



Applying CFIR to assess multi-level barriers to PrEP delivery in rural South Africa: Processes, gaps and opportunities for service delivery of current and future PrEP modalities

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ABSTRACT

Despite established efficacy for oral pre-exposure prophylaxis (PrEP) in reducing HIV incidence, multi-level barriers within the health system, clinics, and the processes that shape practice have hindered service delivery and subsequent population-level effects. We applied the Consolidated Framework for Implementation Research (CFIR) to assess the context of PrEP delivery for adolescent girls and young women (AGYW) in rural South Africa and identify the factors supporting and impeding PrEP implementation to develop strategies to improve PrEP delivery. Between 2021 and 2022, we conducted in-depth interviews with five young women with PrEP use experience and 11 healthcare providers as well as four key informant stakeholder interviews. Tailored interviews organized around the CFIR domains provided multiple perspectives on the inter-connected processes, gaps, and opportunities between health systems, clinics, communities, and PrEP services. Shifts in PrEP policies, funding pressures, and inconsistent communications from the National Department of Health spurred fragmented planning, engagement, execution, and monitoring of PrEP delivery processes within clinics already struggling to address multiple population health needs. Resulting challenges included: conflicting priorities within clinics and across NGO partners, unclear goals and targets, staffing and space constraints, and insufficient community engagement. Individual clinics' implementation climate and readiness to deliver PrEP varied in terms of operational plans and delivery models. Interviewees reported complexity of initiation procedures and support for PrEP maintenance, with opportunities to improve systems communications and processes to facilitate integrated services and more user-friendly experiences. Applying CFIR identified opportunities to strengthen PrEP delivery across levels within this complex service delivery setting.

1. Introduction

Despite its promise as a highly efficacious biomedical intervention for HIV prevention, daily oral pre-exposure prophylaxis (PrEP) poses distinct implementation challenges. PrEP is designed for the prevention of a stigmatized condition among generally healthy individuals, many of

whom may not routinely use health services, and whose need for HIV prevention fluctuates over time (Rousseau et al., 2021; Zablotska et al., 2018). As such, PrEP services require system, provider, and user alignment to deliver on the promise of reducing HIV incidence for those facing disproportionate exposure. Implementation science addresses the alignment of evidence-based interventions within routine health service

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delivery (Nilsen and Bernhardtsson, 2019), providing determinant frameworks that situate interventions within the critical contextual determinants to further successful implementation (Villalobos Dintrans et al., 2019). The Consolidated Framework for Implementation Research (CFIR) is a commonly used determinant framework outlining multiple levels of context in which implementation barriers and facilitators can be identified, understood, and prioritized (Damschroder et al., 2009). CFIR defines five determinant domains: 1) intervention characteristics; 2) outer setting (political, economic, and social context); 3) inner setting (context within the service delivery organization); 4) individuals involved in delivery and receipt of services; and 5) implementation process.

Application of CFIR to the first decade of PrEP implementation has highlighted distinct domains shaping uptake in diverse settings. Research in the US has identified key patient and provider factors, including PrEP awareness, the role of HIV stigma inhibiting access and use, and the importance of provider engagement (Li et al., 2022; Weir et al., 2019). In settings facing generalized HIV epidemics, such as Kenya and Uganda, studies anchored in CFIR have identified similar determinants, while drawing attention to the structural characteristics of the inner setting and outer setting that shaped implementation (Jackson-Gibson et al., 2021; Roche et al., 2022; Thomas et al., 2022). Within the public health sector of these East African countries, structural challenges included resource constraints (e.g., limited space and personnel for youth-focused services), and service delivery decisions, such as the unanticipated consequence that utilizing externally funded staff to jumpstart PrEP delivery would in fact undermine ownership of PrEP within core providers.

In South Africa (SA), daily oral PrEP received regulatory approval in December 2015, followed by the National Department of Health (NDOH) initiating a segmented and sequential roll out of PrEP among high-risk populations before extending guidelines to include all at-risk adults in 2019 (Bekker et al., 2016; Department of Health, 2020). Despite PrEP demonstration projects with adolescent girls and young women (AGYW) reporting high interest and uptake, population-level uptake and persistence in the primary care system remain low (Celum et al., 2021; Rousseau et al., 2021; Shamu et al., 2021). Moreover, the bulk of evidence on SA's PrEP implementation comes from demonstration studies, mainly in urban centers, with dedicated external resource support (Amico et al., 2017; Baron et al., 2020; Celum et al., 2021). For instance, Project PrEP employed four strategies to enhance AGYW's oral PrEP uptake: stakeholder engagement, demand creation, capacity building, and flexible service delivery models with fixed and mobile clinics (Butler et al., 2023). With these resource intensive efforts, over 14,000 AGYW initiated PrEP from 2018 to 2021 across four SA implementation sites. What remains to be seen is how PrEP implementation can be optimized within routine primary care services with fewer targeted resources.

Unlike HIV treatment and mental health care services implementation studies, which have shown high perceived need and benefits (van Heerden et al., 2022; Kemp et al., 2021), preventive healthcare services provide less visible benefits. In the rural sub-district of Ehlanzeni, Mpumalanga where this study takes place, previous research found HIV prevalence was 5.5% in women aged 15–19 years and rose to 27% in 20–24 year-olds (Gómez-Olivé et al., 2013). With government primary care as the dominant source of health services, high demands on clinics raise important issues of relative priority of new programs like PrEP, even creating false dichotomies pitting treatment against prevention services. For AGYW in this rural area, service delivery challenges (e.g., time and cost of reaching care, judgmental or poorly informed providers) complicate health care use and could undermine perceived benefits of PrEP among AGYW and providers (Lanham et al., 2021; Rousseau et al., 2021). Understanding routine implementation of prevention services in rural primary care can inform improved service delivery for oral PrEP and additional long-acting PrEP products as they become available.

In this study, we apply CFIR to identify the factors supporting and impeding PrEP implementation within routine health services in rural SA. As a complement to existing research that centers individuals' PrEP experiences, this manuscript aims to contribute to better understanding the PrEP service delivery context by examining its structures, settings, and processes spanning individual, facility, and district levels. We conducted individual interviews with AGYW PrEP users ('users' moving forward), clinic-based healthcare staff (clinic staff), and key informants (KIs) to provide multiple perspectives on PrEP delivery within the SA primary care system.

2. Methods

2.1. Study design

We conducted a qualitative study using in-depth interviews (IDIs) and key informant interviews (KIIs) to shape a five-year, community-engaged implementation science project aimed at identifying and addressing barriers to PrEP service delivery for AGYW in rural Mpumalanga, SA. This analysis explored how policy, communication, and planning influence engagement, execution and evaluation processes of clinic-level PrEP services. A Stakeholder Working Group (SWG) was formed in October 2021 and has convened at least annually thereafter, bringing together AGYW PrEP ambassadors, district Department of Health (DOH) officials, clinic managers, non-governmental organization (NGO) representatives, and community leaders, to advise on this project.

This study was approved by the Institutional Review Boards at the University of California San Francisco, the Human Research Ethics Committee at SA's University of the Witwatersrand, and the Mpumalanga Department of Health and Social Development Research Committee.

2.2. Study setting

The Bushbuckridge sub-district of Ehlanzeni, Mpumalanga Province, SA hosts the Agincourt Health and Demographic Surveillance System (HDSS) site, some 500 km northeast of Johannesburg. Villages in this area were born out of apartheid-led forced removal programs, leaving lasting legacies of high rates of poverty, unemployment, and circular labor migration (Ehlanzeni District Municipality, 2020; Kahn et al., 2012). Ongoing high HIV incidence among young women in Bushbuckridge compounds these challenges. Between 2011 and 2015, HIV incidence was 3.6% among 19-year-old women and 4.3% among women 20 and older (Pettifor et al., 2016). In Ehlanzeni, oral PrEP should be available to all at-risk adults through DOH-run primary health clinics. Two SA-based NGOs, which receive US bilateral funding, support implementation efforts: one providing clinical mentorship and patient education to fixed clinics and the other delivering PrEP to AGYW via mobile clinics. Despite these efforts, PrEP use remains low: in the third quarter of 2022, daily oral PrEP users represented <4% of AGYW in the study area, with average duration <6 months (Right to Care, 2022). At the time of data collection (2021–2022) and publication (2024), daily oral PrEP was the only PrEP modality implemented at DOH clinics.

2.3. Data collection

Between December 2021 and May 2022, we conducted semi-structured IDIs with current or previous AGYW PrEP users, and with healthcare providers of primary care DOH clinics and non-governmental mobile clinics. KIIs were conducted with implementation partners, including community leaders, program managers, and a policymaker. Participants were selected for their deep local knowledge and lived/work experience with PrEP delivery, while KIs provided expertise and insights on data, policy, and community advocacy. We initially planned to interview 25 individuals, yet reached saturation sooner having

recruited a “culturally cohesive sample” (Morse, 1995, p. 149) that provided richness in data and variation of perspectives. All participants resided and/or work in Bushbuckridge and were purposefully recruited through convenience and snowball sampling. Written informed consent and interview guides were translated to the local language, Xitsonga, and back-translated to English, before being implemented in Xitsonga by trained local field workers. Tailored interview guides for each participant category were based on the CFIR domains and focused on selected constructs that would contribute to our understanding of the interconnected processes between health systems, clinics, and PrEP delivery. For example, each guide addressed AGYW’s challenges with maintaining PrEP use to glean complimentary perspectives. Within the implementation process domain, we asked AGYW about clinic processes (e.g., visit frequency for PrEP refills) that influenced their ability and desire to continue PrEP use; questions for healthcare workers solicited perspectives on tools (monitoring and tracking systems) to support patient follow-up; and KII guides addressed how funding and policy impact resource allocation for clinics to support follow-up PrEP services (See Table 1 for interview topics).

In applying CFIR constructs, we defined the inner setting as PrEP delivery sites, including DOH primary care clinics and NGO-operated mobile clinics; the outer setting included the district DOH, acting on local and national policy, as well as civil society and the larger community. Interviews lasted 45–90 min and were audio recorded. Recordings were simultaneously translated into English and transcribed verbatim. Transcripts were anonymized and quality controlled by the bilingual project site manager, who checked the English transcripts against the audio recordings for accuracy. All transcripts were stored on a password-protected drive.

2.4. Data analysis

Data were imported to Dedoose for coding and analysis. Authors met weekly to discuss emerging findings during data collection, followed by two analysis workshops where themes were identified. We used 38 CFIR constructs (21 codes, 17 sub-codes) across the five domains to develop the codebook, adapting code definitions to a PrEP delivery context (See Supplement 1). Five authors participated in open coding and developed analytic memos on a subset of transcripts that were double-coded. Through this process, the group refined and finalized codes and decision rules. Thereafter, the remaining transcripts were single coded. Coding discrepancies and questions were reviewed and resolved through group consensus. Summary code reports were produced, and multiple thematic matrices were compiled both within and across CFIR domains to compare and contrast salient implementation challenges and facilitating factors for PrEP delivery. In this way, our harmonized guides enabled us to put the interviewees’ diverse perspectives in conversation with each other. Preliminary findings were validated and at times, further contextualized via a SWG consultation in October 2022. For example, a discussion about whether clinics were implementing tracking systems consistently led the research team to re-examine transcripts to clarify specific procedures by clinic, which informed recommendations to improve PrEP delivery tracking systems.

3. Results

Twenty participants took part in the interviews. Young women with PrEP experience ranged from 19 to 26 years old; the 11 clinic staff included nurses, clinic managers, and a pharmacist (aged 30–58; nine identified as female). The four district and community-level KIs were in their mid-thirties to fifties, including two (1 female, 1 male) community leaders and two female policymakers/program managers charged with PrEP implementation training and oversight. Participant perspectives reflected experiences spanning four DOH facilities and one NGO mobile clinic.

We present results thematically by four CFIR domains while

Table 1

Study interview guide topics across participant categories.

Category	CFIR domain: Key topic areas of interview questions ^a
AGYW	<u>Characteristics of individuals and intervention</u> • Motivating factors for initiating and continuing or discontinuing PrEP use • Types of support and access that would help re-start PrEP • Preferences for other prevention methods <u>Inner setting</u> • Experiences with clinic flow, providers • Experiences and assessment of confidentiality and responsiveness • Preferences for location, breadth and types of services provided with PrEP <u>Outer setting</u> • Community views on PrEP: peers, family, community leaders, and media • Media and social media exposure about PrEP <u>Implementation process</u> • Step-by-step process at clinic to initiate PrEP • Frequency of HIV tests, blood draws, counseling, refill visits • Challenges with clinic or staff in maintaining use
Clinic staff	<u>Characteristics of individuals and intervention</u> • AGYW’s need for PrEP, preferences for HIV prevention methods, and challenges in maintaining PrEP • PrEP in context of other health priorities • Complexity and gaps in PrEP delivery, impact on AGYW’s PrEP use <u>Inner setting</u> • Process of learning about PrEP guidelines and targets • Training and training needs • Experiences prescribing PrEP and engaging with AGYW • Clinic factors that support program implementation: leadership, teamwork, communication • Impact of physical space, staffing infrastructure, other resources on PrEP delivery <u>Implementation process</u> • Clinic planning, processes, resources, and gaps in execution • NGOs’ role in PrEP awareness and demand • Monitoring systems
Key informants	<u>Characteristics of individuals and intervention</u> • AGYW’s need for PrEP, preferences with other HIV prevention methods, and challenges with ongoing PrEP use • PrEP in context of other health priorities <u>Inner setting</u> • Planning, tools, and resources available to facilitate PrEP implementation • Impact of infrastructure in rural settings on PrEP delivery • Opportunities to integrate PrEP and reproductive health services <u>Outer setting</u> • PrEP policy, guidance, targets, and communication channels • Funding allocation and PrEP delivery partnerships • PrEP supply chain by sector • Opportunities for PrEP integration (e.g., schools, community-based programs) <u>Implementation process</u> • Influences on planning, execution, and monitoring PrEP delivery in primary care facilities • Barriers to PrEP provision for AGYW at the policy, clinics, and user levels

^a Bullets not listed in order asked during interview.

highlighting interactions and influences between intervention levels. The fifth domain – characteristics of individuals – is integrated throughout where relevant. Fig. 1 summarizes key findings.

3.1. Lost in translation: From communicating to implementing PrEP policy, targets, and funding [outer setting]

Reflecting on the district, provincial, and national levels, interviewees described how shifts in policies, unclear goals and targets, and funding pressures influenced PrEP delivery in Bushbuckridge. Most KIs and clinic staff were aware of national PrEP policy and guidelines. However, the degree of understanding—including eligibility, clinical processes, and policy updates—varied depending on professional role, perceived ‘need to know,’ and personal interests. One policymaker

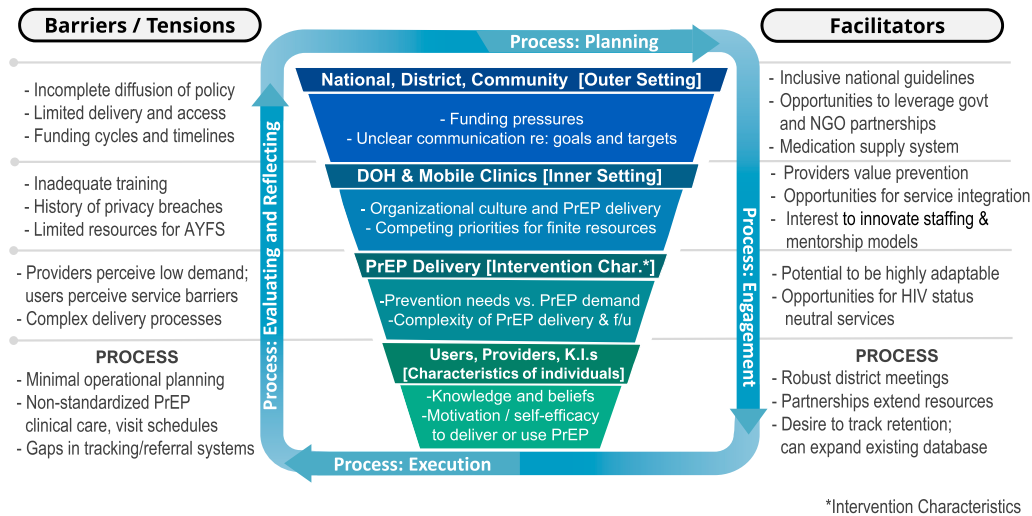


Fig. 1. Summary of facilitating factors and barriers/tensions organized by CFIR domains and salient constructs.

declared:

We do have a guideline for PrEP, [including an] updated one because at first the guideline was not clear in terms of pregnancy and breastfeeding women. So now it has been clarified and we have received the communication last year which we have circulated to all the facilities. [KI 1, District level]

Clinic staff mostly corroborated this narrative, though awareness did not always translate to implementation. One clinic staff knew of the policy change but stipulated her clinic is “waiting for the province to roll it out.” [Staff 9, Mobile clinic clinical mentor] Another reported: “we have never changed the guidelines, if there is a new guideline we don’t know about.” [Staff 4, Clinic A nurse] Meanwhile, according to a community outreach worker: “We [SA] do not have guidelines for PrEP.” [KI 4, Community NGO]

Knowledge of PrEP guidelines seemed to hinge on the messenger and mechanism, which in turn had ripple effects on clinics’ planning and execution of PrEP delivery. Many KIs and clinic staff agreed it was NDOH’s mandate to disseminate policy information, citing district-level meetings and digital communication applications (WhatsApp) as common platforms utilized. Interviewees described trickle down communications, with province and districts funneling PrEP updates to clinic managers, who then relayed information to providers. Dilution and breakdown of messages were common, often resulting in sub-optimal staff training, as aptly described below:

I: How is this policy communicated to providers?

P: From our manager, sometimes we don’t even read them. Maybe that’s why we don’t understand. (participant giggled)

I: ... So, how then are you able to provide the information if you don’t read the policy?

P: When I come back from the meeting with the new policy ... we have to read it as a group, and then sign to show that we understand what it says, although we don’t read it in detail. [Staff 6, Clinic B nurse]

For some clinic staff, NGOs were their primary source for both information and implementation support: “[NGO 2] is the one that is promoting PrEP ... in terms of workshops, training, and everything. [They] are doing more than the government does in terms of PrEP.” [Staff 3, Clinic B manager] In partnership with DOH, these US-funded NGO implementers provide the district with PrEP delivery operational support, including

PrEP demand creation campaigns, community outreach, youth services, and clinical personnel. While users in particular lauded these NGO efforts, some providers viewed the paucity of PrEP-specific communication and training by DOH as indicative that PrEP was a lower government priority among the multiple population health needs that DOH is responsible for addressing.

Just as the guidelines reached clinics unevenly, communication about targets was likewise inconsistent. Policy and program managers described providing clinics with concrete PrEP initiation targets, as required by the DOH and donors. Yet, clinic staff had mixed understanding of who set these targets, numbers expected, and time frames involved. Some were uncertain if targets existed at all. When clinics missed targets, clinic staff attributed shortfalls to resource constraints, poor training, or blaming AGYW:

[The] target for PrEP we have talked [about] as a staff is that [each] month, each and every person must have at least initiated five clients, but uhm We are far behind with that target [so during] our reviews ... it seems like the challenge is on patients’ side, which is one-sided because patients are there, so they [staff] defend themselves by saying patients are refusing ... [but] maybe they were not offered. [Staff 3, Clinic B Manager]

Another salient theme was the influence of external donor funding on local PrEP delivery. Interviewees recounted the benefits of funded NGO partnerships. Yet, they also noted that short funding cycles made for tenuous DOH-NGO partnerships, unreliable interventions fraught with donor-imposed timelines, and a resulting legacy of mistrust:

Although it may look like there is a solid relationship [between DOH and their NGO] it’s not the case, the partnership is there on paper but in reality, there isn’t. [Staff 10, NGO Peer Educator at Clinic A]

Another thing that is so tiring about these funded organizations is that they just come and go. When they come to us, they have money. When they go back, we don’t know how people are going to continue with whatever they introduced to them. They don’t even talk about it when the program is going to end and what we must expect or continue without them. [KI 3, Community NGO]

In sum, clinic staff and KIs recognized the need to streamline communication systems and develop more sustainable partnerships to improve DOH clinics’ delivery of PrEP. Yet, with multiple government priorities and NGO partners driven by donors’ timelines and targets,

clinics were frequently left on their own to operationalize high level guidelines.

3.2. To each their own ... [inner setting]

Within individual facilities, clinic staff described how competing priorities within resource constraints, as well as wide-ranging learning climates and organizational cultures influenced their PrEP services to AGYW. Combined with external pressures from the outer setting, these factors created an ‘every clinic for themselves’ environment with staff and AGYW describing variable clinical care and user experiences.

Clinic staff had mixed feelings about PrEP, especially when considered in relation to the other healthcare services they were expected to provide with finite resources. Some believed PrEP was a priority, as it aligned with primary health clinics’ health education and preventative services mandate. A few refused to rank services: *“All our services are priority, we do have challenges providing PrEP but it doesn’t mean that it’s not a priority.”* [Staff 3, Clinic B manager] Still others situated PrEP as secondary compared with the urgency of treating *“HIV positive patients ... and other chronic patients.”* [Staff 10, NGO Peer Educator at Clinic A] These varying staff attitudes about PrEP were shaped by many factors, including their clinic’s internal capacity and resource constraints, which in turn, influenced each clinic’s service delivery model. Some clinics attempted to integrate delivery of all health services, likening it to a *“supermarket approach, so all services are provided every day.”* [Staff 8, clinic C manager] A subset of DOH clinics leveraged NGO support to expand capacity for PrEP delivery. At one clinic with limited rooms, NGO 1 set up *“a tent [outside the clinic] where they are able to give more people PrEP like 20 a week.”* [Staff 5, Clinic D manager] Another DOH nurse described leveraging NGO staff to help with staff shortages: *“we send patients for PrEP to another nurse from [NGO 1] here at the clinic; she then tests them and takes the blood and sends the patient back to us so that we sign.”* [Staff 1, Clinic C nurse] While these partnerships helped fill critical gaps, staff and users also expressed frustration with these patchwork systems. One PrEP user complained about being shuffled between *“different providers”* [User 5] to get contraceptive, HIV testing and PrEP. Meanwhile, another AGYW who was accessing PrEP through an NGO mobile clinic noted that staff at her DOH clinic don’t even mention PrEP: *“At the clinic, they don’t talk about [PrEP], maybe they don’t know or they don’t have time to explain.”* [User 3] In contrast, the mobile clinics provided dedicated PrEP and related SRH services for women up to age 25—offering an alternative to DOH facilities.

Beyond service scope and resources, organizational culture presented another contrast between PrEP delivery sites. Users wanted confidential and respectful care above all else. Yet their experiences at DOH clinics often entailed negative staff attitudes, denial of services due to their youth, and breaches in confidentiality—leaving many fearful or even refusing to return to DOH clinics. In comparison, the culture of mobile clinics were described as friendly and non-judgmental:

At the [DOH] clinic you will have to lie in order to get a service but on these mobile units they make you feel like you are a priority to them ... they are not judgmental and they will tell you straight from the beginning that they are not here to judge you but they want to help. [User 1]

Despite users’ sentiments, many DOH clinic staff recognized the value of a welcoming environment, with some linking their clinic’s culture directly to achieving targets: *“We as healthcare providers also need to learn to treat every client with respect because we also contribute to the low uptake of PrEP, we need to stop judging people who take PrEP and [anti-retrovirals] ARVs.”* [Staff 7, Clinic D nurse] Thus, although for different reasons, AGYW and staff alike recognized organizational culture as a key factor in AGYW’s decisions to utilize services.

Finally, the learning climate and teamwork within clinics were identified as key inner setting determinants that shaped PrEP delivery. Most prominently, staff discussed PrEP clinical training as insufficient—which, in turn, affected clinics’ readiness for service delivery.

They described a diffusion model of training whereby a clinic “focal person” was sent for training, who was then responsible for training the clinic’s remaining staff. However, not all staff were reached as one nurse noted: *“Most people have not been trained on PrEP.”* [Staff 7, Clinic D nurse] Others observed that second-hand training left staff ill-equipped to deliver PrEP: *“They [nurses] need to be thoroughly trained on PrEP, you may find that some do not provide PrEP because – not because they don’t like it but are not confident enough to explain it and to respond to questions.”* [Staff 10, Clinic A NGO peer education] Yet, as one KI stated, *“Training alone is not enough.”* [KI 1, District level] To nurture an effective learning climate, staff and KIs recommended ongoing mentorship models, staff rotation systems and cross-clinic learning opportunities to facilitate peer-to-peer learning. Many of these recommendations hinge on teamwork. Illustrating this, Clinic A sought to operationalize an organizational culture of teamwork through a staff rotation delivery model:

[W]e are planning that even if you are a focal person we must [use] teamwork ... We agreed that we must rotate on a monthly basis so that everyone must be exposed to every service that we are running in the facility to avoid the situation where it is known that this and that services belongs to a particular nurse that has more information on that service. [Staff 2, Clinic A nurse]

At Clinic D, the operations manager described their teamwork approach, using morning meetings to delegate tasks depending on the demands and resources available on any given day. In contrast, one NGO staff noted how division of duties between their NGO and DOH staff hampered their collaboration: *“I think teamwork plays a huge role because if people are not supporting each other, they will not reach the facility targets. Like at this facility, we do not have strong teamwork.”* [Staff 10, NGO peer educator at Clinic A] Overall, support for training, ongoing learning, and teamwork were identified as critical elements to improving PrEP implementation in DOH clinics.

3.3. What young women want vs. what they need [intervention characteristics]

This domain provided insights into the unique challenges and opportunities involved in delivering an HIV prophylaxis to a young, healthy population in a resource-constrained rural setting. Overall, clinic staff and KIs concurred about AGYW’s need for PrEP, citing risks such as inequitable sexual partnerships that hinder women’s ability *“to negotiate [condom use] for sex”* [KI 4, Community NGO], and clinical experiences seeing *“young girls ... complaining of a lot of STIs and it shows that our teenagers and adolescents are not using condoms.”* [Staff 7, Clinic D nurse] Despite the consensus on need, interviewees recognized that demand for PrEP among AGYW was lacking. One KI attributed low demand to the outer setting, noting:

There has not been a high demand ... due to our start-up or how we introduced the program, I don’t think we consulted the youth to find their views and how they would want to be involved in implementing PrEP. I think the youth are not taking PrEP because they feel that we just imposed it on them. [KI 1, District level]

Many providers felt that even when AGYW initiated PrEP, demand waned after one visit. Reasons included side effects, pill size, and frequent clinic visits, as one user noted: *“traveling to clinic is tiring.”* [User 1] While users focused on the burden of accessing PrEP, one provider blamed the idleness of youth as superseding demand: *“There is demand because some of these young girls know about PrEP, but they are lazy to come to the clinic.”* [Staff 2, Clinic A nurse] At the same time, clinic staff [Staff 2, 6, 7, 8] regularly discussed women’s commitment to attend regular clinic visits for contraception: *“The only thing that they like is to prevent pregnancy. That is why they are coming for family planning.”* [Staff 6, Clinic B nurse] For nearly all interviewees, the prospect of a long-acting injectable PrEP was excitedly anticipated. Only User 1 disagreed: *“I would prefer a pill because I am afraid to be injected,”* providing a valuable

reminder on the importance of product choice.

Beyond challenges with the product itself, staff and users described complexity with the intervention delivery. These included cumbersome clinical initiation processes involving laborious files, multiple blood draws, and time-consuming counseling—issues relevant for any PrEP modality implemented. For instance, national guidelines require screening for Hepatitis B (and kidney function in some cases), and suggest PrEP can be offered while clinicians await results. However, some providers were hesitant to prescribe PrEP without results, noting delays due to infrastructure and other challenges: “*we don’t get the results back [because] laboratory systems are offline.*” [Staff 4, Clinic A nurse] Once initiated, supporting AGYW’s ongoing and potentially intermittent use based on perceived need presented additional complexities. In particular, users consistently reported that counseling was limited to their initiation visit, and all but disappeared thereafter: “*They did educate us [during initiation], but when we return back they don’t talk much about it.*” [User 2] Of note, among the potential complexities in PrEP delivery, there were no reported challenges in the district medication supply chain or PrEP availability.

Clinics described many initiatives to counter the complexities of PrEP interventions, such as expanding access through evening and weekend clinic hours, assigning dedicated trained staff, and instituting “*youth-friendly zones and happy hours which are dedicated to the youth.*” [KI 1, District level] However, few of these efforts appeared operational. At least two clinics had deactivated their youth-friendly services due to prioritizing staff for COVID vaccination campaigns: “*Unfortunately, the one that was running the youth services is now at the COVID-19 station even on Saturdays.*” [Staff 2, Clinic A nurse] At another clinic, inaction was attributed to a single provider’s disinterest: “*Yes, we do have [youth-friendly services], but it’s not active at the moment ... [because] the one who is trained is very lazy to implement it.*” [Staff 5, Clinic D manager]

As clinic staff focused on addressing the complexities, users and KIs considered prospects for adaptability of PrEP interventions. Users suggested expanding both the venues and mechanisms for providing PrEP, such as home-delivery or PrEP pick-up cards so others could obtain refills on their behalf [User 4]. Using the mobile clinics to provide PrEP at high schools and taverns [User 2] was also recommended. The DOH stakeholder discussed plans for the mobile clinics to implement an HIV status-neutral delivery model, noting “*The mobile units have not yet started to initiate ARVs, but they are on a pipeline to start initiating both ARVs and PrEP, this will reduce stigmatization.*” [KI 1, District level] Generally, adaptations and lessons learned from HIV treatment and family planning programs offered promising avenues for further tailoring PrEP delivery.

3.4. Opportunities to improve process at multiple levels [implementation process]

Investigation of PrEP delivery through the lens of the implementation phases of planning, engagement, execution, and monitoring provided critical insights into the tensions, gaps, and facilitating factors within the clinic systems, district structures, and broader societal protocols expected to be followed.

Planning for PrEP delivery and monitoring follow-up emerged as key gaps during interviews with clinic staff. Even when probed directly, staff relayed accounts of day-to-day tasks, yet seldom made connections to work plans or guiding clinic flow/patient management procedures. These gaps in operational planning seemed to magnify once clinics met their DOH-mandated initiation targets. One nurse pointed out:

I said we need to make a plan from now when we want to do follow-ups on those [AGYW] we initiated on this day ... we got a large number of them initiated but just because we initiate them, they are only on files where we registered. They do not come back for follow up, and it is difficult to notice in time. [Staff 2, Clinic A nurse]

Since clinics were primarily required to track patient initiation,

clinics lacked planning and tracking systems to effectively monitor AGYW’s follow-up and discontinuation rates. At the district level, the DOH convened weekly *Phutuma* [‘Hurry up’] meetings to review implementation progress of HIV programs, including PrEP: “*We evaluate our data and performances, zooming into facilities that are performing well and those that are underperforming, PrEP is one of the indicators that we also look at.*” [KI 1, District level] These meetings provided a vital platform for clinic managers and implementation partners; however, they were often limited to reporting initiation numbers versus targets and lacked reflective discussion. Thus, at both the inner and outer settings, implementers cited the need for additional data and monitoring tools, such as dashboards, that could facilitate refinement of processes for providing PrEP follow-up services.

Community engagement was another critical process that facilitated, and at times, hampered PrEP delivery in this setting. Community awareness activities, including PrEP ambassador programs, social media campaigns, and outreach to gatekeepers such as village leaders (*Indunas*), were primarily characterized as short-lived or one-off. Most engagement was conducted by NGO partners, recognizing that “*the clinic staff don’t have time to go do community awareness.*” [KI 4, Community NGO] For AGYW, they described positive experiences with NGO peer educators, and valued the candid HIV prevention and sex education they received. At the broader community level, reports were less consistent. A PrEP user/ambassador described the community’s positive response to introducing the PrEP program: “*[W]e went to the Induna. We went to the ward councilor ... Then the councilor said that there’s no problem as long as we are helping people ... he gave us the go ahead. The community is very supportive of PrEP ...*” [User 3] However, a community elder KI portrayed a different picture, saying the PrEP program “*was not well introduced, they just failed from the beginning ...*” [KI 3, Community NGO] Amidst KI 3’s overarching narrative that more PrEP education and sustained engagement was needed, they recommended this could best be achieved by channeling funding to local organizations trusted in the communities and committed to working there long-term.

Gaps in planning, engagement, and evaluation processes at the outer and inner settings resulted in wide variations of executing clinical care and service delivery of PrEP for AGYW. On the one hand, clinics were able to adapt PrEP delivery as needed, whether designating youth-friendly rooms (Clinic D) or delivering all services together (Clinic B). However, differences in clinical procedures meant services were unpredictable. Users and providers described at least three visit patterns for new users: 1) an initial one-month follow-up visit and then quarterly visits for refills (per national guidelines); 2) visits every two months to align with NET-EN contraception injections; and 3) additional two-week post-initiation visit to assess for side effects followed by monthly refill visits. At the mobile clinic, users reported utilizing HIV self-screening to minimize their clinic visit burden. Furthermore, gaps in clinic referrals and service integration within the district were an impediment to PrEP continuation for AGYW. User 4 reported stopping PrEP due to distance and transport costs to reach the facility where she initiated care without being informed of the option to access PrEP at a closer facility that she already frequented for her child’s immunizations. These missed opportunities reflect a range of process issues needing to be addressed; some only requiring simple modifications while others will entail structural interventions.

4. Discussion

Applying CFIR as an organizing framework to understand PrEP implementation within routine primary care in a rural area, we noted that policies and targets clear to stakeholders in the outer setting were incompletely communicated to and differentially applied within the inner setting of care delivery. This resulted in substantial variation in clinical processes between facilities. Although providers referenced shared values around prevention and user-centered care, the reality of PrEP delivery was shaped by their perception of incomplete government

ownership of PrEP amidst competing priorities, parallel NGO-run PrEP programs, and the relative complexity of delivering ongoing preventive services to AGYW. Elements requiring adaptation of existing practice, like improved training systems or structuring service hours to meet the needs of youth in school, presented a significant challenge. Users, providers, and KIs recommended integrated, youth-friendly, and non-judgmental services supported by consistent community messaging to improve PrEP uptake in this setting.

Previous research has illuminated the PrEP user journey, including the importance of accessing supportive and user-centered care (Daniels et al., 2023; O'Rourke et al., 2021; Rousseau et al., 2021). In rural Bushbuckridge, the user journey is profoundly shaped by the service delivery environment: clinic options are finite, hard to reach during limited operating hours, and staffed by providers perceived as judgmental towards AGYW. Existing research has identified users' mistrust of providers due to previous non-confidential care (West et al., 2021), and delayed rollout of national programs in rural clinics even years after NDOH policy pronouncements (Geary et al., 2014; Lippman et al., 2020). When service options are limited, the impact of a breach of confidentiality by a single provider or inadequate execution of new program guidelines within one facility can have a disproportionate impact on population access to healthcare.

At the time of this study, we found broader-level system assets and challenges that impact PrEP services. For instance, the robust medication supply was attributed to centralized district procurement systems in use for ARV treatment programs. However, maintaining unique facility records rather than national user-centered health records created challenges in both adherence and monitoring (Etoori et al., 2020). As a prophylaxis, PrEP introduces additional monitoring complexity based on changes in user's needs. As efforts to implement universal IDs within the national health insurance plan evolve (National Department of Health, 2017), consideration of appropriate application for prevention services as much as treatment is warranted. Further, we found that for PrEP in particular, clinics lacked functional data tracking systems to monitor ongoing PrEP use and discontinuation. Improved data flow between district and facilities as well as strengthening the data system and provider capacity to use dashboard tools provides an opportunity for improvement, including consideration of what can be drawn from ART monitoring.

Improvements to PrEP implementation must confront the inadequate communications to and within clinics resulting in inconsistent approaches to service delivery. Despite innovations in communication like WhatsApp groups for facility managers, providers in this rural setting had incomplete knowledge of PrEP policy and tools developed to support PrEP delivery. Although the COVID-19 response imposed restrictions on trainings and meetings at varying levels from March 2020 to April 2022, providers did not link deficiencies in PrEP training or communication of guidelines primarily to the pandemic. Our findings are consistent with pre-pandemic studies that noted the inadequacies of the current training approach (Geary et al., 2014; West et al., 2021). Global evidence supports the limitations of short in-service training as a model to produce long-term change among trainees, let alone colleagues (Arsenault et al., 2021; Leslie et al., 2016). While NDOH and partners have produced a broad repository of materials supporting PrEP delivery to AGYW (SADOH, 2020), making resources available and circulating top-down instruction to read them is clearly insufficient, particularly given the competing demands on providers' time. Although patient advocacy has been identified as an important strategy for PrEP access (Li et al., 2022), patient inquiry about PrEP is unlikely to drive learning in this setting given the power imbalance between providers and AGYW. Improving providers' capacity may require multiple modes of content delivery and sustained support across service areas, including strategies that recognize and address issues such as judgmental norms, the role of stress, and competing priorities in shaping provider actions (Afulani et al., 2023). The need to reconcile multiple priorities makes capable leadership and clear communication of shared responsibilities between

the national and local level as well as within the local network of NDOH clinics and NGO mobile clinics even more important.

The similarity between our findings and a 2011 assessment of youth-friendly services in the same area highlights the lack of structural change in the intervening decade (Geary et al., 2014). Health systems are complex and resistant to change; values, incentive structure, policy, and management must be aligned across levels to produce enduring change (Adam and de Savigny, 2012). Programs such as youth-friendly services and daily oral PrEP may be perceived as providing value, but lack the tangible benefit to patients and overstretched providers that has facilitated previous policies like fast track medication refills (van Heerden et al., 2022).

We further found that while bilateral US-funded NGOs filled a critical gap in providing services tailored to AGYW, the bifurcation in service delivery had multiple effects. These effects included perceptions of PrEP as a lower priority for NDOH, of community engagement as incomplete, and of poor integration between DOH and NGO providers, similar to findings on PrEP implementation in public clinics in Kenya (Roche et al., 2022). Uncertainty with the future of PEPFAR and long-term support for US development assistance could further jeopardize collaborative efforts to implement PrEP and may have unanticipated consequences, making DOH ownership and systems updates all the more critical (Ratevosian, 2024). Investing in systems improvements now will further pave the way for the successful implementation of long-acting PrEP options, which like oral PrEP, will be reliant on: integrating a biomedical prevention intervention within routine primary healthcare services; leveraging community partners and health education campaigns; and critically, establishing affordable pricing (Meyer-Rath et al., 2023). Robust communications, monitoring, and delivery systems will not only bolster the NDOH and clinics' capacity to develop integrated delivery of each PrEP modality, but most importantly, cultivate an environment that allows women choice while addressing resource constraints.

CFIR provided a structured approach to understanding the multiple levels shaping oral PrEP delivery in rural primary care facilities. However, we did encounter challenges in distinguishing some constructs given multiple layers of influence. These coding challenges have since been addressed in the recent CFIR 2.0 update (Damschroder et al., 2022). Ultimately, our findings resonate with Means et al.'s (2020) synthesis of CFIR in low- and middle-income countries in terms of the primacy of system characteristics, particularly resource constraints, external funding agent priorities, and the source and continuity of resources.

5. Strengths and limitations

This research represents findings in a single sub-district; findings may not be generalizable to urban areas or as PrEP implementation continues to evolve. Despite outreach efforts, we were unable to interview KIs at the provincial level. While the sample size was small, we did reach saturation with a diverse group of informants providing perspectives from those directly involved in shaping service delivery locally. Interview guides and interpretation of the findings were enhanced through discussion with the project's SWG and our ongoing work to support improved PrEP delivery within this district. Finally, although this study focused on oral PrEP for AGYW, the findings on effectively implementing a user-centered prevention program within a complex and resource constrained health system have broad implications for long-acting injectable PrEP products and other prevention programs.

6. Conclusion

Our study identified key factors of the outer and inner setting and the intervention itself that shaped the implementation process and resulted in incomplete and inconsistent PrEP delivery for AGYW in rural Bushbuckridge. We identified multiple strengths, including an ethos of

prevention and local care delivery innovations to better reach AGYW. Our primary recommendations to improve PrEP delivery center on strengthening and democratizing data systems and data usage for monitoring and improvement, revising training models to provide sustained support and to address provider norms and behaviors, and embedding these approaches at the district level to better align DOH and NGO resources and communications. These changes would not only have positive mutually reinforcing effects for providers and users, but would also fortify systems as new PrEP options are introduced and protect against service delivery disruption in the case of bilateral funding declines.

Ethics approval statement

This study was approved by the Institutional Review Boards at the University of California San Francisco, the Human Research Ethics Committee at SA's University of the Witwatersrand, and the Mpumalanga Department of Health and Social Development Research Committee.

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CRedit authorship contribution statement

Deborah Baron: Writing – review & editing, Writing – original draft, Visualization, Formal analysis, Data curation, Conceptualization. **Hannah H. Leslie:** Writing – review & editing, Writing – original draft, Formal analysis, Conceptualization. **Denny Mabetha:** Writing – review & editing, Project administration, Investigation, Formal analysis, Conceptualization. **Nozipho Becker:** Writing – review & editing, Formal analysis. **Kathleen Kahn:** Writing – review & editing, Funding acquisition, Conceptualization. **Sheri A. Lippman:** Writing – review & editing, Supervision, Funding acquisition, Formal analysis, Conceptualization.

Declaration of competing interest

The authors declare no known conflicts of interest.

Data availability

Data will be made available on request.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.socscimed.2024.117370>.

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