

While *Mitr* clinics have been successful in achieving initial engagement and uptake of HIV testing and PrEP, we observed some attrition. Clients had to present to separate venues to receive confirmatory HIV testing and ART, respectively. Although these venues were in proximity to *Mitr* clinics, and outreach workers navigated clients to these venues, 39% of clients with a positive HIV screening test did not complete confirmatory testing. This confirmatory test at a public sector facility is required to access public sector ART. Psychosocial factors such as HIV stigma and fear of HIV status disclosure were the main reasons for declining HIV testing, while low perceived HIV risk was a prominent reason for declining HIV testing as well as discontinuing PrEP. HIV status disclosure concerns, in addition to fragmented HIV treatment services, also made it challenging to track ongoing ART receipt and viral load measurements (performed yearly at government ART centres) among clients with HIV. Therefore, our estimates of the proportion of clients with HIV continuing to receive ART need to be interpreted with caution—it is likely that a larger proportion are currently on ART as they may be seeking care without accessing *Mitr* clinics' resources. Viral suppression was high among those ascertained to be taking ART and had received viral load measurements. Decentralizing public sector ART initiation and confirmatory testing to community-based settings, such as *Mitr* clinics, with a large volume of people with HIV, could help improve HIV testing and treatment outcomes. Other non-clinic-based strategies we have evaluated, such as confidential virtual platforms coupled with individualized support from virtual counsellors, have also demonstrated improved HIV testing among gender and sexual minority populations in India [75].

Finally, in the context of the 2019 Transgender Persons (Protection of Rights) Act, there is considerable interest in the development of comprehensive care models for transgender people. The National AIDS Control Organization has detailed the delivery of comprehensive services to transgender people as a key priority in a recently published forward-facing white paper [76]. The *Mitr* clinics are highlighted as an illustrative example and represent among the only community-based single window venues to receive both gender-affirming services and HIV services [76]. Drawing from our insights from *Mitr* clinics, co-locating gender-affirming services with TI programmes, integrated counselling and testing centres, and government ART centres, and building a workforce that includes transgender staff in these venues could offer a sustainable pathway to engage transgender people in public sector HIV services. At the same time, scale-up of community-based models like *Mitr* clinics could also be effective in improving population-level HIV prevention and treatment outcomes among transgender people in India. Most notably, this scale-up has already occurred with government investment in the state of Telangana.

The findings from our evaluation of *Mitr* clinics are not without limitations. While the principles of person-centred care would apply broadly, our findings may not be generalizable to all transgender people in India. For example, we observed low injection drug use among clients in the *Mitr* clinics; this finding may not be generalizable to cities in Northeast India, where injection drug use in general is more prevalent. Surveys on client and provider perspectives were only administered at a single clinic site, further limiting generalizability. Also, of importance, our analyses were limited to data routinely collected for programmatic and clinical needs, which resulted in missing data, limiting our ability to fully characterize variables such as HIV care retention and viral load testing on all clients with HIV, PrEP discontinuation reasons and utilization of psychosocial services. Our findings also have several strengths, including the systematic collection of programmatic data over 3 years and the inclusion of data from multiple cities.

5 | CONCLUSIONS

As a single window model of community-based, person-centred care delivery to transgender people, *Mitr* clinics have greatly increased accessibility of gender-affirming services. The clinics successfully reached previously unengaged transgender people. Expansion of this model with the integration of confirmatory HIV testing and ART on site can ameliorate the disparities that transgender people experience in receipt of both gender-affirming services and HIV services, and holds promise for shaping the HIV epidemic in India.

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COMPETING INTERESTS

SSS serves as the Managing Trustee of the YR Gaitonde Medical Educational and Research Foundation, which is the entity that oversees YRGCARE. SSS serves on the Board of Directors of the Serious Fun Children's Network. SSS has also received grants/products to the Institution from Abbott Laboratories and Gilead Sciences, not related to this manuscript. KHM receives grants to the institution from Viiv, Gilead and Merck, not related to this manuscript, and serves on the Scientific Advisory Board for Viiv, Gilead Sciences and Merck that are not related to this manuscript. All other authors have nothing to disclose.

AUTHORS' CONTRIBUTIONS

SS, AS, KHM, SHM and SSS conceived the concept of the *Mitr* clinic. SS, PMR, KP, AE, VA, SO, AS and SSS led the implementation of the clinics with support from SKP and SK. JB, AE, VA, AMM, SHM, RPK and SO developed the database and survey instruments. AK, KA, KHM and SSS provided technical assistance to the delivery of services at the *Mitr* clinics. SS, KHM, SSS and LG conceived the manuscript. LG drafted the manuscript with inputs from SSS, AMM and SHM. All authors reviewed the manuscript and provided critical feedback.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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RESEARCH ARTICLE

"From an HCV and HIV point of view, it's been remarkable": A qualitative study about using prescribed safer supply to support people who use drugs along the HIV and HCV prevention and treatment cascades in Ontario, Canada

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Abstract

Introduction: Despite advances in HIV and hepatitis C virus (HCV) treatment, people who use drugs (PWUD) face significant barriers along prevention and treatment cascades. Safer supply programmes (SSPs) providing prescribed pharmaceutical alternatives to the unregulated drug supply may create opportunities for enhanced healthcare engagement and person-centred care.

Methods: We conducted a qualitative study examining four SSPs in Ontario, Canada between February and October 2021. Semi-structured interviews were conducted with 52 patients and 21 providers (including physicians, registered nurse practitioners, nurses and allied health professionals). Interviews explored experiences with safer supply and HIV/HCV care. Analysis used thematic techniques guided by the Consolidated Framework for Implementation Research.

Results: SSPs supported HIV/HCV care by first addressing patients' substance use needs, which created subsequent opportunities for building trust for broader health engagement. Providers identified the safer supply model as giving PWUD something they wanted, which then opened opportunities to discuss HIV, HCV, and other sexually transmitted and blood-borne infections. SSPs provided opportunities to support patients with HIV and HCV testing and treatment initiation, and safer supply medications were bundled with HIV and HCV medications to support adherence. Non-punitive approaches helped overcome previous negative healthcare experiences by prioritizing patient autonomy. Implementation challenges included balancing flexible, patient-directed care with programme requirements and coordinating comprehensive services around individual needs.

Conclusions: SSPs may improve HIV/HCV care delivery for PWUD by building services around their priorities and lived realities. The integration of safer supply with HIV/HCV care through daily dispensing and wraparound services showed promise for engaging people previously disconnected from care. While findings suggested improved treatment outcomes, limitations included data collection during COVID-19, limited representation of some populations and a focus on opioid-only programmes. Research examining long-term outcomes and programme sustainability is needed as SSPs face growing scrutiny and closure in Canada.

Keywords: addiction; HIV; HCV; harm reduction; opioids; people who use drugs (PWUD); safer supply

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1 | INTRODUCTION

Despite advances in HIV prevention and treatment in North America, delivering person-centred care that fully engages key populations remains challenging. In Canada, approximately 65,270 people were living with HIV in 2020, with an incidence rate of 4.7 per 100,000 population [1]. All-cause HIV diagnoses rose 35.2% from 2022 to 2023; injection drug use accounted for 18.2% and combined male-to-male sexual contact plus injection, 4.5%. The United States reported approximately 1.1 million people living with HIV in 2022 [2]. A parallel epidemic is occurring for the hepatitis C virus (HCV), with an estimated 214,000 people living with chronic HCV in Canada [3] and 2.4 million in the United States [4].

Injection drug use remains a significant concern for HIV and HCV transmission [5, 6], with an estimated 3.6 million people who inject drugs in the United States [7] and an estimated 171,900 in Canada [8]. However, this represents a small subset of all people who use drugs (PWUD), whether by injection or other methods [9–11]. In response, Canadian jurisdictions have implemented a range of drug treatment and harm reduction interventions—such as opioid agonist treatment (OAT), supervised consumption sites (SCS), needle–syringe programmes and naloxone distribution to curb drug-related harms; HIV, HCV, and sexually transmitted and blood-borne infections (STBBIs) transmission; and overdose deaths [12–16]. The United States has adopted some of these approaches, to varying degrees across states, despite considerable opposition and regulatory barriers [15, 17]. However, drug use—especially injection—is considered a significant barrier to optimal HIV and HCV outcomes [18–24].

The HIV and HCV cascades span testing, linkage, ongoing care, treatment initiation, adherence, and ultimately viral suppression (HIV) or sustained virologic response (HCV) [25–28]. PWUD face barriers at each step, including stigma in healthcare settings, competing priorities (e.g. engagement in survival economies to support their drug use) and limited access to comprehensive harm reduction services [29, 30]. These barriers can be partially addressed through the integration of HIV and HCV services with OAT [31–34]. In the Canadian context, OAT refers primarily to methadone and buprenorphine-naloxone, with slow-release oral morphine second-line treatment [35]. In the United States, these medications are collectively termed medications for opioid use disorder (MOUD) and include extended-release naltrexone [36, 37]. Although OAT is considered a first-line treatment for opioid use disorder, engagement and retention remain low [38, 39]. OAT patients often cite punitive cultures—surveillance, medication withholding, mandatory counselling, inconvenient hours—as key barriers [40]. Fentanyl's dominance in the unregulated drug supply has heightened overdose deaths (52,544 in Canada, 2016–2024 [41]; 110,037 in the United States, 2023 [42]) and stalled cascade progress for PWUD. The short half-life of fentanyl may increase HIV and HCV transmission risk due to more frequent injection and equipment sharing [43, 44]. Due to the potency of fentanyl, OAT is harder to initiate, and retention in treatment has dropped significantly [39, 45–47]. Additionally, COVID-19 deepened inequities, substance use [48–50] and housing instability [51–53], generating a "syndemic" effect in which overdose, HIV/HCV risk, and poverty reinforce each other and disrupt care engagement [54, 55].

In response to the impacts of the drug toxicity crisis and related syndemics, there have been calls across Canada [56] and the United States [57] for prescribed alternatives to the toxic drug supply. Building on this, Health Canada sanctioned "safer supply," defined as "prescribed medications to people who use drugs, overseen by a health care practitioner, with the goal of preventing overdoses and saving lives…provided in a less clinical and more flexible way compared to other care options for substance use" [58]. Safer supply programmes (SSPs) are novel healthcare interventions that provide prescribed pharmaceutical alternatives to the unregulated drug supply, including opioids, stimulants and benzodiazepines [55]. Most SSPs have operated through community health centres and other primary care settings, where providers can offer "wraparound services" [59], including primary care, mental health support, harm reduction, with medication dispensed through community pharmacies [60–64]. However, SSPs have also been provided through standalone clinics, shelters, harm reduction and SCS, and one programme dispensed medication through a biometric machine [60, 65, 66]. Most SSP patients have previously tried OAT [67], but show higher retention on safer supply [68]. The first organized SSP started in 2016 [69], but some physicians were offering prescribed alternatives on a case-by-case basis to support people living with HIV/HCV to remain in care during hospital admissions [70]. A quasi-experimental study found that at baseline, 34.1% of patients entering SSPs were living with HIV (compared to 7.6% of the matched cohort), and 69.5% had an HCV diagnosis [71]. While SSPs do not require abstinence from injection or unregulated drug use, reductions in both have been reported [61, 72]. Most SSPs employ a person-centred approach, simultaneously addressing substance use needs while facilitating access to essential health and social services, which supports improved health outcomes and reduces overdose and all-cause mortality [61, 64, 73, 74]. Canada also has injectable OAT (e.g. injectable hydromorphone and diacetylmorphine), which may be considered a safer supply [59, 75], but these programmes have been slow to scale up due to the necessary infrastructure and costs [76].

Although most SSP studies note implications for HIV and HCV [56, 77], only one study has examined combining safer supply with HIV pre-exposure prophylaxis (PrEP) [78]. In-depth studies about the relationship between safer supply and the HIV and HCV care cascades are needed. Subsequently, we sought the perspectives of SSP staff and clients to understand the impact of the safer supply approach and structure on the HIV and HCV care continuums for PWUD.

2 | METHODS

Between February and October 2021, we examined four Canadian SSPs (one in London, three in Toronto). These SSPs utilized a community-based primary care model, where physicians and nurse practitioners prescribed "safer supply" in the form of daily observed doses of long-acting opioids (e.g. slow-release oral morphine) alongside unobserved take-home doses of immediate-release hydromorphone (Dilaudid), which could be self-administered as needed (including via injection). Observed slow-release dosing may reduces HIV/HCV risk by preventing repeated injections with the same equipment [79]. Medications were dispensed through community pharmacies, except one programme in our sample had a small "observed arm" for patients deemed high-risk for overdose due to concurrent high alcohol or benzodiazepine use. These patients could use their medication as desired, but were asked to do so on site in an SCS connected to the SSP.

2.1 | Data generation and analysis

We conducted semi-structured interviews and questionnaires with SSP patients (we use the term "patient" because these

are clinical programmes, but "client" was used by participants and appears in quotations) and providers. Interview guides were developed with input from community advisory members with lived experience and members of the larger team with clinical expertise, including safer supply prescribing. We then pilot-tested the guides with one provider and two patients, incorporating their feedback. Providers were recruited via email and snowball sampling, starting with all prescribers, who then referred other staff. Patient recruitment was facilitated through flyers distributed by the research team during site visits or through providers within participating SSPs. The study adhered to standard research ethics protocols, with individual participants providing informed consent. The University of Toronto Research Ethics Board provided ethics approval (Protocol: 40140).

Provider questionnaires collected data on socio-demographic and professional background. Interviews explored SSP implementation, patient enrolment, prescribing practices and HIV/HCV care. Patient questionnaires gathered socio-demographic characteristics and substance use/medical history, while interviews examined SSP experiences and HIV/HCV outcomes. Audio-recorded interviews (20–105 minutes) were transcribed verbatim. Patients and allied health staff received $40 honoraria; prescribers were not compensated.

Questionnaire data were analysed in SPSSv28; interviews underwent thematic analysis [80] in MAXQDA using codebooks based on the Consolidated Framework for Implementation Research constructs and emergent concepts. Each transcript was coded by one of three primary coders and reviewed by another for consistency. Team members (AG, KR, MG, CS) extracted HIV/HCV-related data, met regularly to identify themes and select quotes, with broader team support for final analysis. Initial analysis concluded March 2022; HIV/HCV sub-analysis ran December 2023–March 2024.

3 | RESULTS

We conducted interviews with 52 SSP patients and 21 providers. Of these 52 patients, all experienced significant inequities: $n = 31$, 59.6% reported housing precarity (e.g. staying in shelters, hotels/motels or experiencing homelessness), 98.1% ($n = 51$) relied on social assistance or disability support programmes and 86.5% ($n = 45$) had a history of incarceration. While predominantly white ($n = 41$, 78.8%), we interviewed Indigenous ($n = 9$, 17.3%), Black ($n = 1$, 1.9%) and Latino ($n = 1$, 1.9%) patients. Participants identified as men ($n = 29$, 55.8%) and women ($n = 23$, 44.2%) with a mean age of 46.6 years (range 29–62).

All seven patient-participants living with HIV (13.5%) were on antiretroviral therapy (ART) and had achieved viral suppression. Of the 40 patient-participants (76.9%) ever-diagnosed with HCV, 20 (50%) had completed treatment, while 19 (47.5%) had never received treatment. Forty-five SSP participants (86.5%) had tried methadone, and 12 (23.1%) were currently receiving OAT alongside safer supply (i.e. hydromorphone to supplement their needs) (see Table 1).

The 21 provider participants interviewed represented different roles within multidisciplinary care teams, including

Table 1. Patient socio-demographic information

	N (52)	%
Programme site		
London InterCommunity Health Centre	21	40.4%
Parkdale Queen West Community Health Centre	15	28.8%
South Riverdale Community Health Centre	11	21.2%
Street Health	5	9.6%
Gender identity[a]		
Man	29	55.8%
Woman	23	44.2%
Indigenous[b]		
No	42	80.1%
Yes, First Nation	8	15.4%
Yes, Métis	2	3.8%
Race[b]		
White	41	78.8%
Indigenous	9	17.3%
Black	1	1.9%
Latino	1	1.9%
Age		
Mean	46.60	
Std. deviation	9.59	Range (29–62)
Housing (past year)		
An apartment, house or condo (Rented)	18	34.6%
Staying with friends, family or partner	13	25.0%
Shelters	7	13.5%
A hotel/motel or room rented by the night/week or month	6	11.5%
Homeless[c]	3	5.8%
An apartment, house or condo (Owned)	2	3.8%
Supportive or transitional group housing	2	3.8%
In a long-term care facility	1	1.9%
Income source (past year)[d]		
Social support (ODSP/OW)	51	98.1%
Paid job	9	17.3%
Other illegal activities	6	11.5%
Other government programme	5	9.6%
Sex work	3	5.8%
Jail or prison		
Ever	45	86.5%
Past year	3	5.8%
HIV		
Positive diagnosis	7	13.5%
Currently on medication[e]	7	13.5%
Undetectable viral load	7	13.5%

(*Continued*)

Table 1. (Continued)

	N (52)	%
HCV		
Positive diagnosis	40	76.9%
HCV medication[f]		
Yes—finished the treatment	20	38.5%
No—never	19	36.5%
Yes—now	1	1.9%
Previous engagement with addiction treatment		
Methadone	45	86.5%
Detox	17	32.7%
Live in	28	53.8%
Buprenorphine	22	42.3%
Outpatient	17	32.7%
Treatment in jail	3	5.8%
Engagement with OAT[g]		
No—not currently	36	69.2%
Yes—currently	12	23.1%
No—never	2	3.8%

Abbreviations: ART, antiretroviral therapy; HCV, hepatitis C virus; HIV, human immunodeficiency virus; OAT, opioid agonist treatment; ODSP, Ontario Disability Support Program; OW, Ontario Works (provincial social assistance programme).
[a]All patients reported being cisgender.
[b]Race/Ethnicity was gathered using a two-part question based on guidance provided by the Ontario Government. Participants were first asked if they identify as Indigenous (First Nations, Inuit or Métis), and second, what race category best describes them. Note: A person who identified as Indigenous could self-report they were a different race category (e.g. white), and participants who did not identify as part of an Indigenous group in Canada could select Indigenous for their race (e.g. from an Indigenous group in another country).
[c]Homelessness was defined as "living on the street, abandoned building, tent/encampment, car/vehicle, outside."
[d]Participants could select all that applied.
[e]Among patients living with HIV.
[f]Among patients ever diagnosed with HCV.
[g]Data missing from two participants.

prescribers (i.e. four physicians (19.0%), five nurse practitioners (23.8%)), five registered nurses (23.8%) and seven allied health professionals (33.3%) (e.g. community health workers, case managers). Most providers had at least 6 years of experience working with PWUD (16 providers) and people living with HIV (15 providers) (see Table 2).

In our presentation of results, we first describe the patient sample's structural vulnerability and medical complexity, followed by the programme model, safer supply as an engagement mechanism, the HIV and HCV cascades, person-centred care within the model, and implementation considerations and challenges. We noted during analysis that while all participants were at risk of HIV/HCV (e.g. past and ongoing injection drug use), responses to those questions were generally very short. We have focused on a subset of participants who were comfortable discussing their HIV/HCV care.

Table 2. Provider demographics and practice history

	N (21)	%
Profession		
Nurse practitioner	5	23.8%
Registered nurse	5	23.8%
Physician	4	19.0%
Community health worker	2	9.5%
Client care support, SSP administrator	1	4.8%
Health/systems navigator	2	9.5%
Outreach worker/site coordinator	1	4.8%
SSP case manager	1	4.8%
Site		
Parkdale Queen West Community Health Centre	9	42.9%
London InterCommunity Health Centre	6	28.6%
South Riverdale Community Health Centre	3	14.3%
Street Health	3	14.3%
Gender identity		
Woman	13	61.9%
Man	6	28.6%
Nonbinary	2	9.5%
Indigenous[a]		
No	42	80.1%
Race[a]		
White	15	71.4%
East Asian	2	9.5%
Indigenous Hispanic	1	4.8%
Mixed	1	4.8%
Southeast Asian	1	4.8%
Black	1	4.8%
Age (category)[b]		
25–29	1	4.8%
30–34	7	33.3%
35–39	5	23.8%
40–44	3	14.3%
45–49	3	14.3%
55–59	1	4.8%
Years worked—at site		
Less than 6 months	1	4.8%
6–11 months	5	23.8%
1–2 years	3	14.3%
3–5 years	5	23.8%
6–10 years	6	28.6%
More than 10 years	1	4.8%
Years worked—HIV		
1–2 years	1	4.8%
3–5 years	4	19.0%
5–10 years	1	4.8%
6–10 years	9	42.9%
More than 10 years	6	28.6%
Years worked—PWUD		
1–2 years	1	4.8%
3–5 years	3	14.3%

(*Continued*)

Table 2. (Continued)

	N (21)	%
5–10 years	1	4.8%
6–10 years	10	47.6%
More than 10 years	6	28.6%
Hours worked		
20–34	2	9.5%
35–39	10	47.6%
40–44	5	23.8%
45–49	2	9.5%
More than 55	2	9.5%
Number of continuing education courses on substance use or harm reduction		
0	3	14.3%
1	3	14.3%
2	6	28.6%
3	7	33.3%
5	2	9.5%

Abbreviations: HIV, human immunodeficiency virus; PWUD, people who use drugs; SSP, safer supply programme (clinical model under study).
[a]Race/Ethnicity was gathered using a two-part question based on guidance provided by the Ontario Government. Participants were first asked if they identify as Indigenous (First Nations, Inuit or Métis), and second, what race category best describes them. Note: A person who identified as Indigenous could self-report they were a different race category (e.g. white), and participants who did not identify as part of an Indigenous group in Canada could select Indigenous for their race (e.g. from an Indigenous group in another country).
[b]Note that one practitioner did not provide their age.

3.1 | Structural vulnerability, medical complexity and HIV/HCV risk

Participating SSPs served a demographically diverse patient population characterized by complex medical and psychosocial needs with elevated HIV and HCV risk profiles. Healthcare providers consistently identified the profound medical complexity of their patient population:

> "Many risks of death, either from intravenous drug use or complex other medical concerns. Extreme mental health concerns that we can tie in their safe supply medication with HIV meds [and] hepatitis. We try to look at the whole picture and say who's at most risk right now." (Allied Health, 1)

A notable challenge was the widespread lack of engagement in healthcare services, with many patients avoiding medical care for extended periods. One patient's response exemplified this disengagement:

> "I'd never really had other doctors. I've never been a person that goes – I wait till I'm almost dead before I get any help." (Patient 1, Woman, age: 48)

Initial clinical assessments frequently revealed previously undiagnosed or untreated conditions. One nurse described their SSP's intake process:

> "Some people have started on the program who have unmanaged medical conditions, so there's some clients who have HIV who have not been on medication for a long time… When we do baseline bloodwork, we do some of the hepatitis serology, so we'll know if people need Hepatitis A or Hepatitis B immunization." (Registered Nurse, 1)

The severity of untreated conditions was particularly evident among patients living with HIV. As one physician noted:

> "We have had quite a few referrals from the hospital-based HIV team, of people who were taking no therapy or—we've probably had at least five from the hospital team that had CD4s of zero and were imminently going to die." (Physician, 1)

3.2 | Safer supply model as engagement mechanism

To address patients' complex needs, participating SSPs integrated HIV and HCV care into their delivery model. This started with the intake process, prioritizing individuals at elevated risk for HIV and HCV transmission:

> "We have a priority system that includes persons who are pregnant… People who are engaged in survival sex work and are at high risk of harm due to that. And people who have had multiple overdose events. Also, people who have untreated HIV or AIDS go to the top of the priority list." (Nurse Practitioner, 1)

These prioritization criteria were further refined to account for multiple intersecting vulnerability factors:

> "So female, [Black, Indigenous, People of Colour], homeless or transiently housed or living alone. Or significant medical complications related to IV drug use. Things like uncontrolled HIV, Hep C" (Physician, 2).

SSPs served as an HIV and HCV cascade engagement mechanism by first responding to participants' self-identified drug use needs:

> "When I say 'engagement tool', what I mean by that is we're giving patients something that's actually useful and wanted in their life… And when they experience us supporting them on their own terms of their own identified needs, that brings them back into health care in other ways." (Physician, 1)

Providers recognized that obtaining opioids and preventing withdrawal were their patients' primary concerns and addressed these needs first. However, subsequent visits for titration (adjusting the dose of opioids to an individualized, therapeutic dose sufficient to suppress withdrawal, manage

pain and meet patient-identified goals) and monitoring facilitated opportunities to build trust and engage patients in discussions about HIV and HCV. The SSP model (care and opioid medication) kept patients engaged in care:

> "From a HepC and HIV point of view, it's been remarkable. I am someone who has done primary care for HIV, and was doing it before safer supply, and it was the really challenging part of my job… and doing the programme and being able to twin the medications alongside their long-acting [opioid] that they're going to the pharmacy for every day has made providing HIV primary care so much easier." (Physician, 2)

3.3 | Integration of HIV and HCV care across the treatment cascades

Building on this engagement foundation, the programmes integrated HIV and HCV care across the prevention and treatment cascades. This integration created opportunities for testing, treatment initiation and ongoing care, as discussed below.

3.3.1 | *Testing and early diagnosis*

After establishing initial relationships with SSP patients, providers systematically incorporated HIV, HCV and other STBBI testing into care. Providers emphasized such comprehensive intake screening:

> "[We] connect with the nurses who usually do the bloodwork. We'll get a history around [HCV] as well as HIV testing, how long ago they had been tested, if they know their status or not, and then get consent to test." (Physician, 2)

> "Even giving a baseline bloodwork just to see what's going on for people. Because we've had people that have popped up as HIV positive and we've had people that have popped up as HepC positive." (Allied Health, 2)

Testing became a regular component of ongoing care:

> "We diagnose quite a few people with Hep C and other STIs like syphilis and gonorrhea and then just general screen bloodwork. So a lot of people haven't had that done in a really long time, and they're accessing it. And we offer it every six months or so." (Nurse Practitioner, 2)

Providers noted that SSPs helped patients overcome traditional barriers to testing:

> "People are getting connected to more. I think people are doing things that they didn't normally do because of the stigma and the medical violence that they experience. So definitely cancer screenings and HIV testing and HepC testing and access to treatment and medication has all increased." (Allied Health, 3)

3.3.2 | *Treatment initiation and supporting adherence*

Following diagnosis or re-engagement in care, the programmes provided structured support for treatment initiation through the integrated service model:

> "I've seen a number of people get connected… we do labwork to get those results, people know their status, and then it's really up to them if they want to go forward with treatment, definitely increases acceptability to all those options… Then, once they can stabilize on their [safer supply] dose, it makes it much more likely that ART will be successful." (Registered Nurse, 2)

Prescribers could also bundle HIV/HCV medications with daily dispensing of opioid medications, accounting for varying levels of support:

> "Also starting people on Hepatitis C treatment, and we had a few people who had never been taking any treatment for HIV, and with this, it was facilitated. And just the fact that they have to go to the pharmacy every day anyways. So, picking up those extra pills was no big deal, and they were willing to do it." (Registered Nurse, 3)

For participants requiring additional support, programmes worked with pharmacies to coordinate medication dispensing:

> "For those folks that aren't great at taking their meds, we will tend to do blister packs with the pharmacies, so that, in order for them to get their safer supply meds, they have to either – they get their HIV or HepC meds or psychiatric meds." (Allied Health, 1)

Participants confirmed the integrated approaches' benefit. When asked if the SSP influenced their decision to start HCV treatment, one participant explained:

> "For me it's been positive keepin' me – my health, I know where I'm at. I am going to be doing my Hep C for the new year. So that's something I'm going to be doing. My next appointment with the doctor, I'll be do my blood and that, find out where my liver is at. They [care team] just told me to let them know when I'm ready for it, and then we'll do it." (Patient 2, Woman, age: 45)

While patients could choose their pharmacies, some of the SSPs had relationships with pharmacies that were familiar with the patient population and the types of scripts (especially high medication dosages), which expanded the care team and reduced medication disruptions.

3.4 | Engagement and retention in care

SSPs established a foundation for sustained HIV/HCV care engagement by addressing clinical needs and structural barriers. Providers described using the SSP to help stabilize patients and facilitate ongoing care coordination:

> "So, HIV has a couple of prongs, we have an in-house HIV testing [programme]. So [the programme] would send them to us if the patients aren't able to take their therapy because of the chaos going into their street drug use, so we'll stabilize them with safe supply and observe the HIV treatment, and then we concurrently manage them with [the program] and the infectious-disease doctor." (Physician, 1)

This integrated approach significantly reduced treatment interruptions, with this physician contrasting the stability of SSP patients compared to previous challenges with patients needing to restart treatment multiple times:

> "Whereas previously, people were coming in, would need to be restarted, have genotype testing done over and over again, deal with infection complications, and that is just not happening. And then when it comes to HepC, almost everyone ends up knowing what their status is, if people are positive [we] line them up to repeat that bloodwork in six months, or find a previous test that was positive so they can get started on treatment." (Physician, 2)

Patients emphasized how the daily opioid dispensing model supported their HIV/HCV medication adherence:

> Interviewer: When you go to the pharmacy to get your Dilaudid, do you also pick up HIV medication at the same time?
>
> Participant: At the same time, yes, thanks god yes, thanks god.
>
> Interviewer: How do you feel about that?
>
> Participant: Great, can you imagine? That's my life. I would not be able to – I don't think – I'd be dead, put it that way, if it wasn't for [safer supply], yes. (Patient 3, Male, age: 53)

Another patient explained how the programme model (with daily opioid medication pick-up and wraparound services), in combination with HIV medication bundling, provided a routine he could follow to remain engaged:

> "I thought I was going to have problems with my routine of going to the drugstore. I love going to take my HIV meds every day when I do that. So now I have my doctor put on – when I go for anything, 'Don't give him his drugs unless he gets his HIV medication'. You know what I mean? It's great… I was overwhelmed by all the support and help everybody's given me over the years. I feel – I tell people I don't deserve it, but I've gotten better at that. Yeah, I do deserve it." (Patient 4, Male, age: 53)

However, providers noted that not all patients required this level of support:

> "I think they were fairly adherent to begin with, these folks, actually. I think that it could potentially make a difference if they're going to the pharmacy every day and even – could they pick up their HIV meds with the safer supply meds. But the folks that we have had in who are HIV positive were already connected to a provider and were doing all right." (Nurse Practitioner, 2)

3.4.1 | Improved treatment outcomes

The comprehensive care model contributed to improvements in HIV and HCV treatment outcomes. One nurse practitioner discussed clinical data demonstrating the programme's impact:

> "Out of all patients who came to safer supply with a palliative designation, a hundred per cent of them are still alive and no longer palliative. The patients who came to us with untreated HIV, that had actually progressed to AIDS, ninety-six per cent were virally suppressed, and on continuous HIV treatment. Out of all patients who came to us with Hepatitis C diagnoses, 92%… had either received Hepatitis C treatment or were in the process of receiving Hepatitis C treatment." (Nurse Practitioner, 1)

These programme-level outcomes were reflected in patient experiences. For example, one patient detailed their HIV viral suppression:

> "I wasn't even takin' my meds before I started the program and now, I'm undetectable and I'm over two hundred [CD4]. So it's good." (Patient 5, Woman, age: 48)

This coordinated approach to HIV and HCV care, anchored by daily safer supply dispensing, created multiple opportunities for health system engagement while reducing traditional barriers to care. The integration of services supported patients across the whole cascade of HIV/HCV care, while maintaining flexibility to accommodate varying levels of need. The clinical outcomes suggest that SSPs effectively support the most medically complex patients in achieving and maintaining viral suppression and completing HCV treatment.

3.5 | Person-centred care approach to service delivery

The SSPs in our study implemented person-centred approaches to care and service delivery that acknowledged how past healthcare experiences (including HIV and drug use stigma) influence current engagement in care. This approach was characterized by non-judgemental, accessible care delivery, recognizing the complex needs and histories of those accessing these programmes. SSP patients emphasized how this approach differed markedly from their previous healthcare experiences. One patient highlighted the more personalized nature of care:

> "You get that one-on-one…it's way more interactive, it's way more personal… it's way more humane than the other ones. It's just more judgmental-free, you lay all

your problems on the table. You know? I don't think the other ones even care to know your problems like that." (Patient 6, Male, age: 29)

The co-location and integration of services, combined with supportive relationships with providers, facilitated sustained engagement in care:

"My HIV doctor is here, so I can – everything's all in one place, counselling, HIV, right? And I can talk about the changes in my life, or my needs, and the staff… they're almost like family, you know what I mean? 'Cause I see them so much'. And I really don't feel like I'm a second-class citizen to anybody. And they treat people how they [want to be] treated, and the people that work here will go to the ends of the earth for you." (Patient 7, Woman, age: 44).

Another patient described how this approach fostered ongoing engagement:

"I feel like one of the family here. They took care of my – I get teary when I think about it. They took care of my HepC. They called me, they made sure I'd come in, and they asked – I started going to the appointments downstairs, and then I started volunteering a little. It's just one thing leads to another to another, I feel like this is my family." (Patient 8, Male, age: 49)

Overall, this patient-centred approach was described by all participants as important for engaging and retaining PWUD in HIV/HCV care.

3.6 | Implementation considerations and challenges

Integrating safer supply with HIV and HCV care raised several important implementation considerations. One significant concern involved ensuring that programme eligibility criteria did not inadvertently create perverse incentives around HIV and HCV treatment. With respect to prioritizing unmanaged HIV and HCV at intake, one physician explained:

"We're very careful not to put these criteria out there, so that clients don't end up purposely going off their treatments, for instance, for HIV and Hep C. That has been a reality at another program." (Physician, 2)

Another key consideration involved the timing and coordination of various health and social services. Providers emphasized that SSPs must be integrated within a comprehensive care approach that simultaneously addressed multiple determinants of health, as one physician articulated:

"And what we know is that, if we don't do things concurrently, no one thing works well. Safe supply, at least the way we do in a community, is only partly about the drugs. But we can only take people so far, even with safe supply, if we're not addressing housing, food security, safety, unmanaged health conditions." (Physician, 1)

Providers emphasized that successful integration of HIV and HCV services into SSPs required attention to not just safer supply and HIV/HCV medications, but also patients' basic needs like housing to ensure programmes achieved their intended outcomes.

4 | DISCUSSION

The SSPs we studied reached structurally vulnerable individuals, enabling HIV/HCV care for people typically disconnected from healthcare. In keeping with the growing body of literature about SSPs, those in our sample provided person-centred care for PWUD and created an environment where PWUD felt valued and were supported in addressing their health needs [59, 60, 66, 68, 69, 71, 73, 75, 78, 81]. Our analysis contributes to this discussion by examining the relationship between SSPs and HIV/HCV. Although designed to prevent overdose by replacing the toxic supply, SSPs can also curb injection-related HIV/HCV risk and foster person-centred care [82]. While PWUD experience disproportionately high rates of HIV/HCV, they have been underserved by conventional care models [19, 29, 30, 83]. The HIV and HCV care cascade literatures focus on how to support PWUD to adapt and meet standard programme requirements and established clinical markers (e.g. viral load) [18–24]. In contrast, SSPs tailor service delivery around patients' daily routines and priorities (including meeting their substance use needs and preventing withdrawal) [81], facilitating care engagement and entry points along the HIV and HCV cascades [84].

Our results highlight how effective HIV/HCV care delivery requires extensive relationship-building before conventional cascade metrics become relevant [85]. Providers described the need to establish trust [64], and give patients something they want. This pre-engagement phase—largely absent in traditional cascade frameworks—was crucial for achieving meaningful outcomes. The patient-centred, relational and non-punitive approach taken by providers proved particularly important for helping clients overcome histories of stigma and negative healthcare experiences and stay engaged in care, as has been called for in the literature [86, 87]. Our findings align with earlier work calling for recognizing patient goals and non-linear cascade pathways, with multiple entry points reflecting people's diverse priorities and circumstances [88–90]. Safer supply participation improves OAT retention [91], and sustained OAT in turn enhances HIV and HCV cascade outcomes [92].

As noted, few patient participants discussed their HIV/HCV risk and care in detail. Despite considerable progress in anti-stigma campaigns for HIV and HCV, especially the "U = U" movement [93], this messaging may not have reached marginalized PWUD. We posit that internalized stigma—combined with the immediate threat of fatal overdose in the current drug-toxicity crisis—diminishes participants' focus on the more abstract risks of HIV or HCV. For participants living with HIV, SSPs supported both initial diagnosis and re-engagement in care, achieving impressive viral suppression rates among previously disengaged patients. Similarly, SSPs reported success for HCV in treatment initiation and completion. The integration of safer supply with HIV/HCV care

offers several advantages aligned with person-centred principles: addressing both immediate needs and longer-term health goals; providing daily structure allowing for treatment initiation and adherence; and combining harm reduction with opportunities for healthcare engagement [94], which may support progress on nested HIV and HCV care continuums [95]. Recognizing the growing interest in prescribed safer supply in the United States [96], it is worth noting that while testing and diagnosis among PWUD are progressing, barriers remain to ART engagement and viral suppression [97]. Strategies to improve ART engagement are cost-effective for reducing incidence [98], and low-threshold access is critical for ending the HIV epidemic in the United States [99]. Maintaining low HIV incidence requires sustained ART engagement support, which is more cost-efficient than large-scale prevention programmes [100]. For HCV, innovative strategies [101] and comprehensive community-based care are needed [102], while the United States may benefit from SSPs and other international approaches that address multiple barriers to achieving elimination [103].

Despite the documented success of SSPs across Canada [60], the model remains controversial, with efforts across the country to restrict and prevent their use [104, 105]. The lack of sustained funding threatens to reverse gains for many patients. Harm reduction service disruptions may lead to increased overdose risk, loss of trusted healthcare relationships and deterioration in social stability [106–108]. While critics have cited concerns about medication diversion [105], this can be effectively managed through non-punitive approaches that maintain therapeutic relationships [109–111]. Debates surrounding SSPs (where fears about PWUD are used to justify restricting access to lifesaving medications) underscore the need to bridge the gap between evidence and policy in addressing both the overdose crisis and the ongoing HIV/HCV epidemics. Whereas HIV treatment-as-prevention and PrEP seemed radical when first introduced—reorienting how medications are used and to what ends—they are now part of comprehensive responses [112]. Radical models are needed to address the ongoing drug toxicity crisis, as slow iteration is not working [113]. The HIV sector has a long history of innovation and adaptation, working closely with those most affected to generate community-relevant interventions that can be scaled across diverse contexts—safer supply is another HIV-prevention tool in a growing toolbox.

4.1 | Limitations

Our study has several methodological limitations that warrant consideration. Data collection occurred during COVID-19, when SSPs faced unique operational challenges that may have influenced service delivery and participant experiences. We also cannot speak to longer-term outcomes or programme sustainability. Additionally, despite programmes prioritizing diverse populations, our sample had limited representation of Black, Indigenous and trans individuals. The programmes we examined focused exclusively on opioid safer supply and did not offer prescribed stimulants. The SSP model discussed in this paper is one across a spectrum that includes community-led compassion clubs [114, 115], which should also be considered for their overdose and HIV/HCV prevention potential. Finally, our study focused on SSPs in a single Canadian province [116], which may limit generalizability to other Canadian jurisdictions and other countries with different health and drug policy environments.

5 | CONCLUSIONS

Our findings demonstrate how person-centred SSPs can transform HIV/HCV prevention and treatment for structurally vulnerable individuals by building services around patients' self-identified priorities, preferences and lived realities. In this model, drug use-related needs serve as the starting point and mechanism for engagement. The person-centred approach used by SSP providers prioritized trust-building and responsive care over rigid protocols, which enabled providers to maintain strong therapeutic relationships even when patient engagement fluctuated. Lessons may be transferable to other contexts dealing with the intersection of HIV and HCV, an increasingly toxic drug supply, and threats to harm reduction services (e.g. the United States, the UK, Australia). Future population-level research is needed to examine the impact of safer supply along each stage of the HIV and HCV cascades, long-term outcomes, compare drug options in trial conditions, consider the role of chronic pain [117], as well as optimal models for stimulant safer supply, and approaches to programme scale-up that maintain fidelity to person-centred principles. Most urgently, research is needed to document the health impacts of SSP closures, including HIV and HCV outcomes, to inform evidence-based policy decisions about the model. There is a clear need to preserve and expand—rather than dismantle—novel services that have effectively reached populations historically underserved by mainstream healthcare models.

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COMPETING INTERESTS

The authors declare that they have no conflict of interest regarding the contents of this paper.

AUTHORS' CONTRIBUTIONS

Dr. Guta and Dr. Strike had full access to all of the study's data and are responsible for its integrity and accuracy. For the larger study from which data for this paper are used, AG, CS, RAS, DK and MP collected the qualitative data and iteratively coded them. RAS conducted a statistical analysis. AG, KR and MG conceptualized this paper, with AG taking the lead on writing duties. GK, AS, DG and CS supported subsequent analysis, interpretation and writing. All authors meaningfully contributed to the writing of the paper and reviewed drafts.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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RESEARCH ARTICLE

Person-centred HIV care and prevention for youth in rural South Africa: preliminary implementation findings from *Thetha Nami ngithethe nawe* stepped-wedge trial of peer-navigator mobilization into mobile sexual health services

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Abstract

Introduction: Despite the efficacy of antiretroviral therapy (ART)-based prevention, population-level impact remains limited because those at high risk of HIV acquisition are not reached by conventional services. We investigated whether youth-centred and tailored HIV prevention, delivered by community-based peer navigators alongside sexual and reproductive health (SRH) services, can mobilize demand for HIV pre-exposure prophylaxis (PrEP) and ART among adolescents and young adults (AYA) in KwaZulu-Natal, South Africa.

Methods: *Thetha Nami ngithethe nawe* is a cluster-randomized stepped-wedge trial (SWT) in 40 clusters within a rural health and demographic surveillance site. Clusters were randomized to receive the intervention in period 1 (early) or period 2 (delayed). Trained area-based peer navigators conducted needs assessments with youth aged 15–30 years to tailor health promotion, psychosocial support and referrals into nurse-led mobile SRH clinics that also provided HIV testing, and status-neutral ART and oral PrEP. Standard of care was PrEP delivered through primary health clinics. We report SRH service uptake from the 20 intervention clusters during the first period of the SWT (NCT05405582).

Results: Between June 2022 and September 2023, peer-navigators reached 9742 (74.9%) of the 13,000 youth in the target population, 46.8% males. Among 9576 individuals with needs assessment, peer-navigators identified 141 (1.5%) with social needs, and 4138 (43.5%) had medium to high health needs. These individuals were referred to mobile clinics, with 2269 (54.8%) attending, including 959 (42.3%) males. HIV testing uptake was high (92.7%; 2103/2269), with 10.1% (212/2103) testing positive for HIV, 62 (29.2%) of whom started ART for the first time. The prevalence of HIV was higher among females compared to males (15.1% vs. 3.3%; $p < 0.001$). Among clinic attendees, 96.8% were screened for PrEP eligibility, with 38.5% deemed eligible and offered PrEP. Of the 1433 (63.2%) individuals tested for sexually transmitted infections (STIs), 418 (29.2%) tested positive, with females having higher STI prevalence (37.2% vs. 17.9%; $p < 0.001$). Of these, 385 (92.1%) received STI treatment. Among 1310 females, 769 (58.7%) reported not using any contraception at their initial visit, and 275/769 (35.8%) started contraception during the trial.

Conclusions: Community-based and person-centred approaches delivered through trained peer-navigators can link AYA with SRH and HIV prevention/care needs with mobile SRH services.

Keywords: person-centred; HIV prevention; pre-exposure prophylaxis; adolescents and young adults; sexual and reproductive health; South Africa

Additional information may be found under the Supporting Information tab of this article.

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1 | INTRODUCTION

South Africa has the largest HIV epidemic globally, with an estimated 7.8 million people living with HIV (PLHIV) in 2022 [1]. Despite expanded HIV programmes offering effective and free biomedical interventions, such as HIV testing, universal test and treat (UTT), and oral pre-exposure prophylaxis (PrEP), HIV incidence remains high among young people, particularly adolescent girls and young women (AGYW) aged 20–24 in rural KwaZulu-Natal (KZN) [2, 3].

Antiretroviral therapy (ART)-based HIV prevention strategies have demonstrated efficacy at the individual level but have not yet achieved population-level impact in southern Africa [4], particularly among adolescents and young adults (AYA). Barriers to access include gender and sexuality norms, HIV stigma, and the time and cost of facility-based care [5–7]. Community-based and peer-led interventions can help overcome these barriers by generating demand and improving delivery of sexual and reproductive health (SRH) services, including PrEP [8–11]. Such approaches often adopt person-centred care (PCC), which is associated with improved PrEP uptake [12] and treatment adherence [13, 14]. PCC is endorsed by the Joint United Nations Programme on HIV/AIDS (UNAIDS) through its 2025 targets, emphasizing context-specific, comprehensive services and removal of societal and legal barriers to access [15].

Peer-led HIV prevention is well-supported among key populations such as sex workers, men who have sex with men and people who inject drugs, with one review reporting a 36% reduction in HIV incidence [10]. However, evidence among AYA, particularly in sub-Saharan Africa, remains limited. Of 54 peer-based HIV prevention interventions reviewed, only 12 targeted youth, mostly using school-based education or participatory learning to influence knowledge and behaviour, without evaluating biomedical outcomes [16]. Moreover, few studies have assessed the population-level impact of peer navigator models delivering person-centred SRH services to youth in high-prevalence, rural settings [10].

Between 2019 and 2021, we co-created and adapted a peer navigator-led intervention with AYA to support engagement with person-centred HIV care and prevention, including oral PrEP in rural KZN [5, 17–20]. The resulting intervention, *Thetha Nami ngithethe nawe* (loosely translated as "Let's Talk"), is currently being evaluated in a stepped-wedge cluster randomized trial (SW-CRT) for its effectiveness, implementation and cost-effectiveness in increasing uptake of oral PrEP and reducing sexually transmissible HIV among 15- to 30-year-olds [21].

This paper reports early descriptive implementation findings from the first trial period in 20 intervention clusters. The intervention aligns with PCC principles by addressing unmet health and social needs through tailored HIV and SRH services delivered via community-based peer support and mobile clinics. Here, we describe patterns of service uptake, focusing on the reach of HIV testing, sexually transmitted infection (STI) screening and treatment, and PrEP offer and initiation among AYA in these early clusters.

2 | METHODS

2.1 | Overview of *Thetha Nami Ngithethe Nawe* (Let's Talk) trial

Thetha Nami ngithethe nawe (*Thetha Nami* for short) has been described in detail elsewhere [21]. Briefly, it is an SW-CRT evaluating the implementation and effect of a peer navigator–led, biosocial HIV prevention intervention targeting young people aged 15–30 in rural KZN, South Africa (trial registration NCT05405582). Forty clusters (administrative areas) were randomized in a public ceremony to receive the intervention either in the first period ("early") or in the second period ("delayed"), with rollout staggered over two 24-month periods. Randomization was restricted to ensure balance by population size of 15-to 30-year-olds, geographic region of the study area (north vs. south) and proximity to a major road.

Each cluster had a pair of resident peer navigators delivering the intervention. The first 20 clusters began implementation in June 2022 and will continue receiving the intervention until the planned study end date in January 2026. The second step (remaining clusters) began in September 2023 and will also continue until the study concludes in January 2026. During the first period of the stepped-wedge rollout, the delayed clusters did not receive any study-related outreach or intervention activities. These clusters continued to access routine services through public health facilities, and no peer navigator engagement occurred until their scheduled intervention rollout.

2.2 | Setting

Thetha Nami is embedded in the Africa Health Research Institute's (AHRI) health and demographic surveillance system (HDSS) in uMkhanyakude district, rural KZN [22]. The area has approximately 160,000 residents, including around 26,000 aged 15–30 years with high youth unemployment (> 85%) and HIV burden. Our previous studies have shown that there is a high unmet sexual health need among young people, including low engagement with existing HIV prevention and care services in this setting [7, 19, 20, 23–25]. The area has 11 primary healthcare (PHC) clinics, which have started to provide free oral PrEP since 2021. All people residing in AHRI HDSS have a unique identifier enabling us to link young people who engage with peer navigators to the study clinics.

2.3 | Study population

All 15- to 30-year-olds residing in 40 clusters are eligible to receive the intervention. Based on our pilot work using a screening tool aligned with South African national guidelines, an estimated 16% of this population is at risk of HIV acquisition and would benefit from PrEP.

2.4 | Study interventions

Clusters were randomly assigned to early or delayed rollout of the *Thetha Nami* intervention. Delayed clusters received

standard of care (SOC) during the first period of the trial.

2.5 | SOC clusters

In SOC clusters, participants had access to free nurse-led HIV prevention and treatment services at PHCs within the surveillance area, including HIV counselling and point-of-care testing, with immediate initiation of ART for individuals testing positive or PrEP for eligible HIV-negative individuals following South African National PrEP guidelines. According to these guidelines, individuals initiated on PrEP are scheduled for follow-up visits at 1 month and every 3 months thereafter for repeat HIV testing, counselling, adherence support and prescription refills. Similarly, individuals initiated on ART attend follow-up visits every 3 months for prescription refills and adherence counselling, with viral load monitoring conducted at 6- and 12-months post-initiation and annually thereafter if viral suppression is maintained. In addition, SRH services, such as family planning support and syndromic management of STIs, were also provided in line with the South African National Department of Health guidelines.

2.6 | Thetha Nami ngithethe nawe intervention clusters

This is a peer-led, person-centred intervention offering tailored psychosocial support and mobilizes youth into community-based SRH services. It also facilitates differentiated HIV prevention and care, including PrEP and UTT. Peer navigators are 18- to 30-year-olds residing in the clusters in which they work and who have completed high school. They are selected through a process of referral by traditional and municipal leaderships and assessments. They undergo 6–8 weeks of formal classroom training in a range of core competencies: namely certification for HIV counselling and testing; SRH, HIV treatment and PrEP health promotion; child protection, confidentiality and good clinical practice; youth development; community engagement and strategies for safely entering homesteads; and use of an electronic clinical management tool in REDCap. Training incorporates conducting needs assessments, role play activities, facilitating safe spaces with young people, and weekly debriefings with a review panel including nurse and social worker support. Approximately 90 peer navigators work part-time within the intervention clusters, supported by supervisors (experienced peer navigators), a review panel and a mobile sexual health clinic that visits areas designated by the peer navigators monthly.

Peer navigators conduct community mobilization through events and safe spaces, engage youth in broad health promotion conversations, and perform needs assessments (health, social, legal or education) and triage the urgency of the need (low to high):

- Low need: provide health promotion and a toll-free clinical hotline to link with the clinic or peer navigator should a need arise prior to the scheduled 3-month follow-up.
- Medium need: referral to clinical or social services and a scheduled follow-up for within a week.
- High need: immediate escalation to the social worker or nurse with a follow-up within 3 days.

Based on these holistic assessments, they agree on an action plan including health promotion and counselling, referrals and follow-up scheduling. All interactions and plans are recorded electronically, which enables real-time integration with clinical and social services.

The mobile clinics are nurse-led, HIV-status neutral, gender-neutral and provide adolescent- and youth-friendly HIV testing, prevention and care, integrated with SRH services, including point-of-care HIV testing with confirmatory testing and ART initiation as needed. PrEP eligibility is assessed following national guidelines. STI testing for syphilis, hepatitis B, gonorrhoea and chlamydia is offered with treatment and partner notification. PrEP or ART initiators receive a monthly supply and follow-up care, including a 7-day post-initiation phone call and subsequent clinic visits at 1 month and then every 3 months. Full intervention details and protocols have been published elsewhere [21].

2.7 | Data collection

Between 6 June 2022 and 18 September 2023, process data were collected on peer navigator outreach, needs assessments, referrals, clinic attendance, and uptake of HIV and SRH services. The outcomes reported in this paper reflect data from the 20 early intervention rollout clusters at the end of the first period of the stepped-wedge trial. Based on population enumeration data from the AHRI HDSS, the 20 clusters comprise approximately 13,000 AYA (aged 15–30 years), representing half of the total study population enrolled in the trial. Key measures include HIV testing and the offer of PrEP and ART, seroconversion rates, testing for common and curable STIs, and contraception uptake among females.

2.8 | Statistical analysis

We conducted descriptive analyses to evaluate the uptake and outcomes of HIV prevention and SRH services by sex and age among early intervention clusters. Categorical variables are presented as frequencies and percentages; continuous variables as medians and interquartile range. Analyses accounted for clustering by peer navigator catchment (the unit of randomization and intervention delivery) using Stata's *svy* commands with Taylor-linearized variance estimation for standard errors. Sex-specific differences in proportions were assessed using design-based Pearson's chi-square tests with Rao–Scott corrections. For continuous variables, mean differences were tested using linearized standard errors under the *svy* framework.

Key outcomes analysed included:

1. HIV testing, seroconversion, PrEP uptake and ART initiation.
2. STI testing, prevalence of common and curable STIs (chlamydia, gonorrhoea and trichomonas) and treatment.
3. Contraceptive use and receipt during the trial. New contraceptive users were defined as female participants who received a contraceptive method during their visit to a

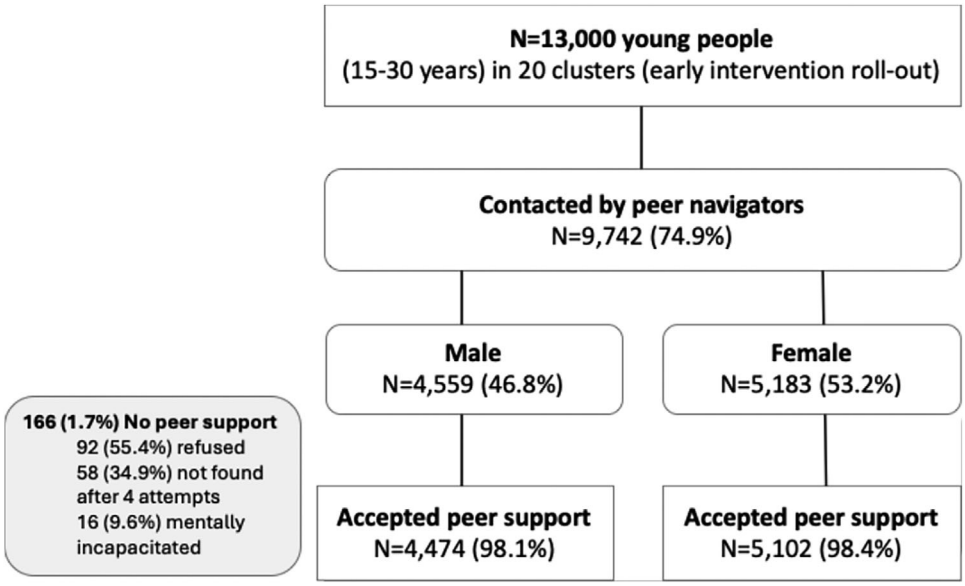

Figure 1. Peer navigator reach.

study clinic and had reported not using any contraception at the time of their initial clinic visit.

4. Pregnancy during the study.

All analyses were stratified by sex and age to assess sex-specific trends. Data were analysed using Stata 18.

2.9 | Ethical considerations

The study followed ethical guidelines per the Declaration of Helsinki. Ethical approvals were obtained from the University of KwaZulu-Natal Biomedical Research Ethics Committee (BREC/00003735/2021) and UCL Research Ethics Committee (5672/006). The study team, including the implementing staff, received ethics training covering confidentiality, voluntary participation and good clinical practice. Each participant was assigned a unique, non-identifying participant identification number to ensure confidentiality. Participants were provided with detailed information about the study and were given the opportunity to ask questions for clarification before providing consent. Participants aged 18+ provided written informed consent; those aged 15–17 provided assent with parental/guardian consent. Participants could withdraw from the study at any time without consequences. All study services adhered to national and clinical guidelines.

3 | RESULTS

3.1 | Peer navigators reach and need assessments

Peer navigators reached 9742 (74.9%) of the 13,000 young people in the target population across the 20 clusters with early intervention rollout (Figure 1). Of those reached, 46.8% were male participants. A total of 9576 (98.3%) young people accepted peer support and underwent needs assessment.

Among the young people assessed, sexual health needs were the most frequently reported, with 9508 (99.2%) assessed, of whom 4138 (43.5%) were identified as having medium to high needs and were referred for mobile adolescent and youth-friendly clinical services. In contrast, assessments for social support, education and legal needs revealed much lower proportions of medium or high need: 1.5% (141/9192), 0.7% (66/9179) and 0.2% (14/9164), respectively, and were referred for social, educational or legal services as needed. The patterns of needs were similar across sexes. Among females, 43.7% (2216/5062) had medium or high sexual health needs compared to 43.2% (1922/4446) among males (Figure 2).

3.2 | Participants who attended mobile adolescent and youth-friendly clinical services

Among the 4138 individuals identified with medium or high sexual health needs and referred for clinical services, 2269 (54.8%) successfully linked to care. Linkage rates were higher among females, with 59.1% (1310/2216) successfully linking to care, compared to 49.9% (959/1922) among males. There were more females than males across all age groups. About one in five participants were residing in urban or peri-urban areas (Table 1).

3.3 | Uptake of HIV testing and assessment for HIV prevention and care

Table 2 presents uptake of HIV testing by sex. A total of 2103 (92.7%) of clinic attendees underwent HIV testing, with a similar uptake rate of HIV testing between males (93.4%) and females (92.1%). Of those tested, 212 (10.1%) were living with HIV; this was higher in females (15.1%) than males (3.3%), $p < 0.001$. Among those diagnosed as living with HIV, 62 (29.2%) were newly diagnosed and started on ART, with

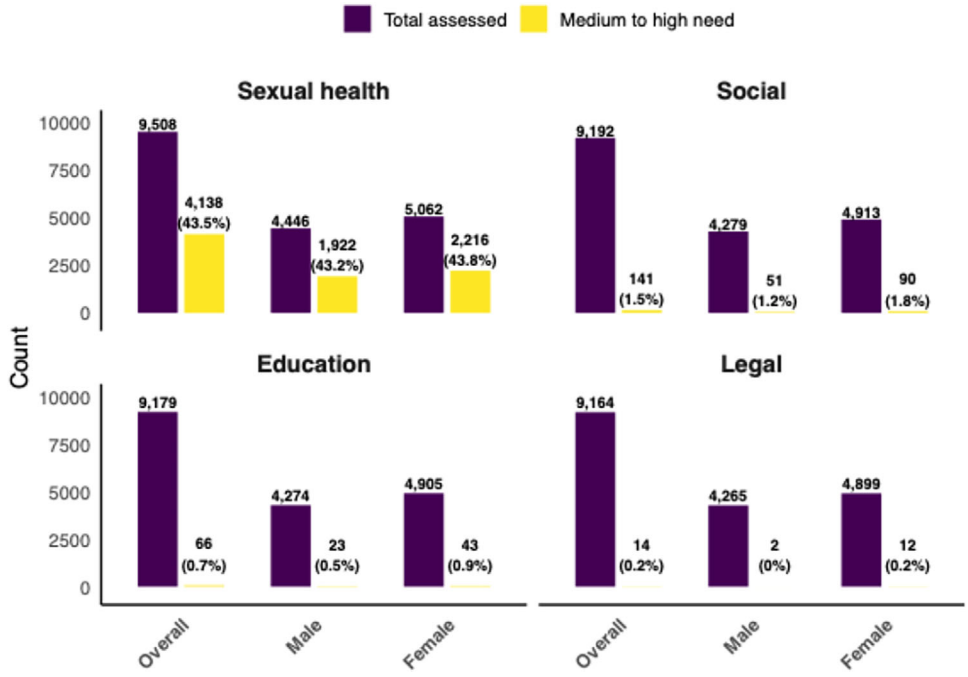

Figure 2. Needs assessment and urgency grading, overall and by sex.
Observed differences in denominators across domains reflect occasional missing responses to specific items within the needs assessment tool.

Table 1. Demographic characteristics of the participants who attended mobile adolescent and youth-friendly clinical services

	Total *n* = 2269		Male *n* = 959		Female *n* = 1310		*p*-value
Age at enrolment (years)							0.010
Median [IQR]	21.7	[18, 26]	21.0	[18, 25]	22.1	[19, 26]	
Age group							0.06
15–19	860	37.9%	394	41.1%	466	35.6%	
20–24	783	34.5%	328	34.2%	455	34.7%	
25–30	626	27.6%	237	24.7%	389	29.7%	
Area of residence							0.05
Rural	1789	78.9%	775	80.9%	1014	77.5%	
Urban/peri-urban	477	21.1%	183	19.1%	294	22.5%	

Abbreviation: IQR, interquartile range.

more males (46.7%) than females (26.4%) newly diagnosed (p = 0.05). Repeat HIV testing was conducted in 28.2% (n = 594) of participants, with a higher proportion among females (30.4%) compared to males (25.3%; p = 0.02). Seroconversion occurred in 1.0% (n = 6) of participants who retested, five of whom were female. The overall HIV incidence rate was 2.53 per 100 person-years (95% CI: 1.13–5.62). Among the 2269 clinic attendees, 2196 (96.8%) were screened for PrEP eligibility, and 845 (38.5%) were deemed eligible and offered PrEP. More males (46.1%) than females (32.9%) were offered PrEP. Uptake of PrEP was 85.3% among 845 who were offered PrEP and did not differ by sex (86.5% among males vs. 83.7% among females, p = 0.42).

3.4 | Uptake of STI testing and prevalence of common and curable STIs

A total of 1433 (63.2%) clinic attendees were tested for common and curable STIs (chlamydia, gonorrhoea and trichomonas) with similar proportions for males (62.0%) and females (64.0%) (Table 2). Overall, 418 (29.2%) tested positive for any STI, with a higher prevalence among females (37.2%, 95% CI: 34.4%–40.1%) than males (17.9%, 95% CI: 15.4%–20.8%) (Table S1). Among those who tested positive, 385 (92.1%) received STI treatment. Treatment uptake did not differ significantly by sex (p = 0.67).

Table 2. Uptake of HIV testing and assessment for HIV prevention and care among adolescents and young adults in rural South Africa, June 2022–September 2023

	Total *n* = 2269		Male *n* = 959		Female *n* = 1310		*p*-value
HIV testing							
DBS collected for HIV testing							0.27
No	166	7.3%	63	6.6%	103	7.9%	
Yes	2103	92.7%	896	93.4%	1207	92.1%	
HIV status							< 0.001
Negative	1891	89.9%	866	96.7%	1025	84.9%	
Positive	212	10.1%	30	3.3%	182	15.1%	
ART status							0.05
On ART	150	70.8%	16	53.3%	134	73.6%	
Started/initiated ART	62	29.2%	14	46.7%	48	26.4%	
Tested at least twice							0.02
No	1509	71.8%	669	74.7%	840	69.6%	
Yes	594	28.2%	227	25.3%	367	30.4%	
Seroconverted							0.31
No	588	99.0%	226	99.6%	362	98.6%	
Yes	6	1.0%	1	0.4%	5	1.4%	
PrEP eligibility assessment							
Assessed for PrEP eligibility							0.45
No	73	3.2%	26	2.7%	47	3.6%	
Yes	2196	96.8%	933	97.3%	1263	96.4%	
Considered suitable for PrEP following risk assessment							< 0.001
No	1351	61.5%	503	53.9%	848	67.1%	
Yes	845	38.5%	430	46.1%	415	32.9%	
Started PrEP							0.42
No	124	14.7%	58	13.5%	66	15.9%	
Yes	721	85.3%	372	86.5%	349	84.1%	
Common curable STI testing							
Tested for STI							0.42
No	836	36.8%	364	38.0%	472	36.0%	
Yes	1433	63.2%	595	62.0%	838	64.0%	
Any STI[a]							< 0.001
Negative	1012	70.8%	486	82.1%	526	62.8%	
Positive	418	29.2%	106	17.9%	312	37.2%	
Number treated for STI[b]	385	92.1%	99	93.4%	286	92.0%	0.67

Abbreviations: ART, antiretroviral therapy; DBS, dried blood spot; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.
[a]Chlamydia, gonorrhoea or trichomonas.
[b]Among 33 participants who were not treated for a positive STI, 19 (57.5%) could not be traced (lost to follow up), 7 (21.2%) migrated out of the study area, 1 (3.0%) refused treatment, 6 (18.2%) other.

Across all age groups, the prevalence of any STI was consistently higher among females compared to males, and it was highest in females aged 15–24 and men aged 20–24 (Figure 3 and Table S2). For instance, in the 15–19 age group, 39.8% (95% CI: 35.3%–44.8%) of females tested positive for any STI compared to 14.2% (95% CI: 10.1%–19.6%) of males. Similarly, among females aged 20–24 years, 41.4% (95% CI: 37.2%–45.7%) tested positive for any STI, compared to 22.3% (95% CI: 16.0%–30.1%) of males.

Chlamydia was the most prevalent STI, with an overall prevalence of 25.8% (95% CI: 21.8%–30.2%) in the 15–19 age group, declining to 18.1% (95% CI: 14.6%–22.1%) in the 25–30 age group. Among females, the highest prevalence of chlamydia was observed in the 15–19 age group, at 34.7% (95% CI: 30.4%–39.2%). Among males, the highest prevalence of chlamydia was in the 20–24 age group, at 20.9% (95% CI: 15.0%–28.2%). The prevalence of gonorrhoea was markedly lower, with overall rates of 7.0% (95% CI: 4.8%–10.1%) in the 15–19 age group and 6.5% (95% CI: 4.2%–9.9%) in the 25–30 age group. Trichomonas acquisitions were rare, with the highest prevalence observed among females aged 20–24 years at 8.3% (95% CI: 5.5%–12.3%).

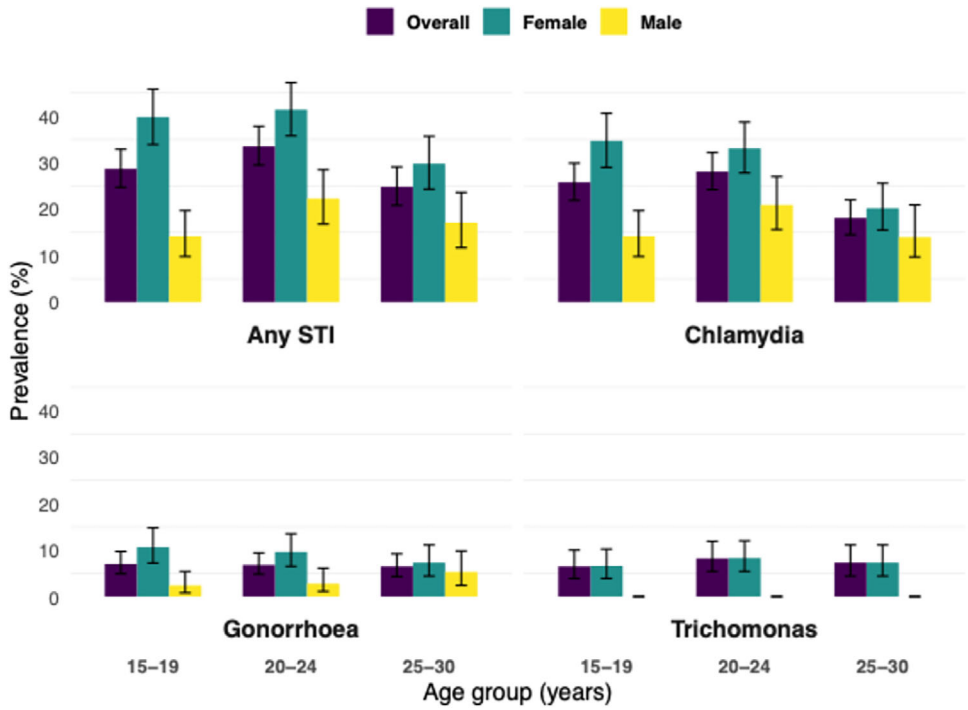

Figure 3. Prevalence of sexually transmitted infections (STI) by sex and age group.

3.5 | Contraception use and pregnancy among female participants

Contraception use was reported by 65.6% (859/1310) of female participants. Among various age groups, contraception use was most prevalent in the 25–30 age group, where 79.7% (310/389) of participants reported current contraception use. Overall, 65.0% (558/1310) of contraception users received contraception through the study, with higher uptake rates among those in the 15–19 age group (70.5%, 148/210). The majority (72.8%, 406/558) of the participants who received contraception from our study clinics received injectable contraception. Among the 769 participants who were not using contraception at their initial clinic visit, 275 (35.8%) initiated a method during the study. New use was highest among participants aged 25–30 years (49.7%), followed by those aged 20–24 (41.9%) and 15–19 (25.3%) ($p = 0.001$). A total of 905 (69.1%) had a point-of-care test for pregnancy. Of these, 48 (5.3%) tested positive for pregnancy, with similar rates across the age groups. When including those who self-reported current pregnancy, the number of pregnant individuals increased to 118 (9.0%), again with no substantial differences by age groups (Table 3).

4 | DISCUSSION

Community-based, peer-led, PCC achieved substantial reach, engaging about 75% of the target population and ensuring equitable sexual health needs assessments across sexes. Among those who linked to care, there was a high burden of SRH and HIV care and prevention needs, highlighting the potential of peer-led needs assessments to mobilize demand for SRH and differentiated HIV care and prevention services. However, the trial's final outcomes are needed to determine the population-level impact of the intervention.

We found that more than half of the AYA, including men who linked to care through this person-centred community-based approach, were at high risk of HIV acquisition or transmission and would potentially benefit from ART-based prevention. Our preliminary findings are consistent with a 2021 Zambian study evaluating a peer-led, community-based SRH intervention, which reported a significant increase in service uptake among AYA. In the intervention arm, 64% accessed SRH services compared to only 5% in the control arm [26]. Emotional dynamics, lived experiences and shared personal characteristics influence young people's decisions to engage with care, demonstrating the importance of tailored, PCC [27].

Peer navigators, embedded in their communities, significantly enhanced SRH and HIV service uptake in part by being relatable to the target population, sharing cultural, linguistic, and socio-economic contexts and supporting their agency in navigating services [28, 29]. This model can potentially address health inequities and reproductive justice [29]. However, only just over half of those referred into services by the peer-navigators utilized the accessible youth-friendly SRH services, suggesting further barriers, such as internal and external stigma and societal and cultural taboos around adolescent and youth sexuality. These barriers need to be overcome to really provide equitable and timely access to sexual health and HIV prevention services to young people in these rural communities.

Table 3. Contraceptive use and pregnancy among female adolescents and young adults in rural South Africa

	Overall *n* = 1310	15–19 *n* = 466	20–24 *n* = 455	25–30 *n* = 389	*p*-value
Contraception use					
Self-report current contraception use at initial clinic visit					
No	769 (58.7)	364 (78.1%)	234 (51.4%)	171 (44.0%)	< 0.001
Yes	541 (41.3%)	102 (21.9%)	221 (48.6%)	218 (56.0%)	
Self-report current contraception use at any time during the study					
No	451 (34.4%)	256 (54.9%)	116 (25.5%)	79 (20.3%)	< 0.001
Yes	859 (65.6%)	210 (45.1%)	339 (74.5%)	310 (79.7%)	
Received contraception from study clinics					
No	301/859 (35.0%)	62/210 (29.5%)	135/339 (39.8%)	104/310 (33.5%)	0.09
Yes	558/859 (65.0%)	148/210 (70.5%)	204/339 (60.2%)	206/310 (66.5%)	
Injectable contraception	406 (72.8%)	107 (72.3%)	158 (77.5%)	141 (68.5%)	0.26
Oral contraception	152 (27.2%)	41 (27.7%)	46 (22.6%)	65 (31.6%)	
Started contraception during the study					
No	494/769 (64.2%)	272/364 (74.7%)	136/234 (58.1%)	86/171 (50.3%)	0.001
Yes	275/769 (35.8%)	92/364 (25.3%)	98/234 (41.9%)	85/171 (49.7%)	
Pregnancy					
Point of care test for pregnancy done					
No	405 (30.9%)	126 (27.0%)	146 (32.1%)	133 (34.2%)	0.20
Yes	905 (69.1%)	340 (73.0%)	309 (67.9%)	256 (65.8%)	
Pregnancy test results					
Negative	856/904 (94.7%)	321/340 (94.4%)	290/308 (94.2%)	245/256 (95.7%)	0.73
Positive	48/904 (5.3%)	19/340 (5.6%)	18/308 (5.8%)	11/256 (4.3%)	
Self-report currently pregnant					
No	1174/1280 (91.7%)	419/451 (92.9%)	412/449 (91.8%)	343/380 (90.3%)	0.46
Yes	106/1280 (8.3%)	32/451 (7.1%)	37/449 (8.2%)	37/380 (9.7%)	
Positive pregnancy test results or self-reported currently pregnant					
No	1192/1310 (90.1%)	428/466 (91.9%)	413/455 (90.8%)	351/389 (90.2%)	0.72
Yes	118/1310 (9.0%)	38/466 (8.1%)	42/455 (9.2%)	38/389 (9.8%)	

We observed a high prevalence of curable STIs, particularly gonorrhoea and chlamydia, with higher rates among females and those under 24. Given the SRH complications associated with untreated STIs and their frequently asymptomatic nature, this signals the urgent need for enhanced STI screening, testing, contact tracing and early treatment models. Consistent with our findings, a 2019 systematic review and meta-analysis on the global epidemiology of STIs among PrEP users reported that nearly one-quarter of patients at PrEP initiation had an STI (chlamydia, gonorrhoea or early syphilis). Furthermore, the study documented an STI incidence rate of 72.2 per 100 person-years during the first 3 months of PrEP use [30].

This person-centred and community-based delivery approach substantially reached AGYW with unmet contraceptive needs, with a significant proportion, particularly among adolescents, initiating use through the mobile sexual health services. These findings mirror a Kenyan study that reported a 12.5% increase in contraceptive use paired with a significant decrease in pregnancy incidence associated with integrated family planning into HIV care services [31]. A systematic review on family planning and HIV integration also found an 8% increase in contraceptive use [32]. Additionally, a 2020 South African study reported an increase in contraceptive prevalence among AGYW using PrEP from 62.3% at baseline to 74.5% during the trial [33]. These support the integration of SRH and HIV services, especially with community-based, person-centred service delivery models in addressing young women's reproductive health needs (Table 3).

Our study has several limitations. The duration of observation limits our ability to confirm long-term trends in service utilization. We could not determine how many participants, particularly those diagnosed with HIV, had disengaged from care, which constrains our assessment of the true extent of service gaps. While our findings may not be generalizable to the entire country, the similar socio-economic and healthcare contexts in rural settings across the region suggest potential applicability. Finally, although the peer navigator model seems to be an acceptable and feasible model of delivering PCC to AYA with a high unmet SRH and HIV care and prevention need, we need to await the final outcomes of the trial to understand its effectiveness and scalability. Despite these limitations, the study has notable strengths. The peer navigator-led, community-based approach enhanced access to SRH and

HIV services among AYA by addressing disparities in healthcare access through equitable health needs assessments. Peer navigators provided person-centred, personalized psychosocial support, which resulted in successful linkage to healthcare. Additionally, the comprehensive SRH and HIV serostatus neutral service delivery model simultaneously addressed multiple unmet health needs.

5 | CONCLUSIONS

Community-based and person-centred approaches delivered through trained peer-navigators are acceptable and feasible to reach AYA, including young men, with unmet SRH and HIV prevention and care needs and mobilize them into mobile SRH services. Providing HIV services with mobile SRH clinics creates demand for PrEP and supports ART initiation among AYA at high risk. These preliminary findings suggest that task shifting PCC to trained and supervised peer-navigators could be a vital component of HIV prevention strategies, particularly for key populations and can fill unmet sexual health and social needs. After trial completion, we will evaluate the effectiveness of this intervention package in improving population-level health outcomes and reducing sexually transmissible HIV among young people.

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COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

MS conceived the study. MS, AC, KB, JB, NC, TZ, JD, CH, NO and JS designed the study. JB, AC, MS, JD and KB have access to the study data. JB conducted the analysis. JB and NN wrote the first draft of the manuscript. JB, NN, MS, KB, AC, TZ, LL, JS, TS and NC read and critically revised the manuscript. All authors read and approved the final manuscript.

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DATA AVAILABILITY STATEMENT

Data sharing will be available upon completion of the study. All the protocols, study tools, data and data analysis plans from the study and the findings will be made available in compliance with the Bill and Melinda Gates Foundation's data sharing and open access policy. All data are collected, maintained, and analysed under the local IRB-approved Policies and Procedures for data access and sharing, which will be made available in the AHRI repository at the time of publication of the primary outcome paper.

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SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:
Table S1: Prevalence of STIs by sex.
Table S2: Prevalence of STIs by sex and age group.

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

SHORT REPORT

Harnessing digital health data for person-centred HIV prevention monitoring: a survey of national health information systems

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Abstract

Introduction: Measuring HIV prevention impact is challenging because prevention is started and stopped as needed, and individual-level data availability has been suboptimal or not collected. WHO's 2022 *Consolidated guidelines on person-centred HIV strategic information* aim to bridge this gap by recommending a minimum dataset for HIV prevention monitoring.

Methods: We surveyed the availability of 42 HIV prevention data elements collected on an individual from WHO's recommended minimum dataset in 21 countries' national health information systems during a Prevention Outcome Monitoring Workshop held in September 2024 in Gaborone, Botswana. Over 150 participants representing ministries of health and programme implementers from 21 countries in Africa and Asia, as well as representatives from global organizations, attended. National HIV prevention managers completed the survey covering: registration (client demographics, use of unique identification, key population status), HIV testing, HIV prevention and vertical transmission. Data element availability determined which prevention indicators each country could calculate. Additionally, we describe global data on the use of unique identification for key populations.

Results: Of the 21 attending countries, 18 completed the survey. Fifteen countries (83%) used unique identification in their national health information systems. All 18 countries collected HIV testing data elements, while 14–18 countries (78–100%) collected those for vertical transmission. However, prevention data availability varied widely. Different data elements on pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) were collected by 13–17 (72–94%) countries, condoms by 15 (83%) and voluntary medical male circumcision by 11 (61%) countries. Data elements on harm reduction were available in 4–6 countries among 8–10 countries providing services. While all countries could calculate HIV testing indicators, around 90% could for vertical transmission, 50–94% for PrEP/PEP and 40–75% for harm reduction. Only two countries could calculate linkage to prevention, which incorporates all prevention interventions. Kenya was the only country that collected all recommended person-centred data elements. Overall, up to 37 of 105 reporting countries had a nationally harmonized personal unique identification method for key populations.

Conclusions: Data building blocks for HIV prevention exist in most national health information systems. Aligning these systems with global standards offers potential to further strengthen person-centred HIV prevention monitoring.

Keywords: data; surveillance; testing; HIV; prevention; health information systems

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1 | INTRODUCTION

Although HIV incidence continues to decline, it is far from the global target of < 370,000 new infections in 2025, with 1.3 million people acquiring HIV in 2024 [1]. Particularly affected are key populations (men who have sex with men, sex workers, people who inject drugs, trans and gender diverse people, and people in prisons and other closed settings) and their partners in all world regions, and adolescent girls and young women in sub-Saharan Africa [2, 3]. Reaching individuals at elevated risk of HIV acquisition with their choice of effective HIV prevention is critical to reducing incidence [4]. Yet, monitoring

HIV prevention programmes to identify gaps in coverage and opportunities for improvement has been a challenge due to the episodic nature of HIV prevention need and use, a lack of individual-level data, and the common practice of aggregating information across interventions, which make composite indicators difficult to interpret.

The evolution of health information systems towards digital, person-centred (or individual-level) data can be harnessed for HIV prevention. Digitizing routine programmatic data and using it for HIV prevention can help identify individuals at elevated risk of HIV acquisition, generate prevention demand and determine intervention uptake. By comparison, aggregate counts of prevention services delivered do not allow for deduplication and make it difficult to assess whether programme coverage is over-saturating a small population or has a broader reach across a priority population. Since routine data only capture those who access health services, they need to be adjusted for population size to derive population-level estimates.

Routine national monitoring systems are essential for data collection for the HIV response. The World Health Organization's (WHO) 2022 *Consolidated guidelines on person-centred HIV strategic information* aim to strengthen the analysis and use of routinely collected data at each stage of a person-centred cascade of care for HIV and related infections [5]. For the first time, a minimum dataset for HIV prevention was recommended to measure interventions received and health outcomes among individuals seeking prevention. The minimum dataset describes specific data elements to be collected that indicate the date and the intervention received for each client. For example, the date an individual was prescribed pre-exposure prophylaxis (PrEP), the product prescribed and the volume dispensed. Such standardization of data collection tools enables calculation of indicators and is a critical component in developing a comprehensive monitoring system. Additionally, unique identification facilitates monitoring individuals across various services, enabling the measurement of prevention outcomes over time.

In this paper, we present the findings from a survey on national HIV prevention monitoring conducted among 18 participating countries to assess the availability of prevention data elements in national health information systems. We reviewed the potential for calculating HIV prevention indicators based on these data to inform current and future programme planning.

2 | METHODS

We shared a survey containing 42 data elements required for individual-level, person-centred HIV prevention monitoring as described in the WHO Strategic Information Guidelines [5], with 21 countries attending a HIV Prevention Outcome Monitoring Workshop in September 2024 in Gaborone, Botswana. There were over 150 participants with representatives of ministries of health and programme implementers from 21 countries in Africa and Asia, as well as representatives from global organizations. National HIV prevention managers completed the survey, administered as a series of yes/no questions on specific data elements. We categorized the data elements into four sections covering registration (client demographics, use of unique identification, key population status), HIV testing, HIV prevention and vertical transmission. The data elements were then used to determine which prevention indicators could be calculated.

Additionally, we present global data on the use of unique identification for key populations from the publicly available Global AIDS Monitoring National Commitments and Policies Instrument. This is an annual national survey conducted by UNAIDS, WHO and UNICEF [6]. We analysed 10 questions from the survey, two for each key population.

WHO guidelines suggest two options for indicator denominators: (1) Service-level denominators, which include all people who have sought services. These denominators use available data and are actionable at the individual or facility level, but exclude people who have not sought services and may be at risk for HIV. (2) Population-based denominators that require the use of population size estimation or modelling to determine the population at risk and, therefore, provide a comprehensive picture of prevention coverage. In this analysis, we used service-level denominators for simplicity, as population-based denominators were not always available.

No data was collected on individuals which required ethical clearance.

3 | RESULTS

3.1 | Review of WHO-recommended minimum dataset for HIV prevention

Eighteen of 21 attending countries completed the review of data elements (Botswana, Cameroon, Cote d'Ivoire, Eswatini, Ghana, India, Indonesia, Kenya, Malawi, Mozambique, Namibia, Nigeria, Philippines, South Africa, South Sudan, Tanzania, Uganda, Zambia). The availability of data elements varied considerably, with the widest variation observed in HIV prevention data elements (Table 1). Among 18 reporting countries, 15 used at least one unique identifier – 10 countries used a national identification number, of which nine countries additionally used a national health/ programme/insurance identifier, and only Botswana used no other identifier. Five countries without national identifiers used at least one of the following: national health/programme/insurance identifiers. Most countries collected the date of birth (n = 16); one used estimated age. In categories for sex or gender, five countries collected options other than male/female. Under key populations, most countries collected categories for men who have sex with men and sex workers (n = 16; 89%); 12 countries (67%) did for trans and gender diverse people and people in prisons and other closed settings; 14 countries (78%) did so for people who inject drugs; and 10 countries (56%) collected all key populations. All 18 countries collected HIV testing data elements, while 14 (78%)–18 (100%) countries collected different data elements on vertical transmission.

HIV prevention data elements collected consistently included PrEP, post-exposure prophylaxis (PEP), condoms and voluntary medical male circumcision (VMMC) (Table 1). Up to one-third of all countries collected data elements on harm reduction such as needle and syringe programmes (NSPs) and

Table 1. Availability of WHO-recommended minimum data elements [5] for HIV prevention monitoring in national surveillance systems

Area/intervention	Data element	Countries reporting (n = 18)	
		Number	Percent
Unique identification method	Any form of unique identification[a]	15	83%
	National unique identifier	10	56%
	National health identifier	9	50%
	Programme identifier (such as ART number)	12	67%
	National health insurance identifier	9	50%
Demographics	Date of birth[a]/age	17	94%
	Sex[a]	16	89%
Key population member	Sex worker	16	89%
	Men who have sex with men	16	89%
	Trans and gender diverse people	12	67%
	People who inject drugs	14	78%
	People living in prisons and other closed settings	12	67%
HIV testing	HIV test sample date[a]	18	100%
	HIV test result[a]	18	100%
Prevention referral	Elevated risk for HIV acquisition (based on risk factors)	10	56%
PrEP	Date PrEP prescribed, including initial prescription[a]	17	94%
	Date PrEP dispensed[a]	16	89%
	PrEP product prescribed[a]	13	72%
	Volume of PrEP product prescribed or dispensed (e.g. number of pills, number of devices)[a]	14	78%
PEP	Date PEP prescribed[a]	15	83%
	Date PEP course completed (ascertained at follow-up)[a]	14	78%
NSP	Date injecting equipment provided[a]	4	22%
	Number of needles–syringes provided[a]	5	28%
OAMT	Date OAMT initiated[a]	5	28%
	Date OAMT dose received[a]	6	33%
	Date OAMT take-away dose(s) dispensed[a]	6	33%
	Date of first maintenance dose received[a]	6	33%
	Date of loss to follow-up or OAMT stopped[a]	6	33%
VMMC	VMMC procedure conducted	11	61%
	VMMC procedure date[a]	10	56%
Condom programming	Condom provision date[a]	15	83%
	Condoms distributed (at service delivery points or national warehouse)	15	83%
Vertical transmission of HIV, hepatitis B and syphilis	ANC contact date[a]	14	78%
	Date of first ANC visit[a]	16	89%
	Maternal HIV status at first ANC visit[a]	17	94%
	Date of ART initiation[a]	16	89%
	Already on ART at first ANC visit[a]	17	94%
	Newly on ART during pregnancy[a]	18	100%
	HIV-exposed infant or child[a]	17	94%
	HIV-exposed infant or child test result of HIV assay 1[a]	17	94%
	Final diagnosis of HIV-exposed infant[a]	16	89%
	Maternal syphilis test result	17	94%
	Hepatitis B diagnosis	15	83%

Abbreviations: ANC, antenatal care; ART, Antiretroviral therapy; NSP, needle and syringe programme; OAMT, opioid-agonist maintenance therapy; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; VMMC, voluntary medical male circumcision.
[a]Data element included in WHO-recommended minimum dataset described in Consolidated guidelines on person-centred HIV strategic information [5].

Table 2. Methods of unique identification used by countries for key population prevention services

	Number of countries using different types of unique identifiers					
Key population	Nationally harmonized personal unique identifier	National unique identifier	Combination of personal identifying information	HIV-specific unique identifier	Biometric	Other
Men who have sex with men	37	11	12	7	1	6
Sex workers	35	10	12	7	1	5
Trans and gender diverse people	26	10	7	5	0	4
People who inject drugs	22	7	5	4	1	5
Other priority population	15	5	4	3	1	2

opioid-agonist maintenance therapy (OAMT), including India, Kenya, Malawi, Mozambique, Tanzania and Uganda. When restricted to countries known to provide NSP (n = 10) or OAMT (n = 8) services, data element availability increased to 40–75% of countries.

3.2 | Global analysis of use of unique identification for key population prevention services

A total of 105 countries responded to questions on unique identification for key population prevention services in the Global AIDS Monitoring National Commitments and Policies Instrument in 2023. Overall, 37 countries had a nationally harmonized personal unique identification method for men who have sex with men, 35 countries for sex workers, 26 countries for trans- and gender diverse people, 22 for people who inject drugs and 15 for other priority populations, such as people in prison or migrants (Table 2). The most common method for identifying and removing duplicate health information across key populations was a combination of routinely collected personal identifying information. This was followed by the use of HIV-specific unique identifiers and then national unique identifiers. The use of biometric identification was uncommon.

3.3 | Assessment of indicators

The prevention indicators that we assessed required between one and nine data elements for calculation: one data element for simple counts and nine for the more complex linkage to the prevention indicator, which incorporates referral to all prevention services. Some HIV testing indicators could be calculated by all (n = 18) countries, with the exception of the linkage to prevention indicator, which could only be calculated by two countries (Table 3). Indicators for vertical transmission were possible to assess for up to 94% (n = 17) of countries. Harm reduction indicators were the lowest, ranging from 40% (NSP coverage and regular NSP access, n = 4) to 75% (OAMT coverage, n = 6) of countries able to calculate those indicators. Kenya was the only country with all data elements needed to calculate all indicators, including suggested gender, age and key population disaggregations.

4 | DISCUSSION

Operationalizing person-centred data for HIV prevention requires data building blocks in health information systems for calculating prevention indicators to monitor services and address gaps. Overall, our findings show that data element collection for HIV testing, condom usage, PrEP, PEP, VMMC and vertical transmission was generally good across countries, although some gaps remain. In contrast, harm reduction services were only offered in 8 (OAMT)–10 (NSP) countries, 4–6 of which collected the relevant data elements. Harm reduction data collection is influenced by existing laws and policies that criminalize drug use, therefore, limiting service provision and reducing data availability. Our results indicate that with a few strategic additions, prevention data in national systems can be significantly enhanced. Political will and robust healthcare infrastructure are crucial for building and maintaining effective monitoring systems for HIV prevention. International development assistance cuts as seen in 2025 can undermine these efforts, leading to gaps in service delivery, reduced data security and weaker programmes. Ongoing investment and leadership are essential for building robust systems and preventing programmatic reversals.

A critical aspect of prevention monitoring is effectively addressing elevated risk for HIV. Our review suggests that the collection of clinical and behavioural information on factors associated with HIV acquisition is possible within health information systems, with all countries collecting at least six prevention data elements. However, the gaps seen highlight a need for additions. Health information systems must also adapt to include new interventions such as lenacapavir and long-acting formulations in electronic medical records, and enable disaggregation by service type. Given that an individual's need for HIV prevention changes over time, frequent updates to information collected during routine visits and other points of contact are necessary to maintain the relevance of prevention interventions offered [5, 7]. Offering HIV prevention services both to those identified with risk factors for HIV, as well as those who self-identify and request prevention, will ensure that individuals receive the prevention services they need.

Key populations face a disproportionate burden of HIV, sexually transmitted infections (STIs) and viral hepatitis (particularly hepatitis B and hepatitis C), and good quality data are critical for understanding and improving services for them [2].

Table 3. HIV prevention-related indicators, required data elements, and the number and proportion of countries that can analyse the indicators based on individual-level data

Indicator number [5]	Indicator name	Required data elements	Countries that could analyse indicator (n = 18)	
			Number[a]	Proportion
HIV prevention				
PRV.1	Condoms distributed	Condoms distributed	15	83%
PRV.2	Total PrEP recipients	Date PrEP prescribed	17	94%
PRV.3	PrEP coverage	At elevated risk for HIV acquisition; HIV test date; HIV test result; date PrEP prescribed	9	50%
PRV.4	Volume of PrEP prescribed	Date PrEP prescribed; volume PrEP prescribed	14	78%
PRV.5	Number of PEP recipients	Date PEP prescribed	15	83%
PRV.6	PEP completion	Date individual completed PEP course (ascertained at follow up)	14	78%
PRV.7	HIV in PEP recipients	Date individual completed PEP course (ascertained at follow up); HIV test date; HIV test result	14	78%
PRV.8	NSP coverage	Date injecting equipment provided; key population member type	4[a]	40%
PRV.9	Regular NSP access	Date injecting equipment provided; key population member type	4[a]	40%
PRV.10	Needles-syringes distributed	Number of needles-syringes provided	5[a]	50%
PRV.11	OAMT coverage	Date OAMT prescribed; key population member type	6[a]	75%
PRV.12	Total person-years on OAMT	Date OAMT initiated; date of loss to follow-up or OAMT stopped	5[a]	63%
PRV.13	OAMT minimum duration	Date OAMT initiated; date of first date maintenance dose received	5[a]	63%
PRV.15	VMMC	VMMC procedure date	10[a]	56%
HIV testing and knowledge of status				
HTS.1	PLHIV know status	HIV status	18	100%
HTS.2	HTS volume and positivity	HIV test date; HIV test result	18	100%
HTS.3	Individuals testing positive for HIV	HIV test date; HIV test result	18	100%
HTS.7	HTS linkage to prevention	HIV test date; HIV test result; elevated risk for HIV acquisition; date PrEP prescribed; date PEP prescribed; date injecting equipment provided; date OAMT initiated; VMMC procedure date; condom provision date	2	11%
HTS.8	HIV retesting coverage	HIV test date; HIV test result; elevated risk for HIV acquisition	10	56%
Vertical transmission				
VER.2	Early infant diagnosis coverage	HIV test date; HIV-exposed infant or child	16	89%
VER.6	Final outcome of PMTCT	Final diagnosis of HIV-exposed infant or HIV-exposed infant or child; HIV test date; HIV test result	16	89%
VER.7	HIV prevalence among women attending ANC	ANC contact date; HIV status; HIV test date; HIV test result	17	94%

Note: All indicators and metadata are described in detail in WHO's Consolidated guidelines for person-centred HIV strategic information [5].
Abbreviations: ANC, antenatal care; HTS, HIV testing services; NSP, needle andsyringe programme; OAMT, opioid-agonist maintenance therapy; PEP, post-exposure prophylaxis; PLHIV, people living with HIV; PrEP, pre-exposure prophylaxis; VMMC, voluntary medical male circumcision.
[a]Analysis restricted to 10 countries with NSP programmes and eight countries with OAMT programmes.

Our findings show that while several countries collect data on key populations, a comprehensive approach including all key populations is lacking. Only 10 countries collected data on all key populations. The National Commitments and Policies Instrument results further underscore the importance of unique identification methods for key population prevention services. The most common method for identifying and removing duplicate health information was a combination of

routinely collected personal identifying information, which is not recommended by WHO for secure unique identification [5]. Rather, a unique identifier for health should not include any personally identifying information. The criminalization and stigmatization of behaviours associated with key populations contribute to barriers in accessing health services and complicate data collection efforts [2]. There can be serious negative consequences if data indicating an individual has engaged in an activity that is stigmatized or criminalized is not kept confidential. People may be less inclined to reveal this information or to engage in services if they fear information about them might be compromised.

The most frequently used unique identifier reported by countries in our analysis was a programme identifier for HIV; 10 used a foundational national identifier. While programme-specific identifiers are useful for monitoring individuals in HIV care and treatment, they may not provide the cross-disease linkage necessary to identify HIV prevention need – for example individuals who have had an STI in the previous year [8–10]. Furthermore, the use of a national identifier rather than a unique identifier for health raises the potential for exposure of sensitive health information in settings unrelated to healthcare where that identifier is used, and may inhibit disclosure of HIV risk factors to healthcare workers. Digital health data systems must foster public trust through transparent governance and be protected by legal frameworks to ensure the confidentiality and security of client information [5, 11–14]. Maintaining the separation of sensitive behavioural data from personally identifying information, even when linking to other clinical datasets, is recommended to protect individual privacy [5].

While data are crucial for granular and timely analyses, the quality and reliability of these data can vary significantly across different settings. Data quality depends on how diligently information is captured by health service providers and health information systems, and how it is cleaned, reviewed and used. As countries continue using individual-level routine facility data, their quality will inevitably improve. Implementing appropriate unique identifiers will help eliminate duplicate patient records and improve data accuracy. Innovations such as artificial intelligence can further aid in data quality checks. However, de-identification protocols, restricted access and transparency in algorithmic processes are needed. Engaging and training data stewards, and regularly evaluating data quality, will be important to ensure that collected information remains accurate, reliable and actionable.

The results from our review are from a few countries, predominantly in sub-Saharan Africa, and, therefore, are not representative of all countries globally. We also did not assess data or their quality in the national health information systems, but rather focused on the building blocks of a robust data system for HIV prevention. However, our results show the types of prevention data commonly collected in high HIV burden countries and identify data collection gaps.

5 | CONCLUSIONS

Strengthening person-centred health information systems is crucial for improving person-centred care and effective programme planning. By addressing the gaps in prevention data availability and ensuring the confidentiality and security of sensitive information, HIV programmes can enhance the offer of prevention interventions and support better programme monitoring and health outcomes.

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COMPETING INTERESTS

No conflicts of interest for any authors have been declared.

AUTHOR CONTRIBUTIONS

SD conceptualized the manuscript and wrote the first draft. BM and LMN contributed to writing and reviewing. DS analysed data and reviewed and edited the manuscript. FA, DA, SPB, SM, BM, TM, LM, PM, LN, LMN, MSN, and IS contributed data for analysis and reviewed and edited the manuscript. RA, MAG, PC, AG, KI, GK, AM, GP, ASA, MT, AV, and DLB reviewed and edited the manuscript.

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DISCLAIMER

The authors alone are responsible for the views expressed in this article, and they do not necessarily represent the views, decisions or policies of the institutions with which they are affiliated.

DATA AVAILABILITY STATEMENT

Global AIDS Monitoring National Commitments and Policies Instrument data is available publicly from https://aidsinfo.unaids.org/. The de-identified data that support the findings of this study are available from the corresponding author upon reasonable request.

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REVIEW

Oral pre-exposure prophylaxis initiation, continuation and adherence among pregnant and postpartum women receiving antenatal and postnatal care: a systematic review

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Abstract

Introduction: In 2023, one-fourth of new HIV acquisitions in children globally resulted from vertical transmission following incident HIV during pregnancy or breastfeeding. Oral pre-exposure prophylaxis (PrEP) with tenofovir disoproxil and emtricitabine is safe and effective in pregnancy and postpartum, with long-acting options emerging. Integrating PrEP into antenatal and postnatal care (ANC/PNC) is a crucial person-centred approach to prevent maternal HIV acquisition and vertical transmission. This review summarizes oral PrEP initiation, continuation and adherence among pregnant and postpartum women receiving ANC/PNC.

Methods: We systematically searched three databases for English-language quantitative studies published between 1 January 2015 and 28 March 2024. Eligible studies focused on pregnant and/or postpartum women accessing PrEP through ANC/PNC, and reported on initiation (receipt of prescription or self-reported use), continuation (persistent use over time) and/or adherence (self-reported and/or objective).

Results: We identified 481 articles; 12 studies from Kenya, Lesotho, Malawi and South Africa met our inclusion criteria. Study heterogeneity (e.g. definitions used, population included, follow-up time) precluded meta-analysis. All studies enrolled pregnant women; three also enrolled postpartum women. Median gestational age at enrolment ranged from 20 to 26 weeks, and follow-up periods from 1 month post-enrolment to 12 months postpartum. Oral PrEP initiation ranged from 14% to 84%. Continuation at 3 months ranged from 22% to 90% and declined postpartum in all studies. Self-reported adherence (daily use) ranged from 11% to 81% in the past 7 or 30 days at 1 month (four studies) and from 54% to 81% at 3 months (two studies). Objectively measured adherence ranged from 34% to 62% for detectable tenofovir or tenofovir diphosphate levels at 1 month (three studies). One Kenyan trial demonstrated that universal versus risk-based offers of oral PrEP resulted in similar PrEP use and HIV incidence. Two-way SMS communication (Kenya) and real-time adherence biofeedback counselling using urine tenofovir testing (South Africa) enhanced PrEP continuation/adherence compared to standard-of-care.

Discussion: Integrating oral PrEP into ANC/PNC showed high initiation among pregnant/postpartum women; however, continuation and adherence were suboptimal.

Conclusions: Oral PrEP integration into ANC/PNC can reach pregnant/postpartum women. Maximizing its impact will require offering long-acting PrEP, person-centred interventions to support adherence/continued use and differentiated delivery responsive to women's needs.

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Keywords: antenatal care; postpartum period; pre-exposure prophylaxis; pregnancy; review; women

Additional information may be found under the Supporting Information tab of this article.

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1 | INTRODUCTION

In 2023, women and girls constituted 44% of all individuals who newly acquired HIV worldwide [1]. Women's risk of acquiring HIV is elevated during pregnancy and postpartum [2, 3]. This elevated risk is attributable to a combination of biological, behavioural and social factors, including changes in the vaginal microbiome [4]. Acquiring HIV during pregnancy

or postpartum not only poses a threat to maternal health, but also increases the risk of vertical HIV transmission [4]. In 2023, one in four new HIV acquisitions in children globally resulted from mothers acquiring HIV during pregnancy or breastfeeding [5]. HIV prevention among pregnant and postpartum women is a global health priority and a key pillar to ending HIV-related deaths among children by 2030 [6].

Oral pre-exposure prophylaxis (PrEP) with tenofovir disoproxil and emtricitabine is an efficacious biomedical HIV prevention tool. In settings with high HIV burden, the World Health Organization (WHO) recommends PrEP for pregnant and postpartum women who are HIV negative [4]. Although PrEP rollout is expanding globally, with 7.5 million individuals having initiated PrEP by the second quarter of 2024, initiation among pregnant or postpartum women remains limited [7–9]. Evidence from a systematic review confirmed that oral PrEP is safe for use during pregnancy and postpartum, making it crucial to expand use among pregnant and postpartum women [10].

The integration of provider-initiated HIV testing and counselling into antenatal care (ANC) increased the diagnosis of pregnant women living with HIV and improved access to comprehensive care [11]. This serves as a valuable model for the integration of PrEP services in antenatal and postnatal care (ANC/PNC), an approach recommended by WHO [4, 12]. Given that 88% of pregnant adolescent girls and women aged 15–49 years worldwide attended at least one ANC visit in 2023 [13], and 71% of adolescent girls and women received routine PNC within 2 days after birth [14], integrating and delivering oral PrEP as part of routine ANC/PNC is a promising approach to reach pregnant and postpartum women [13, 11]. Evidence on how to operationalize integration remains sparse and mainly stems from a few African countries, primarily Kenya and South Africa [15]. This available evidence suggests that daily PrEP use by pregnant and postpartum women presents unique challenges (e.g. concerns of impact on infant development), with substantial early discontinuation being reported [16]. Factors influencing PrEP use include side effects, perceived risk of HIV acquisition, limited partner and family support, or negative endorsement, or limited knowledge among providers [16–18], with structural barriers related to logistics, transport and affordability to take PrEP [15, 19–21].

To enhance understanding of oral PrEP use among pregnant and postpartum women globally, this systematic review aims to provide a comprehensive overview of oral PrEP initiation, continuation and adherence among pregnant and postpartum women receiving ANC/PNC. These findings aim to inform strategies for delivering oral PrEP through person-centred and differentiated service delivery approaches. These approaches prioritize the unique needs and preferences of women during pregnancy and postpartum and facilitate access by integrating PrEP services with essential maternal healthcare services that women already attend. These insights on oral PrEP use will inform how emerging long-acting PrEP options, such as the dapivirine ring [22], injectable lenacapavir [23] and cabotegravir [24, 25]—supported by evidence of safety and efficacy in pregnant and postpartum women—may complement oral PrEP by offering greater choice and longer efficacy of product compared to daily use.

2 | METHODS

This systematic review addressed the research question: "What are the initiation rates of oral PrEP, the continuity of its use, and adherence levels among pregnant and postpartum women when administered through antenatal and postnatal care?", and was conducted in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines [26]. The study was registered on PROSPERO (ID: 2024 CRD42024513442) [27].

2.1 | Search strategy and selection criteria

We searched PubMed, Web of Science Core Collection and Global Health covering the period 1 January 2015 (following WHO recommendations on oral PrEP) to 28 March 2024. Database searches were performed on 28 March 2024. We used the following core search terms across all databases: (hiv OR "human immunodeficiency virus") AND ("postpartum period" OR postpartum OR pregnan* OR perinatal OR breastfeed* OR lactati*) AND (wom?n OR "adolescent girl" OR "adolescent girls" OR "young women" OR "young woman" OR female) AND ("pre-exposure prophylaxis" OR "preexposure prophylaxis" OR "prep"). Appendix S1 provides details of the search strategy for each database. While we had no geographical restrictions, we restricted our selection to English articles. Studies were eligible if they were published in peer-reviewed journals, used a quantitative study design (e.g. observational and (quasi)experimental studies), focused on pregnant and/or postpartum women accessing PrEP through ANC/PNC and reported on one or more of the specified outcomes: initiation of PrEP (e.g. prescription receipt at the first or any ANC/PNC visit or self-reported use at a follow-up visit after accepting PrEP at a prior ANC/PNC visit), continuation of PrEP (persistent use at each visit, e.g. self-reporting continued use, prescription receipt or attendance follow-up visit where PrEP was dispensed) and adherence to PrEP (e.g. self-reported or objectively measured through blood or urine samples in the previous 7 or 30 days). Studies exploring willingness to use PrEP or assessing use outside of clinics offering ANC/PNC, including maternal and child health clinics, were excluded. Additionally, we conducted a secondary search for references in all eligible studies. Conference abstracts were not considered as they often lack sufficient methodological detail around outcome definitions and study context that were needed for our assessments of risk of bias and data synthesis.

2.2 | Study selection

All identified references were uploaded to Rayyan [28]. We extracted the DOI number, year of publication, authors, title and abstract for each reference. Initially, one reviewer (AR) conducted a title-and-abstract screening for all articles identified through the search strategy to de-duplicate articles. Subsequently, one reviewer (AR) independently evaluated the titles and abstracts to determine if they met the eligibility criteria. To assess the reliability of the screening process, a second reviewer (ZE) screened the titles and abstracts of a random 10% of all articles, resulting in a 94% agreement. Discrepancies between the reviewers were resolved through

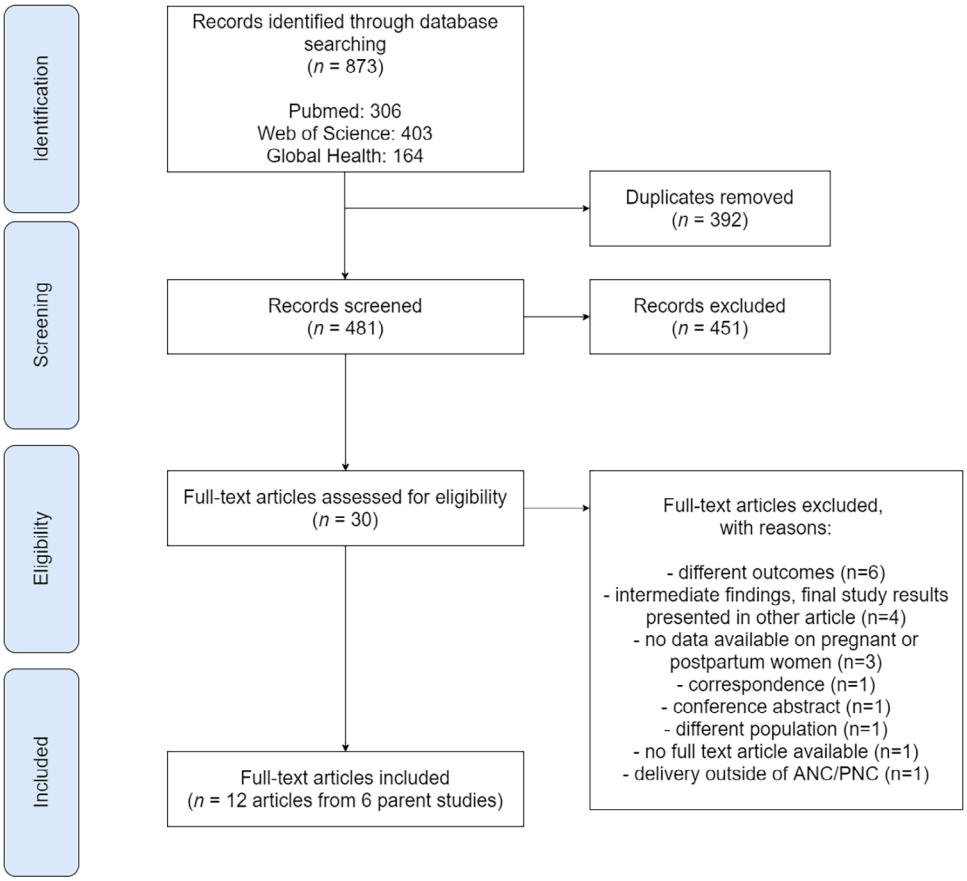

Figure 1. Prisma flowchart for article selection. Abbreviations: ANC/PNC, antenatal and postnatal care.

consensus or by consulting a third reviewer (DJD/BH). Articles that met the eligibility criteria were then obtained in full-text and reviewed by the same two reviewers (AR/ZE), and conflicts were resolved through consensus. The included articles were presented and discussed within the research team for final approval. Reasons for exclusion were recorded accordingly (Figure 1).

2.3 | Data extraction and management

We used a standardized data extraction form to extract study design attributes and methodologies along with baseline characteristics (e.g. study population, sample size, median gestational age) and essential outcomes of interest (i.e. PrEP initiation, continuation and adherence). Definitions used for each outcome of interest were also extracted. The heterogeneity in study design, objectives, populations included, outcome definitions and follow-up periods among the included articles precluded a meta-analysis.

2.4 | Risk of bias assessment

We used the modified Newcastle Ottawa scale and Cochrane Risk of Bias 2 (ROB2) tools to assess the risk of bias of observational and experimental studies, respectively. The Newcastle Ottawa scale evaluates biases such as representativeness of the cohort, ascertainment of exposure and assessment of outcome. The ROB2 tool examines randomization processes, deviations from intended interventions and measurement of outcomes. This assessment helped identify factors in study design, conduct or reporting that may skew results, affecting their validity. Two reviewers (AR and ZE) independently evaluated the risk of bias in each study, and any discrepancies were resolved through mutual agreement or by consulting a third reviewer (BH/DJD). Studies were not excluded based on their risk of bias score.

3 | RESULTS

3.1 | Description of included studies

The search yielded 481 unique records, of which 30 were reviewed as full text and 12 met all eligibility criteria (Figure 1). The secondary search of references did not identify any additional records.

The 12 records report results from six parent studies conducted in four countries, that is Kenya (n = 5) [17, 18, 29–31], South Africa (n = 5) [16, 32–35], Lesotho (n = 1) [36] and Malawi (n = 1) [37] (Table 1). Six of the studies were cohort studies [16–18, 30, 33, 34], four were (cluster) randomized controlled trials (RCTs) [29, 32, 35, 37], one was a pre-/post-evaluation [31] and one was a retrospective chart

Table 1. Characteristics of articles eligible for inclusion (*N*=12)

Study, first author, publication year	Country and study period	Study design	Study objectives	Study population	Type of clinic	Sample size	Median gestational age	Follow-up time
Chi, 2024 [37]	Malawi, June 2020–November 2020	Randomized pilot trial	Evaluate the effectiveness of a combination package (patient-centred counselling and the option of a participant-selected adherence supporter) (intervention) to enhance antenatal and postnatal PrEP use versus SOC	Pregnant women, aged ≥ 18 years	Public ANC, Lilongwe	200; 100 intervention, 100 control	26 weeks (IQR 19–33)	6 months post-enrolment
Masenyetse, 2023 [36]	Lesotho, January 2019–May 2022	Retrospective chart review	Characterize the PrEP cascade and use patterns among pregnant and postpartum women	Pregnant and postpartum women[a] screened for PrEP and/or enrolled in PrEP programmes (January 2019–June 2021)	26 government/Christian Health Association-run healthcare facilities, Lesotho	389	NR	NA
PrEP in Pregnant and Postpartum women (PrEP-PP) in South Africa								
Joseph Davey, 2022 [16]	August 2019–October 2021	Prospective cohort	Evaluate PrEP initiation and continuation, and correlates of these outcomes	Pregnant adolescent girls and women, aged ≥ 16 years	Public health clinic, Cape Town	1201	21 weeks (IQR 15–31)	12 months postpartum
Davey, 2021 [32]	August 2020–April 2021	Randomized controlled pilot trial	Test impact of a combined intervention (HIVST for PrEP users and male partners, and real-time adherence biofeedback) (intervention) on PrEP adherence versus SOC	Postpartum cisgender adolescent girls and women (4–24 weeks postpartum), aged ≥ 16 years, initiating PrEP		106; 53 intervention; 53 control	NA	1 month post-enrolment
Joseph Davey, 2022 [33]	August 2019–October 2021	Prospective cohort	Quantify PrEP use by measuring TFV-DP in DBS in a cohort study	Pregnant adolescent girls and women, aged ≥ 16 years, reported PrEP use in the last 30 days		382	54% (206/382) ≥ 20 weeks	12 months postpartum

(*Continued*)

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Table 1. (Continued)

Study, first author, publication year	Country and study period	Study design	Study objectives	Study population	Type of clinic	Sample size	Median gestational age	Follow-up time
Khadka, 2023 [34]	August 2019–October 2021	Prospective cohort	Evaluate PrEP initiation, continuation and persistence	Pregnant and postpartum AGYW, aged 16–24 years	486	24 weeks (IQR 17–34)	12 months postpartum	
Sexually Transmitted Infections and PrEP in Pregnancy Study (STIPPS)								
De Voux, 2023 [35]	South Africa, November 2021–May 2022	Randomized controlled trial	Evaluate the effect of STI POC testing (intervention) on PrEP initiation, early persistence and adherence versus SOC	Pregnant women ≤ 34 weeks, aged ≥ 18 years	Public antenatal clinic, Cape Town	268; 133 intervention; 135 control	22 weeks (IQR 18–26)	1 month post-enrolment
PrEP Implementation for Mothers in Antenatal care (PrIMA) in Kenya								
Kinuthia, 2023 [29]	January 2018–July 2021	Cluster randomized trial	Compare universal (intervention) and targeted (risk-guided) approaches to PrEP delivery	Pregnant adolescent girls and women, aged ≥ 15 years	20 public ANCs, Siaya and Homa Bay counties	4447; 2250 intervention; 2197 control	24 weeks (IQR 20–30)	9 months postpartum
Pintye, 2023 [18]	January 2018–July 2021	Prospective cohort	Quantify and identify cofactors of PrEP initiation, persistence and adherence			2949		
PrEP Implementation for Young women and Adolescents (PriYA) in Kenya								
Kinuthia, 2020 [17]	November 2017–December 2018	Prospective cohort	Provide real-world evidence on delivering PrEP in maternal and child health clinics	Adolescent girls and women, aged >15 years, receiving antenatal care or child welfare services	16 public, faith-based and private sector maternal and child health clinics, Kisumu County	9376; 4912 pregnant; 4464 postpartum	26 weeks (IQR 20–32)	6 months post-initiation
Pintye, 2020 [30]	November 2017–December 2018	Prospective cohort	Evaluate detection of TFV-DP among women who initiated PrEP			233 DBS samples from 201 unique women[b]	NR	NA
Pintye, 2020 [31]	February 2018–October 2018	Pre-/post-evaluation	Assess implementation of a two-way SMS intervention on PrEP continuation and adherence			190[c]	25 weeks (IQR 20–28)	1 month post-enrolment

Abbreviations: AGYW, adolescent girls and young women; ANC, antenatal care; DBS, dried blood spot; HIVST, HIV self-testing; IQR, interquartile range; NA, not applicable; NR, not reported; PNC, postnatal care; POC, point-of-care; PrEP, pre-exposure prophylaxis; SOC, standard of care; SMS, short message service; STI, sexually transmitted infection; TFV-DP, tenofovir-diphosphate.

[a]Those pregnant and postpartum women with a documented entry point through antenatal or postnatal care service points.

[b]Attending first PrEP follow-up visit at a median of 5 weeks of PrEP initiation.

[c]Enrolled in intervention.

review [36]. All studies were conducted in public health clinics, three also recruited through private-sector maternal and child health clinics in Kenya [17, 30, 31]. Sample sizes ranged from 106 to 9376 participants, with follow-up periods varying from 1 month post-enrolment to 12 months postpartum. Refill durations for PrEP ranged from 1 to 3 months of supply. All studies enrolled pregnant women; three studies also enrolled postpartum women [17, 30–32, 36]. Median gestational age at enrolment ranged from 20 to 26 weeks. The study objectives included: describing PrEP initiation (n = 7), continuation (n = 10) and adherence (either self-reported or objective, n = 10), as well as evaluating the effect of an intervention on one or more PrEP use outcomes (n = 5). Among the five intervention studies, two focused on enhancing PrEP continuation and adherence; a Malawian pilot trial evaluating a combination package, and a Kenyan pre-/post study investigating a two-way SMS intervention [31, 37]. Two studies aimed to improve all three outcomes; a South African RCT assessing sexually transmitted infection (STI) point-of-care testing (i.e. *Chlamydia trachomatis*, *Neisseria gonorhoeae* and *Trichomonas vaginalis*), and a Kenyan cluster RCT comparing universal versus risk-based PrEP delivery [29, 35]. A South African RCT implemented partner HIV self-testing and real-time biofeedback to enhance adherence [32].

3.2 | Risk of bias

The Newcastle Ottawa scale identified potential bias in three studies due to unaccounted loss-to-follow-up (Table 2). The ROB-2 assessment revealed some bias in all (quasi)experimental studies, mainly due to a lack of blinding and uncertainty regarding the presence of a statistical analysis plan (Table 2). Notably, the inability to blind participants and providers was inherent to the nature of the study interventions, such as the use of an SMS communication platform. The Kenyan PrEP implementation for young women and adolescents (PriYA) study had a high risk of bias due to its pre-post design and missing outcome data, as 60% (99/166) of women in the control arm and 46% (87/190) in the intervention arm were lost to follow-up at 1 month [31]. Concerns were also raised about the absence of an objective adherence measurement, also noted in the Kenyan PrEP Implementation for Mothers in Antenatal care (PrIMA) study [29, 31].

3.3 | PrEP initiation

Seven studies reported on PrEP initiation, defined as the percentage of women either accepting a PrEP prescription at the first or any ANC/PNC visit or self-reporting PrEP use at a follow-up visit after accepting PrEP at a prior ANC/PNC visit, among those eligible for PrEP (Table 3).

In the observational studies (n = 5), initiation ranged from 14% to 84% (Table 3). The initiation of 84% was reported in the PrEP-PP cohort study in South Africa, where 1014 out of 1201 pregnant adolescent girls and women aged ≥ 16 accepted a PrEP prescription at their first ANC visit [16]. PrEP initiation was higher among those diagnosed and treated for an STI (93%, 153/165) compared to those not diagnosed with an STI (84%, 707/845; $p < 0.001$) [16]. A sub-analysis of the PrEP-PP study found a similar initiation of 83% (403/486) among pregnant adolescent girls and young women (AGYW) aged 16–24 [34].

In contrast, the PriMA cohort sub-study in Kenya reported an initiation (defined as the participant-reported swallowing of PrEP pills following acceptance at a prior visit) of 14% (405/2949) among adolescent girls and women aged ≥ 15 in their second trimester [18]. Women were more likely to initiate PrEP if they had a syphilis diagnosis during pregnancy (adjusted RR [aRR]: 1.84, 95% CI 1.24–2.75, $p = 0.003$) or a partner known to be living with HIV (aRR: 6.37, 95% CI 4.18–0.69, $p < 0.001$) [18]. The PriYA cohort study in Kenya reported that 22% (2030/9376) of pregnant or postpartum adolescent girls and women aged > 15 receiving ANC or child welfare services initiated PrEP, though specific definitions of initiation were not provided [17]. Uptake was highest among women whose partners were living with HIV (79%, 153/193) (adjusted prevalence ratio: 6.96, 95% CI 5.46–8.89, $p < 0.001$) compared to women with partners of unknown HIV status (37%, 1178/3165) (adjusted prevalence ratio: 3.08, 95% CI 2.50–3.81, $p < 0.001$), and partners not living with HIV (12%, 696/5997) [17]. Women who were diagnosed or treated for an STI were also more likely to initiate PrEP (adjusted prevalence ratio: 1.57, 95% CI 1.20–2.06, $p < 0.001$).

In the experimental studies (n = 2), PrEP initiation ranged from 15% to 67% (Table 3). In the PrIMA trial in Kenya, 20 public maternal and child health clinics were randomized to universal (i.e. all women received PrEP counselling) or targeted (i.e. HIV risk-guided) PrEP counselling/offer [29]. Initiation in the universal arm was 18% (397/2250) compared to 15% (323/2197) in the targeted arm (aRR: 0.68, 95% CI 0.46–1.02, $p = 0.062$) [29]. There was no significant difference in appropriate PrEP use decision-making, meaning, PrEP initiation among those at high risk of acquiring HIV and no PrEP initiation for those not at risk, between the universal (68%) versus targeted arm (59%) (aRR = 1.03, 95% CI = 0.96–1.10, $p = 0.37$) [29]. In the RCT of STI screening and PrEP in pregnancy study (STIPPS) in South Africa, pregnant women were randomized to either point-of-care STI screening (i.e. *Chlamydia trachomatis*, *Neisseria gonorrhoea* and *Trichomonas vaginalis* using Cepheid GeneXpert) versus syndromic management [35]. There was no difference in PrEP initiation in the point-of-care arm (67%; 89/133) compared to syndromic management (62% [84/135], $p = 0.42$); however, an STI diagnosis (i.e. positive STI test or reporting STI symptoms) at initiation was associated with higher PrEP initiation (aRR = 1.28, 95% CI = 1.08–1.52, $p = 0.00$), when controlling for study arm, maternal and gestational age [35].

3.4 | Continuation

Ten studies reported on PrEP continuation or persistence, with the definitions used for each outcome detailed in Table 3. In the South African PrEP-PP study, 66% (629/953) of pregnant women who initiated PrEP received a prescription at 1 month and 58% (493/844) at 3 months follow-up, indicating continued use at 3 months post-enrolment [16]. Slightly lower persistence was reported in the sub-analysis among pregnant and postpartum AGYW (1-month follow-up: 63% [253/403], 3 months: 54% [212/395]) [34].

Table 2. Risk of bias assessment

Observational studies						
Newcastle-Ottawa Scale	**Representativeness of the cohort**	**Ascertainment of exposure**	**Assessment of outcome**	**Adequate follow-up duration**	**Loss-to follow-up accounted for**	**Total**
PrEP in Pregnant and Postpartum women (PrEP-PP) in South Africa						
Joseph Davey et al., 2022 [16]	1	1	1	1	0	4
Joseph Davey et al., 2022 [33]	1	1	1	1	1	5
Khadka et al., 2023 [34]	1	1	1	1	1	4
PrEP Implementation for Mothers in Antenatal care (PrIMA) in Kenya						
Pintye et al., 2023 [18]	1	1	1	1	1	5
PrEP Implementation for Young women and Adolescents (PriYA) in Kenya						
Kinuthia et al., 2020 [17]	1	1	1	1	0	4
Pintye et al., 2020 [30]	1	1	1	1	1	5
Masenyetse et al., Lesotho, 2023 [36]	1	1	1	1	0	4

(Quasi) experimental studies						
Risk of Bias 2 score domains	**Randomization process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported result**	**Overall**
Chi et al., Malawi, 2024 [37]	Low risk	Some concerns	Low risk	Low risk	Some concerns	Some concerns
PrEP in Pregnant and Postpartum women (PrEP-PP) in South Africa (sub-study on HIVST + urine TFV biofeedback)						
Davey et al., 2021 [32]	Low risk	Some concerns	Low risk	Low risk	Some concerns	Some concerns
Sexually Transmitted Infections and PrEP in Pregnancy Study (STIPPS) in South Africa						
De Voux et al., 2023 [35]	Low risk	Some concerns	Low risk	Low risk	Some concerns	Some concerns
PrEP Implementation for Mothers in Antenatal care (PrIMA) in Kenya						
Kinuthia et al., 2023 [29]	Low risk	Some concerns	Low risk	Some concerns	Some concerns	Some concerns
PrEP Implementation for Young women and Adolescents (PriYA) in Kenya						
Pintye et al., 2020 [31]	High risk	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns

Note: The Modified Newcastle-Ottawa scale assigns stars based on the quality of each domain, with a maximum score of 5 indicating a well-designed study with minimal or no bias, and a score of 0 representing a flawed study with significant bias across all domains.
Abbreviations: HIVST, HIV self-testing; TFV, tenofovir.

In the Kenyan PrIMA study, which defined continuation based on self-reported PrEP use, 58% (212/363) of initiators continued PrEP use at 9 months postpartum, excluding 42 women who had restarted PrEP after stopping [18]. The lowest continuation was observed in the Kenyan PriYA study, which declined from 39% at 1 month to 12% at 6 months [17]. Data from Lesotho demonstrated that 40% (157/389) of women had at least two PrEP follow-up visits after initiating PrEP, while an equal proportion (40%, 156/389) had no follow-up visits [36].

In a pilot RCT in Malawi, which aimed to evaluate the effect of a combination intervention package, including integrated Next Step Counselling and an adherence supporter option on retention and adherence compared to standard care [37], continuation was 90% (90/100) versus 89% (89/100), respectively, at 3 months (adjusted probability difference [aPD]: 5.1%, 95% CI −3.7%, 14.0%) and 88% versus 83%, respectively, at 6 months (aPD: 7.4%, 95% CI −2.7%, 17.4%) [37]. A pilot RCT in South Africa, embedded in the PrEP-PP study, offered postpartum women adherence biofeedback counselling after point-of-care urine tenofovir testing and HIV self-testing for them and their partners [32]. The control group received standard-of-care routine counselling without biofeedback and facility-based HIV tests [32]. At 1 month post-enrolment, 91% (48/53) of women in the intervention arm and 98% (52/53) in the control arm returned for PrEP

Table 3. Studies reporting on PrEP initiation and continuation

		Initiation		Continuation post-enrolment			
Study reference	**Study population**	**Definition[a]**	**% (*n*/*N*)**	**Definition**	**1 month % (*n*/*N*)**	**3 months % (*n*/*N*)**	**6 months (unless otherwise reported) % (*n*/*N*)**
Observational studies							
PrEP in Pregnant and Postpartum women (PrEP-PP) in South Africa							
Joseph Davey et al., 2022 [16]	Pregnant adolescent girls and women, aged ≥ 16 years	Accepting PrEP prescription at first ANC visit (baseline)	84% (1014/1201)	Receiving a PrEP prescription at both baseline and the 3-month follow-up visit	66% (629/953)[b]	58% (493/844)[c]	NR
Khadka et al., 2023 [34]	Pregnant and postpartum AGYW, aged 16–24 years		83% (403/486)	Receiving a PrEP prescription at each study visit after the baseline visit among those who initiated PrEP at baseline	63% (253/403)	54% (212/395)	39% (149/380)
PrEP Implementation for Mothers in Antenatal care (PrIMA)							
Pintye et al., Kenya, 2023 [18]	Pregnant adolescent girls and women aged ≥ 15 years	Participant reports swallowing PrEP pills at a follow-up visit	2949 were offered PrEP, 14% (405/2949) initiated	Participant reports continuing with PrEP medication	NR	NR	58% (212/363)[d, e]
PrEP Implementation for Young women and Adolescents (PriYA)							
Kinuthia et al., Kenya, 2020 [17]	Adolescent girls and women, aged >15 years, receiving antenatal care or child welfare services	NR	9376 women were offered PrEP, 22% (2030/9376) initiated	NR	39% (786/2030)	22% (441/2030)	12% (189/1618)

(*Continued*)

Table 3. (Continued)

		Initiation		Continuation post-enrolment			
Study reference	**Study population**	**Definition[a]**	**% (*n*/*N*)**	**Definition**	**1 month % (*n*/*N*)**	**3 months % (*n*/*N*)**	**6 months (unless otherwise reported) % (*n*/*N*)**
Masenyetse et al., Lesotho, 2023 [36]	Pregnant and postpartum women screened for PrEP and/or enrolled in PrEP programmes (January 2019–June 2021)	NA[f]	389 pregnant or postpartum women identified from ANC/PNC service points initiating on PrEP	Participants having any documented PrEP FU visit after PrEP initiation	40% (156/389) no recorded FU visits; 20% (76/389) has one recorded PrEP FU visit; 40% (157/389) had at least two documented PrEP FU visits	NR	NR
(Quasi) experimental studies							
Chi et al., Malawi, 2024 [37]	Pregnant women, aged ≥ 18 years	NA	I: 100 C: 100	Participants presenting for study visits were classified as retained	I: 94% (94/100) C: 92% (92/100)	I: 90% (90/100) C: 89% (89/100)	I: 88% (88/100) C: 83% (83/100)
PrEP in Pregnant and Postpartum women (PrEP-PP) (sub-study on HIVST + urine TFV biofeedback)							
Davey et al., South Africa, 2021 [32]	Postpartum cisgender adolescent girls and women, aged ≥ 16 years, initiated PrEP during recent pregnancy	NA	I: 53 C: 53	NA	I: 91% (48/53) C: 98% (52/53)	NR	NR
Sexually Transmitted Infections and PrEP in Pregnancy Study (STIPPS)							
De Voux et al., South Africa, 2023 [35]	Pregnant women ≤ 34 weeks, aged ≥ 18 years	Number and proportion of participants who initiated PrEP at baseline	I: 67% (89/133) C: 62% (84/135)	Proportion of participants who initiated PrEP and returned to the clinic to refill their PrEP prescription	I: 79% (70/133) C: 80% (67/135)	NR	NR

(*Continued*)

Table 3. (Continued)

		Initiation		Continuation post-enrolment			
Study reference	**Study population**	**Definition[a]**	**% (*n*/*N*)**	**Definition**	**1 month % (*n*/*N*)**	**3 months % (*n*/*N*)**	**6 months (unless otherwise reported) % (*n*/*N*)**
PrEP Implementation for Mothers in Antenatal care (PrIMA)							
Kinuthia et al., Kenya, 2023 [29]	Pregnant adolescent girls and women, aged ≥ 15 years	PrEP acceptance: participant accepted PrEP at any visit; PrEP confirmation visit: participant reports swallowing PrEP pills at visits after PrEP acceptance with the PrEP initiation date defined as the median date between the PrEP acceptance and PrEP confirmation visits.	I: 64% (2250/3537) enrolled; 20% (441/2250) accepted PrEP; 18% (397/2250) initiated PrEP (universal) C: 45% (2197/4890) enrolled, 18% (387/2197) accepted, 15% (323/2197) initiated (targeted)	PrEP duration: time between the PrEP initiation date and discontinuation or study end.	NR	NR	I: Median: 8.6 (IQR 3.2–11.4) months in FU[g] C: Median: 9.0 (IQR 3.8–11.9) months in FU[g]
PrEP Implementation for Young women and Adolescents (PriYA)							
Pintye et al., Kenya, 2020 [31]	Adolescent girls and women, aged >15 years	NA	I: 190 C: 166	A confirmed dispensation of a PrEP refill at an attended follow-up visit	I: 43% (81/190) C: 22% (37/166)	NR	NR

Abbreviations: AGYW, adolescent girls and young women; ANC, antenatal care; FU, follow-up; HIVST, HIV self-testing; NA, not applicable; NR, not reported; PNC, postnatal care; PrEP, pre-exposure prophylaxis; TFV, tenofovir.

[a]Among participants eligible for PrEP.

[b]*N* = 61 women were censored at 1 month (e.g. due to pregnancy loss).

[c]At the timing of interim analysis, 844 women were eligible for their 3-month PrEP refill.

[d]*N* = 42 women restarted PrEP after stopping and were excluded from continuation analysis.

[e]Follow-up period was defined as 9 months postpartum.

[f]No records of pregnant or postpartum women being screened and not initiating PrEP.

[g]PrEP duration in months, to the first reported discontinuation of PrEP or study end.

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http://onlinelibrary.wiley.com/doi/10.1002/jia2.70035/full | https://doi.org/10.1002/jia2.70035

[32]. The PrIMA cluster randomized trial in Kenya reported no differences between the intervention and control arms in terms of duration of PrEP use. They found that the median duration of PrEP use did not differ between arms (9 months in the targeted arm and 8.6 months in the universal arm) [29].

A pre-/post-evaluation sub-study embedded in the Kenyan PriYA study offered a two-way SMS communication platform to pregnant and postpartum women [31]. Compared to women who initiated PrEP the month before implementation, women who received SMS reminders were more likely to return for their first PrEP follow-up visit (40% [67/166] vs. 53% [101/190], aRR: 1.26, 95% CI 1.06–1.50, $p = 0.008$) and more likely to continue with PrEP (22%, 37/166 vs. 43%, 81/190, aRR: 1.75, 95% CI 1.21–2.55, $p = 0.003$) [31]. In the STIPPS RCT in South Africa, 79% (70/133) of women in the intervention arm (i.e. point-of-care STI testing) and 80% (67/135) in the control arm (i.e. syndromic STI management) returned at 1-month visit and requested a PrEP prescription ($p = 0.49$) [35].

3.5 | Adherence

Ten studies—five observational, four experimental and one quasi-experimental—reported on PrEP adherence; three measured self-reported adherence only [16, 29, 31] defined as the number of missed doses or daily use in the past 30 days (Table 4). Three studies measured adherence objectively [30, 34, 37] through tenofovir-diphosphate (TFV-DP) concentrations in dried blood spots (DBS), tenofovir plasma concentrations from women who reported PrEP use in the past 30 days or through tenofovir detection in urine.

In four studies that reported both measures, self-reported PrEP use was higher than objective measures [18, 32, 33, 35]. In the South African PrEP-PP study, among a subset of women returning for follow-up and reporting PrEP use in the past 30 days, 81% (148/183) of pregnant women and 71% (97/136) of postpartum women reported daily PrEP use at 3 months [33]. TFV-DP levels, corresponding to seven doses/week, were identified among 7% (14/183) of pregnant and 2% (3/136) of postpartum women [33]. At 6 months, self-reported adherence was 79% (46/58) among pregnant and 76% (89/117) among postpartum women; objective adherence (TFV-DP levels corresponding to ≥ 2 doses/week) was 29% (18/62) and 22% (25/113), respectively [33].

In the South African pilot RCT among postpartum women, 62% (33/53) of women in the intervention group (i.e. HIV biofeedback counselling after point-of-care tenofovir test and HIV self-testing for them and their partners) had tenofovir in their urine at 1 month post-enrolment compared to 34% (18/53) in the standard-of-care arm (risk ratio [RR] = 1.83, 95% CI = 1.19–2.82, $p = 0.001$) [32]. Discrepant results between self-reported adherence and urine tenofovir tests were significantly lower in the intervention compared to the control arm (RR = 0.33; 95% CI 0.17–0.67, $p = 0.03$) [32].

The Kenyan PrIMA study found that 54% (114/212) of women reported no missed PrEP doses at 9 months postpartum. Among DBS collected at randomly selected visits where participants persisted with PrEP, 9% (38/427) had TFV-DP levels reflecting daily use. Quantifiable TFV-DP was twice as likely in pregnancy than postpartum (53% vs. 27%, aRR = 1.90; 95% CI = 1.40–2.57; $p < 0.001$) [18]. In the South African STIPPS study, 49% (44/89) of women in the point-of-care STI testing arm and 45% (38/84) in the syndromic management arm had detectable TFV-DP in DBS at 1 month ($p = 0.67$) [35]. Self-reported daily use in the past 7 days was reported by 11% (10/89) and 12% (10/84) of women, respectively ($p = 0.69$); no women had TFV-DP levels equivalent to seven doses in the past week.

In the South African PrEP-PP study, 46% (387/844) of pregnant women reported missing ≥ 1 dose in the last 30 days at 3 months post-enrolment [16]. In the Kenyan PrIMA cluster randomized trial, 53% (206/2250) of women self-reported PrEP use in the past 30 days at first study visit after accepting PrEP compared to 63% (200/2197) in the targeted arm (aRR: 1.13, 95% CI 0.91–1.41) [29]. In the Kenyan pre-/post-evaluation study, 73% (74/101) of women who returned for a follow-up visit in the SMS intervention arm self-reported PrEP adherence (i.e. < 1 missed pill/week) compared to 55% (37/67) in the control arm (aRR: 1.35; 95% CI 1.28–1.41; $p < 0.001$) [31].

In the Kenyan PriYA study, 62% (125/201) of DBS samples collected at a first follow-up visit scheduled 30 days post-PrEP initiation among participants who self-reported having used PrEP in the last 14 days had quantifiable levels of TFV-DP. Detectable TFV-DP was more likely among postpartum women compared to pregnant women (66% [100/152] vs. 51% [25/49], RR: 1.29; $p = 0.055$) [30]. In the Malawian RCT, adherence consistent with 4–7 doses/week among intervention and control groups was low at 3 (31% vs. 33%, respectively) and 6 months (25% vs. 32%, respectively), with no significant differences observed between groups at 3 (aPD: −1.8%, 95% CI −16.2%, 12.7%) or 6 months (aPD: −5.5%, 95% CI −18.0%, 6.9%) [37]. In the PrEP-PP sub-study among pregnant AGYW, 49% (85/175) had detectable TFV-DP at 3 months, dropping to 20% (21/107) at 6 months [34].

4 | DISCUSSION

This systematic review is the first to comprehensively describe PrEP use—including initiation, continuation and adherence—among pregnant and postpartum women receiving ANC and/or PNC services. The integration of PrEP into these services demonstrated varying levels of PrEP initiation (from 14% to 84%). PrEP initiation was higher among women at increased risk of HIV acquisition, such as those diagnosed with an STI or with partners living with HIV. However, PrEP continuation and adherence declined rapidly in observational studies, especially during the postpartum period. While self-reported adherence was generally high, objective adherence measurements revealed inadequate levels of adherence to effectively prevent HIV acquisition. Two-way SMS communication and real-time adherence biofeedback counselling using urine tenofovir testing enhanced PrEP continuation and adherence. These findings highlight that effective, sustained PrEP use among pregnant and postpartum women in ANC/PNC is suboptimal. Despite these challenges, the integration of PrEP into ANC/PNC services represents a promising, person-centred approach to HIV prevention, providing HIV prevention support to pregnant and postpartum

Table 4. Studies reporting on self-reported and/or objective PrEP adherence

		Definition		Adherence post-enrolment (unless otherwise reported)					
				1 month		3 months		≥ 6 months	
Study reference	Study population	Self-reported	Objective	Self-reported	Objective	Self-reported	Objective	Self-reported	Objective
Observational studies									
PrEP in Pregnant and Postpartum women (PrEP-PP) in South Africa									
Joseph Davey et al., 2022 [16]	Pregnant adolescent girls and women, aged ≥ 16 years	Missed daily doses in the past month	NA	NR	NR	46% (387/844) missed ≥ 1 daily doses	NR	NR	NR
Joseph Davey et al., 2022 [33]	Pregnant adolescent girls and women, aged ≥ 16 years, reported PrEP use in the last 30 days	Self-reported PrEP use in the last 30 days before study visit	TFV-DP in DBS in women who reported taking PrEP in the last 30 days prior to the visit. Lower limit of quantification for TFV-DP: 16.6 fmol/3-mm punch. Separate thresholds for pregnant versus postpartum women	NR	NR	**pregnant women**: 81% (148/183) and **postpartum women**: 71% (97/136) reported daily use 63 women did not report PrEP use in the past 30 days	**pregnant women**: 67% (122/183): any TFV-DP detected, of those 37% (68/183) TFV-DP ≥ 2 doses/week, 7% (14/183) TFV-DP 7 doses/week **postpartum women**: 60% (82/136): any TFV-DP detected, of those 31% (42/136) TFV-DP ≥ 2 doses/week, 2% (3/136) TFV-DP 7 doses/week	**pregnant women**: 79% (46/58) and **postpartum women**: 76% (89/117) reported daily use	**pregnant women**: 29% (17/58) and **postpartum women**: 22% (26/117) TFV-DP ≥ 2 doses/week

(*Continued*)

Table 4. (Continued)

		Definition		Adherence post-enrolment (unless otherwise reported)					
				1 month		3 months		≥ 6 months	
Study reference	Study population	Self-reported	Objective	Self-reported	Objective	Self-reported	Objective	Self-reported	Objective
Khadka et al., 2023 [34]	Pregnant and postpartum AGYW, aged 16–24 years	NA	TFV-DP in DBS in women who reported taking PrEP in the last 30 days prior to the visit. Separate thresholds for adherence in pregnant versus postpartum women.	NR	NR	NR	TFV-DP was detected for 49% (85/175); 51% (90/175) had unquantifiable levels or did not report PrEP use in the last 30 days; 23% (40/175): < 2 doses/week; 20% (35/175): 2–5 doses/week; 6% (10/175): 7 doses/week	NR	TFV-DP detected for 20% (21/107); 80% (80/107) had unquantifiable levels or did not report PrEP use in the last 30 days; 14% (15/107): < 2 doses/week; 5% (5/107): 2–5 doses/week; 1% (1/107): 7 doses/week
PrEP Implementation for Mothers in Antenatal care (PrIMA)									
Pintye et al., Kenya, 2023 [18]	Pregnant adolescent girls and women aged ≥ 15 years	Number of missed doses in the past 30 days	TFV-DP in DBS from visits with self-reported PrEP use in the past 30 days. Lower limit of quantification for TFV-DP: 25 fmol/punch	NR	NR	NR	NR	at 9 months postpartum: 54% (114/212) not missing any PrEP pills in the last 30 days at 9 months postpartum	Among DBS randomly selected from visits where participants continued with PrEP, 50% (214/427) had quantifiable TFV-DP (**pregnant women: 53% vs. postpartum: 27%**); 26% (111/427): TFV-DP < 2 doses/week; 65% (278/427): TFV-DP 2–6 doses/week; 9% (38/427): TFV-DP 7 doses/week.

(*Continued*)

Table 4. (Continued)

		Definition		Adherence post-enrolment (unless otherwise reported)					
				1 month		3 months		≥ 6 months	
Study reference	Study population	Self-reported	Objective	Self-reported	Objective	Self-reported	Objective	Self-reported	Objective
PrEP Implementation for Young women and Adolescents (PriYA)									
Pintye et al., Kenya, 2020 [30]	Adolescent girls and women, aged >15 years, receiving antenatal care or child welfare services	NA	TFV-DP in DBS from first follow-up visit scheduled 30 days post-PrEP initiation among participants reporting using PrEP in the last 14 days. Lower limit of quantification for TFV-DP: 25 fmol/punch	NR	62% (125/201) of DBS samples had detectable TFV-DP; median 492 fmol/sample (IQR 335–718); 30% (61/201) had >500 fmol/sample (≥ 4 doses/week)[a]	NR	NR	NR	Among DBS from first FU visits: 62% (125/201) had detectable TFV-DP, median concentration 492 fmol/sample (IQR 335–718); **postpartum women**: 66% (100/152) versus **pregnant women**: 51% (25/49). Among DBS from later FU visits: 90% (28/31) DBS samples had quantifiable TFV-DP, median concentration 635 fmol/sample (IQR 436–761).[b]
(Quasi) experimental studies									
Chi et al., Malawi, 2024 [37]	Pregnant women, ≥ 18 years	NA	Plasma TFV (days) and intracellular TFV-DP in upper layer packed cells and scored according to algorithm by Corneli et al.	NR	NR	NR	**I**: 31% (28/89) and **C**: 33% (29/89) had 4–7 doses/week	NR	**I**: 25% (22/88) and **C**: 32% (26/82): had 4–7 doses/week

(*Continued*)

Table 4. (Continued)

		Definition		Adherence post-enrolment (unless otherwise reported)					
				1 month		3 months		≥ 6 months	
Study reference	**Study population**	**Self-reported**	**Objective**	**Self-reported**	**Objective**	**Self-reported**	**Objective**	**Self-reported**	**Objective**
PrEP in Pregnant and Postpartum women (PrEP-PP) (sub-study on HIVST + urine TFV biofeedback)									
Davey et al., South Africa, 2021 [32]	Postpartum cisgender adolescent girls and women (4–24 weeks postpartum), aged ≥ 16 years, initiated PrEP during recent pregnancy	Self-reported PrEP use in the past week	POC TFV detection in urine (reflecting adherence in past 48–72 hours)	**I**: 77% (41/53) and **C**: 81% (43/53) reported daily use in past week	**I**: 62% (33/53) and **C**: 34% (18/53) had quantifiable TFV in urine	NR	NR	NR	NR
Sexually Transmitted Infections and PrEP in Pregnancy Study (STIPPS)									
De Voux et al., South Africa, 2023 [35]	Pregnant women ≤ 34 weeks, ≥ 18 years	Number of pills taken in the past week	TFV-DP in DBS among participants who initiated PrEP at baseline	**I**: 11% (10/89) and **C**: 12% (10/84) reported daily use in the past 7 days	**I**: 49% (44/89) and **C**: 45% (38/84) had detectable TFV-DP	NR	NR	NR	NR

(*Continued*)

Table 4. (Continued)

		Definition		Adherence post-enrolment (unless otherwise reported)					
				1 month		3 months		≥ 6 months	
Study reference	Study population	Self-reported	Objective	Self-reported	Objective	Self-reported	Objective	Self-reported	Objective
PrEP Implementation for Mothers in Antenatal care (PrIMA)									
Kinuthia et al., Kenya, 2023 [29]	Pregnant adolescent girls and women, aged ≥ 15 years	Participant-report of swallowing PrEP pills; dichotomized as no missed doses versus any missed doses in the past 30 days	NA	**I**: 53% (206/2250) and **C**: 63% (200/2197) daily use in the past 30 days prior PrEP confirmation visit[c]	NR	NR	NR	NR	NR
PrEP Implementation for Young women and Adolescents (PriYA)									
Pintye et al., Kenya, 2020 [31]	Adolescent girls and women, aged >15 years, receiving antenatal care or child welfare services	Number of missed PrEP doses in the past month	NA	**I**: 73% (74/101) and **C**: 55% (37/67) < 1 missed pill/week	NR	NR	NR	NR	NR

Abbreviations: AGYW, adolescent girls and young women; ANC, antenatal care; c, control; DBS, dried blood spot; FU, follow-up; HIVST, HIV self-testing; I, intervention; IQR, interquartile range; NA, not applicable; NR, not reported; POC, point-of-care; PrEP, pre-exposure prophylaxis; TFV, tenofovir; TFV-DP, tenofovir-diphosphate.

[a]Samples taken from unique women attending their first PrEP follow-up visit, at a median of 5 weeks (IQR 4–18).

[b]Samples were from subsequent visits after first PrEP follow-up visit among the same women, at a median of 24 weeks since PrEP initiation (IQR 17–37).

[c]A PrEP confirmation visit was defined as participant's first study visit after accepting PrEP.

women during critical periods of vulnerability to HIV. Further interventions, tailored to the needs and preferences of these women, are necessary to enhance prevention-effective PrEP use and maximize impact.

PrEP initiation among pregnant and postpartum women varied widely across studies. This variability could partially be explained by differing PrEP initiation definitions. Some studies measured initiation as prescription pick-up at baseline [16, 33, 34], while others relied on self-reported use during a follow-up visit [18]. These varying definitions make direct comparisons of PrEP initiation challenging. The WHO and the European Centre for Disease Prevention and Control (ECDC) list PrEP uptake as a core indicator for monitoring and evaluating PrEP use, but allow flexibility in data source selection (e.g. written or filled prescription data, facility registers for self-reported PrEP use) depending on local availability and context-specific feasibility [38, 39]. While these PrEP use indicators, first published in 2018, provide a useful foundation, they may not fully reflect the context of pregnancy and the postpartum period. Revisiting these indicators could improve consistency in outcome measurement and better guide future research in this population. Additionally, while UNAIDS 2025 targets aim for 95% coverage of pregnant and breastfeeding women, among other key populations, with people-centred HIV prevention programmes, no explicit PrEP coverage target exists for pregnant and postpartum women. Establishing such a target could enhance accountability and stimulate progress towards improved PrEP uptake among this population.

PrEP initiation was higher among women who were more likely to be exposed to HIV, such as those diagnosed with an STI or with partners living with HIV [16–18, 35]. This suggests that women's self-perceived HIV acquisition risk and awareness of partner HIV status play critical roles in a woman's decision to start PrEP, as also reported in a qualitative study in Malawi on PrEP decision-making among pregnant women [40]. However, targeted PrEP delivery based on risk scores resulted in the same levels of PrEP use and HIV incidence compared to delivery to all women [29], suggesting that universal PrEP delivery should be considered to reach pregnant and postpartum women in high HIV burden settings. Universal delivery could enable task-shifting, facilitating group counselling strategies and broader PrEP education within maternal and child health services, thereby facilitating PrEP integration into ANC/PNC [29]. By informing all women receiving ANC/PNC about PrEP availability, following regular HIV testing, this approach may also promote person-centred care, by addressing individuals' needs in a non-stigmatizing, inclusive manner, similar to the universal offer of provider-initiated HIV testing and counselling [11]. It can empower women to make informed decisions about their health and increase community awareness [29].

The median gestational age at PrEP initiation was 20–26 weeks, as such, many women were not using PrEP prior to pregnancy (in the conception period) nor during their first trimester. Delayed initiation could result from late presentation to ANC (i.e. second or third trimester) as PrEP was mostly offered during women's first ANC visit. These findings underscore the need to develop and implement strategies to promote PrEP integration into family planning services for conception coverage and earlier ANC engagement and PrEP initiation to ensure timely use of prevention services [41]. Strategies might include community outreach, involving pharmacies, to increase awareness of ANC benefits and integrating PrEP education into pre-pregnancy counselling, family planning services and STI care [41].

PrEP continuation declined rapidly within the first 3 months after initiation, particularly in the observational studies, with further declines in the postpartum period. Two-way SMS communication enhanced early PrEP continuation, while patient-centred counselling showed no effect, highlighting mixed effects of these interventions in promoting early PrEP continuation/adherence [31, 37]. In comparison, findings from an RCT among young Kenyan women in general, evaluating the effect of SMS reminders on PrEP adherence over a 2-year period, showed that SMS reminders were ineffective in promoting PrEP continuation/adherence [42]. With mobile health ("mHealth") interventions, a frequently investigated option to enhance effective PrEP use, awareness of the digital divide is warranted [43, 44]. For example, in the Kenyan two-way SMS communication study, nearly half of the women screened for study enrolment were ineligible due to cell phone-related issues (e.g. not having a phone). As such, the intervention excluded a large population who lacked access to the necessary technology to benefit from it; reflecting a substantial digital divide. This underscores the importance of thoughtfully leveraging digital technology by developing, with pregnant and postpartum women, and evaluating digital health interventions that are tailored to the specific needs of pregnant and postpartum women and are cognizant of the digital divide.

This review highlights that adherence to oral PrEP is a substantial challenge among pregnant and postpartum women. Discrepancies between self-reported and objective adherence measures were common. While early adherence improved among participants receiving adherence biofeedback counselling after point-of-care urine tenofovir testing compared to standard-of-care [32], patient-centred counselling was ineffective in another study [37]. Long-acting PrEP formulations, such as twice-yearly lenacapavir and bi-monthly cabotegravir injections, the new 3-monthly dapivirine vaginal ring and MK-8527, a monthly PrEP pill, found to be safe and well-tolerated in a phase II clinical trial, offering promising solutions to address adherence issues [22–25, 45, 46]. A phase III efficacy study is planned for late 2025. A study in Kenya and South Africa reported that 75% of pregnant and postpartum women who had used oral PrEP expressed a theoretical preference for long-acting injectable PrEP, suggesting its potential to improve effective use [47]. Similarly, pregnant and breastfeeding women participating in a discrete choice experiment in Botswana and South Africa strongly favoured long-acting injectable PrEP over oral PrEP [48]. Evidence from family planning has shown that expanded choice improves product use, but there is less evidence of this effect for PrEP, which involves different challenges, such as recognizing the risk of acquiring HIV [49]. Understanding how pregnant and postpartum women make decisions about using these female-controlled PrEP products, uptake, switching products and continuation in real-life will be critical to inform person-centred care to reduce HIV incidence among women and their children. Ongoing collection of safety data for these products

during pregnancy and breastfeeding is essential to ensure their safe and effective use among these populations.

Postpartum PrEP continuation and adherence posed challenges. Studies suggest that this decrease is often driven by changes in risk perception, such as postpartum abstinence, or reduced perceived HIV risk, alongside less frequent contact with healthcare facilities during the postpartum period [17, 19]. As sexual activity often resumes after childbirth, and the risk of HIV transmission via breastfeeding remains substantial, the postpartum period is a critical time for HIV prevention [2, 3, 50]. To address these challenges, future strategies should also offer the option of decentralized, person-centred models as being developed and scaled-up among other key populations, such as men who have sex with men, for oral PrEP and for the delivery of antiretroviral therapy [51]. Specifically, efforts could focus on community-based delivery approaches, which prioritize postpartum women, such as establishing community pick-up points and mobile services, and engaging pharmacies, co-created with postpartum women based on their needs and values, could enhance the accessibility and uptake of PrEP among these women [52].

This systematic review has limitations. This review focused on oral PrEP, excluding other prevention methods such as the vaginal ring and long-acting injectable PrEP. Additionally, PrEP delivery was limited to ANC/PNC settings, which may have resulted in an underestimation of overall PrEP use among pregnant and postpartum women. Furthermore, we limited our search to English papers and excluded conference abstracts, which may have resulted in an underrepresentation of evidence from non-English speaking countries and novel insights, potentially affecting the comprehensiveness and generalizability of our findings. Despite these limitations, the review, which involved multiple reviewers and searching multiple databases, highlights critical knowledge gaps and emphasizes the importance of further research on PrEP use in this vulnerable population. The findings contribute valuable insights into integrating PrEP into maternal health services in regions with high HIV prevalence.

Limitations may be present within the studies included in this review. The number of published and included studies on PrEP use among pregnant and postpartum women remained limited, with most studies conducted in Kenya and South Africa, limiting generalizability to other countries and regions. Definitions used for PrEP outcomes also varied across studies, limiting comparability between studies. The lack of long-term follow-up in many studies, often limited to 1–3 months, restricts understanding of long-term PrEP continuation and adherence. More longitudinal research is needed to assess how PrEP continuation changes through pregnancy and postpartum periods. Despite quality control measures and expert input, the absence of a full dual-reviewer screening may have limited the review's comprehensiveness. Moreover, several studies were conducted during the COVID-19 pandemic, which may have influenced healthcare access and PrEP use, potentially skewing results. The potential bias in studies not reporting women's loss-to-follow-up may limit the understanding of (dis)continuation of PrEP in those women not returning for a follow-up visit. Lastly, the inability to blind women participating in the RCTs, due to the nature of the study interventions, may have overestimated adherence due to social desirability bias, particularly in studies using self-reported PrEP use only as outcome measures.

5 | CONCLUSIONS

This systematic review provides essential insights into PrEP use among pregnant and postpartum women, showing promising initiation within ANC/PNC services, but substantial challenges in continuation and adherence, with self-reported measures overestimating true adherence. The variability in adherence highlights a need for more person-centred, supportive interventions to ensure effective HIV prevention during pregnancy and the postpartum period. Long-acting PrEP options may better align with women's preferences and overcome adherence challenges associated with daily oral regimens. To ensure equitable access to these innovations, global funding mechanisms must continue to prioritize maternal PrEP as a core component of HIV prevention efforts. Expanding access to long-acting PrEP options through differentiated models of delivery, including pharmacies and community delivery, could help improve continuity and reduce the risk of HIV acquisition. To eliminate vertical transmission and end the HIV epidemic, it will be critical to safeguard against reductions in global health funding by ensuring sustained international investment and strengthened national commitment to maternal HIV prevention.

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AUTHORS' CONTRIBUTIONS

AR and BH conceived the study. AR and ZE did the literature search and bias assessment. DJD/BH reviewed for conflict. AR did data extraction and drafted the primary draft of the manuscript. AR and ZE did the risk of bias assessment. Discrepancies were resolved by DJD/BH. AR, ZE, SB, DJD and BH contributed critically to the manuscript and revisions, and approved the final version of the manuscript.

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DATA AVAILABILITY STATEMENT

All data supporting the findings of this review were extracted from publicly available sources. The specific sources of the data have been cited within the manuscript. Due to the nature of the systematic review, no new data were created or collected. Detailed search strategies are available in the Supplementary Appendix.

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SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:
Appendix 1: search strategies per database

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RESEARCH ARTICLE

Empowering at-risk Thai adolescents and young adults: an observational study of "Stand By You" – a person-centred online service model for HIV self-screening, text-based counselling and linkage to care

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Abstract

Introduction: Adolescents and young adults (AYA) are disproportionately at risk of HIV acquisition. Person-centred online platforms could effectively reach AYA with HIV testing services. We assessed the effectiveness of Stand By You, a mobile application, in delivering HIV-related services to at-risk Thai AYAs.

Methods: Deidentified data from clients who accessed Stand By You services between August 2022 and February 2024 were analysed. HIV self-testing (HIVST) services were promoted through TikTok influencers to target AYAs vulnerable to HIV. An automated chatbot provided real-time responses to client inquiries, and trained counsellors provided confidential, text-based counselling daily. Clients who completed risk assessments received personalized recommendations for HIVST based on their risk profile. Clients who submitted their HIVST results received post-test counselling and linkage to care and prophylactic treatment. Multivariable logistic regression was used to assess risk factors for reactive HIVST kit results. The per unit direct cost of the programme's performance metrics were assessed.

Results: A total of 8863 clients provided 11,536 risk assessments. The majority were male (76.3%), under the age of 30 (76.0%), identified as members of key populations (60.4%) and first-time testers (56.1%). Additionally, 27.8% had a history of sexually transmitted infections (3,202/11,536), 16.5% reported receiving money or incentives for sex (1908/11,536) and clients indicated an average of 2.6 sexual partners in the past month (SD 3.4). Out of 7585 submitted HIVST results, 3.6% were reactive (n = 274); 60.2% were linked to care (n = 165/274) and 10.4% are in the process of linkage (n = 23/274). Of the 5.3% invalid results reported (n = 401/7585), nearly all were non-reactive by the second HIVST (117/187). A history of testing HIV negative (adjusted odds ratio [aOR] 0.54 [95% CI 0.40–0.72], $p < 0.001$) and receiving pre-exposure prophylaxis (aOR 0.20 [95% CI 0.06–0.64], $p = 0.007$) were independently associated with reduced odds of a reactive result. Average direct cost was $18.7, $40.3 and $1100 USD per distributed HIVST kit, first-time tester and new client linked to care, respectively.

Conclusions: AYA populations at risk for HIV can be effectively reached through mobile phone applications that provide services anonymously. Online strategies for HIVST delivery and supportive text-based counselling can generate high demand, engagement and successful linkage to care.

Keywords: HIV; internet-based intervention; patient-centred care; risk factor; self-testing; sexual and gender minorities

Additional information may be found under the Supporting Information tab of this article.

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1 | INTRODUCTION

HIV incidence in Thailand has decreased by 49% since 2010 [1] due to large-scale HIV prevention and treatment in Thailand [2]. Despite this, adolescents and young adults (AYA) are disproportionately at risk of HIV acquisition, with nearly half of new acquisitions in 2023 occurring in those aged 15–24 years [3]. The key populations (KPs) at high risk include men who have sex with men (MSM), transgender women (TGW), people who inject drugs and sex workers [3].

Online channels effectively reach KPs by offering anonymous, convenient alternatives for AYA who cannot seek in-person services or consultations due to cost, stigma and discrimination concerns [4]. Web-based, mobile and social media platforms facilitate linkage to care and are preferred over in-person options for first-time testers [5–7]. With the rise of machine learning and artificial intelligence models, chatbots have recently gained traction for providing quick, real-time, non-stigmatized responses regarding HIV care, treatment and testing [8, 9]. Prompt intervention with differentiated service delivery to reach [6, 10], educate and diagnose HIV across AYA is crucial to preventing HIV passage and ensuring early treatment.

HIV self-testing (HIVST) was recommended by the World Health Organization (WHO) in 2016 [11] and approved by the Thai Food and Drug Administration in April 2019 [12] due to its safety, accuracy and acceptability among testers. While Thailand incorporated HIVST into its National HIV programme in 2015 and included it in the universal health coverage (UHC) package in 2023 [13], significant implementation barriers remain. The UHC theoretically offers free HIVST; however, access is limited to two tests per person annually and requires Thai citizens to pre-register using their national ID at designated healthcare institutions – discouraging uptake due to privacy concerns.

Online platforms have proven effective for HIVST distribution [14], particularly in hard-to-reach populations and first-time testers, with uptake and linkage-to-care rates comparable or exceeding traditional approaches [5, 7, 14–22]. Our prior YM2M programme demonstrated the potential of online outreach but was hindered by mandatory on-site testing [23]. The Stand By You programme addresses these gaps through its multidisciplinary, user-friendly, person-centred approach that prioritizes anonymity and accessibility – offering home-delivered HIVST without identity requirements, aligning with the preferences of Thailand's working-class AYA who face logistical and privacy barriers to on-site, institutional testing.

The Stand By You programme was launched in August 2022 by the Faculty of Medicine Siriraj Hospital, Mahidol University, in collaboration with the Division of AIDS and Sexually Transmitted Infections (STIs), Department of Disease Control, Ministry of Public Health and Thailand-U.S. Cooperation Centre for Public Health (TUC). It operates through Thailand's widely used LINE application (@standbyyou) and a dedicated website (https://standbyyou.info/) to target and proactively reach AYAs vulnerable to HIV – providing HIV and STI prevention knowledge, text-based counselling, free HIVST delivery, and a referral and follow-up system. This comprehensive approach improves both testing accessibility and empowers AYA to engage with HIV care on their own terms.

The primary objective of this study was to assess the effectiveness of Stand By You, a mobile application, in delivering HIV-related services to at-risk Thai AYAs, through the number of submitted risk assessment questionnaires, distributed HIVST kits, submitted kit results, newly tested clients, reactive results identified and linked to confirmatory testing and care. Its secondary objectives were to characterize the factors influencing self-reported HIV reactive test results and determine the direct cost of each aspect of our programme's performance, from client engagement to linkage to confirmatory testing and care.

2 | METHODS

2.1 | Study design and clients

This retrospective observational study analysed deidentified data from clients who accessed Stand By You services between August 2022 and February 2024. Clients who did not complete risk assessment questionnaires or submit HIVST kit results were excluded from the analyses (n = 1274).

2.2 | Intervention

HIVST services were promoted through local well-known celebrities or influencers with large follower counts on TikTok to target AYAs at risk of HIV acquisition. An automated chatbot using natural language processing provided real-time responses to client inquiries and facilitated ongoing engagement (Figure S1).

After completing a risk assessment, clients received personalized recommendations for HIVST based on their risk profile. HIVST kits included instructional videos from medical practitioners, pre-test counselling messages, and free condoms and water-based lubricants delivered nationwide. Per Thai Ministry of Public Health guidelines [24], clients with invalid results could request additional kits; clients who tested invalid after their second HIVST were referred to institutional testing and care. Invalid results were defined as operational errors or equipment malfunctions that hindered the interpretation of HIVST results. Clients with non-reactive results who wished to re-test could request an additional HIVST kit 6 months after their previous delivery. Clients received automatic reminders to submit their test results within 24–48 hours of receiving the test kit. After submitting their test results, all clients received post-test counselling. Clients with reactive HIVST results were offered linkage to care for confirmatory (laboratory) HIV-testing and care as appropriate. Clients with non-reactive HIVST results were individually asked by counsellors about their most recent instance of unprotected sexual intercourse, how they performed their HIVST and whether they had ongoing HIV risk exposure. Those who had unprotected sexual intercourse within the past 3 weeks were advised to retest, and those with continuous exposure to risks were offered linkage to pre-exposure prophylaxis (PrEP) services. Clients who had unprotected sexual intercourse or were at risk of HIV exposure within 72 hours received automated messages from @standbyyou recommending post-exposure prophylaxis (PEP) and are offered counselling and linkage to PEP services. Clients were linked

to free care and treatment at healthcare centres of the HIV clinic network under the universal coverage scheme of the National Health Security Organization.

Trained counsellors provided confidential, text-based counselling through online chatrooms daily between 10:00 AM to 10:00 PM. Counselling sessions were not held face-to-face or verbally to respect clients' privacy and autonomy. Counsellors reminded clients who did not submit their HIVST results after 48 hours of receiving HIVST kits and provided post-test counselling for those with reactive results. Clients could request counselling regarding HIV-related and STI-related or reproductive health-related issues regardless of their results.

Three main WHO-prequalified HIVST kits were distributed subject to availability and supply constraints at the time of the study: iCARE ("Kit 1," blood-based, JAL Medical Singapore Pte., Ltd.), INSTI ("Kit 2," blood-based, bioLytical Laboratories Inc.) and OraQuick ("Kit 3," oral-fluid-based, OraSure Technologies Inc.).

2.3 | Study outcomes and independent variables

2.3.1 | *Primary measured outcomes*

Programme performance metrics included the number and direct cost per client, risk assessment, distributed HIVST kit, submitted HIVST result, newly tested client, HIVST reactive results identified and linked to confirmatory testing and care.

Online self-assessments for HIV acquisition risks collected data on assigned sex at birth, age, latest self-identified gender identity and orientation, number of sex partners within the past month, overall drug or substance use, overall practice of receiving money, gifts or valuables for sex, history of STIs, overall frequency of condom use, and history of HIV testing and PrEP and PEP (Table S1). Clients' latest sexual orientation was grouped into "heterosexual," or cis or trans women or men exclusively sexually attracted to persons of a different gender, and LGBTQIA+ ("non-heterosexual"), or cis or trans women or men not exclusively sexually attracted to persons of a different gender.

2.3.2 | *Secondary measured outcomes*

For clients with reactive HIVST results, we assessed follow-up actions (linkage to care, block communications/no response, confirmatory testing and care), results from confirmatory testing and type of healthcare/service provider (public hospital/clinic, private hospital/clinic, community-based organization). For clients with invalid HIVST results, we analysed the frequency of invalid results stratified by HIVST kit type and results of repeat HIVST. Both HIVST kit outcomes were further stratified by age (<25 and ≥ 25 years).

Additional direct costs assessed included start-up, recurrent, and total costs for platform and technology development, personnel, HIVST kits and related services, and project management and administration of the programme. We also assessed the direct cost per unit for the performance metrics. As of 11 December 2024, direct costs were calculated using a Thai Baht (THB) to US dollar (USD) exchange rate of 0.030.

2.4 | Community engagement

A multidisciplinary advisory committee established by the Faculty of Medicine Siriraj Hospital, including representatives and caregivers of people living with HIV, informed service design through focus groups.

2.5 | Ethics statement

The institutional review board of the Faculty of Medicine Siriraj Hospital, Mahidol University approved this study (COA no. Si 343/2024), waiving individual informed consent due to the anonymous, retrospective nature of data collection. All clients provided opt-in consent for the use of deidentified data for academic purposes during the risk assessments.

2.6 | Sample size calculation

A sample size of 3334 clients provided 80% statistical power to detect at least 10 reactive results per HIV acquisition risk factor [25]. HIV prevalence in our clients was compared to a background rate of 0.8% in healthy Thai male conscripts aged 20–21 years in 2022 [26]. These conscripts provide a relevant benchmark for comparison as they are of a similar age range to clients and represent the general, healthy Thai population.

2.7 | Statistical analyses

Clients were assigned user IDs to track data. Descriptive statistics were displayed as mean (standard deviation [SD]) or *n* (%), where appropriate. Student's *t*-test was used to analyse differences between the means of two groups, and analysis of variance to analyse differences between three or more groups. Chi-squared or Fisher's exact tests were used to determine relationships between grouped variables. Multivariable logistic regression identified risk factors for reactive HIVST kit results, including variables significant ($p < 0.05$) in univariable analyses: latest sexual orientation, HIV testing history, HIV chemoprophylaxis use, drug or substance use, receiving money or incentives for sex and STI history. Sex assigned at birth and latest self-identified gender identity were excluded due to collinearity with latest sexual orientation (which was retained as a representative). Duration since the most recent exposure to risks was excluded for lacking clinical relevance. Backward stepwise selection (entry $p = 0.10$, removal $p = 0.15$) refined the model, excluding drug or substance use ($p > 0.15$). Crude (OR) and adjusted odds ratios (aOR) were reported with 95% confidence intervals (CIs). All data were visualized using Microsoft Excel (version 2410 Build 16.0.18129.20158) and analysed using STATA (v18.0, StataCorp LLC, TX, USA). Statistical significance was defined by $p \leq 0.05$.

3 | RESULTS

3.1 | Key performance metrics and socio-demographic characteristics

Between August 2022 and February 2024, the platform had 43,100 unique views, and 8863 received services (Figure S2).

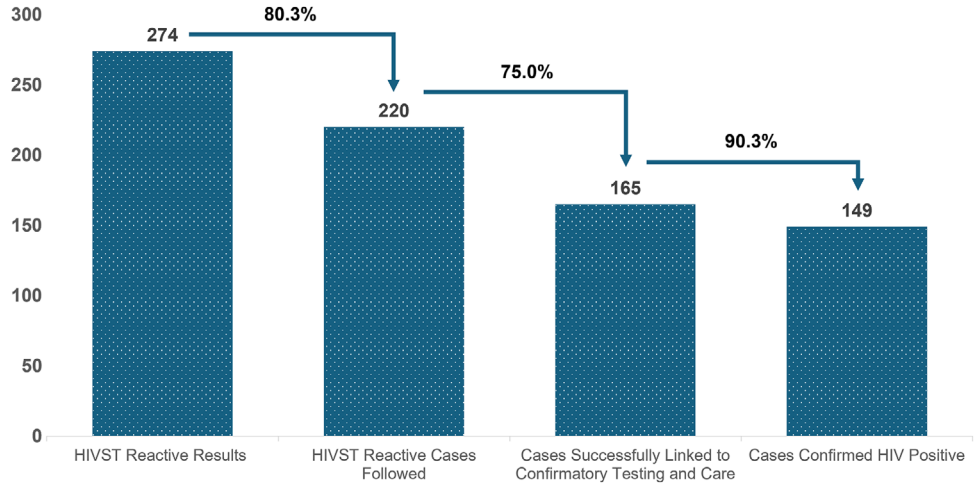

Figure 1. HIV cascade for linkage to care among HIVST reactive self-testers. Data are shown in the number of clients. Abbreviation: HIVST, HIV self-test.

Online learning resources available through the Stand By You website were accessed 2007 times, and 1,701 invitations to the platform were sent by the clients to their peers vulnerable to HIV (Figure S2).

Most clients were < 30 years old (76.0%) – with a mean age of 25.4 (SD 6.8) years, male (76.3%), part of KPs at high risk of HIV (self-identified as being gay or MSM [51.8%], TG [6.5%], persons who use drugs or substances [2.1%]) and first-time testers (56.1%) (Table 1). From 11,536 clients who completed risk questionnaires, 80.4% had irregular or no condom use overall (n = 9268), 16.5% (n = 1908) had received money or other incentives for sex in the past, 27.8% had a history of STIs (n = 3202) and had an average of 2.6 sexual partners within the past month (SD 3.4) (Table 1). Of the 9252 HIVST kits distributed across all 77 provinces in Thailand (Figure S3), mainly Bangkok, 82.0% submitted their test results (n = 7585) (Table 1). For clients who had unprotected sexual intercourse or were exposed to HIV acquisition risks within 72 hours, 5.4% self-assessed having a high-risk of HIV exposure and requested PEP counselling (n = 50/923) (Figure S2); 90.0% were successfully linked to PEP services (n = 45/50) (Figure S2).

Of the submitted results, 3.6% were reactive overall (n = 274), with 60.2% successfully linked to confirmatory testing and care (n = 165) (Table 2). These proportions were similar between clients aged < 25 and ≥ 25 years (Table 2). Of these clients, 90.3% (n = 149) were diagnosed with HIV (Figure 1 and Table 2) – a 4.1 times higher prevalence than that observed among healthy 20- to 21-year-old Thai military conscripts (including estimated positive results from linkage-to-care clients) [26]. For the remaining reactive clients, 10.4% (n = 23) are in the process of linkage, and 14.6% (n = 32) were lost to follow-up after blocking or not responding to our counsellors' messages (Figure 1 and Table 2). More than half (56.4%) of newly identified clients living with HIV were linked to public hospitals/clinics (n = 93/165) (Table 2). Of the 5.3% HIVST-invalid results (n = 401/7585), 47.1% agreed to repeat HIVST (n = 187/401), and 1.0% tested reactive by the second HIVST (n = 2/187) (Table 2). Kit 2 had the highest reported frequency of invalid results (22.1%), followed by Kit 3 (8.4%) and Kit 1 (2.1%) (Table 2 and Figure S4).

3.2 | HIV-related risks associated with HIVST reactive results

In multivariable analysis, membership of the LGBTQIA+ community (aOR 8.64 [95% CI 4.98–14.99], p < 0.001), receipt of money for sex (aOR 1.56 [95% CI 1.13–2.16], p = 0.007) and having a history of STIs (aOR 1.98 [95% CI 1.49–2.62], p < 0.001) were independently associated with higher odds of a reactive result (Table 3). Having a history of negative HIV testing results (aOR 0.54 [95% CI 0.40–0.72], p < 0.001) and receiving PrEP (aOR 0.20 [95% CI 0.06–0.64], p = 0.007) were independently associated with reduced odds of a reactive result.

3.3 | Overall direct costs and costs of key performance metrics

Total direct costs incurred by this programme until the data analyses were roughly 5.8 million THB (around $173,400 USD) (Table S2). The average direct cost was 660.2 THB ($19.6 USD) per client who enrolled to receive services, 507.2 THB ($15.0 USD) per risk assessment, 632.4 THB ($18.7 USD) per distributed HIVST kit, 771.4 THB ($22.9 USD) per self-reported HIVST results, 1400 THB ($40.3 USD) per first-time tester, 26,600 THB ($788.0 USD) per identified reactive result, 35,500 THB ($1100.0 USD) per new HIV reactive status linked to testing and care, and 39,300 THB ($1200.0 USD) per confirmed positive client linked to antiretroviral therapy (ART) (Table S2).

4 | DISCUSSION

HIV testing is a critical first step towards ending AIDS. Programmes like Stand By You demonstrate how overcoming barriers to testing can improve AYA engagement. While approximately one-third of clients were lost to follow-up, those who

Table 1. Demographic characteristics by number of clients and events

Demographic/characteristic by number of clients	
Number of clients	8863
Sex assigned at birth; *n* (%)	8863 (100.0)
Male	6,767 (76.3)
Female	2,096 (23.7)
HIVST kit assessments (per client); *n* (%)	8,863 (100.0)
0	1255 (14.2)
1	6922 (78.1)
2	638 (7.2)
> 2	48 (0.5)
Demographic/characteristic by number of events	
Total number of risk assessments	11,536
Age (years); mean (SD)	25.4 (6.8)
Age group; *n* (%)	11,536 (100.0)
< 20	1822 (15.8)
20–< 25	4267 (37.0)
25–< 30	2680 (23.2)
30–< 35	1330 (11.5)
35–< 40	678 (5.9)
40–< 45	281 (2.4)
> 45	190 (1.6)
No information available	288 (2.5)
Latest self-identified gender identity[a]; *n* (%)	11,536 (100.0)
Cis man	1676 (14.5)
Cis woman	2190 (19.0)
Gay or MSM	5975 (51.8)
Lesbian	45 (0.4)
Bisexual	820 (7.1)
Trans man	111 (1.0)
Trans woman	636 (5.5)
Queer	83 (0.7)
Latest sexual orientation; *n* (%)	11,536 (100.0)
Heterosexual	3513 (30.4)
Non-heterosexual (LGBTQIA+)	8023 (69.6)
History of HIV testing (before HIVST); *n* (%)	11,536 (100.0)
No	6468 (56.1)
Yes	5068 (43.9)
Latest HIV-test results (before HIVST); *n* (%)	5068 (100.0)
Non-reactive	4697 (92.7)
Invalid	283 (5.6)
Reactive	88 (1.7)
History of HIV chemoprophylaxis; *n* (%)	11,536 (100.0)
PrEP	674 (5.8)
PEP	841 (7.3)
HIV-related risks identified from online questionnaires; *n* (%)	11,536 (100.0)
No	1662 (14.4)
Yes	9874 (85.6)
Ever used condoms; *n* (%)	11,536 (100.0)
Never	1601 (13.9)
Sometimes	7667 (66.5)
Always	1925 (16.7)
Not applicable[b]	343 (3.0)
Ever used drugs or substances; *n* (%)	11,536 (100.0)
No	11,300 (97.9)
Yes	236 (2.1)
Ever received money or incentives for sex; *n* (%)	11,536 (100.0)
No	9628 (83.5)
Yes	1908 (16.5)
History of STI(s); *n* (%)	11,536 (100.0)
No	8334 (72.2)
Yes	3202 (27.8)
Number of sex partners within the past month; mean (SD) (*n* = 11,536)	2.6 (3.4)
Duration since the most recent exposure to a risk event; *n* (%)	9874 (100.0)
< 72 hours	923 (9.3)
72 hours–3 weeks	3185 (32.3)
> 3 weeks	5528 (56.0)
No answer	238 (2.4)
Time period when latest HIV risk assessment was performed; *n* (%)	11,536 (100.0)
08:00–16:00	4135 (35.8)
16:00–22:00	3816 (33.1)
22:00–08:00	3585 (31.1)
Number of HIVST kit[c] requests; *n* (%)	10,768 (100.0)
Approved	9252 (85.9)
Unapproved[d]	1516 (14.1)
Rate of reported HIVST results[e]; *n*/*N* (%)	7585/9252 (82.0)
Duration between HIVST kit approval and response (days); mean (SD) (*n* = 7585)	11.3 (25.8)

Abbreviations: HIVST, HIV self-test; MSM, men who have sex with men; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; SD, standard deviation; STI, sexually transmitted infection.

[a]Thai discourse on gender and orientation is framed as a single category that incorporates differences in assigned sex, self-identified gender and sexuality, as discussed by Jackson and Sullivan [27]. Borrowed Western terminology like "gay," "lesbian" or "bisexual" may denote both gender and orientation identities for some clients in this study.

[b]Clients who did not engage in penetrative sexual intercourse or sexual intercourse in general.

[c]Clients can request more than one kit. HIVST kits were manufactured by JAL Medical Singapore Pte., Ltd. (Kit 1), bioLytical Laboratories Inc. (Kit 2) or OraSure Technologies Inc. (Kit 3). Distributed HIVST kits were subjected to availability and supply constraints at the time of the study and mostly consisted of Kit 1 (78.3%, *n* = 7247/9252), followed by Kit 2 (16.3%, *n* = 1509/9252), Kit 3 (3.8%, *n* = 348/9252) and other (1.6%, *n* = 148/9252). Other entailed kits manufactured by Abbott Diagnostics Korea Inc.

[d]Kits were unapproved should clients request a kit within 6 months after their latest approved HIVST kit.

[e]Only includes submitted responses from clients with approved HIVST kits.

Table 2. HIVST kit outcomes among clients who reported reactive or invalid results

HIVST kit outcomes (n = 7585)[a]	Overall	In clients < 25 years	In clients ≥ 25 years
Reported reactive results[b]; *n/N* (%)	274/7585 (3.6)	136/4114 (3.3)	138/3471 (4.0)
HIV reactive clients from HIVST kit/clients who responded; *n/N* (%)	220/6185 (3.6)	103/3317 (3.1)	117/2868 (4.1)
HIV reactive clients who followed up; *n* (%)	220 (100.0)	103 (100.0)	117 (100.0)
Currently being linked to care	23 (10.4)	14 (13.6)	9 (7.7)
Blocked communications or no response	32 (14.6)	11 (10.7)	21 (18.0)
Received confirmatory testing and care	165 (75.0)	78 (75.7)	87 (74.4)
Healthcare/service provider; *n* (%)	165 (100.0)	78 (100.0)	87 (100.0)
Public hospital/clinic	93 (56.4)	44 (56.4)	49 (56.3)
Private hospital/clinic	15 (9.1)	6 (7.7)	9 (11.3)
Community-based organization	8 (4.9)	4 (5.1)	4 (4.6)
Missing data[c]	49 (29.7)	24 (30.8)	25 (28.7)
Results of confirmatory testing; *n* (%)	165 (100.0)	78 (100.0)	87 (100.0)
Non-reactive	16 (9.7)	8 (10.3)	8 (9.2)
Reactive	149 (90.3)	70 (89.7)	79 (90.8)
Reported invalid results; *n/N* (%)	401/7585 (5.3)	236/401 (58.8)	165/401 (41.2)
Frequency of invalid results by type of HIVST kit[d]; *n/N* (%)	7577 (100.0)	4109 (100.0)	3468 (100.0)
Kit 1	127/6028 (2.1)	74/3238 (2.3)	53/2793 (1.9)
Kit 2	271/1219 (22.2)	161/673 (23.9)	110/535 (20.6)
Kit 3	2/239 (0.8)	0/120 (0.0)	2/118 (1.7)
Other	1/91 (1.1)	1/78 (1.3)	0/22 (0.0)
Results of HIVST kit reassessments of previously reported invalid results; *n* (%)	187/401 (46.6)	102/236 (43.2)	85/165 (51.5)
Remained invalid	68 (36.4)	41 (40.2)	27 (31.8)
Non-reactive	117 (62.6)	59 (57.8)	58 (68.2)
Reactive	2 (1.0)	2 (2.0)	0 (0.0)

Abbreviations: HIVST, HIV self-test; MSM, men who have sex with men; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; SD, standard deviation.
[a]Table only includes data from clients who self-reported their HIVST kit results. Clients who received PrEP/PEP without performing HIVST were not included.
[b]Some clients reported multiple reactive results (retested).
[c]These clients chose not to disclose this information.
[d]HIVST kits were manufactured by JAL Medical Singapore Pte., Ltd. (Kit 1), bioLytical Laboratories Inc. (Kit 2) or OraSure Technologies Inc. (Kit 3). Distributed HIVST kits were subjected to availability and supply constraints at the time of the study.

learned their HIV status could adopt preventive measures and potentially re-engage with care later. Promoting HIVST is essential to help prevent HIV transmission, as most new HIV diagnostics occur before a person living with HIV starts ART.

In line with previous literature [28, 29], having a non-heterosexual preference, receiving money or incentives for sex and having a history of STIs were identified as independent risk factors associated with reactive HIVST results. We found that a history of HIV testing and receiving PrEP were independently associated with reduced odds of HIVST reactive results. This highlights the importance of knowing one's HIV status, receiving preventive treatment and the effectiveness of online platforms in offering widely accessible self-testing resources to AYAs at risk of HIV acquisition.

In accord with our previous programme [23] and other studies' findings [4–7], the use of online platforms and social media outlets substantially increased AYA outreach. Our study was one of the few published that explored the use of chatbots to facilitate HIV prevention intervention [8, 9], allowing us to provide timely responses to AYA – maintaining continuous lines of communication. This continuity was previously restricted by the limited operational hours of Facebook chatrooms in our previous study [23]. Integrating online, real-time instructions through chatbots with pre- and post-HIVST counselling – as we implemented – could fuel behavioural changes and linkage to care in AYA [7, 20, 30, 31].

Compared to facility-based approaches, online HIVST distribution with kit delivery to homes effectively reached AYA and KPs [15–21, 32] – due to its offered convenience and anonymity [5]. Home-based testing increased the frequency of HIV testing and counselling in first-time testers and hard-to-reach populations [33, 34], facilitating early diagnosis [31] and linkage to care [33]. Our programme circumvented barriers to AYA undergoing HIV testing [35]

Table 3. Univariable and multivariable analyses of risk factors associated with reactive HIVST kit results (*n* = 5857)

Factors	Non-reactive HIVST[a] (*n* = 5637)	Reactive HIVST[a] (*n* = 220)	OR (95% CI)	*p*-value	aOR (95% CI)	*p*-value
Sex assigned at birth; *n* (%)						
Male	4263 (75.6)	207 (94.1)	5.13 (2.92–9.02)	< 0.001		
Female	1374 (24.4)	13 (5.9)	1.00			
Age (years); mean (SD)	25.3 (6.2)	26.0 (6.2)	1.02 (0.99–1.04)	0.087		
Age group						
< 20	842 (14.9)	27 (12.3)	1.00			
20–< 25	2171 (38.5)	75 (34.1)	1.08 (0.69–1.68)	0.744		
25–< 30	1420 (25.2)	58 (26.4)	1.27 (0.80–2.03)	0.307		
30–< 35	678 (12.0)	34 (15.4)	1.57 (0.94–2.62)	0.087		
35–< 40	325 (5.8)	19 (8.6)	1.82 (1.00–3.32)	0.051		
≥ 40	183 (3.2)	7 (3.2)	1.19 (0.51–2.78)	0.681		
No information available	18 (0.3)	–	–	–		
Latest self-identified gender identity[b]; *n* (%)						
Cis man	714 (12.7)	9 (4.1)	1.00			
Cis woman	1182 (21.0)	9 (4.1)	0.60 (0.24–1.53)	0.287		
Gay or MSM	2912 (51.7)	181 (82.3)	4.93 (2.51–9.67)	< 0.001		
Lesbian	19 (0.3)	–	–	–		
Bisexual	411 (7.3)	11 (5.0)	2.12 (0.87–5.16)	0.097		
Trans man	37 (0.7)	1 (0.4)	2.14 (0.26–17.37)	0.475		
Trans woman	331 (5.9)	8 (3.6)	1.91 (0.73–5.01)	0.184		
Queer	31 (0.6)	1 (0.4)	2.56 (0.31–20.84)	0.380		
Latest sexual orientation; *n* (%)						
Heterosexual	1731 (30.7)	14 (6.4)	1.00		1.00	
Non-heterosexual (LGBTQIA+)	3906 (69.3)	206 (93.6)	6.52 (3.78–11.24)	< 0.001	8.64 (4.98–14.99)	< 0.001
History of HIV testing (before HIVST); *n* (%)						
No	3227 (57.2)	147 (66.8)	1.00		1.00	
Yes	2410 (42.8)	73 (33.2)	0.66 (0.50–0.88)	0.005	0.54 (0.40–0.72)	< 0.001
Latest HIV-test results (before HIVST); *n* (%)						
Non-reactive	2315 (96.1)	53 (72.6)	1.00			
Invalid	91 (3.8)	13 (17.8)	6.24 (3.28–11.85)	< 0.001		
Reactive	4 (0.2)	7 (9.6)	76.4 (21.72–269.02)	< 0.001		
History of HIV chemoprophylaxis; *n* (%)						
PrEP	343 (6.1)	3 (1.4)	0.21 (0.07–0.67)	0.008	0.20 (0.06–0.64)	0.007
PEP	384 (6.8)	8 (3.6)	0.52 (0.25–1.05)	0.069		
HIV-related risks identified from online questionnaires; *n* (%)						
No	603 (10.7)	10 (4.6)	1.00			
Yes	5034 (89.3)	210 (95.4)	2.51 (1.33–4.77)	0.005		
Ever used condoms; *n* (%)						
Never	799 (14.2)	21 (9.6)	1.19 (0.27–5.18)	0.811		
Sometimes	3985 (70.7)	179 (81.4)	2.04 (0.50–8.36)	0.320		
Always	762 (13.5)	18 (8.2)	1.07 (0.24–4.71)	0.924		
Not applicable[c]	91 (1.6)	2 (0.9)	1.00			

(*Continued*)

Table 3. (Continued)

Factors	Non-reactive HIVST[a] (*n* = 5637)	Reactive HIVST[a] (*n* = 220)	OR (95% CI)	*p*-value	aOR (95% CI)	*p*-value
Ever used drugs or substances; *n* (%)						
No	5538 (98.2)	212 (96.4)	1.00			
Yes	99 (1.8)	8 (3.6)	2.11 (1.01–4.39)	0.046		
Ever received money or incentives for sex; *n* (%)						
No	4782 (84.8)	166 (75.4)	1.00		1.00	
Yes	855 (15.2)	54 (24.6)	1.82 (1.33–2.49)	< 0.001	1.56 (1.13–2.16)	0.007
History of STIs; *n* (%)						
No	3970 (70.4)	133 (60.4)	1.00		1.00	
Yes	1667 (29.6)	87 (39.6)	1.56 (1.18–2.05)	0.002	1.98 (1.49–2.62)	< 0.001
Number of sex partners within the past month; mean (SD)	2.6 (3.5)	2.5 (1.8)	0.99 (0.95–1.03)	0.743		
Duration since the most recent exposure to risks; *n* (%)						
< 72 hours	426 (8.5)	8 (3.8)	1.00			
72 hours–3 weeks	1639 (32.6)	52 (24.8)	1.69 (0.80–3.58)	0.172		
> 3 weeks	2898 (57.6)	146 (69.5)	2.68 (1.31–5.50)	0.007		
No answer	71 (1.4)	4 (1.9)	3.00 (0.88–10.22)	0.079		
Time period when latest HIV risk assessment was performed; *n* (%)						
08:00–16:00	2025 (35.9)	77 (35.0)	1.00			
16:00–22:00	1878 (33.3)	70 (31.8)	0.98 (0.70–1.36)	0.906		
22:00–08:00	1734 (30.8)	73 (33.2)	1.11 (0.80–1.53)	0.541		

Abbreviations: aOR, adjusted odds ratio; CI, confidence interval; HIVST, HIV self-test; LGBTQIA+, lesbian, gay, bisexual, transgender, queer/questioning, intersex, and asexual and others; MSM, men who have sex with men; OR, odds ratio; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; SD, standard deviation; STI, sexually transmitted infection.
[a]Includes only the most recent HIVST kit results; excludes invalid results.
[b]Thai discourse on gender and orientation is framed as a single category that incorporates differences in assigned sex, self-identified gender and sexuality [27]. Borrowed Western terminology like "gay," "lesbian" or "bisexual" may denote both gender and orientation identities for some clients in this study.
[c]Clients who did not engage in penetrative sexual intercourse or sexual intercourse in general.

by delivering free HIVST kits straight to our clients, more than half of whom were first-time testers – which is greater than previously reported percentages (10–45%) in recent HIVST implementation programmes [36, 37]. This highlights the effectiveness of our strategy towards reaching vulnerable AYAs with no prior testing. While HIVST does not replace facility-based confirmatory testing, it empowers individuals and facilitates subsequent linkage to care. Consistently involving target users, utilizing phased implementation and employing multiple distribution strategies can enhance programme sustainability [38], which is crucial for future HIV diagnosis and prevention strategies.

While both blood- and oral fluid-based rapid diagnostic tests can screen for HIV [39, 40], the sensitivity and specificity of the former were reportedly greater [41]. According to a systematic review, HIVST demonstrated moderate-to-high acceptability among young people [42], with variations based on age, education level, prior HIVST knowledge, HIV testing history, HIVST type and sexual risk behaviour. Previous studies reported that a lack of experience with HIVST kits, misscomprehension of kit instructions or delayed test interpretations could also increase the risk of invalid or false positive results [40, 43–45]. The invalid results observed may be due to lower-than-expected performance fidelity instead of technological problems [46]. To address this, we offered retesting to all clients with invalid results. Performance fidelity can be increased through internet- and community-based campaigns targeting HIV-health literacy [46]. Promoting retesting and refining kit instructions and counselling services can help minimize testing errors and determine clients' true HIV

status [45, 47, 48]. While some test kits may yield more invalid results than others, comparing HIVST proficiency lies beyond the scope of this study.

MSM and TGW were willing to pay for HIVST kits priced between $7.70 and $9.30 USD [49]. The estimated cost per HIVST kit ranged from $8.15 to $18.07 USD on average across sites in Africa [50–52], which was more cost-saving than standard on-site HIV testing [53, 54]. Different site-level fixed costs may explain inter-site variation [50, 52]. The largest cost items per distributed kit entailed the kit itself, testing supplies and/or personnel costs [50, 51]. Our largest cost items aligned with this, and its individual adjusted cost per HIVST kit lay within previously described ranges [50, 52]. The costs per test delivered, new client tested and new HIV diagnosis reported were $59, $65 and $10,160 USD, respectively, for the TakeMeHome programme (0.6% positivity rate) [55]. Combined with real-time text-based counselling and essential preventative messaging, our cost estimates (3.6% positivity rate) were 3–10 times less than the TakeMeHome programme. However, HIVST and shipping costs in Thailand are less costly than in some high-income countries ($4 vs. $15 USD per kit, respectively) [55]. While early diagnosis through HIVST may increase immediate expenditures [56, 57], these initial costs are defrayed over time as patients' health improves [56] and costs per new diagnosis and HIV acquisition are lowered [19, 57], saving nearly $1.6 million USD in lifetime HIV treatment costs per person [54]. Significantly higher treatment costs and morbidities are accumulated with late diagnoses [57], with the Thai Ministry of Public Health reporting $502 USD per capita person living with HIV spent in 2022 [2].

This study had some limitations. First, to maintain clients' anonymity, medical providers and counsellors could not directly contact clients without their consent or a substantive reason. Due to this, many clients in denial may have decided to block the programme's communication platforms, hence those were lost to follow-up and linkage to care. Despite this, at least our programme made clients aware of their HIV status, allowing them to eventually seek care elsewhere when they came to terms with their results. Second, clients were not required to complete all the questions in the risk assessment questionnaires. This led to some data being missing or incomplete. Third, there is a risk of recall bias as clients had to recall their previous behaviour. Regardless of both these points, the statistical power of our results remained sufficient. Fourth, the lack of formal evaluation channels limited the amount of feedback from clients. While we have since improved the platform to accommodate this feature, the feedback we received thus far through individual chatrooms regarding the text-based counselling utilized in this programme was positive and considered a key factor for their retention and linkage to care.

5 | CONCLUSIONS

Our online mobile phone platform, Stand By You, provided person-centred, anonymous, convenient, HIV prevention knowledge, risk assessments, HIVST kit delivery and text-based supportive counselling. We successfully engaged hard-to-reach populations, encouraging vulnerable AYAs to self-test and ensuring their linkage to care. The factors associated with an HIV-positive status were as expected, but prior HIV testing emerged as an independent protective factor, highlighting the importance of regular testing for all individuals at risk of HIV acquisition to maintain their HIV-negative status. Integrating social media platforms and HIVST distribution underscores the programme's impact in addressing public health challenges in reaching and recruiting AYA at risk of HIV acquisition. Beyond diagnosing and providing treatment for individuals living with HIV, such programmes enable AYA who test non-reactive yet engage in risky behaviours to access counselling and preventive medication early. This approach raises awareness about HIV prevention strategies, reduces risky behaviours and empowers AYAs to self-test.

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COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHOR CONTRIBUTIONS

KS, SR and KC were responsible for the conceptualization, methodology and supervision of the study. KS, SR, YD, TT, VB, PW, YS, PU, PP, BK and KC were responsible for data curation and resources. AM performed the formal analysis and visualization. KS and KC drafted the manuscript. All authors reviewed and edited the manuscript.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available in the Supplementary Material of this article.

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SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:

Supplementary Figure 1. Stand by You chatbot interaction sequence.

Supplementary Figure 2. Flowchart of participants' journey through the Stand by You programme.

Supplementary Figure 3. Number of HIV self-testing kits requested by province in Thailand.

Supplementary Figure 4. HIV self-testing kit performance by type.

Supplementary Table 1. English translation for online risk assessment questionnaire.

Supplementary Table 2. Cost analysis from August 2022 to February 2024 for key metrics.

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SHORT REPORT

Enhancing PrEP adherence through person-centred mobile app interventions: a real-world data and machine learning approach using UPrEPU among gay, bisexual and other men who have sex with men in Taiwan

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IRB: The study was approved by the Institutional Review Board of National Cheng Kung University Hospital (A-ER-110-201).

Abstract

Introduction: Pre-exposure prophylaxis (PrEP) is an effective HIV prevention tool that relies on good adherence in high-risk scenarios. To understand the factors that predict adherence, technology such as mobile applications like UPrEPU—allowing for logging users' daily behaviours at close to the time they have sex or PrEP intake—can be used as a person-centred, self-care intervention. This study aims to develop a machine learning model using logs of sexual activities and user attributes recorded in the UPrEPU mobile application in Taiwan to predict whether a sexual event was protected by oral PrEP among gay, bisexual and other men who have sex with men (GBMSM).

Methods: We used data from the UPrEPU app collected between January 2022 and May 2023 in Taiwan. The dataset included information on users' sex events, such as the timing and users' sex roles (e.g. versatile, receptive or insertive partner), and the dynamic user-based attributes related to sexual behaviours and PrEP use. Various subsets of these features were employed in CatBoost models to predict whether the sex events were associated with correct PrEP use. We evaluated the models' performance using five-fold cross-validation. The influential features were identified through feature importance analysis and Shapley Additive Explanations (SHAP) values to explain the models.

Results: A total of 198 users recorded 2356 anal sex events on UPrEPU. The model with dynamic user-based attributes outperformed those without them. The most parsimonious model had a good prediction performance (accuracy = 75%, precision = 78%, recall = 90%, F1-score = 83%) and identified the key features of PrEP protection. The model with five dynamic user-based attributes—age, cumulative PrEP use, condom use and the proportion of anal sex events with HIV-negative partners not on PrEP—significantly outperformed the model based on event-level attributes alone.

Conclusions: Behavioural patterns significantly influence PrEP adherence among GBMSM. Person-centred mobile applications such as UPrEPU provide valuable data for tailored, just-in-time interventions, enhancing adherence. Recognizing these patterns can guide person-centred interventions. Incorporating these insights into clinical care or digital tools may improve consultations and support timely, informed HIV prevention decisions.

Keywords: pre-exposure prophylaxis; gay bisexual and other men who have sex with men; adherence; machine learning; Taiwan

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1 | INTRODUCTION

Oral HIV pre-exposure prophylaxis (PrEP) is highly effective but requires adequate adherence. Alongside daily dosing, event-driven PrEP—added to Taiwan's guidelines in 2018 [1] – has gained popularity among gay, bisexual and other men who have sex with men (GBMSM) in western Europe, Australia and Taiwan, the focus of this study [2–5]. Event-driven PrEP involves two pills between 2 and 24 hours before sex, then one daily until 48 hours after the last sexual encounter. However, a prospective cohort study of GBMSM in Taiwan found that adherence to event-driven PrEP may be challenging due to unexpected sexual situations, lack of opportunity to plan in advance and the regimen's complexity [4]. While overall adherence was high, switching from daily to event-driven PrEP was associated with poorer adherence [4]. Conventional self-report tools often miss episodic behaviours, while daily diaries using ecological momentary

assessment (EMA) offer context into sexual behaviours [6].

We, therefore, leveraged EMA data from UPrEPU, a self-monitoring system designed to monitor and improve adherence to event-driven and daily HIV PrEP among GBMSM in Taiwan [7]. Developed with user-centred design incorporating user input, the app accommodates complex dosing behaviours linked to sexual practices and dynamic dosing choices, and allows users to log behaviour close to the time of sex or PrEP intake. To enhance adherence, the app used the calendar feature to track the user's dosing regimen and scheduled sexual activity, sending push notifications for upcoming pill doses accordingly. UPrEPU app supported 68.6% correct PrEP use during anal sex events, with users reporting it was helpful for self-management [7].

Our objective was to develop machine learning models to predict PrEP protection using logs of sexual activities and user attributes data. We examined whether adding user-level attributes improves PrEP protection prediction and identified key behavioural and contextual predictors. The use of predictive models informed by individual data fosters a more person-centred approach to PrEP adherence by providing targeted support and enhanced monitoring.

2 | METHODS

2.1 | Study design and setting

We conducted a retrospective analysis of data from individuals enrolled in the UPrEPU application, publicly available in Taiwan since 1 January 2022 (732 downloads up to May 2023).

2.2 | Study participants

Eligible participants were assigned male at birth, aged ≥20, identified as GBMSM and provided informed consent to use the app for logging PrEP intake or sexual activity. Those self-reporting HIV-positive status at enrolment were excluded. For users who later reported seroconversion, only pre-seroconversion data were analysed. Inclusion also required at least one logged PrEP or sexual activity event.

2.3 | Variables

Data in the UPrEPU app from January 2022 to May 2023 were included in the present study, including users' demographic attributes and logs of their PrEP use and anal sex events.

2.4 | Outcome

Our primary outcome is a binary variable indicating whether PrEP was taken correctly for an anal sex event. A correct intake was determined if one of the following two criteria was satisfied:

1. For at least 4 out of 7 days before a sexual event, at least one pill was taken each day.
2. Two pills of PrEP were taken between 2 and 24 hours before, followed by one pill taken between 24 and 48 hours, respectively, after the first pill intake. However, if at least one pill was taken within 7 days before each sexual event, taking only one pill 2–24 hours before each sexual event was allowed.

2.5 | Predictors and machine learning model choice

We categorized all predictors involved in this study into two groups:

(a) Event-based attributes: characteristics of each sexual event, such as the user's sex role, timing of the event and condom use.

(b) User-based attributes: personal characteristics, primarily derived from cumulative or average data across events, such as the cumulative number of anal sex events, the cumulative number of times PrEP was taken and the proportion of condom use up to the current event.

2.6 | Training, evaluation and explanation of machine learning models

We used CatBoost to construct our machine learning models. Among the models tested (see code and results on GitHub: https://github.com/jayenliao/uprepu-prep-adherence-ml), CatBoost was selected for its significantly better performance compared to Random Forest and XGBoost in our empirical evaluation [8–10]. It is particularly well-suited to our data, as it natively handles categorical features using permutation-based target statistics and accommodates missing values through sentinel imputation, eliminating the need for normalization or scaling [8].

Two CatBoost classifiers were constructed:

1. Model 1 (M1): All 11 event-based attributes.
2. Model 2 (M2): Besides 11 event-based attributes, 19 dynamic user-based attributes with contextual information were also included, resulting in 30 features. Five nested variants of M2 (M2-a through M2-e), containing successively fewer features (i.e. 25, 20, 15, 10 and 5), were also evaluated.

To prevent overfitting and respect the temporal ordering of events, we employed a temporal 10-fold cross-validation scheme, thereby avoiding peeking into the future. The full dataset was sorted by sex and event timestamp and split into 11 consecutive time-based blocks. For each fold ($i = 1, \ldots, 11$), training was performed on blocks 1 through i, and testing was performed on block $i+1$. This procedure yields 10 train–test splits that preserve temporal integrity and prevent information leakage. For each split, we computed accuracy, precision (i.e. positive predictive value, PPV), recall (i.e. sensitivity) and F1-score, and reported their means and standard deviations across folds [11]. All hyperparameters were set to their default values. To test whether M1 and M2 perform significantly, we applied Wilcoxon signed-rank tests to the F1-scores observed in folds [12]. The F1-score is the harmonic mean of the precision and recall scores and thus contains information about both the positive predictive value and the sensitivity [13].

Feature importance values extracted from the best-performing model were used to identify and eliminate the five least influential attributes, resulting in more parsimonious variants with similar predictive power [14]. Wilcoxon signed-rank tests comparing M2 with its reduced-feature variants (M2-a through M2-e) confirmed no significant performance differences, and the code (including model comparison table) is available at: https://github.com/jayenliao/uprepu-prep-adherence-ml.
Finally, we employed Shapley Additive Explanations (SHAP), a game-theory–based framework, to quantify the direction and magnitude of each feature's contribution to the predicted probability [15]. All analyses were conducted using Python software version 3.9.10.

2.7 | Ethical approval

Ethical approval was granted by the Institutional Review Board of National Cheng Kung University Hospital [A-ER-110-201]. Participants were not required to provide names when using the app. The app included explicit consent prompts. Data was securely stored, encrypted during transmission and protected against unauthorized access.

3 | RESULTS

3.1 | Cohort characteristics

From January 2022 to May 2023, 198 users in Taiwan recorded 2356 anal sexual events on UPrEPU. On average, the users spent 155 days and 19.5 hours on the application. The average number of sexual events for each person was 11.9 (standard deviation 19.8), and the median was 4.5. Among all anal sex events, 1662 (70.5%) were protected with the correct PrEP use based on our definition. Descriptive statistics of the demographic attributes and other variables included in the models are presented in Table 1.

3.2 | Machine learning models

Table 2 presents the testing performance of models with different feature sets and two prediction targets, evaluated using four indices. The positive label (i.e. the protected event) is our primary target for prediction. We also presented the negative label (i.e. the unprotected event) for reference due to label imbalance, as the proportion of protected events was much higher than its counterpart (i.e. 70.5% vs. 29.5%). This imbalance naturally drives lower scores for the minority class (i.e. the unprotected event).

The Wilcoxon signed-rank test showed that M2 significantly outperformed M1 with a higher F1-score ($p < 0.005$), underscoring the value of incorporating user-based attributes with contextual information into the prediction model.

No significant difference was observed between M2 and its variants. Exclusion of the five least important features (yielding M2-b through M2-e) did not materially affect performance ($p > 0.05$), indicating that the top predictors alone capture the majority of the signal for protected-event prediction. Among M2's variants, M2-e, its most parsimonious form, comprising only five features and proves sufficiently powerful to predict correct PrEP use, with all evaluation metrics remaining on par with those of more complex variants.

Figure 1 presents five variables included in the M2-e, namely dose cumulative sum, age, user duration, condom use proportion, and proportion of having anal sex events with a partner who was HIV negative and not on PrEP, and their feature importance and SHAP values. Among the five variables, the dose cumulative sum has the highest feature importance. The SHAP value indicated that the duration of using UPrEPU and the proportion of condom use were negatively associated with correct PrEP use.

4 | DISCUSSION

Correct PrEP use was closely linked to each individual's behavioural patterns, which were influenced by their habitual tendencies and personal choices in the Taiwanese context. The model with five dynamic user-based attributes—age, cumulative PrEP use, condom use and the proportion of anal sex events with HIV-negative partners not on PrEP—significantly outperformed the model based on event-level attributes alone. Understanding these patterns can enhance predictive models and support person-centred interventions. Integrating this insight into clinical care or digital tools may improve consultations and support timely, informed HIV prevention decisions.

The cumulative number of taking PrEP was the most influential factor, suggesting that adherence may involve a learning curve in recognizing behaviours and risks to adopt more effective prevention strategies. This finding aligns with prior research showing that frequent self-monitoring and visual feedback through mobile apps can reinforce PrEP adherence by enhancing users' ability to recognize behavioural patterns and implement timely prevention strategies [16, 17].

Our study indicated that certain longitudinal behavioural patterns within a person are indicative of correct PrEP use, such as cumulative condom use and proportion of sex encounters involving HIV-negative partners not on PrEP. Such longitudinal data are important because prior research on HIV risk factors and PrEP adherence has examined both individual characteristics and contextual factors. Situational variables, such as weekends or unusual days, were strongly associated with non-adherence in several studies [6, 18, 19], while fluctuating emotional or motivational states have been tied to higher-risk sexual activity, including condomless anal intercourse [6]. A valuable next step could be the collection of psychosocial attributes and clinical characteristics through the app and utilizing those in the machine learning models.

Interestingly, we observed that lower rates of condom use indicated a higher probability of correct PrEP use during sexual encounters among users. This suggests the importance of considering both prevention and adherence strategies simultaneously when evaluating HIV prevention approaches in real-world settings, which echo the importance of preventive-effectiveness adherence [20].

Our study indicated that the longer duration of using UPrEPU is negatively associated with reported correct PrEP use, possibly due to declining engagement with the app's logging features over time. This highlights the need to distinguish

Table 1. Descriptive statistics of event-based and user-based variables used in predictive models of PrEP adherence (*N* = 2356 anal sex events recorded by 198 participants)

Name and description	Mean (SD)/*N* (%)[a]
(a) Event-based (included in M1 and M2)	
Time of the sex event: hour of day, 24-hour format, that is 0, 1, . . ., 23.	15.0 (7.3)
Pre-date: Whether the user had created the dating record before sex time for the current anal sex event.	215 (9.1%)
Sex role: User's sex role in the event	
Receptive partner	1203 (51.1%)
Insertive partner	908 (38.5%)
Versatile	245 (10.4%)
Mood: User's reported mood in the event	
Terrible/bad/so-so	579 (24.6%)
Good	987 (41.9%)
Fabulous	790 (33.5%)
Condom: Whether a condom was used during the event	491 (20.8%)
Icon default: Whether the user set a default icon for the partner in the current event	1738 (73.8%)
Partner age: Age group of the partner in the event	
Younger than 21	252 (10.7%)
21–30	980 (41.6%)
31–40	876 (37.2%)
41–50	220 (9.3%)
51–60	21 (0.9%)
Older than 60	7 (0.3%)
Older partner: Whether the partner in the event was older than the user	568 (24.1%)
Younger partner: Whether the partner in the event was younger than the user	719 (30.5%)
Same-age partner: Whether the user and the partner in the event belonged to the same age group	1069 (45.4%)
Partner HIV status: The HIV status of the partner in the event	
Unknown	1282 (54.4%)
Negative and on PrEP	449 (19.1%)
Negative but not on PrEP	458 (19.4%)
Positive and undetectable	124 (5.3%)
Positive and viral load unknown	9 (0.4%)
Missing	34 (1.4%)
(b) User-based (included in M2)	
User duration: How long has the participant joined in the study up to the current event (unit: hour)	137.7 (110.7)
Age: How old the participant was at the time of the current anal sex event (unit: year)	31.2 (5.8)
Sex cumulative sum: The cumulative number of anal sex events the participant has recorded up to the current event.	22.9 (30.4)
Date cumulative sum: The cumulative number of dating records the participant has recorded up to the current event.	23.0 (30.5)
Dose cumulative sum: The cumulative times the participant has taken PrEP up to the current event.	62.7 (68.5)
Switch cumulative sum: The cumulative times of switching the regimen of taking PrEP the participant has conducted up to the current event.	0.6 (1.4)
Condom use proportion: Proportion of condom use up to the current event.	0.2 (0.3)
Pre-date proportion: Proportion of dating records created on the app before sex up to the current event.	0.1 (0.2)
Receptive proportion: Proportion of being the receptive partner during anal sex up to the current event.	0.4 (0.4)
Insertive proportion: Proportion of being the insertive partner during anal sex up to the current event.	0.5 (0.4)
Versatile proportion: Proportion of being versatile during anal sex up to the current event.	0.1 (0.2)
Older partner proportion: Proportion of having older partner(s) up to the current event.	0.2 (0.3)

(*Continued*)

Table 1. (Continued)

Name and description	Mean (SD)/*N* (%)[a]
Younger partner proportion: Proportion of having younger than partner(s) up to the current event.	0.3 (0.3)
Same-age partner proportion: Proportion of belonging to the same age group of partner(s) up to the current event.	0.5 (0.3)
HIV-unknown partner proportion: Proportion of having anal sex with a partner whose HIV status was unknown.	0.5 (0.4)
HIV– & PrEP+ proportion: Proportion of having anal sex with a partner who was HIV negative and on PrEP.	0.2 (0.3)
HIV– & PrEP– proportion: Proportion of having anal sex with a partner who was HIV negative and not on PrEP.	0.2 (0.3)
Undetectable HIV+ partner proportion: Proportion of having anal sex with a partner living with HIV with undetectable viral load.	0.0 (0.1)
HIV+ & viral load unknown partner proportion: Proportion of having anal sex with a partner living with HIV with unknown viral load.	0.00 (0.02)

Abbreviations: HIV–, HIV-negative status; HIV+, HIV-positive status; M1, model 1, the CatBoost classifier with all 11 event-based attributes; M2, model 2, the CatBoost classifier with 11 event-based attributes and 19 dynamic user-based attributes; PrEP, pre-exposure prophylaxis; PrEP+, on PrEP; PrEP–, not on PrEP.
[a]Values are generally reported to one decimal place. For very small proportions (< 0.05), two decimals are shown to avoid rounding to zero.

Table 2. The performance of models with different feature sets and two prediction targets regarding four evaluation indices: accuracy, precision, recall and F1-score (averaged scores of 10 folds ± standard deviations; *N* = 2356 anal sex events recorded by 198 participants)

Model[a]	Prediction target[b]	Accuracy[c]	Precision[d]	Recall[e]	F1-score[f]
M1: CatBoost with 11 features	Protected	0.70 ± 0.05	0.73 ± 0.03	0.92 ± 0.08	0.81 ± 0.04
	Unprotected		0.43 ± 0.19	0.15 ± 0.09	0.21 ± 0.11
M2: CatBoost with 30 features	Protected	0.76 ± 0.05	0.79 ± 0.03	0.91 ± 0.07	0.84 ± 0.04
	Unprotected		0.64 ± 0.13	0.40 ± 0.10	0.48 ± 0.10
M2-a: CatBoost with 25 features	Protected	0.76 ± 0.05	0.79 ± 0.02	0.90 ± 0.07	0.84 ± 0.04
	Unprotected		0.62 ± 0.14	0.39 ± 0.10	0.48 ± 0.11
M2-b: CatBoost with 20 features	Protected	0.76 ± 0.05	0.79 ± 0.02	0.91 ± 0.06	0.84 ± 0.04
	Unprotected		0.65 ± 0.12	0.40 ± 0.09	0.49 ± 0.09
M2-c: CatBoost with 15 features	Protected	0.76 ± 0.05	0.79 ± 0.02	0.90 ± 0.08	0.84 ± 0.04
	Unprotected		0.63 ± 0.14	0.39 ± 0.11	0.47 ± 0.10
M2-d: CatBoost with 10 features	Protected	0.75 ± 0.05	0.78 ± 0.02	0.89 ± 0.09	0.83 ± 0.05
	Unprotected		0.63 ± 0.13	0.37 ± 0.10	0.45 ± 0.09
M2-e: Catboost with 5 features	Protected	0.75 ± 0.05	0.78 ± 0.02	0.90 ± 0.07	0.83 ± 0.04
	Unprotected		0.61 ± 0.14	0.35 ± 0.08	0.44 ± 0.09

Abbreviations: M1, model 1; M2, model 2.
[a]Model 1 (M1) includes all 11 event-based attributes. For Model 2 (M2), besides 11 event-based attributes, 19 dynamic user-based attributes with contextual information were also included, resulting in 30 features. M2-a, M2-b, M2-c, M2-d and M2-e are M2's variants with features reduction.
[b]The prediction target can be either a protected or an unprotected event. Evaluation metrics are calculated accordingly based on the chosen prediction target.
[c]Accuracy is the proportion of correctly predicted events (whether protected or unprotected) out of all events.
[d]Precision (i.e. Positive Predictive Value, PPV) is the proportion of correctly predicted events of the target type (e.g. unprotected) among all events predicted as that type.
[e]Recall (i.e. Sensitivity) is the proportion of actual events of the target type (e.g. protected) that were correctly identified by the model.
[f]F1-score is the harmonic mean of precision and recall, representing a balance between the two.

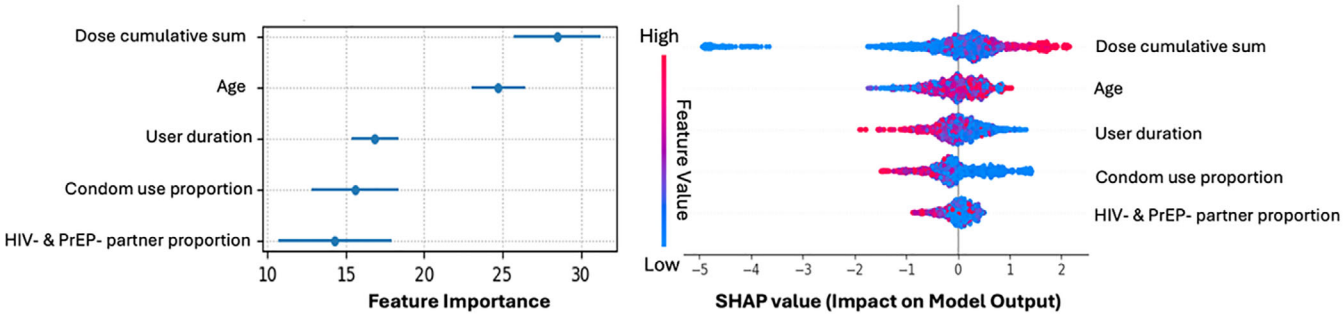

Figure 1. (a) Plot of feature importance of M2-e. (b) Summary plot of SHAP value of M2-e. M2-e is the CatBoost model with five features (*N*=2356 anal sex events recorded by 198 participants). In Figure (a), dots indicate the averaged importance values, and error bars are the standard deviation among 10 folds of cross-validation. In Figure (b), each sexual event is represented by a dot in each feature row. Dots in deeper red represent higher feature values, while those in deeper blue indicate lower values. Negative SHAP values have a negative impact on the final prediction probabilities, and vice versa. Abbreviations: Age, sex event time minus user's birthday; Condom use proportion, proportion of using condom of the user up to the current event; Dose cumulative sum, cumulative total count of times of taking PrEP; HIV– and PrEP– proportion, proportion of having anal sex events with a partner who was HIV negative and not on PrEP; M2, model 2; PrEP, pre-exposure prophylaxis; SHAP, Shapley Additive Explanations; User duration, sexual event time minus user's time of APP registration.

between the app as an adherence support tool and as a self-report platform. Given the limitations of self-reported data, future studies using objective biomarkers like drug concentrations could provide more accurate adherence measures. Sustaining engagement remains a challenge, as seen with other self-logging health apps [21–23], and automated solutions such as Internet of Things integration may help reduce user burden.

The present study has the following limitations. The major limitation of the study is non-response bias, such as not reporting all sexual activities or PrEP use on the app. Individuals who are keener on actively monitoring and logging their behaviour in the app might be those with better adherence. Further, an assumption is made that most individuals engage in planned sexual activity, allowing our app to remind them to take medication in advance. However, for those primarily involved in unplanned sexual encounters, this assumption may not hold, potentially leading to decreased adherence and incomplete or inaccurate adherence patterns. Lastly, our analysis may have potential over-representation bias since we did not differentiate inter- and intra-participant variability. The model results may be dominated by a few users who have much frequent logins than others.

5 | CONCLUSIONS

Our study explores the predictive value of sexual behavioural patterns in PrEP adherence in Taiwan, highlighting the need for person-centred approaches to strengthen prevention strategies and support timely, informed decisions.

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COMPETING INTERESTS

The authors declare no competing interests.

AUTHOR CONTRIBUTIONS

JCL conceived the presented research idea and verified the underlying data. JCL, T-TC and T-WC conducted the data collection, laboratory activities, and reviewed the collected data for quality and reliability. JCL analysed the data and constructed machine learning models. JCL, H-JW and CS contributed to interpreting the results and took the lead in writing the manuscript. CS was in charge of the overall direction and planning. All authors provided critical feedback, shaped the research, analysed the manuscript and approved the final submitted manuscript.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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