PrEP in Primary Care; Health Care Worker Adaptations to PrEP Delivery in Eswatini

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Research

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Abstract

Background

Implementation evidence for pre-exposure prophylaxis (PrEP) for the general population in primary-care clinics in Southern Africa is limited. Perspective from those providing PrEP in 'real world' settings is needed to better inform future programming, policy, and scale up.

Methods

From September 2017 to January 2019 we conducted 54 semi-structured in-depth interviews with purposively selected healthcare workers (HCWs) from six public sector, nurse-led, primary-care clinics in Eswatini. Data from observational notes, daily debriefing sessions and interview transcripts were analyzed using Nvivo 12 following the tenets of Grounded Theory. We present our results within six domains of a modified Consolidated Framework for Implementation (CFIR).

Results

HCWs said that they adapted implementation guidelines in order to inform more people of PrEP. HCWs said that clinic and community based PrEP education and promotion was essential for demand creation, uptake and continued PrEP use. Clinic modifications included conducting PrEP risk assessments during existing TB screening services, and targeting PrEP counselling for pregnant women and clients with sexually transmitted infections. HCWs described streamlining the PrEP initiation process by fast-tracking at-risk clients for initiation and pill collection. HCW said they emphasised PrEP as being for 'everyone' to avoid stigma.

Conclusions

Integration of PrEP delivery into existing screening and treatment services may help reach those most vulnerable to HIV infection, avoid time-consuming referrals, and prevent loss of clients between different components of the care continuum. PrEP education and promotion should be both clinic and community based to ensure potential clients have enough information before reaching the clinic, prevent PrEP-associated stigma and assist in family and partner understanding of PrEP use. HCWs providing PrEP in public-sector clinics have first-hand knowledge of implementation in 'real world' settings in a field where policy and program implementation is largely undefined. Integrating their feedback into future programming and policy may support effective PrEP delivery in Eswatini and other high prevalence settings in Southern Africa.

Contributions To The Literature

- Research shows that interventions' clinical efficacy may not be replicated in real-world settings. Tacit knowledge from health care workers delivering interventions outside of trial conditions is essential to inform future design and implementation.

- While clinical capacity, clinic processes and information influenced implementation of a PrEP programme in eSwatini, HCWs' self-efficacy and ability to adapt implementation guidelines in a way they believed would be most effective was of equal importance.
- These findings address gaps in SSA PrEP primary care literature, including where, when and how PrEP interventions should incorporate the feedback of HCWs into revising implementation guidelines.

Introduction

With approximately 800,000 new HIV infections annually, the Sub-Saharan African (SSA) region is by far the most affected by the HIV epidemic [1]. SSA represents 12% of the global population, but accounts for 65% of the global total of new HIV infections [1]. The region lies at the centre of a 'prevention crisis' where incidence is stabilising rather than falling [2], and the UNAIDS 2020 prevention target – to reduce annual new infections to less than 500,000 globally – is far out of reach [3]. Novel combination approaches to HIV prevention are urgently required to reduce incidence in this region [2, 4, 5].

Pre-exposure prophylaxis (PrEP) for the prevention of HIV is a safe and efficacious form of HIV prevention when high levels of adherence are achieved [6, 7]. Emerging studies from SSA where a once daily oral PrEP regimen has been made available for high-risk population groups, identify PrEP as a viable strategy for HIV prevention when provided as a combination prevention method [8-10].

However, as a bio-behavioural intervention, the success of PrEP as an effective prevention tool is dependent on many factors unrelated to clinical efficacy [4, 11, 12]. One such pivotal factor is how health care workers (HCW) implement PrEP within the existing primary healthcare system, where at present there are few normative implementation guidelines at national level [13]. This is largely due to the relative novelty of PrEP in SSA, but also because PrEP interventions have targeted key-population groups via specialised outreach methods, rather than the general population through the primary care system [14]. As integration of HIV services into primary care is seen as an accessible, equitable and sustainable approach [15, 16], the majority of future PrEP services are likely to be provided via this route.

Research about implementation relates largely to HCWs' willingness to provide PrEP [17, 18], attitudes [19], intentions and behaviours towards PrEP [20], and providers' perceptions about the barriers to providing PrEP in the United States [21]. But there is limited evidence regarding HCW and client implementation preferences, the logistical implications of providing PrEP and experiences from HCWs in SSA primary-care settings. More research in this regard is essential for ensuring the effective scale up and future roll out of PrEP [13].

We present longitudinal qualitative data from the first group of HCWs providing PrEP to the general population in public-sector nurse-led clinics in Eswatini and, to the best of knowledge, within the Sub-Saharan African region. We describe HCWs' experiences and implementation practices to better inform

the development of PrEP implementation guidelines for general populations at high risk of HIV accessing PrEP via primary care.

Methods

Study Setting

Eswatini is a landlocked country with a population of approximately 1.3 million [22]. At 27.2%, HIV prevalence is the highest globally and incidence peaks at approximately 4% for women ages 18-25 and 2% for men ages 30-38 [23]. The study was conducted in six rural and semi-urban nurse-led, primary health care facilities in the northerly Hhohho region, where all HIV prevention, care and treatment services are free at point-of-care. Clinic population catchment ranges from approximately 7,000 to 14,000.

The PrEP implementation project

From the beginning of September 2017, clinic based, routine morning health education sessions sensitised all clinic attendees in waiting areas regarding the availability of PrEP as a new HIV prevention method. Sensitization included information regarding how and when to use PrEP, and encouraged attendees to complete a MoH designed- HIV risk screening tool and to undergo routine HIV testing. Clients testing positive for HIV were linked to HIV care and treatment services. Clients testing HIV negative received Eswatini's standard, comprehensive HIV prevention package which includes HIV prevention counselling, promotion of and free access to condoms, Sexual Transmitted Infection (STI) testing and treatment and further information about PrEP. Clients identified to be at risk of HIV and those requesting PrEP were offered PrEP. The initiation process is described in Table 1.

The Eswatini PrEP implementation framework was developed in country by the MoH, relevant stakeholders, HCWs and implementation partners, informed by the WHO framework for country level protocol development [24]. The implementation project was conducted by the Eswatini MoH with implementation assistance from the Clinton Health Access Initiative (CHAI) and scientific support from Heidelberg Institute for Global Health (HIGH) and WITS School of Public Health.

Sampling and Recruitment

In September 2017 and July 2018, we conducted semi-structured in-depth interviews with purposively selected health care workers (HCWs) involved in any stage of PrEP initiation at the six implementation sites. HCWs included nurses, nurse's assistants, HIV Testing Services (HTS) counsellors, expert clients, and mentor mothers.

Data Collection

Five Emaswati research assistants (RAs) – 2 males, 3 females - were trained to collect qualitative data using standardized instruments. These instruments included the semi-structured interview guide – with a section for reflexive and observational notes - participant information sheets, and consent forms.

Instruments were pretested and revised throughout data collection. Cover sheets captured socio-demographic data including; sex, age, HCW cadre, children, marriage/partner status, and religion. RAs were fluent in siSwati and English and were qualified to a high school degree level. Daily debriefing sessions were conducted throughout data collection to discuss and triangulate findings, amend interview guides, refine lines of inquiry and consider where saturation of themes was being reached [25].

Interview Protocol

The MoH granted permission to conduct interviews with HCWs and consent was obtained from clinic managers. One month prior to data collection, staff from CHAI coordinated viable dates for interviews with each clinic. A phone call was made on the morning of the pre-arranged interview date to remind clinics of the RAs intention to conduct interviews. HCWs were invited to participate in an audio-recorded interview at a time and in a private place of their choosing. Written informed consent was obtained from all study participants prior to beginning interviews. Interviews were 45-70 minutes long.

The first phase of interviews began at the outset of the implementation project in September 2017, and were designed to obtain broad responses regarding HCWs perspectives on PrEP in general, their intention and ability to provide PrEP, and to gain feedback on the PrEP promotion materials available in the clinics. The second phase of interviews began in July 2018, and elicited responses regarding experiences when providing PrEP, their perspectives of PrEP after one year of its availability, and any recommendations in relation to PrEP delivery. The decision to include questions relating to recommendations for PrEP delivery in the second phase of interviews came after analysis of the first round of transcripts, as here we began to identify themes in relation to HCW-led changes or amendments to PrEP delivery. This is consistent with a grounded theory method where questions can be formulated based on emerging findings [26]. RAs probed on themes that were of importance to the participant or that were recurring through the debriefing process. Interview transcripts were simultaneously translated and transcribed. Ten transcriptions were selected at random for quality checks.

Data Analysis

The first and last authors conducted a recurrent cross-sectional analysis of our longitudinal data [27, 28]. In each phase, data analysis was guided by the tenets of Grounded Theory, a systematic approach to developing theory through inductive analysis of qualitative data [26]. We began our inductive approach during data collection with analysis of notes from the daily debriefing sessions [29]. By the time data collection was completed, several reoccurring themes had been identified, and were used as a preliminary coding template. We expanded and restructured this template following line-by-line analysis of transcripts. Concepts were named with the terms used by the HCWs themselves. Over three phases of coding – open, axial and selective – we were able to connect approximately 30 recurring sub-themes and structure narratives around 10 broader categories [30]. These narratives and categories were reviewed to establish the significance of the reoccurrence within the data and then discussed with, and refined by lead authors. Data was managed and coded using NVivo Pro 12 [31].

Analytical framework

When finalizing our codebook, we felt our themes resonated with the core constructs of the Consolidated Framework for Implementation research (CFIR) [32]. The CFIR combines constructs developed across many implementation theories to provide a framework of the summative and formative outcomes of interventions, to assess the extent to which implementation is effective in a specific setting, ensures sustainability, and can be disseminated into other settings. The original CFIR is formed of five main domains; the intervention, the inner and outer setting, the individuals involved, and the process by which implementation is accomplished [32]. We organised and synthesised the interacting and multi-level themes identified in our data around the five domains of the CFIR, and added a sixth domain which captures the PrEP intervention as modified by the HCWs (Figure 1).

The first domain of the CFIR represents the intervention being implemented into a particular organization. The CFIR assumes that, without adaptation, the intervention is likely to be a poor fit, and possibly resisted by the individuals the intervention affects. We present this domain using the accounts of HCWs regarding their broad perceptions of the PrEP implementation project. The second domain of the CFIR, the outer setting, considers the economic, political, and social context within which an organization resides. We relate themes of policy constraints and broader social issues that influenced implementation of the implementation project to this domain. The third domain, the inner setting, includes the structural, political, and cultural contexts through which the implementation process will proceed. We describe the inner setting in relation to the structural constraints for PrEP delivery and the culture of a 'Swazi aversion to pills' which linked to themes of adherence and stigma. The fourth domain of the CFIR refers to the individuals involved with the intervention and the implementation process, which is expressed in our data as the 'main influencers' on the intervention. The fifth domain represents the implementation process. The CFIR posits that successful implementation usually requires an active change process aimed to achieve individual and organizational level use of the intervention as designed. We present this domain through HCWs descriptions and experience implementing the PrEP project. The sixth domain of our modified CFIR highlights the self-determined enacted amendments to PrEP implementation, carried out by HCWs without support or input from those running the implementation project. Most of these amendments were considered essential to the successful implementation of PrEP.

Results

Over the two phases of data collection a total of 54 HCWs participated in IDIs, including nurses, nurse's assistants, HTS counsellors, expert clients (long-term adherent ART clients), and mentor mothers (Table 2). No HCWs refused to participate. All HCWs had received PrEP training, either within the clinic via senior colleagues or at an MoH and CHAI led PrEP training initiative. We present our results within a modified CFIR framework consisting of six domains. All domains are supported by quotations available in Table 3. These are described as the domain (D) and the quotation number (Q, #).

1. Intervention characteristics

As HCWs were interviewed at both the beginning and the second stage of the PrEP implementation project, we saw how some perceptions relating to the project's characteristics persisted, while others changed over the course of a year. Most HCWs at both interview points were happy with the prevention 'tool' PrEP, were motivated to provide PrEP, and felt that this was an additional method to add to their toolbox of HIV prevention strategies (D1, Q 1&2). Providing PrEP bolstered HCWs' professional counselling skills (D1, Q3), but some aspects of the implementation guidelines prevented them from reaching the most vulnerable clients, such as young women <16 years old. By the second round of interviews, HCWs described a more pragmatic approach to providing PrEP, indicating that any HIV negative person should be offered PrEP.

While most HCWs were positive about the availability of PrEP, many at the first stage of interviews had concerns regarding a subsequent decline in condom use, a rise in pregnancies and STIs, and a fear of resistance forming in non-adherent clients. The implications of resistance on future prescribing possibilities for HIV positive patients, and resources at the clinic level, were a major concern. Although these concerns did not prevent HCWs from prescribing PrEP, HCWs were cognizant that more training, or information on perceived impact of PrEP on other health issues, would be useful for their understanding of the larger impact of PrEP on the health of their clients (D1, Q4 & 5).

In the second round of interviews, these concerns were absent from nearly all the HCW interviews. HCWs accepted PrEP with the perspective that, for example, STIs and teenage pregnancy were already exceptionally high, and that the introduction of PrEP would do little to increase this. HCWs remarked that condom use had always been suboptimal, and that PrEP would support those who were inconsistent condom users or those who never used condoms (D1, Q6).

2. Outer setting

Interviewees said PrEP provided a viable alternative for people who did not pursue existing HIV prevention methods and was particularly effective for women, to whom they often had little to offer in terms of protection that they themselves could manage. HCWs spoke about young women under the age of 16 that would benefit from PrEP but were not eligible due to age. HCWs described how many young women who presented at the clinic with an STI or as pregnant (mentioning girls as young as 13) were those at most need of PrEP, but were not eligible to take PrEP because of their age, and said this was another major barrier to their ability to help girls and adolescents. HCWs desired a different criterion for prescribing PrEP, such as using the body weight or risk of a client to define eligibility rather than age (D2, Q7).

3. Inner setting

HCWs explained that PrEP was not suitable for many of their clients as adherence to a daily oral regimen was difficult, and that pills were not popular among Swazis in general (D3, Q8).

HCWs felt that many clients would be discouraged from taking PrEP because, by virtue of queuing and having the risk assessment, they would be inadvertently conveying to other clients that their partner was HIV positive, or, that they were promiscuous. This extended to the PrEP pills themselves, which HCWs explained, were too similar to ARVs and would cause confusion among partners and family members of PrEP users who would be unlikely to believe PrEP was to prevent HIV rather than to manage it (D3, Q9).

HCWs highlighted structural constraints such as that PrEP was only available at certain locations, and that clinic opening times were not conducive to most working people. Specified blood collection days limited the ability for confirmatory HIV testing, baseline creatinine and Hepatitis B testing. HCWs recommended alternative collection points for PrEP including general hospitals and pharmacies, where blood could be drawn and samples stored. HCWs felt that initial counselling should be completed in the community or clinic, but that pharmacies offered a more practical and accessible point for refills (D3, Q10).

4. Individuals involved

Rather seeing themselves as core influencers, HCW workers spoke of two key groups who influenced the intervention considerably. These were the husbands or male partners of female PrEP clients, and community members who held influence within the clinics catchment area. HCWs described how women said they needed to discuss with and gain permission from their partners regarding their PrEP use, and therefore needed more time to consider. This often led to those eligible for PrEP not returning to the clinic (D4, Q11 & 12).

HCWs explained that obtaining support from community leaders would allow for community events and community sensitization to take place. Designing outreach that was popular with rural communities, such as events with food and targeted counselling, would allow for accurate information to be received, and for an increase in knowledge and awareness of PrEP (D4, Q13).

HCWs explained that community information directed at men would not only encourage men to test and initiate on PrEP, but was also another way of supporting women. By giving men information and counselling, it may encourage them to speak to someone about PrEP, and then allow PrEP within their homes, if not for them but for their partners (D4, Q14).

On the rare occasion that a HCW described deliberately influencing the process of PrEP implementation, it related mostly to intention to prescribe. HCWs said that there were occasions where they had not provided PrEP to an eligible patient, as a result of a client showing 'significant mental illness' which would prevent them from fully understanding how to use and adhere to PrEP. HCWs also explained

that on days where clinic patient volume was beyond the capacity of the staff, HCWs would be deterred from providing PrEP (D4, Q15).

5. Implementation process

HCWs said that the initiation process was too long – for both the client and the HCWs – and that this prevented many clients from being initiated and other patients from receiving care quickly. The risk assessment form was described as taking 30-35 minutes which, along with the wait time to initially be seen, and then the wait between HIV testing and initiation – which varied between 30 minutes to three hours - was considered unsustainable. Clients were ‘lost’ at any point between the completing the risk assessment, receiving a negative HIV test and waiting to see a nurse-led antiretroviral therapy initiation (NARTIS) trained nurse to receive their PrEP (D5, Q16, 17 & 18).

HCWs spoke extensively about client knowledge levels and said the information they received in clinic was often insufficient for them to make a decision whether or not to initiate PrEP on the day PrEP was introduced and offered. This issue persisted throughout both rounds of data collection. As there was no extension of PrEP information to and within the community, those eligible for PrEP would not be reached because high risk clients do not always visit clinics (D5, Q19).

HCWs consistently explained that the provision of PrEP would be easier if more HCWs could provide PrEP, and complete all parts of the PrEP initiation process. If this was not possible, HCWs said they needed more, or at least one, NARTIS trained nurse that could focus exclusively on promoting and providing PrEP (D5, Q20).

HCWs said they needed a more systematic approach to monitoring and supporting PrEP clients. If there was a process in place which alerted the HCWs to the number of clients who should return for a PrEP refill on any given day, this would allow them to prepare and allocate staff. Clients could also be given an appointment time, which would prevent them from waiting in line with ‘sick’ people (D5, Q21).

6. The adapted intervention

HCWs described several amendments to the delivery of PrEP which they felt would increase uptake, improve retention and simplify the initiation process. HCWs said that they followed guidelines for PrEP delivery, but adapted certain elements to inform more people and better suit the clinic environment, and made special arrangements to support certain individual Clients. The majority of HCWs said that clinic-based PrEP education and promotion was insufficient and that community education would allow for clients to discuss and consult with their family, gain permission from their partners and from community leaders.

As many HCWs felt the information in clinics was not effective as it was considered ‘too much to take in’, HCWs said that they had begun community outreach via talks at community meetings, by providing

community health workers with information leaflets to take to houses, and by wearing the PrEP t-shirts to and from work, so that people could read and ask questions at bus ranks and when travelling. These actions began approximately six months after the initial round of interviews. HCW said they would like to provide more community services, but that their work schedule did not allow for it (D6, Q22).

HCWs spoke extensively about trying to find ways to support women who felt they wanted and needed PrEP, but were prohibited by their husbands. At one clinic, a male HCW had developed a system of informing and gaining permission from partners whereby the potential PrEP client could invite the partner to the clinic, as well as sharing the PrEP information leaflet at home. However, as the information was delivered by the woman and not the male HCW, it had not been successful (D6, Q23).

Clinic-based modifications included conducting PrEP risk assessments alongside existing TB screening services – which is standard procedure upon entering the clinic - and targeting PrEP counselling for pregnant women and patients with STIs. HCWs described streamlining the PrEP initiation process by fast-tracking at risk clients for initiation and pill collection (D6, Q24).

HCW said they placed emphasis on PrEP being for ‘everyone’ to avoid unnecessary stigma. By the second round of interviews, this included giving the new self-risk assessment form to everyone, and morning talks which emphasised that in Eswatini, most people are at high risk of HIV infection (D6, Q25).

Discussion

We present findings from 54 HCWs providing PrEP in primary health care facilities for the general population in Eswatini. HCWs described the intervention as important for HIV prevention in Eswatini, and felt that high-risk vulnerable populations such as young vulnerable women would benefit significantly. Initial concerns regarding PrEP and subsequent falls in condom use, non-adherence fomenting resistance, and increases in unwanted pregnancies and STIs were absent by the second round of interviews. HCWs said they needed more human resources at clinic level, and systematic, client-friendly initiation and refill processes. HCWs said clients had insufficient information regarding PrEP at point-of-care and explained that community based delivery of information supported by couples counselling, and population-specific outreach techniques was essential for the ‘success’ of PrEP.

Our findings resonate with much of the literature from the USA in relation to HCWs’ willingness to provide PrEP [33, 34], fears of non-adherence and resistance [33, 35], sexual risk taking [33], the excessive staff time required to counsel and initiate PrEP [36], lack of client information before reaching the clinic [37, 38], and insufficient clinical capacity [20]. We also find similarities with changing perceptions regarding client sexual risk-taking upon PrEP initiation, where HCWs come to perceive condom use and sexual risk-taking as remaining the same as before PrEP [39].

Although there is some evidence in relation to ‘community’ support facilitating PrEP use from the USA, this mainly refers to the community an individual identifies with in terms of sexual orientation rather than the community in which they reside [40, 41]. In Eswatini, HCWs see community leaders and the

community where clients live as especially important, both in terms of achieving acceptance and ability of people to take PrEP, but also as a viable location in which information can be shared and received. This resonates with the literature on the provision of ARVs in SSA, where community-based delivery [42], coupled with specialised and targeted outreach and counselling services for couples [43, 44], men [44], and women [45] are thought to address broader issues in relation to stigma, access and knowledge [45]. These approaches may also specifically address women's access to, and ability to take PrEP which here – and in other studies – is described as disrupted by fear of violence and disapproval from male sexual partners [46-48]. Adopting our HCWs' suggestions for providing PrEP to women – such as PrEP in combination with other services, male partner engagement and a further safety assessment – may support women in both access to and continued use of PrEP [49-51].

We use a modified version of the CFIR to organise and synthesise the interacting and multi-level themes identified in our data, describe how PrEP implementation is viewed by HCWs in Eswatini, and explain the adaptations made and those considered important for future PrEP implementation. While each domain is useful to describe the implementation environment HCWs described, of equal importance are several of the constructs which form each domain of the CFIR, developed from over 19 theories of implementation [32]. Firstly, the construct of 'patient needs and resources', which considers the extent to which patient needs and facilitators to meet those needs are known by the implementers, has particular salience for our work. Our HCWs demonstrate a deep understanding of the needs and resources of clients, leading them to enact a series of adaptations designed to ensure the intervention was client centered and would improve client outcomes. Many of these changes relied on local, cultural and community knowledge, and are unique to rural and semi-rural clinical settings in a country such as Eswatini.

Secondly, the construct 'implementation climate' which refers to the absorptive capacity of the organization for change, is of importance. Here we see three sub-constructs – (1) tension for change [52] (the degree to which stakeholders perceive the current situation as intolerable or needing change), with HCWs expressing a real need for another tool for HIV prevention, as existing mechanisms were deemed insufficient. (2) Compatibility [52, 53] (whether the meaning and values attached to the intervention fits those of the implementers) with HCWs implementing the intervention not only within the implementation framework they were given, but also by actively seeking and undertaking amendments that were felt to improve the intervention design. And, (3) the relative priority [53, 54] (the shared perception of the importance of the intervention) where HCWs make a concerted effort to improve the experience of PrEP clients by fast-tracking PrEP clients through the clinic, providing promotional materials and talks outside of work hours and the clinic environment, and attempting novel approaches to reach those most at risk of HIV infection.

Thirdly, HCWs' self-efficacy – an individual's belief in his or her capacity to carry out certain actions [55] – appears to be the essential construct underpinning all adaptations made to the PrEP intervention. HCWs seemed empowered to make changes within their clinic environment, and implemented without notifying the intervention partners and without additional resources. This may be because of an enabling, entrusting work culture that exists within the clinics in Eswatini, or that the perceived need and

importance of PrEP surpasses any formal pathways or structures in place for intervention implementation. HCWs seem to have been cognizant of a HIV prevention service with limited resources, which led them to make changes which were viable within the existing environment. Recommended – but not implemented - adaptations were mostly those outside of the reach of the clinics, and were those that would require more human resources and financing. Understanding the extent to which self-efficacy facilitates implementation and adaptations to delivery will be essential to ensure the sustainability of PrEP within the public health system in Eswatini, and to support HCWs in their ability to provide PrEP in the way they see as most effective.

Limitations

For a number of reasons, we do not consider all the constructs of the CFIR which may limit the complexity of our analysis. There is much overlap between the domains of the CFIR – especially in relation to the inner and outer settings and the individuals involved – which may blur the distinctions we try to make between domains in relation to social norms or cultural practices, or the nuance between male social dominance and male influence over implementation. However, as with many frameworks, the approach is designed to reduce the complexity, in order to make use of the structure in a meaningful way.

As we didn't begin data collection or analysis with the CFIR in mind, we did not specifically investigate certain constructs which emerged as highly important, such as HCW self-efficacy and the implementation environment. As these appear to be essential components to the provision of PrEP within primary-care clinics, future research should focus on better understanding these constructs more broadly, and identifying how HCWs can be supported in communicating and implementing changes they feel are of most use and importance.

Conclusion

Incorporating tacit knowledge from HCWs providing PrEP into future PrEP policy and implementation guidelines is essential to ensure contextually adapted and culturally relevant HIV prevention services. Frameworks such as the CFIR can be used to structure this knowledge, to plan and organize implementation, and to support hypotheses regarding how implementation activities can facilitate desired change. Through the use of the CFIR, we identify tangible and important changes that need to be made at different implementation 'domains' which may address the 'loss' of clients and also support their ability to access PrEP and continue to take it.

In eSwatini, we recommend extending initiation support and PrEP information into communities, with specialized outreach and services for the sexual partners of those initiating PrEP, men and younger women. Clinic initiation and refill options for PrEP could be better integrated into existing and accepted services such as TB screening and family planning, alongside fast-tracking new and continuing PrEP clients for pill collection. Ensuring the implementation climate of the intervention aligns with HCWs priorities, and that HCWs feel empowered to make changes to implementation that suit their clinic and

community - whilst reporting their experiences and needs to policy and implementation decision makers - is essential to the development of PrEP guidelines for the general population in Eswatini and beyond.

Abbreviations

AIDS – Acquired Immunodeficiency syndrome

ARV – Antiretroviral

CFIR – Consolidated Framework for Implementation Research

CHAI – Clinton Health Access Initiative

HCW – Health Care Worker

HBsAg - Hepatitis B Surface Antigen

HIGH – Heidelberg Institute for Global Health

HIV- Human Immunodeficiency Virus

HTS - HIV Testing Services

MoH – Ministry of Health

MSM – Men who have sex with men

NARTIS - Nurse-Led Antiretroviral Therapy Initiation

PrEP – Pre Exposure Prophylaxis

SSA- Sub-Saharan Africa

STI – Sexually Transmitted Infection

TDF/3TC - Tenofovir Disoproxil Fumarate plus Lamivudine

UNAIDS - The Joint United Nations Programme on HIV/AIDS

USA – United States of America

Declarations

Ethics approval and consent to participate

The study received ethical approval from the Eswatini Ministry of Health National Health Research Review Board (MH/599C/IRB 0009688/NHRRB538/17), Chesapeake Institutional Review Board, USA (Pro00021864). This study was exempted from additional ethical review from the Ethics Committee of the Medical School of Heidelberg University.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

All authors declare no conflict of interest.

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Authors' contributions

KB and SAM contributed to study design, engaged in data collection and data analysis, and wrote the manuscript. SM, ABH, AH, TB, SD and KK contributed to the study conception and design, supported data collection, and revised the manuscript in a manner critical for intellectual content. All authors read and approved the final manuscript.

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Tables

Table 1: Clinic procedures for PrEP initiation

Visit	Clinic procedures
First (screening) visit Counsellor/clinician visit	<ul style="list-style-type: none"> · Conduct HIV testing and counselling · Educate about the risk, benefits and limitations of PrEP · Behaviour risk assessment · Evaluate for eligibility, willingness and readiness to take oral PrEP · STI screening, contraceptive counselling and services · Take baseline bodyweight · Last menstrual period and contraceptive use (for women; if pregnancy suspected, obtain a pregnancy test (However, pregnancy is not a contraindication for PrEP) · Adherence counselling · Discuss combination prevention · Laboratory evaluation: Creatinine to calculate Creatinine Clearance, Hepatitis B Surface Antigen (HBsAg) screen, pregnancy test, STI screening <p>→ If no contraindication to TDF and the client is eligible and ready, prescribe fixed dose TDF300mg/3TC300mg one tablet once daily for 30 days.</p> <p>→ Provide follow up date after 28 days</p>
Visit 2 (month 1) Counsellor/clinician visit	<ul style="list-style-type: none"> · HIV testing and counselling · Assess tolerability, side effects and effective use · Actively manage side-effects · Adherence and risk reduction counselling · Review of laboratory results · Offer Hepatitis B Virus vaccination if available and HBsAg negative · Provide 2 month TDF/3TC prescription and follow up date
Visits months 3, 9, 15, 18 Counsellor led visits	<ul style="list-style-type: none"> · HIV testing and counselling · Assess tolerability, side effects and effective use · HIV risk review and assessment for PrEP continuation · Discuss combination prevention · Support adherence counselling · 3 month TDF/3TC refill
Visits at months 6, 12, 18	<ul style="list-style-type: none"> · HIV testing and counselling · Assess tolerability, side effects and effective use

Clinician led visits	<ul style="list-style-type: none"> · Measure and record body weight · HIV risk review and assessment for PrEP continuation · Discuss combination prevention · Support adherence counselling · STI screen including urine dipstick and rapid syphilis test if clinically indicated. · Measure serum creatinine and calculate creatinine clearance · 3 month TDF/3TC refill
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Table 2. Characteristics of interviewees in round 1 (2017) and round 2 (2018) of data collection.

Characteristic	Round 1	Round 2	Total
Gender, n%			
Female	21 (80.8)	21 (72.4)	42 (76.4)
Male	5 (19.2)	8 (27.6)	13 (23.6)
Age group, n (%)			
<20 years	0 (0.0)	1 (3.4)	1 (1.8)
20-29 years	9 (34.6)	13 (44.8)	22 (40.0)
30-39 years	12 (46.2)	12 (41.4)	24 (43.6)
40-49 years	2 (7.7)	1 (3.4)	3 (5.5)
50-59 years	1 (3.8)	2 (6.9)	3 (5.5)
Missing	2 (7.7)	0 (0.0)	2 (3.6)
Cadre, n (%)			
Nurse	14 (53.8)	17 (58.6)	31 (56.4)
Expert Client	5 (19.2)	2 (6.9)	7 (12.7)
HTS Counsellor	3 (11.5)	4 (13.8)	7 (12.7)
Nursing Assistant	2 (7.7)	0 (0.0)	2 (3.6)
Mentor Mother	2 (7.7)	2 (6.9)	4 (7.3)
Other	0 (0.0)	4 (13.8)	4 (7.3)
Total	26	29	55

Table 3. Supporting quotations

**Domain 1: Intervention characteristics. Domain 2: Outer setting. Domain 3: Inner setting. Domain 4: Individuals involved. Domain 5: Implementation process. Domain 6: The adapted intervention*

Domain (D)* & quote number (Q)	Supporting quotation
D1, Q1	<i>"For me without lying I am happy about it. If we were to understand it better PrEP would help in reducing HIV infections. It is one of the best methods to reduce the virus."</i> (Female Nurse, First round)
D1, Q2	<i>"I feel ok with it because there are many advantages over the previous prevention methods we had. People did not use the condoms the right way and we see through the new infections. But I think this will help a lot because if there are no new infections then there will be no opportunistic infection. That means less people are sick and all the things that are caused by HIV can be reversed back."</i> (Female HTS Counsellor, First round)
D1, Q3	<i>"I think it helped me, as for me on how to counsel people and the knowledge that they gave us I think it is it which gave us the know how when you come across a client, this is how you will then be in a position to talk to that client."</i> (Female HTS Counsellor, First round).
D1, Q4	<i>"There were some concerns during the training because they thought that people will become resistant. They thought this pill was PEP (post exposure prophylaxis) so they thought people were being exposed to ART. I think they also didn't understand that PrEP is given to HIV negative people so that person won't become resistant. The concern they had was around resistance."</i> (Male HCW, First round)
D1, Q5	<i>"I am worried that these pills will tell people that they no longer need the condom. They will stop using the condom."</i> (Female HCW, First round)
D1, Q6	<i>"I've had this box of condoms for years. It's still nearly full. People don't like to use the condom. They never did,"</i> (HCW, Male, Second round)
D2, Q7	<i>"A different criteria would be useful for the young girls. We could use their weight instead of their age."</i> (Female Nurse, Second round)
D3, Q8	<i>"People are interested when you talk about PrEP and how it's offered. But as soon as you say it's a pill that you take every day, just 50% just walk out. People just stop right there. You can watch their eyes glaze over (respondent imitates watching eyes stop moving when a hand waves in front of eyes). They start complaining – a pill every day, most people are discouraged."</i> (Male Nurse, Second round)
D3, Q9	<i>"There was this pill that was orange and black I think that we used to give them, I think at that time there were many people who had it who came to get PrEP but now that we are using PrEP that is like ART there are now a few people who take it because they are afraid of the stigma that people will say they are now on ART."</i> (Male Nurse, Second round)
D3, Q10	<i>They can be motivated if they can also be able to go the Chemist and say that they are here to get PrEP and produce their paper that they had gone to Manzini and they said they should come back on this date and now I am in Piggs Peak and I cannot get it. You see so I should be able to get PrEP anywhere in Swaziland, whether it is Lavumisa and I was working in Mankayane I must be able to go to Lavumisa clinic or even at the Chemist. You see that every point where people enter. You see even at Shoprite there is a pharmacy that side so people must be able to go in and take PrEP."</i> (Female Nurse, Second round).
D4, Q11	<i>"They get tested and then they tell you they cannot start because they need to go home and think about it and then they will come back yet they end up not coming back."</i> (Male Expert Client, Second round)

D4, Q12	<i>Maybe their partners will not want them to take the pill. When you have tested them they tell you that they still have to go and their partners, things like that. You find that they go and do not come back. Maybe the partner refused while they wanted to take it. (Female Nurse, Second round)</i>
D4, Q13	<i>"Educating people during meetings, the community meetings that are held at the chiefdoms. I think that would bring about change or maybe educate them and then screen them during those meetings like PSI; New Start, they pitch tents and test people in the sports groups. We could screen the people and then provide PrEP just like them who after testing a person they then refer them to be initiated at the clinic so I feel like even with PrEP if they feel like the PrEP pill can protect them then they will come to the clinic." (Female Nursing Assistant, First round)</i>
D4, Q14	<i>"Brand the cars. Give clients pens- the pen is an opportunity to talk about PrEP. Of course, I know that women don't really have bargaining power like women in other countries have- of course if a husband asking a question it could mean you are interrogated. The pen doesn't mean I'm on PrEP. It means I went to the clinic and I'm considering PrEP. Let's talk about PrEP and talk about what it means. It's the same thing with the card. This is like a Pen (picks up small card), but the pen I get to keep it with me, it becomes mine. The idea is not disclosing to people that you're on PrEP but it's getting people to talk about prep and find out the misconceptions they have, their ideas, what's going on with PrEP." (Male HCW, Second round)</i>
D4, Q15	<i>"What makes me to not offer PrEP is the pressure of the line. The line may be so long that I may say yes to this patient who has tested and they are negative and we talk about PrEP while we wait for the results. But you find that the pressures of the line are too much to start risk assessment. Those are the things." (Female Nurse, First round)</i>
D5, Q16	<i>"PrEP takes a long time; firstly, to teach the patient. 2 the patient agrees and you have to do the risk assessment.3 you have to initiate PrEP and you have to take blood. You need the NARTIS. And that is just one patient and you find that there are 3 others still waiting and the line is long and there are other things that you need to do." (Female HTS Counsellor, First round).</i>
D5, Q17	<i>"We lose some people because there is no one to initiate. For instance they have been standing in long the whole day and they were just there to get tested and now they are being told about PrEP and they need it so then they get lost... because you find that some people end giving up." (Female, HTS Counsellor, Second Round)</i>
D5, Q18	<i>"Maybe in the radio they do not talk about it. I am also someone who is always at work, I do not know why they do not have the information. The information is very small on PrEP." (Female Mentor Mother, First round).</i>
D5, Q19	<i>"Everything went well. The only problem was on our side, since we are not NARTIS trained, we can't initiate PrEP but can only do the risk assessment and blood samples taking, initiation must only be done by a NARTIS trained nurse" (Female Nurse, First round)</i>
D5, Q20	<i>"In terms of them defaulting, the random stops and resumes in taking the pill, I think maybe we need to introduce a system that will help monitor and encourage the clients. Like... because for PrEP, it is about appointing someone, in order to increase the efficiency of the program we do need an appointment book to record everything. We need to know that in a particular day, how many people who need to refill PrEP should we expect." (Male Nurse, Second round)</i>
D5, Q21	<i>"I think it depends on you because the exposure is seen by you. There are children that are 16 years and they are already sexually active. Maybe there could be no age restriction on the PrEP, it must be someone who wants it and not limit the age." (Female Nurse, Second round)</i>

D6, Q22	<i>"Nurse X attends meetings at the chief's kraal and talk about the PrEP pill. You find that during weekends she has gone to attend those meetings and gets the chance to talk about PrEP." (Female HTS Counsellor, Second round)</i>
D6, Q23	<i>"When it comes to women who have been prohibited by their husbands, it becomes even harder, we try to get them to invite their husbands to come to the clinic by giving them cards only to be rejected. (Male Nurse, Second round)</i>
D6, Q24	<i>"When we see the regular PrEP clients, we take the straight through so we can get on with giving them their pills and then they can leave. If you see them queuing you think 'it's not good to make them wait' because they might leave." (Female HCW, Second round)</i>
D6, Q25	<i>"All of us are exposed. You do not live with a person all the time so you do not know what they are getting up to. We say 'so it is all of us that are exposed.' We are eligible to take PrEP." (Female Nurse, Second round)</i>

Figures

Figure 1

A modified Consolidated Framework for Implementation Research with six domains: the intervention, the inner and outer setting, the individuals involved, the process by which implementation is accomplished and the adapted intervention.

Supplementary Files

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