Enhancing Health Services to Improve Adolescent Engagement in HIV Prevention

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Abstract

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Introduction: Adolescent girls and young women (AGYW) in Eastern and Southern Africa have high HIV incidence. Pre-exposure prophylaxis (PrEP) once daily oral medication is recommended by the World Health Organization (WHO) as an effective intervention for individuals with risk behaviors associated with HIV acquisition. PrEP initiation is low among AGYW. This dissertation draws from two large studies to explore user experiences of PrEP service delivery for AGYW to determine how to improve quality and tailor services to address AGYW needs: 1) the *PrEP Implementation for Young Women and Adolescents Program: Standardized Patient* (PrIYA-SP) study, and 2) a pilot study delivering PrEP in retail pharmacies.

Methods: PrIYA-SP was a cluster randomized trial based in Kisumu County, Kenya that aimed to improve the quality of PrEP delivery by implementing a standardized patient actor (SP)-led training for providers to enhance communication skills and adherence to national PrEP guidelines. At baseline and after conclusion of the intervention training, unannounced patient actor (USP) “mystery shoppers”

presented to clinics portraying AGYW in common PrEP scenarios to assess PrEP delivery. To understand PrEP seeking experiences by the USPs, we added open-ended questions to their quantitative checklist evaluations of PrIYA-SP PrEP providers immediately following their encounters. Debriefings were audio-recorded, transcribed, and analyzed using thematic analyses to identify themes relating to why the USP had a positive or negative experience with the PrEP provider. To understand whether the PriYA-SP training had impact on real-world AGYW, and not just actors, we utilized facility-level PrEP reporting tools to abstract 26 months (May 2019-June 2021) of data to describe patterns of PrEP initiation among AGYW utilizing PrIYA-SP study facilities. We then conducted linear regression analyses to compare the effect of the intervention on AGYW PrEP initiation between intervention and control sites. Finally, to assess whether non-clinic based locations such as retail pharmacies would be more acceptable to AGYW, we analyzed qualitative data from a pilot study in the same region. In this study, PrEP delivery was piloted at three retail pharmacies. AGYW who were purchasing contraception were offered PrEP by study nurses in the pharmacy. Among AGYW who accepted PrEP, we conducted 41 in-depth interviews (IDIs) one month post-PrEP acceptance. We purposefully recruited equal numbers of AGYW who accepted and ingested PrEP and AGYW who took the pills home but did not swallow them. IDIs were audio-recorded, transcribed, and analyzed using thematic analysis to identify themes about user experiences and acceptability of pharmacy-based PrEP delivery for AGYW.

Results: We conducted 91 USP debriefings at 24 clinics and identified three primary influences on PrEP service experiences: 1) Privacy improved likelihood of continuing care, 2) respectful attitudes created a safe environment for USPs, and 3) patient-centered communication improved the experience and increased confidence for PrEP initiation among USPs. During the study time period, 1,375 AGYW presented to PrIYA-SP sites and were eligible for PrEP (baseline: n=706, post-intervention: n=669). Among 669 PrEP-eligible AGYW in the post-intervention period (intervention: n=360, control: n=309), 591 (88.3%) initiated PrEP (intervention: n=335, control: n=256). PrEP initiation was 93.9% at intervention sites and 82.8% at control sites. Adjusted for baseline initiation rates, initiation was 12.1%

higher at intervention sites compared to control sites (p<0.001, [95% CI: 0.09, 0.15]). Among the 41 AGYW interviewed in the pharmacy study, the median age was 18 years. Approximately half (49%, n=20) purchased emergency contraception at enrollment, and 54% (n=22) had swallowed PrEP pills since obtaining them. AGYW preferred pharmacies over clinics for accessing PrEP and they were willing to pay for PrEP at pharmacies, even if available for free at clinics. Reasons for this preference included ease of access, lack of queues and medication stockouts, privacy, anonymity, and autonomy over one's health. High-quality counseling from study nurses stationed at pharmacies also facilitated PrEP initiation. AGYW reported that they received more attention, time, and better education regarding PrEP and contraception at pharmacies with nurse delivery compared to public clinics.

Conclusion: User experiences, including patient-centered communication, privacy, and respect for autonomy, contribute to AGYW willingness to accept PrEP for HIV prevention. Interventions and policies that improve health provider and clinical setting factors may increase PrEP initiation, and ultimately contribute to decreased HIV acquisition in this priority population.

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Chapter 1: Introduction

Adolescent girls and young women (AGYW) in Southern and Eastern Africa account for 63% of the world's new HIV acquisitions annually,[1] placing this population at high priority in the global efforts to end HIV. Tenofovir-based daily oral pre-exposure prophylaxis (PrEP) is a highly affordable and scalable drug option for preventing HIV acquisition when taken correctly.[2] Kenya is a leader of PrEP scale-up[3] and has integrated PrEP delivery in many existing and new points of care, including antiretroviral therapy (ART) programs, family planning (FP) clinics, maternal-child health (MCH) clinics, hospitals, mobile clinics, youth-friendly clinics, and private pharmacies, however, uptake of PrEP by AGYW remains low..[4-7]

AGYW report difficulty with seeking and maintaining HIV prevention services in health care facilities because of stigmatizing interactions and judgment from providers, other non-clinical staff, and members of their communities.[8-10] *Positive user experience* in health systems is a marker for quality care and incorporates *respect* and *user focus* as key components of a high-quality health care system. *Respect* in a health system should include "dignity, privacy, non-discrimination, autonomy, confidentiality, and clear communication"; *user focus* should include "choice of provider, short wait times, patient voice and values, affordability, and ease of use."[11]

This dissertation tackles key aspects of *positive user experience* that could inform future HIV prevention efforts among AGYW with PrEP by improving the quality of care received by AGYW. Chapter 2 describes the experiences of standardized patient actors posing as AGYW seeking PrEP in the PrIYA-SP study in Kisumu County, Kenya. A qualitative addition to PrIYA-SP quantitative measures, it answered key questions posed by the study team about *why* an SP had a positive or negative interaction with a PrEP provider and *how* that affected their willingness to continue to care with that provider. Using routine clinic data in PrEP eligibility and initiation at PrIYA-SP sites, Chapter 3 describes PrEP initiation patterns of real-world AGYW attending PrIYA-SP study facilities and compares the effect of the training intervention between control and intervention sites. Chapter 4 describes AGYW experiences accessing PrEP from a different kind of venue, retail pharmacies in Kisumu, Kenya.

Chapter 2: *"I was given PrEP, but had no privacy"*: Mystery Shopper Perspectives of PrEP Counseling for Adolescent Girls and Young Women in Kisumu County, Kenya

ABSTRACT

Introduction: Pre-exposure prophylaxis (PrEP) is being scaled up to prevent HIV acquisition among adolescent girls and young women (AGYW) in Eastern and Southern Africa. In a prior study, more than one-third of AGYW unannounced patient actors (USPs), or 'mystery shoppers,' stated they would not return to care based on interactions with health providers. We examined the experiences of USPs posing as AGYW seeking PrEP at Kenyan clinics to identify main barriers to effective service delivery.

Methods: As part of outcome assessment in randomized controlled trial, USPs posed as AGYWs seeking PrEP using standardized case scenarios eight months after providers had received training to improve PrEP services. We conducted targeted debriefings using open-ended questions to assess PrEP service provision and counseling quality with USPs immediately following their visit. Debriefings were audio-recorded and transcribed. Transcripts were analyzed using thematic analysis to explore why USPs reported either positive or negative encounters.

Results: We conducted 91 USP debriefings at 24 facilities. USPs identified three primary influences on PrEP service experiences: 1) Privacy improved likelihood of continuing care, 2) respectful attitudes created a safe environment for USPs, and 3) patient-centered communication improved the experience and increased confidence for PrEP initiation among USPs.

Conclusions: Privacy and provider attitudes were primary drivers that influenced decision-making around PrEP in USP assessments. Improving quality of the counseling experience, including ensuring privacy and using patient-centered counseling techniques, may contribute to higher PrEP uptake, and ultimately, lower HIV incidence among AGYW.

INTRODUCTION

Adolescent girls and young women (AGYW) in Eastern and Southern Africa experience disproportionately high HIV incidence compared to other age groups.[12] Although, new HIV infections among young people ages 15-24 have declined over the past decade (56% decline for males and 42% for AGYW),[1] the incidence of new HIV infections are 3-fold higher among AGYW (32%) than their male peers (10%) in this region.[13] In Kenya, new HIV infections among AGYW are approximately twice that of their male peers annually (approximately 12,500 compared to 6,300, respectively).[14]

Pre-exposure prophylaxis (PrEP) is recommended by the World Health Organization[2] (WHO) and the Kenya Ministry of Health for those at-risk for acquiring HIV, with tenofovir (TFV)-based daily oral PrEP scaling up[3] in Kenya primarily through local hospitals, maternal child health (MCH) clinics, and family planning (FP) clinics to reach AGYW.[15-17] Despite these ongoing efforts to increase PrEP access among AGYW in Kenya, initiation in this priority population remains suboptimal, with studies suggesting only 4-16% of Kenyan AGYW with behaviors associated with HIV acquisition initiate PrEP when offered in FP clinics.[15,16,18] In one study, among those who initiated PrEP, only 37% of AGYW persisted with PrEP medication after three months.[19]

Negative health care user experiences, including stigmatizing interactions with health providers, contribute to low initiation of PrEP among AGYW by dissuading their engagement in care.[8,17,20-23] Stigma has been shown to have devastating consequences to health outcomes in the HIV care continuum, including loss of social support, isolation, depression, and decreased utilization of preventive care.[24] Accessing and maintaining care is key to correctly taking PrEP and ultimately preventing HIV acquisition.[25] Thus, stigmatizing interactions with health care providers may be a key barrier to effective scale-up of PrEP for AGYW.

During a cluster randomized trial of a clinical training intervention to improve quality of provider-patient PrEP interactions through destigmatization,[26] we used unannounced standardized patient actors (USPs)[27] posing as AGYW seeking PrEP at health facilities in Kenya.[28] During the baseline phase of this study, USPs quantitively measured quality of PrEP counseling delivery. More than a third of USPs stated they would not want to return to the health care provider they saw due to stigmatizing interactions or other complaints.[29] To explain USP ratings, and gain a more in-depth understanding of USP experiences, we conducted a qualitative analysis of debriefing interviews following their unannounced encounters.

METHODS

Study Design

This qualitative analysis is nested in a cluster randomized trial of a clinical training intervention to improve quality of PrEP services for AGYW. During the outcome assessment phase, we audio-recorded debriefings between trained USPs and study staff following visits to clinics by actors posing as AGYW seeking PrEP services. USP quantitative checklist scores are reported in the parent study; this analysis explores answers to open-ended, qualitative questions related to user experiences of USPs seeking PrEP.

Population and Setting

USPs presented to 24 facilities (12 intervention, 12 control) to assess quality of PrEP services. Facilities for the trial were purposively selected based on expected AGYW patient volume, and included FP and MCH facilities from the county, subcounty, and health center levels. Facilities were an even mix of urban, peri-urban, and rural settings, and included public and private/faith-based facilities. Health providers at intervention sites participated in an educational training intervention. At all sites, health providers consented to USP encounters but did not know when the USP would happen. USPs are professional Kenyan actors, hired and trained as part of the study team.

Data Collection

Eight months post-training, eight actors (aged 19-23 years) visited facilities posing as PrEP seeking AGYW. USPs used scripted PrEP scenarios (Table 1) to seek PrEP services at all 24 facilities. Immediately following USP encounters, research assistants trained in qualitative methods (E.A. and V.K.) guided the USPs through a debriefing process. Debriefings included a quantitative checklist to capture primary trial endpoints, and open-ended questions to explore why USPs rated the encounters either positively or negatively (Table 2). Research assistants were provided with a list of probing questions to elicit sufficient details and concepts to explore why the USP rated the provider as they did and how the experience felt for them. Debriefings took place in local languages, if necessary, were audio-recorded, and covered themes related to provider language use, stigmatizing or judgmental behaviors, time allowed for questions, respectful or disrespectful behaviors, privacy, listening skills, and whether the USP would return to the provider in the future. USP debriefs were transcribed verbatim by one Kenyan study staff (C.K.), and initial transcripts were independently verified against the original audio file by a member of the analysis team (M.V.). Repeat interviews and review of transcripts for correction were not offered to USPs due to COVID-19-related travel restrictions and logistical challenges.

Data Analysis

Transcripts were uploaded into Dedoose version 9.0.54 (SocioCultural Research Consultants, LLC, Los Angeles, CA, USA). Using principles of thematic analysis,[30,31] the analysis team (M.V., C.K., H.A., and C.O.) reviewed transcripts to identify, and evaluate themes related to *positive user experience* concepts from the High-Quality Health System Framework[11]. The High-Quality Health System Framework focuses on health system function, user experience, and how people benefit from healthcare. *Positive user experience* encompasses two concepts: respect and user focus. *Respect* incorporates dignity, privacy, non-discrimination, autonomy, confidentiality, and clear communication. *User focus* incorporates choice of provider, short wait times, patient voice and values, affordability, and ease of use. The analysis team developed a codebook from a close read of a subset of 15 transcripts using inductive and deductive methods. Deductive codes were derived from concepts of *positive user experience* in the High-Quality

Health System Framework. Inductive codes were developed through multiple reviews of the transcripts by the analysis team. The codebook went through several iterations, with the clarification of codes and code definitions occurring through group discussion and consensus as additional transcripts were reviewed. After the codebook was finalized, transcripts were coded independently by a member of the analysis team and received a secondary review by a different analysis team member. Differences in coding were discussed until resolved through consensus. Coded data were put into framework matrices to identify themes across all 91 debriefings.[32]

Ethical Considerations

Participant providers provided written informed consent and knew they would be visited by a USP but were not given details of the time or date of the visit. Provider names were not linked with assessment data. The University of Washington Institutional Review Board (IRB, approval number CR00006099) and the Kenyatta National Hospital Ethical Review Committee (ERC, approval number P751/10/2018) reviewed and approved the conduct of this study.

RESULTS

In total, 91 USP debriefings were audio-recorded and transcribed for analyses: 18 (20%) depicted case 1 (married, new PrEP initiator), 14 (15%) case 2 (serodiscordant adherence challenge), 15 (16%) case 3 (transactional sex), 14 (15%) case 4 (PrEP continuation, adherence challenge), 17 (19%) case 5 (young, seeking contraception), 13 (14%) case 6 (new PrEP initiator). Overall, USPs reported a mix of positive and negative experiences receiving care from providers, where an encounter that incorporated privacy, compassionate communication, and education on PrEP elicited a more favorable experience for the USP. We identified three major themes related to PrEP seeking experiences from the concept of *respect* under the domain of *positive user experience* from the High-Quality Health System Framework:[11] 1) privacy improved willingness to continue in care, 2) respectful attitudes created a safe and caring experience for USPs, and 3) patient-centered communication improved USP experience and PrEP initiation confidence

Privacy as a determining factor for returning to a provider

Most USPs reported that privacy was of great concern for them while visiting a healthcare facility for PrEP. Multiple USPs described having several people in the room during their encounter with the provider. Interruptions by other patients or providers made some feel they were not in a safe space to receive PrEP counseling. Some USPs felt that the amount of people and open doors, paired with loud provider voices, created feelings of unease and limited sharing honest information with their provider.

> *"The door was wide open, in the room there were four other people, one other person came in during our encounter, and he consulted somebody else concerning the records. When we were in the encounter, he would be asking me questions and also speaking with other colleagues in the room, so it wasn't private. Then there was another client who came in [and] just interrupted our session, so I did not feel like my privacy was protected." (case 1, married new PrEP initiator)*

Lack of privacy was a common concern, and multiple USPs responded positively about all aspects of their encounter with their provider except the privacy aspect. These USPs reported unwillingness to return because of this lack of privacy, even though the encounter was generally favorable.

> *"I would go back to the medical provider because…she respected me and treated me without being judgmental and she also offered me the medication…but I would probably not go back because of the privacy state. There were so many people in the room and the interruptions, so I felt that my privacy was not 100% guaranteed." (case 3, transactional sex)*

In contrast, USPs who described situations where their privacy was protected stated that they would return to the same provider for care because they felt respected. Providers who were aware of their surroundings and shifted the direction and questions within the encounter accordingly, were viewed positively.

> *"It was just the two of us in the room and even during the encounter when somebody else called her from outside she told them to wait a little bit because she was in the session with me, so I felt…that my privacy was protected, and she was concerned about handling me without having interruptions." (case 5, young seeking contraception)*

Respectful attitudes created a safe and caring experience for USPs

Provider attitude was an important aspect in deciding whether one would want to return to the same provider. USPs described providers with good attitudes as those who were friendly, personable, and non-judgmental, and showed they cared about the patient by asking about their personal lives. Providers with good attitudes were also described as being vulnerable, honest, and thorough, offering help and providing additional resources.

> *"I will go back to the healthcare provider because…she was very friendly. She inquired how I was doing, my personal health, [my] family…She apologized for keeping me [and] was respectful by…address[ing] me by my name. She even apologized for not having condoms, but then she advised me to go to a public hospital where I could be given condoms. She was not judgmental…She was just nice (both laugh)." (case 1, married new PrEP initiator)*

On the other hand, providers who were confrontational were viewed as having a negative attitude. One USP described a confrontational provider who used a harsh tone of voice, was terse in communication

style, and did not maintain eye contact or adopt an open body posture. In addition to being viewed as confrontational, the USP described this provider as being disorganized, uncaring, and unprofessional, which came across as disrespectful to the USP.

> *"When I entered the room, the first thing he asked me was, 'Why are you here?'…I told him I am here for PrEP and then he told me, 'That is not a reason.'…he was fidgeting [in] the chair and there were some things he was noting down…he was doing that while one leg was on top of the chair and then…he stopped attending to me and he started looking for some other files, sitting on the table, so I felt disrespected." (case 6, new PrEP initiator)*

Judgement played an important role in how provider attitudes were viewed by USPs. Providers that were non-judgmental were often aligned to those having a positive attitude and encouraged USPs to continue care with them by being attentive, active listeners.

> *"She was attentive, she was really listening to me and she never judged me from my situation [because] I told her that I have a partner who has a wife and she was never judgmental… the body posture and the language showed respect, so I felt respected." (case 2, serodiscordant adherence challenge)*

Among USPs who described feeling judged, evidence of judgment came through verbal language, tone, and body language. Judgmental providers not only dissuaded USPs from continuing care, but they limited USP willingness to be open and honest about their care and questions. USPs also viewed unwillingness or reluctancy to provide PrEP as being judgmental.

> *"The clinician said I was not eligible for PrEP because he felt that only sex workers and miscoded couples should be given PrEP…He told me that most people waste drugs because*

they don't take them, so he said that I should go and think twice." (case 6, new PrEP initiator)

Some USPs experienced judgment not only from providers, but from staff in the pharmacy or reception areas. Similarly, these judgmental encounters made them feel very uncomfortable and less likely to seek further care, as this negative treatment experience occurred in spaces that were more public than the provider's examination rooms.

"In the pharmacy, the nurse was very judgmental, and she was asking me why I am using PrEP [because I] am still young; that I should just dump my boyfriend because it is not worth sacrificing my life. She even sneered." (case 6, new PrEP initiator)

Body language was seen to impact how USPs felt during their encounter. Some reported that the provider seemed closed-off in demeanor, did not face them directly, did not employ much eye contact, with one USP noting that their provider was physically handling papers and files not related to the USP during their encounter.

"Most of the time he was not concerned with whatever I was saying. He was just concentrating on writing and doing other things in the office, in the file, which I didn't know what he was doing. So, I did not feel respected, also because he did not maintain eye contact at all. Even [while] asking me questions about the session or the drug, he was just doing his own things and ticking the file, so I didn't feel respected at all. So, I will not go back." (case 6, new PrEP initiator)

Conversely, providers that made eye contact, nodded that they were listening and showed through their body positioning that they were paying attention, were seen as creating a welcoming environment where the USP could have issues addressed, and further, that the provider cared about the USP's health.

> *"He was very welcoming, his tone was soft and friendly…During the whole session he was attentive. He would maintain eye contact with me. He was listening by his body language…nodding the head. [When I] said I had a problem forgetting to swallow my drugs sometimes, he turned now facing me directly…so that he could find out why…I forget [and] what can we do to sort out the issue." (case 3, transactional sex)*

Patient-centered communication improved USP experience and PrEP initiation confidence

USPs reported several aspects of patient-centered communication that influenced their feelings about their care experiences. Showing care through listening made some USPs want to come back for further care. Providers that were seen as "interactive" were viewed more positively by USPs. Being interactive included asking questions about the USP and asking if the USP had questions for the provider.

> *"At…first, she counselled and gave an opportunity to ask any questions if I had any and then continued with the counseling. Then she also gave me an opportunity where she told me that she is not going to talk anymore unless I ask a question." (case 1, married new PrEP initiator)*

USPs that did not receive an interactive session were less willing to return to the provider for further care because they didn't feel their questions would be answered, which decreased their confidence in taking PrEP. Allowing more time to interact with the provider was seen as giving better care. USPs who had providers that spent plenty of time with them, asking questions and providing guidance, reported feeling cared for and understood.

"I felt that she was very welcoming and understanding…She took me through an elaborate counseling session on how I am supposed to take my drugs and how it would affect me, not only because I'll get HIV, but how…I would develop resistance to the drugs, and they wouldn't be of help to me. And also when she was describing how…I should speak to my partner so that we can come for testing, she even went further to say if I found that my partner is positive, they would offer counseling on how we can take the next step…I found that she treated me with a lot of care and understanding." (case 3, transactional sex)

USPs who did not feel they received quality time with or the opportunity to ask questions of their provider were hesitant to return for follow-up care, even if PrEP was prescribed.

"The provider dominated the whole encounter, there wasn't any point where I was given a chance to ask any question or to raise any concern it was just him talking through the whole encounter and me answering any questions that he asked." (case 3, transactional sex)

USPs noted how language used by providers were important aspects of receiving patient-centered care. Using words that were familiar (i.e., not medical jargon), or were accompanied by explanations if unfamiliar, was seen positively by most USPs. Simple, easy to follow language allowed USPs to understand more fully what the provider was communicating, increasing their positive regard for the encounter.

"Throughout the session, from the start to the end, she used a simple language that I could understand…There is a point where she used a medical term adherence, she went ahead and explained [that] adherence means taking the medication…daily, consistently, the way

[we] had been told by the physician…so I understood [what] she said." (case 1, married new PrEP initiator)

DISCUSSION

This analysis complemented and explained quantitative endpoints of a clustered randomized trial assessing a clinical training intervention for healthcare providers.[29] We found that AGYW USPs preferred to return to providers who protected their privacy, didn't allow for interruptions to happen during the encounter, maintained respectful and caring verbal and non-verbal communication, and allowed time for questions and concerns to be addressed.

Privacy was a priority for USPs in our study. USPs reported that having a private physical space, no interruptions during their encounter, and providers who used a quiet tone of voice were perceived as providing a better experience. A study among AGYW in South Africa similarly found that privacy was of great concern among AGYW and hindered them from accessing sexual and reproductive health care due to fears of stigmatizing behaviors from clinical and nonclinical staff, to being "outed" by structural issues that allow AGYW to be physically seen by community members in clinics while interacting with a provider.[33] Another study in Kenya found that improving access to PrEP (including HIV testing, counseling, clinical assessment, and drug dispensing) in a one-stop-shop (OSS) model improved privacy issues by decreasing the amount of movement from place to place to receive all the services needed for HIV prevention care.[4] Our study suggests that measures to enhance patient privacy by improving the physical space in clinics may be a key aspect to improving PrEP delivery, as it was reported as a barrier by USPs even when the provider's communication skills were acceptable. Further, our study suggests that in addition to physical space, provider and nonclinical staff behaviors contribute to privacy during PrEP service delivery.

Respectful attitudes among healthcare providers were found in our study to be essential for creating a safe and positive experience for AGYW in the clinic setting. Similar findings have been described in other settings, where disrespectful or stigmatizing interactions with health providers are consistently reported as a barrier to continuing care across a number of populations and health conditions.[35] The resulting anticipated stigma also has been shown to affect health outcomes, including delays in treatment,[35] life-threatening disease complications,[36] and not accessing healthcare.[33] Other research indicates that providers may not be aware of the stigma they are inflicting on AGYW and that their own beliefs and values influence willingness to offer PrEP to young people. In South Africa, investigators found that 75% of clinical and nonclinical staff felt providing PrEP to AGYW would increase behaviors of sexual risk, pregnancy, and STI incidence.[33] Our study contributes to the global narrative by highlighting the unique stigma faced by AGYW seeking PrEP and offering more perspectives that providers need to augment or adjust their communication skills to decrease stigmatizing behaviors, even if they believe they are not being stigmatizing.

Finally, patient-centered communication was the last theme found to influence confidence in PrEP and overall experiences seeking care. Patient-centered communication is asking patients open-ended questions to gain understanding of their needs and desires for their care, not interrupting, and practicing active listening. [37] Patient-centered communication should elicit the patient's concerns, values, expectations for care, available resources, and informed consent for their care plan.[37] Patient-centered communication ideally incorporates relationship building, sensitivity to patient needs, compassion, empowering discussion of care, and respect for patient privacy and decisions. Our findings found that providers who did not display active listening skills (i.e maintaining eye contact, nodding of the head, not interrupting) and who did not ask open-ended questions were much less likely to elicit a positive experience for the USP during the encounter. The findings of our study suggest that implementing better patient-centered communication during encounters between providers and AGYWs seeking PrEP could potentially increase PrEP initiation and continuation of care among this population.

Limitations

Our study draws upon data from standardized patient actors portraying young women seeking PrEP and may not be generalizable to the greater AGYW communities of Kenya or other HIV high-burden countries globally. AGYW in the community who were not recruited may have different challenges that we are unable to include in these analyses. To make a qualitative analysis seamless we added open-ended questions to an already-existing quantitative checklist, which may have influenced what actors perceived as good care. Lastly, we completed debriefings from encounters with some providers who were involved in an educational intervention in the parent study, possibly skewing how USPs experienced care. This may not be generalizable to the greater community of PrEP providers.

Conclusions

Privacy and provider attitudes were primary drivers of return to care decision-making among actors portraying AGYW at Kenyan clinics. Improving AGYW experiences in the clinic setting is critical to improving PrEP service delivery. Future research is needed that includes a broader sample of non-actor AGYW participants to evaluate of whether provider and health systems interventions to improve these interactions will result in improved uptake and persistence in this priority population.

Table 1. PrEP Scenarios Depicted by Patient Actors

Case Number	Case Type	Scenario Depicted
1	New PrEP initiator	18-year-old female seeking information about PrEP; husband's HIV status is unknown, he does not use condoms.
2	PrEP continuation, adherence challenge	24-year-old female seeking PrEP refill; her husband is HIV-positive and on ART. She has an irregular daily schedule, making it harder for her to adhere to daily PrEP.
3	PrEP continuation, transfer-of-care case	19-year-old female transferring PrEP care to a new facility; engaging in transactional sex relationships with multiple partners including one main older "sponsor"; HIV status is unknown for all partners and they do not use condoms.
4	PrEP continuation, adherence challenge	17-year-old female seeking PrEP refill; her boyfriend is a truck driver and is out of town for long periods of time; she is adherent to daily PrEP when he is in town, but stops when he is away.
5	Seeking contraception	16-year-old female seeking contraception; her boyfriend's HIV status is unknown.
6	New PrEP initiator, young AGYW	18-year-old female seeking information about PrEP; her boyfriend's HIV status is unknown and they do not use condoms regularly. Now that she is sexually active, the girl is seeking self-controlled HIV prevention.

Table 2. Quantitative Checklist Measurement Objectives with Qualitative Additions for End-Line Debriefing

Quantitative Measurement Objective	Qualitative Question Added
Language use	In what ways did the provider use language that was easy or hard to understand?
Judgment/stigma	Were there specific things the provider said or did that made you feel judged, if at all?
AGYW questions during encounter	What did the provider say or do to make you feel encouraged or discouraged to ask questions?
Respect	What were specific things the provider did to make you feel respected or disrespected?
Privacy	What specifically made you feel your privacy was or was not being protected?
Listening skills	What specific things did the provider say or do that showed that he/she was listening or not?
Return to provider	Would you go back to see this provider? Why or why not?

Chapter 3: Adolescent PrEP initiation at clinics participating in a randomized trial of a standardized patient actor training intervention in Kisumu, Kenya

ABSTRACT

Introduction: Adolescent girls and young women (AGYW) in Kenya have low PrEP initiation rates in part to stigmatizing interactions with health care providers. Our recent randomized trial of a standardized patient actor (SP) training intervention for providers found higher quality PrEP delivery at intervention sites, however it was unclear whether improved quality improved initiation.

Methods: We used routine data from clinics participating in the PrIYA-SP study, a randomized trial aimed to improve provider communication and adherence to Kenyan guidelines when offering PrEP to AGYW. Record sources included facility-level PrEP registers from May 2019-June 2021. May-December 2019 was the baseline period and December 2020-June 2021 was the post-intervention period. We analyzed facility-level data and used linear regression with percent initiating as the outcome, intervention and baseline initiation levels as covariates, and the number eligible post-intervention at each facility as frequency weights.

Results: Overall, 1,375 AGYW presented to PrIYA-SP sites, were eligible for PrEP, and were included in analyses (baseline: n=706, post-intervention: n=669). Among 669 PrEP-eligible AGYW in the post-intervention period (intervention: n=360, control: n=309), 591 (88.3%) initiated PrEP (intervention: n=335, control: n=256). PrEP initiation was 93.9% at intervention sites (range: 0%-100%) and 82.8% at control sites (range: 0%-100%). Adjusted for baseline initiation rates, initiation was 12.1% higher at intervention sites compared to control sites ($p<0.001$, [95% CI: 0.09, 0.15]).

Conclusions: Our study found significant improvement in PrEP initiation among AGYW who presented to facilities in the PrIYA-SP study. SP training interventions that improve quality of service delivery for AGYW could lead to higher population-level PrEP coverage.

INTRODUCTION

HIV infection rates among adolescent girls and young women (AGYW), aged 15-24 years, in Eastern and Southern Africa remain unacceptably high, accounting for 63% of new infections annually.[1,12] Although new HIV infections in this region have decreased by 42% since their peak in 1996, AGYW populations remain high priority due to increased risk factors of acquiring HIV.[1] The World Health Organization (WHO) recommends pre-exposure prophylaxis (PrEP) for anyone at-risk of acquiring HIV[2] and prioritizes AGYW in settings with high HIV prevalence.

Kenya is a global leader in adoption and scale-up of tenofovir-based daily oral PrEP,[3] yet AGYW in Kenya continue to have low initiation of PrEP medication. Program analyses based in maternal child health (MCH) and family planning (FP) clinics suggest that 4-16% of AGYW in Kenya who are eligible for PrEP go on to initiate PrEP.[15,16] In the POWER study, PrEP initiation at Kenyan and South African facility-based and mobile van evaluation sites was high (94%) among eligible AGYW, however only 31% returned for their 1-month refill.[38]

AGYW report that low uptake of PrEP is caused by both individual-level and health systems factors, including stigmatizing interactions with health providers that contribute to negative health care user experiences.[8,17,20-23] A previous study assessing health provider training experiences in Kenya found providers felt that supportive and inclusive atmospheres underpin more positive outcomes among those in the HIV care continuum, reporting that their improved counseling, rapport-building, and youth-engagement skills improved experiences for their adolescent patients by helping them open up and engage with providers during encounters.[39]

Our recent randomized trial of a standardized patient actor (SP) training intervention for health providers—the *PrEP Implementation for Young Women and Adolescents Program: Standardized Patient (PrIYA-SP)* study—aimed to improve quality of PrEP services for AGYW in Western Kenya. [26,29] Quality was defined as provider adherence to national guidelines and use of patient-centered communication

skills and was measured by unannounced SPs seeking routine PrEP care and posing as real clients. The trial found significant higher quality scores at intervention facilities; however, it was unclear whether improved quality of counseling led to higher AGYW PrEP initiation.

We compared the effect of the PrIYA-SP provider training intervention on programmatic AGYW PrEP initiation between intervention and control sites with the overall goal of extending primary trial outcomes to evaluate when improved quality is associated with higher PrEP initiation

METHODS

Study Design

This secondary analysis of a cluster randomized trial used routine clinic reports from health facilities participating in the PrIYA-SP study. We aimed to describe PrEP eligibility and initiation patterns over time and to compare PrEP initiation between intervention and control arms among AGYW clients who visited the study sites during the same time period as the parent trial.[26,29]

Population and Setting

PrIYA-SP sites included 24 MCH and FP clinics in Kisumu County, Kenya. During the PrIYA-SP trial, 12 clinics were randomized for the educational intervention, and 12 were the control with standard of care. Clinics included county hospitals, sub-county hospitals, and health centers that had previously participated in a PrEP implementation program[15] but had no other ongoing PrEP research activities. Trained providers included clinic officers, adherence counselors, and nurses (Table 1). For this secondary analysis, we used routine records documenting PrEP eligibility and initiation counts among AGYW clients ages 15-24 at each site.

Outcome Definition

PrEP initiation was defined as the proportion of eligible AGYW initiating PrEP, as documented in aggregate form on clinic records. The Kenyan Ministry of Health (MOH) and facility reporting tools tracking PrEP data within health care facilities include the MOH 731 Plus, District Health Information System (DHIS), PrEP Summary Reporting Tool, PrEP Daily Activity Report (DAR), and the PrEP Register (Table 2). The data in these reports are reported every month and include those eligible for PrEP, the number that initiated PrEP, the number continuing PrEP (i.e. returning for refills), the number restarting PrEP, the number currently on PrEP, the number that tested positive for HIV while on PrEP, the number diagnosed with an STI, and the number that discontinued PrEP use. Data are grouped by gender, age group, and key populations. The data points included in these analyses included counts of those eligible for PrEP and the number that initiated PrEP.

Data Collection

We abstracted data from monthly reports dated May 2019-June 2021 (312 control months, 312 intervention months; 624 months of report data). A study team member entered count data from MOH paper and electronic registries into a REDCap database[40,41] mirroring the report forms using an electronic tablet. The REDCap database had repeating instruments to capture data from all available sources. The study data manager reviewed six randomly selected reports (XX% of all reports) input into REDCap against the monthly report abstracted to ensure accuracy of count data.

Data Analysis

Mirroring trial timelines, we defined May-December 2019 as the baseline period, during which pre-intervention trial outcomes were captured. December 2020-June 2021 was defined as the post-intervention outcome assessment period, the same months during which primary intention-to-treat trial endpoints were collected. We used descriptive proportions to describe PrEP eligibility and initiation patterns over the 26-month period of data abstraction and the baseline and outcome assessment periods. We analyzed data at the facility level and used linear regression with percent initiating as the outcome,

intervention and baseline initiation rates as covariates, and the number eligible during post-intervention at each facility as frequency weights. All analyses were completed using Stata version 17.0.[42]

Ethical Considerations

This analysis used de-identified information abstracted from routine clinic records. The University of Washington Institutional Review Board (IRB, approval number CR00006099) and the Kenyatta National Hospital Ethical Review Committee (ERC, approval number P751/10/2018) reviewed and approved the conduct of this study. Prior to abstraction, study staff sought appropriate permissions from the clinic staff to access PrEP reports at a time of day that minimized disruptions to service provision.

RESULTS

Site characteristics

The 24 health facilities involved in data abstraction consisted of county hospitals (n=2, 8%), sub-county hospitals (n=9, 38%), and health centers (n=13, 54%). There were 9 (38%) clinics with adolescent-specific PrEP services and 19 (79%) clinics had information about PrEP available to AGYW. Only one clinic (4.2%) had a medication stock-out in the last 30 days. The average number of providers trained to prescribe PrEP per facility was 4 (IQR 3-6) (Table 1). There were no significant differences in site characteristics among the intervention and control sites.

Record sources

Most records (61.9%) came from the MOH 731 Plus paper booklet on-site at each facility. When the MOH 731 Plus record was unavailable, we used other record sources. Other records were derived from the computer-based version of the MOH 731 Plus booklet, the District Health Information System (DHIS) (16.2%); the PrEP Summary Reporting Tool (15.7%), an earlier version of the MOH 731 Plus booklet; the PrEP Daily Activity Report (DAR) (3.4%), a facility-level tool with the same categories of the MOH 731 Plus booklet; and the PrEP Register (2.9%), a basic patient-level PrEP data report (Table 2).

PrEP initiation

Total absolute proportions of eligibility over PrEP initiation was 72%, overall and across control and intervention arms for the 26-month period of data abstraction (Table 3). When restricting analysis to baseline and post-intervention data (i.e. leaving out intervention period data) across all facilities, 1,375 PrEP-eligible AGYW presented to PrIYA-SP sites, 706 during the baseline period and 669 during the post-intervention period. Among 706 PrEP-eligible AGYW in the baseline period (441 at intervention sites and 265 at control sites) 410 (58.3%) initiated PrEP. This included 46.0% initiation at intervention sites and 78.1% at control sites.

Among 669 PrEP-eligible AGYW in the post-intervention period (360 at intervention sites and 309 at control sites), 591 (88.3%) initiated PrEP. This included 93.9% initiation at intervention sites and 82.8% at control sites (Table 3). Facility-level initiation ranges were 0%-100% in baseline and post-intervention periods, and in both arms. Adjusted for baseline initiation rates, there was a 12.1% higher PrEP initiation among AGYW presenting to intervention sites compared to control sites ($p<0.001$, [95% CI: 0.09, 0.15]) (Table 3).

DISCUSSION

Our study found a significant improvement in AGYW PrEP initiation at PrIYA-SP facilities that participated in a clinical training intervention aimed to improve PrEP provider communication and adherence to Kenyan national guidelines. In this analysis, programmatic data augmented trial endpoints of care quality, measured by patient actors, to demonstrate higher PrEP initiation among real-world AGYW who attended participating facilities.

Our findings complement existing interventions for increasing PrEP initiation for AGYW populations. In a scoping review, existing interventions to increase PrEP initiation among AGYW include SMS

reminders, peer support groups, drug-level feedback, decision support tools, social protection, economic empowerment, social marketing, and conditional economic incentives.[43] These interventions have had varied success with initiation levels falling between 0% and 95%, depending on the study.[43] Interventions with the highest initiation levels incorporated drug-level feedback, adherence support counseling, weekly SMS reminders in the first 3 months, and monthly adherence clubs and youth-friendly clinics and decision support tools.[43] Interventions with the lowest initiation levels used social protection, economic empowerment, and adherence support through existing HIV prevention programs.[43] Our study showed PrEP initiation levels at similar levels of the more successful existing interventions aimed at increasing initiation. Our study was unique because we focused on clinical delivery and user experience, emphasizing training in communication skills, adherence to national guidelines, and decreasing stigmatizing interactions. These skills pose a worthwhile addition to usual provider training and complement interventions focused more on AGYW behavior.

Experiencing stigma in HIV prevention health care is a key barrier to service utilization and is increasingly recognized as a central determinant of health and health inequity.[44,45] Clinical training has the potential to be a scalable approach to rapidly improve clinical practice, and subsequently client outcomes. The Partners PrEP study found significant increase in knowledge among PrEP providers and sustained PrEP initiation at trained sites following a modular 2-day training.[46] Our study further addressed training in values clarification and communication skills to destigmatize health care interactions and promote positive user experiences among AGYW. Using data on real-world AGYW clients, our study showed a statistically significant increase in PrEP initiation with our trained PrEP providers among a highly targeted population in Kenyan HIV prevention efforts, not just among participants enrolled in a research study. Our findings add to the growing literature that health services interventions that work on decreasing stigma are valuable, viable, needed, and are potentially important additions to existing HIV prevention strategies involving provider-AGYW interactions.

Limitations

The COVID-19 global pandemic influenced how many AGYW presented to clinics during the study period and strained health care systems overall. The data were from monthly programmatic reports, which were aggregate counts of AGYW and did not follow individuals through time. Data on eligible AGYW and those who initiated were complete, however, other variables in the reports (e.g. STI screening data) had missing values. To ensure accurate initiation in our dataset, we checked accuracy at point of entry into REDCap, during data cleaning and from the six randomly selected reports. Lastly, data only captured those seeking PrEP in clinics and left out those in the community not presenting to clinics for HIV prevention services.

Conclusion

Our study found a significant improvement in PrEP initiation among AGYW who presented to facilities that had been randomized to SP training. SP-training interventions that improve quality of service delivery could lead to enhanced PrEP coverage. More research is needed to ascertain if training for providers may be useful for other health care settings where stigma is a barrier.

Table 1. Health Care Facility Characteristics by Study Arm

Facility-level characteristics	**Overall *(n=24)****
County Hospital Sub-County Hospital Health Centre	2 (8.3%) 9 (37.5%) 13 (54.2%)
Providers trained to prescribe PrEP per facility	4.0 (3.0, 6.0)
PrEP Services for Adolescents and Young Adults	
Any adolescent-specific PrEP services Information about PrEP for AGYW available Stockouts of PrEP in last 30 days	9 (37.5%) 19 (79.2%) 1 (4.2%)
Provider participants	***(n=232)***
Female	134 (57.8%)
Age (years)	31.0 (28.0, 35.0)

*N or Median, % or IQR

Table 2. PrEP Summary Report Data Sources

Data source	Description	Percentage from Total Reports Abstracted (n=624)
1) MOH 731 Plus	The Kenyan Ministry of Health (MOH) reporting tool that tracks PrEP data within health care systems	386 (61.9%)
2) DHIS	Same as *731 Plus*, soft copy of the 731 booklet, computer-based	101 (16.2%)
3) PrEP Summary Reporting Tool	Earlier version of the reporting template, revised to *731 Plus*	98 (15.7%)
4) PrEP DAR	"Daily Activity Register", facility-level tool with same categories as *731 Plus*	21 (3.4%)
5) PrEP Register	Patient-level PrEP data reports within facility, our last data source if the other four were not available	18 (2.9%)

Table 3. Absolute Counts, Proportions, and Linear Regression

	Control Eligible	Control Initiated	Control Proportion	Intervention Eligible	Intervention Initiated	Intervention Proportion	Total Eligible	Total Initiated	Total Proportion
May 2019-Dec 2019: ***Baseline Totals***	*265*	*207*	***.781***	*441*	*203*	***.460***	*706*	*410*	***.581***
Jan 2020-Nov 2020: ***Intervention Totals***	*483*	*300*	***.621***	*448*	*360*	***.804***	*931*	*660*	***.709***
Dec 2020-Jun 2021: ***Endline Totals***	*309*	*256*	***.828***	*360*	*335*	***.939***	*669*	*591*	***.888***
TOTAL OVERALL	**1,057**	**763**	**0.722**	**1,249**	**898**	**0.719**	**2,306**	**1,661**	**0.720**
Confidence Interval	40.7 ±7.2	29.3±6.9	0.7±0.1	48.0 ±11.4	34.6 ±10.5	0.7 ±0.1	0.7 ±0.1	63.9±13.2	0.7 ±0.1

Linear Regression Findings	**PreP Initiation: Control Sites n(%)**	**PreP Initiation: Intervention n(%)**	**Adjusted coefficient**	**95% Confidence Interval**
	256 (82.8%)	335 (93.9%)	0.131	[0.09, 0.15]

Chapter 4: *"Pharmacies are everywhere and you can get it at any time":* Experiences with pharmacy-based PrEP delivery among adolescent girls and young women in Kisumu, Kenya

ABSTRACT

Introduction: Many Kenyan adolescent girls and young women (AGYW) with behaviors associated with HIV acquisition access contraception at retail pharmacies. Offering daily oral pre-exposure prophylaxis (PrEP) in pharmacies could reach AGYW reluctant to assess health clinics for HIV prevention. Understanding AGYW's experiences of accessing PrEP in this setting could guide implementation.

Methods: From October 2020 to March 2021, we piloted PrEP delivery at 3 retail pharmacies in Kisumu, Kenya. AGYW (aged 15-24 years) purchasing contraception were counseled and offered PrEP per national guidelines by nurses with remote prescriber oversight. AGYW who decided to take PrEP were provided with a free one-month supply. We conducted in-depth interviews (IDIs) with AGYW 30 days post-obtaining PrEP pills, purposively sampling an approximately even balance of those who initiated PrEP and those that did not. Transcripts were analyzed using thematic analysis to explore experiences of AGYW accessing PrEP at pharmacies.

Results: Overall, we conducted 41 IDIs. The median age was 18 years; 49% (n=20) purchased emergency contraception at enrollment, and 54% (n=22) had swallowed PrEP pills since obtaining them. AGYW preferred pharmacies over clinics for accessing PrEP and they were willing to pay for PrEP at pharmacies, even if available for free at clinics. Reasons for this preference included ease of access, lack of queues and medication stockouts, privacy, anonymity, and autonomy over one's health. High-quality counseling from our study nurses stationed at pharmacies also facilitated PrEP initiation. AGYW reported that they received more attention, time, and better education regarding PrEP and contraception at pharmacies with nurse delivery compared to public clinics.

Conclusions: Accessing PrEP at pharmacies was preferred over public clinics among AGYW seeking contraception at pharmacies. Pharmacies may be an important PrEP access point option for this population.

INTRODUCTION

Adolescent girls and young women (AGYW) in Kenya experience persistently high HIV incidence.[12] Despite ongoing efforts to increase PrEP access among AGYW in Kenya, initiation in this priority population remains low, with evidence suggesting that only 4-16% of Kenyan AGYW initiate PrEP when offered in family planning (FP) clinics.[15,16,18]

AGYW seeking sexual and reproductive health services face unique challenges, such as stigmatization over behaviors associated with HIV acquisition, decreased ability to access healthcare due to transportation and school/work schedules, and a dissuading fear of stigma related to seeking and obtaining PrEP. [8,10,24,47-49] To maximize the HIV prevention impact of PrEP for AGYW, there is a need for wider availability of PrEP access points, especially for AGYW who do not frequently seek care at health clinics. Retail pharmacies are utilized for many reasons and provide relative anonymity and stigma reduction to those who purchase PrEP. Recent research demonstrates that retail pharmacy-based PrEP delivery is acceptable and preferred in non-AGYW populations.[5,48,50-52] To date, few data on pharmacy-based PrEP delivery exist among AGYW but available evidence suggests feasibility.[18]

Our team recently completed a pilot evaluation of nurse-facilitated PrEP delivery at retail pharmacies in Kisumu, Kenya.[18] We found that 85% of AGYW participants seeking contraception at retail pharmacies accepted daily oral PrEP when offered and 69% of those who initiated PrEP were willing to purchase it at retail pharmacies even if it is available for free in public clinics. To complement our quantitative results, we conducted a qualitative evaluation to understand AGYW experiences with pharmacy-based PrEP, including reasons for preferring pharmacy-based PrEP delivery as this is not well characterized among AGYW to date. Our overall objective was to inform implementation of pharmacy-based PrEP for AGYW in Kenya.

METHODS

Study design and population

This qualitative study was nested in a pilot evaluation of pharmacy-based PrEP delivery among AGYW seeking contraception at 3 retail pharmacies in Kisumu, Kenya. Recruitment, eligibility and exclusion criteria, follow-up procedures, and detailed study participant characteristics have been previously described.[18] Briefly, from October 2020 to March 2021, pharmacy personnel referred female clients seeking contraception to our study nurses who then screened them for eligibility, continuing to enroll eligible AGYW until 200 participants accepted PrEP pills. We used nurses in this study for their communication skills and experience with counseling AGYW in HIV prevention and other topics of health, aiming to create a space where AGYW could receive ample one-on-one time with a practitioner for education regarding PrEP initiation, which is not always possible in the pharmacy setting. AGYW aged 15-24 years who purchased contraception (emergency contraception [EC], oral contraceptive pills [OCP], injectables, implants, condoms) at the retail pharmacy and were willing to discuss PrEP were eligible for the pilot study. Study nurses provided counseling that followed Kenyan national guidelines, performed HIV tests on AGYW using OraQuick kits, provided OraQuick HIV self-test kits to AGYW to take home for partner testing, and PrEP pills to all eligible AGYW at the participating pharmacies under supervision of a remote physician. Additionally, nurses counseled on topics raised by AGYW, including contraceptive options and issues related to relationships and navigating PrEP use.

At 30 days post-obtaining of PrEP pills, AGYW were purposively recruited for in-depth interviews (IDIs) from the 200 AGYW who accepted PrEP pills in the pilot study and currently had a male sexual partner. IDIs were intended to capture individual experiences with pharmacy-based PrEP delivery. The purposive sampling strategy aimed at having a balance of AGYW who did and did not initiate PrEP use after accepting PrEP pills at the pharmacy to glean more information on the reasons AGYW decide to take or not take PrEP. Those who met IDI eligibility criteria were offered participation in the IDIs by the study nurse until 41 AGYWs were recruited.

Data Collection

Following IDI informed consent and enrollment, qualitative interviewers recorded basic demographic information of each participant (age, gender, relationship status). Semi-structured IDI guides were created collaboratively between the study team members (J.P., H.A., C.O., E.B., J.O.) and were based on literature reviews and research experience in this population and location and covered themes related to family planning, HIV prevention, and pharmacy services. IDIs were conducted by experienced social scientists (H.A. and C.O.) who identify as young Kenyan women. IDIs took place in either a private room within the retail pharmacy or at the Kisumu research study office, depending on space availability and participant preferences. IDIs were conducted in Kiswahili, Dholuo, or English. Interviews were audio recorded and transcribed verbatim into English by interviewers (H.A. and C.O) and initial English transcripts were independently verified against the original audio file by the primary investigator (M.V.). Repeat interviews and review of transcripts for correction were not offered to participants due to COVID-19-related travel restrictions and logistical challenges.

Data Analysis

Using the principles of thematic analysis,[30,31] the research team reviewed transcripts to code, identify, and evaluate themes related to *positive user experience* concepts from the *processes of care* domain of the High-Quality Health System Framework. This framework came from a need to redefine what defines high-quality health systems, their processes, inputs, and concepts. Our study focused on two concepts under *positive user experiences*: *respect* (dignity, privacy, non-discrimination, autonomy, confidentiality, and clear communication) and *user focus* (choice of provider, short wait times, patient voice and values, affordability, and ease of use).[11] Transcripts were uploaded into Dedoose version 9.0.54 (SocioCultural Research Consultants, LLC, Los Angeles, CA, USA). A coding team, comprising the primary investigator (M.V.) and two additional study staff from Kenya (H.A. and C.O.), developed a codebook from a close read of a subset of 10 transcripts using inductive and deductive methods. Deductive codes were derived from concepts of *positive user experience* in the High-Quality Health System Framework. Inductive codes

were developed through multiple reviews of the transcripts by the coding team. The codebook was developed as an iterative process, with the refinement of codes and code definitions occurring through repeated discussion and consensus as additional transcripts were reviewed. All transcripts were coded independently by a member of the coding team (H.A., C.O., M.V.) using a final version of the codebook, and received a secondary review by another coding team member (H.A., C.O., M.V.). Disagreements in coding were discussed until resolved through consensus. Coded data were summarized in framework matrices to identify themes across all IDI transcripts.[32]

Ethical Considerations

This study involved field procedures in Kisumu, Kenya and data analyses in Kisumu and Seattle, Washington. The Kenya Medical Research Institute Scientific and Ethics Research Committee (SERU) and University of Washington Human Subjects Review Committee reviewed and approved the study protocol, informed consent forms, and data collection tools. All study participants received a KES 300 (approximately USD 3) reimbursement for their time at each study visit and were welcome to end the study visit and/or participation at any point.

RESULTS

Overall, 41 AGYW participated in IDIs. The median age for all participants was 18 years (IQR 16-20.25) and their partners' median age was 25.8 years (IQR 22-29). The most frequently purchased contraceptive method at enrollment into the parent study was EC (49%, n=20) followed by condoms (27%, n=11). Among all participants, 49% (n=20) accessed EC more than twice in the last 6 months. Almost two-thirds (63%, n=26) of participants did not know their partner's HIV status and 100% (n=41) had sex without a condom in the last 6 months. Of the 41 sampled participants, 22 (54%) started taking PrEP after acceptance and 19 (46%) did not start taking PrEP after initially accepting it in the pharmacy (Table 1). Reasons for not initiating PrEP included no longer feeling at risk for HIV acquisition, not having sex within the last month, and male partners testing HIV negative with the self-test kits participants took

home. Some participants had not yet initiated PrEP use but planned to do so in the future when they would be sexually active (e.g., boyfriend returns, school break, etc.).

Three key themes surfaced from the IDIs about positive user experiences with pharmacy-based PrEP delivery, all relating to the *processes of care* domain in the High-Quality Health System Framework: 1) pharmacies are more accessible than health facilities, 2) client-centered communication increases interest in PrEP, and 3) pharmacies provide anonymity and decrease stigma. Further, HIV self-tests complemented user experiences with PrEP delivery due to ease of use, painless and efficient testing process, privacy, and peace of mind provided by knowing one's HIV status or their partner's status.

Pharmacies are more accessible than health facilities

Participants consistently reported that the pharmacies were preferred for obtaining PrEP compared to health facilities because of easy access. Many participants reported not having reliable transportation to health facilities which may be located outside of urban hubs. Additionally, participants reported that PrEP is not universally or reliably available at all facilities in the community which makes it challenging to locate. Pharmacies were considered a better option because of their extensive locations across communities. Many AGYW walk from place to place, making pharmacies an attractive alternative for accessing both FP and HIV prevention care.

> *"The pharmacy is easily accessible. If I want PrEP, I will not run to the hospital when the pharmacy is next door. I will go to the pharmacy." (age 22, initiated PrEP)*

Participants also reported retail pharmacies have longer hours of operation than hospitals and clinics, which offers more opportunities to access PrEP given typical work and school schedule restraints. The burden of getting time off work or to take time out of class were reasons given by participants for not going to a healthcare facility for PrEP.

> *"Maybe, one can come from a far place and if it is not [open at] night then you can be stressed on how to get PrEP. But when it's [open at] night, you can just come at any time." (age 20, did not initiate PrEP)*

Some participants stated that hospitals are limited in the days they offer certain services or medications. This was seen as a barrier by some participants. If a person wants to initiate PrEP use or obtain a refill, not only would they have to potentially take time off from work or school and get transportation to a healthcare facility, but they may also be turned away because it was the wrong day for PrEP distribution.

> *"At the hospital, there are limits. You will go on a certain day, and they tell you that today they are not issuing [PrEP]. It is not every day that [PrEP is] issued at the hospital pharmacies. They have specific days for [PrEP]. So, you know with a [retail] pharmacy, at any time you want, you can easily access it." (age 22, did not initiate PrEP)*

Many participants reported that facilities frequently have long wait lines, which was a deterrent and significant barrier to accessing PrEP at facilities. One participant reported waiting in line for over two hours for PrEP in a crowded waiting room. This was seen by the participant as a 'waste of time' and an unwanted chance to experience stigmatization by others waiting in the queue, which was reported by many participants as a consideration when deciding whether to continue taking PrEP. Participants perceived pharmacies as a better 'value for the time' option for accessing PrEP, especially for AGYW who tend to have less acute reasons to attend healthcare facilities (e.g., seeking contraception or preventive services) and are therefore treated with less urgency in those settings.

> *"In the hospitals, you may find a lot of people in the line. You know the pharmacy is quick. At the hospital, maybe there is a queue. You fear the queue." (age 22, initiated PrEP)*

> *"Since you have come there [the health facility] for the drug [PrEP] and they know you are not that sick, they tend to ignore or just let young women sit there. While at the pharmacy…you can just go and be given what you want." (age 20, did not initiate PrEP)*

Among IDI participants, over half (54%) reported they were willing to pay for PrEP even if it was freely offered in clinics. Reasons for preferring to pay at pharmacies over getting PrEP for free at clinics reported included the convenience of pharmacy locations, the lack of queues and medication stock-outs, and the lack of stigma at retail pharmacies when making purchases.

> *"For example, you've ran out of drugs, and you went to the hospital and find the long queue…and when you get to the counter they have run out of stock. It will force you to go the following day so it will be like you will be missing your drug for the day." (age 17, initiated PrEP)*

> *"Personally, the pharmacy is a good venue for me because they are quick. If you go to the hospital to access PrEP, there is no PrEP. If you come on that day, they tell you to come another day and if you go again, you don't find it. So, to me pharmacy is good because here if you come…they just give it to you, but [hospitals] they tell you to come another day…." (age 18, initiated PrEP)*

Client-centered communication increases interest in PrEP

Client-centered communication was a crucial factor in initiating PrEP in the retail pharmacy. Some participants reported that the study nurse had a 'good attitude', which made it easier to talk about health issues. Behaviors that demonstrated having a 'good attitude' were eye contact, listening to the participant, asking questions and leaving time for the participant to ask questions, showing genuine care for the

participant's needs and values, and being kind and approachable in demeanor. This provided a perceived safe space for participants, which encouraged PrEP initiation.

> *"You know when you go to the hospital, maybe that person [PrEP provider] gives you an attitude that you can't even open up to that person. But with the pharmacy, personally, I felt very comfortable. So, attitude makes people prefer pharmacy to the hospital." (age 22, initiated PrEP)*

> *"I came to buy a medicine and [the study nurse] welcomed me really well. She told me that she wants to talk to me about something that will help me. So, we talked and talked and she explained so many things and I thought it was a good idea." (age 16, initiated PrEP)*

Providing adequate information regarding medications in general was perceived by participants to be an important aspect of client-centered communication. Participants cited both contraception and PrEP education from the study nurse as highly satisfactory with little room for confusion or unanswered questions regarding both medications. Some participants felt that the lack of information provided in public hospitals was a reason they preferred the retail pharmacy.

> *"At the hospital, you will just go, and request contraception and they will give you without informing you more about it. You will not be told about the side effects. But [at the pharmacy], you can get time, ask the nurse how it works, any side effects. You can get to know more." (age 23, did not initiate PrEP)*

In the retail pharmacy, participants were allowed time to get to know more about PrEP, which built safety and trust among the participants. The study nurse was seen as a trusted source to guide medication decisions because she built rapport and gave well-rounded education regarding PrEP.

> *"The [study nurse] created an environment where we could share anything with her and feel safe. She was also so informative. She clearly told me everything I needed to know about PrEP." (age 22, did not initiate PrEP)*

More quality time was reported by almost all participants to be of utmost importance when deciding where to go for medication needs. PrEP was perceived by participants as a medication that required time for explanation. Some participants voiced concerns over not knowing how to take the medication and what side effects to be aware of. These participants stated that they would prefer the retail pharmacy over healthcare facilities because they had time to speak with the study nurse, which is not the case in healthcare facilities.

> *"At the pharmacy, I am not hurried. I take my time and there is a nurse who will be patient with me. But at the hospital, people are many and they rush you so you will not get enough time to be open and talk to a nurse for long." (age 23, did not initiate PrEP)*

Some participants felt that the study nurse taking the time to provide in-depth education was the deciding factor to take PrEP pills home, even if the participant had not initiated by the time of the IDIs.

> *"Then [the study nurse] asked me if I would mind to learn more about PrEP. Then I said 'yes' because I was curious to know this PrEP. Yes, then she explained to me everything, that is when I made my decision [to accept PrEP pills]." (age 22, did not initiate PrEP)*

Pharmacies provide anonymity and decrease stigma

Almost all participants reported that privacy was of great concern for them regarding PrEP access. The retail pharmacy was an ideal option because one could be going to the pharmacy for a multitude of

reasons and not be stigmatized for overtly purchasing PrEP. One participant was specifically drawn to the retail pharmacy due to its relatively stigma-free space.

> *"My main like was that, at the pharmacy, you know it is a place where you come and go and unlike, let's say a hospital, where you frequently visit when you are sick. [You can] come get your PrEP without stigmatization or someone judging you as a sex worker or something. The fact that you won't get stigmatized is what really caught my attention." (age 16, initiated PrEP)*

Many participants perceived utilizing hospitals as a signal to others that they are ill. The overarching fear reported is that people in the community will think they are living with HIV and discriminate against them due to that perception. Participants desired avoidance of HIV-related stigma. Many participants specifically stated they did not want people in their community to think they were taking antiretroviral therapy (ARVs) for treating HIV.

> *"You have come [to a health facility], and you meet one of your neighbors there. It is always one room where people access this PrEP and also [ARVs]. You have come for PrEP, but later you hear them say 'so and so is also taking this drug of ours [ARVs], we were with her at the hospital.' This discourages me. You say to yourself, 'So how will I go? People will think that I also take ARVs,' but for me I know I have just gone for a drug that is going to protect me." (age 23, initiated PrEP)*

Some participants felt that healthcare facilities had too many people waiting and talking, even the healthcare workers. This situation made some participants feel like their privacy was not assured when community members were waiting for care and the healthcare workers were talking amongst themselves.

"In hospitals there are so many people. They have a bench and people are seated all over…people looking at you so I even fear explaining that this is what brought me [in]. Then, you know, public hospitals [are] noisy. Nurses shout, make noise, discuss stories, and laugh even if you are there… so they even make it difficult for me to share my issues…when they come in and laugh, you feel guilty. But here at the pharmacy, it is peaceful, you can open up and talk about your personal issue and get help." (age 23, initiated PrEP)

Another aspect of privacy and retail pharmacies that was mentioned among participants is the control of participants' time while in the pharmacy. At a clinic or hospital, a patient is called when it's their turn, regardless of what's going on around them in the greater environment. Some participants reported feeling safer being able to control when they go into a pharmacy, or even when to go up to the pharmacist to purchase PrEP. They could wait for a time when they felt comfortable.

"That is the same way people do with [emergency contraception]. You wait, even if they have many customers, you stand at a distance and wait. When they are all gone, you run, purchase the drug and leave. You can even ask the pharmacist to wrap it in a way that somebody won't know what you are carrying." (age 22, initiated PrEP)

HIV self-tests complement pharmacy-based PrEP delivery

HIV self-tests for partners were liked by most participants and complemented the experience of pharmacy-based PrEP delivery by amplifying another important facet to HIV prevention care: partner and self-knowledge of HIV status. Reasons for the positive regard for self-tests were that they were free, easy to use, quick, painless, provided peace of mind, a sense of safety because of status knowledge, and it could be done in the privacy of their home with or without their partner.

"The positive effect is that I got peace of mind. I also got my sex partner's HIV status according to the self-test I was given. I now knew his status, so even if we were having sex, I knew that I was safe." (age 23, did initiate PrEP)

"What I liked was that [self-testing at home] was between us, we had privacy; we are in the house testing together and I liked it. What I also like is that no one forced the other. We were both willing and there was no forcing." (age 23, did initiate PrEP)

The only negative comments were related to cost and being alone with a self-test kit. A few participants thought being alone taking a self-test might become a problem if that was how someone found out they had tested positive for HIV.

DISCUSSION

This qualitative evaluation is part of a pilot study exploring the acceptability and user experiences of AGYW accessing PrEP in the pharmacy setting in Kisumu, Kenya. The quantitative[18] evaluation found that the majority of AGYW in the pharmacy prefer obtaining PrEP from retail pharmacies over health facilities. Through IDIs, we found that the reasons for this preference include greater accessibility, superior client-centered communication from study nurses, and the relative anonymity provided in the retail pharmacy setting. More specifically, participants decided to accept PrEP pills based on the quality of care and privacy provided in the retail pharmacy setting. These findings contribute to prior quantitative studies[16,18,48] by explaining and identifying reasons for the overall preference of pharmacy-based PrEP delivery over health facility-based models. Our findings highlight concerns AGYW have when seeking PrEP and the potential for pharmacy-based PrEP delivery to address these concerns and maximize PrEP access for AGYW in Kenya.

Our findings suggest that addressing concerns beyond PrEP (i.e. contraceptive methods) in tandem with HIV prevention may be an effective approach to responding holistically to sexual and reproductive health needs of AGYW. Nurses addressed other concerns during counseling (e.g. relationship issues, contraception, and HIV testing) which was valued by AGYW, though this approach may not be scalable outside of research settings. We are testing the cost-effectiveness of utilizing nurse-navigators for AGYW within a pharmacy-based PrEP delivery model.[53] In a 2021 study,[54] Donnell et al. found a significant decrease in HIV acquisition among participants accessing contraception with PrEP offer (2.2 HIV seroconversions in 100 person-years) compared to those accessing contraception when PrEP was not available on-site (4.6 HIV seroconversions in 100 person-years). The behavioral profile among participants in our pilot suggests AGYW seeking contraception may especially benefit from PrEP delivery integrated at sites where they already access contraception.

Our study found that client-centered communication is essential for high-quality interactions between AGYW and study nurses in pharmacies. Client-centered communication incorporates using open-ended questions early on to ascertain the client's values and health goals, not interrupting, using active listening techniques; all which convey understanding, support, care, and empathy toward the client being served.[37] These communications skills were used by our nurses and are a tangible approach for any PrEP provider to ascertain health concerns of AGYW clients to offer the most appropriate services possible in one place.[55] AGYW with behaviors associated with HIV acquisition may be especially vulnerable to stigma while also being those most likely to benefit from PrEP. Similarly, supportive provider communication facilitated adolescent HIV testing[56] and AGYW contraception services.[57] Well-trained, client-centered communicators at PrEP access points could promote PrEP initiation among AGYW by addressing their unique needs and questions.[58]

Accessibility was a key theme in our study. Generally speaking, access to retail pharmacies improves health outcomes by providing a conduit for life-saving tests and medications beyond PrEP and

contraception. Maloney et al.[59] found that providing access to malarial testing in retail pharmacies in Tanzania increased malaria diagnoses and treatment of malaria infection. Rutta et al.[60] found that retail pharmacists in Tanzania are key in aiding tuberculosis detection and treatment. In a 2016 study,[61] an increase in adult vaccinations followed an increase in the availability of vaccines at retail pharmacies, decreasing vaccine-preventable deaths. This evidence laid the groundwork for the COVID-19 vaccine response, where retail pharmacies played a huge role in increasing vaccination rates.[62] In the context of AGYW and HIV prevention, pharmacies could play a broad role in improving health outcomes by providing OraQuick HIV tests, eligibility screenings for PrEP, and wide access to PrEP medication.

Privacy in PrEP delivery was a core concern among AGYW in our study. Privacy provides a safe space for people to receive care where otherwise they would not. Studies on opioid dependence in Australia[63] and sexual health in Britain[64] both found that private spaces where one can speak openly to a health provider in the pharmacy setting was a key factor among marginalized populations and those with sensitive health concerns seeking and maintaining care. AGYW are particularly vulnerable to stigma and need more access points for testing and medication purchasing options. Retail pharmacies could play a pivotal role in providing lasting care due to the access and privacy they provide.

Limitations

Our study uses data from only three retail pharmacies and may not be generalizable to the greater communities of Kenya or other HIV high-burden countries. We sampled AGYW already in the retail pharmacy setting accessing contraceptives, which likely does not include AGYW who experience further barriers to pharmacy-based PrEP initiation. Our sample also does not include AGYW who prefer FP and MCH clinics for PrEP access, thus leading to a potential bias in reported preference of pharmacy over clinic. These AGYW who were not recruited may have more intense or different challenges that we are unable to include in these analyses. Lastly, our study nurses may differ from other nurses in public health

spaces, providing a skewed perspective of how a nurse in a retail pharmacy would be perceived by AGYW.

Conclusion

AGYW seeking contraception are a critically important population to reach with HIV prevention services. It is crucial to expand PrEP delivery access point to reach a larger proportion of the AGYW population, especially those that may not frequently access health facilities. Future research is needed that includes a broader sample of pharmacies and AGYW participants to further evaluate pharmacy-based PrEP in this population. With the emergence of novel PrEP agents (e.g., vaginal ring, injectables, etc.), further research is needed that incorporates these new models within a variety of delivery platforms, including further research into the scale-up and sustainability of nurse-led PrEP delivery models.

Table 1. Demographic Characteristics of Participants (N=41)

Variable	N (%) or Mean (IQR)
Pharmacy site	
Lolwe	20 (49%)
Medstar	16 (39%)
Win-Win	5 (12%)
Age (years)	18.2 (16-20.25)
Age of partner (years)	25.8 (22-29)
Education level	
In college	9 (22%)
Secondary school	9 (22%)
Vocational/Trade	2 (5%)
None	21 (51%)
Years of completed education	11.3 (10-12)
Relationship status	
Casual partners only	3 (7%)
One primary + casual partners	11 (27%)
One primary only	26 (63%)
Single	1 (2%)
Partner provides financial support	
Yes	35 (85%)
No	6 (15%)
Primary sexual partner has other partners	
No other partners	13 (32%)
Unsure	19 (46%)
Partner has other partners	9 (22%)
Partner HIV status	
Negative	15 (37%)
Unknown	26 (63%)
Employment status	
Unemployed	38 (93%)
Currently employed	3 (7%)
Ever had HIV test before enrollment visit	
Yes	39 (95%)
No	2 (5%)
Condomless sex*	
Yes	41 (100%)
No	0 (0%)
Exchanged sex for money or favors*	
Yes	8 (20%)
No	33 (80%)

Characteristic		n (%)
Consumed alcohol in last 30 days		
	Yes	14 (34%)
	No	27 (66%)
Used EC more than twice*		
	Yes	20 (49%)
	No	21 (51%)
Experienced forced sex		
	Yes	2 (5%)
	No	39 (95%)
Experienced intimate partner violence		
	Yes	2 (5%)
	No	39 (95%)
Ever had a previous pregnancy before		
	Yes	16 (39%)
	No	25 (61%)
Ever heard of PrEP before enrollment visit		
	Yes	33 (80%)
	No	8 (20%)
High self-perceived HIV risk		
	Yes	35 (85%)
	No	6 (15%)

*in the last 6 months

Chapter 5: Conclusion

This dissertation sought to better understand aspects of user experience among AGYW seeking HIV prevention medication. Our motivation to understand these aspects of user experiences in PrEP delivery are important to informing ways in which existing PrEP delivery models (i.e. health care facilities and retail pharmacies) can improve and enhance their services to better facilitate PrEP initiation and care-seeking behaviors among AGYW.

In Chapter 2, we described experiences of standardized patient actors posing as AGYW seeking PrEP services at FP and MCH health care facilities. In Chapter 3, we described PrEP initiation patterns over the timeline of the PrIYA-SP study and evaluated the impact of a provider training in improving provider communication skills and adherence to PrEP guidelines. In Chapter 4, we described AGYW experiences seeking PrEP in the private, retail pharmacy setting. We found that the provision and maintenance of privacy improved the likelihood of AGYW continuing care with the same provider, respectful interactions with providers created an atmosphere of safety where AGYW were more likely to return to the provider and provide honest answers to providers' questions, and that patient-centered communication provided AGYW with positive experiences and amplified their confidence in starting PrEP for HIV prevention.

Privacy was a common thread in our findings and is part of the definition of *respect* under the *positive user experience* domain from the High-Quality Health Systems Framework.[11] Privacy is an important part of providing care to adolescents and is perceived as an aspect of physical (spatial and acoustic[67]) and psychological safety.[68] Privacy "has a strong effect on trust, which in turn affects the level of commitment, intentions to use the provider's services in the future, and engagement in positive word-of-mouth."[69] The implication of PrEP providers consistently maintaining physical and audible privacy in their interactions with AGYW is likely an increase in trust among AGYW clients, and thus AGYW returning to their PrEP provider for continued care and telling peers about their positive experience. Physical spaces must be adapted to ensure privacy and creativity is needed to elucidate scalable ways in

which physical space can be altered to improve physical privacy concerns among AGYW utilizing health systems for care.

Respect and *user focus* from the High-Quality Health Systems Framework stress the importance of providers having clear communication and services that are easy to use and easy to understand.[11] Improving health care provider communication skills and attitudes are key aspects of improving AGYW user experiences, with the potential to increase PrEP seeking and initiation. In other care settings around sensitive health topics, stigma and judgmental interactions with providers were significant barriers to accessing and continuing care.[33,65,66] Training providers to deliver better experiences for AGYW seeking HIV prevention care is scalable and has the potential to have an impact on whether AGYW seek care and maintain it. With many interventions being implemented to increase PrEP initiation among AGYW,[43] this dissertation revealed that it is crucial that we are contemplating *how* these interventions are being experienced by AGYW. Incorporating *respect* and *user focus* considerations could bridge the gap between available interventions and the AGYW who are not currently accessing those interventions.

With the mounting interest and research in retail pharmacy-based PrEP delivery, it is important to consider how to best serve AGYW consistently using this delivery model for HIV prevention medication. According to the High-Quality Health Systems Framework, health care systems need to maintain ease of use and anonymity when providing care to clients. PrEP services for AGYW in retail pharmacies are a viable option for providing an additional access point for those AGYW who may not utilize health care facilities because of the perception that they are not easy to access or anonymous. Allowing PrEP to be prescribed in settings where large numbers of individuals with behaviors associated with HIV acquisition go for other health needs is a promising next step in the scale-out of acceptable PrEP services for AGYW.

This dissertation sought to understand aspects of user experience affecting AGYW seeking PrEP services. Our aim was to understand these aspects to improve PrEP services, thus increasing PrEP initiation, ultimately decreasing HIV incidence in this important population. Integrating provider communication-building trainings that address stigmatizing behaviors, finding creative solutions to AGYW privacy concerns when seeking preventative care, and maintaining easily accessible PrEP

delivery in non-clinical settings are promising solutions to improving PrEP initiation among AGYW in this region.

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