Standardized Patient Encounters to Improve Counseling for Pre-Exposure Prophylaxis (PrEP) for HIV Prevention to Adolescent Girls and Young Women (AGYW) in Kenya

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SUMMARY

Background: The incidence of HIV in adolescent girls and young women (AGYW) continues to rise despite promising innovation in female-controlled HIV prevention strategies. In 2016, 34,000 women ages 15+ were infected with HIV in Kenya. Pre-exposure prophylaxis (PrEP) has been shown to reduce the risk of HIV acquisition through sexual intercourse by 92% among sero-discordant partners. While PrEP is a highly efficacious intervention, its real-world effectiveness at scale is threatened by low adherence. Improving medication adherence through improved health counseling at the first clinical consultation is necessary. Standardized patient actors (SPs) are an effective tool for health providers to improve communication and counseling skills Evaluating the effectiveness of SP education for health care workers (HCWs) delivering PrEP to AGYW can identify new training approaches to facilitate improved communication and PrEP delivery for AGYW seeking PrEP services in Kenya.

Goal: To facilitate AGYW uptake of and adherence to PrEP through a clinical training program using SPs to improve HCW communication skills and delivery of PrEP counseling services to AGYW at risk for HIV.

Aims: 1. To assess quality of PrEP counseling and adherence to National AIDS and STI Control Programme (NASCOP) guidelines among HCWs delivering PrEP to AGYW in Kenya.

2. To implement and evaluate the effectiveness of an SP training intervention designed to improve HCW counseling and communication skills, and adherence to national guidelines, in delivery of PrEP to AGYW in Kenya

Methods: During the first phase (Aim 1) we will conduct a cross-sectional baseline assessment of PrEP counseling practices using unannounced SP actors as evaluators at 24 facilities in Western Kenya. We will then randomly assign 12 facilities to an SP training intervention and 12 facilities to a control arm where they will continue standard of care (Aim 2). We will evaluate outcomes of the training program through a parallel cluster-randomized trial, repeating the cross-sectional unannounced SP assessment.

Population: HCWs who provide HIV care and treatment and/or PrEP services in Western Kenya.

Outcomes: The primary outcome will be quality of the PrEP counseling session, defined as adherence to NASCOP guidelines of PrEP counseling/delivery and use of non-judgmental interpersonal skills, and measured as a score on a SP checklist after unannounced visits. The secondary outcome will be HCWs communication quality, including clarity of information, non-judgment, listening without interruption, encouraging questions, empathetic statements, and showing interest in the patient's concerns.

Timeframe: January 2019 to August 2022

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LIST OF ABBREVIATIONS

AGYW	Adolescent girls and young women
ARV	Antiretroviral drugs
ERC	Ethics Review Committee
GoK	Government of Kenya
HCWs	Health care workers
HIV	Human immunodeficiency virus
IDI	In-depth interviews
IRB	Institutional Review Board
KNH	Kenyatta National Hospital
MOH	Ministry of Health
NASCOP	National AIDS and STI Control Programme
PrEP	Pre-exposure prophylaxis
RCT	Randomized control trials
SPs	Standardized Patient Actors
STI	Sexually transmitted infection
UON	University of Nairobi
UW	University of Washington
WHO	World Health Organization

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BACKGROUND AND LITERATURE REVIEW

1a. Background Information

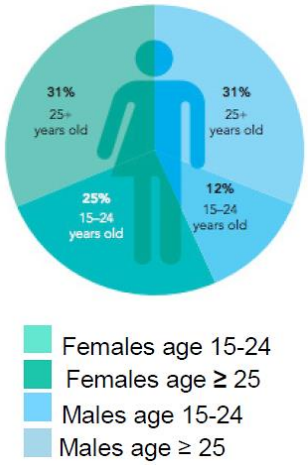

Figure 1. New HIV infections by sex, sub-Saharan Africa, 2015 (1)

Adolescent girls and young women experience a disproportionate risk of HIV infection: Adolescent girls and young women (AGYW) in Southern and Eastern Africa are at high risk of HIV acquisition. In 2015, an estimated 390,000 new HIV infections occurred in AGYW ages 15-24, globally, and AGYW have a 9-fold increase in HIV prevalence compared with males of the same age (2). Recent HIV prevention trials also show higher HIV incidence in AGYW cohorts than in cohorts of women in sero-discordant partnerships (Figure 1) (3-7). In these trials, the incidence of HIV among AGYW ranged from 5 to 9.1 HIV infections/100 person-years (3-7). The 2016 United Nations Global Assembly Fast Track goals aim to decrease the annual number of new HIV infections among 15 to 24-year-old women to 100,000. This will require a 74% reduction in the current annual number of AGYW infected with HIV (8).

PrEP is an effective tool to decrease HIV incidence in young women:
The United Nations recommends a multifaceted approach that addresses structural determinants and gender inequity while leveraging powerful new biomedical tools for HIV prevention (9-12). Biomedical interventions, including expansion of antiretroviral treatment (ART) combined with pre-exposure prophylaxis (PrEP), offer alternatives to complement structural approaches to rapidly decrease HIV incidence in AGYW. PrEP, a once a day, oral ARV medication consisting of tenofovir (TDF) and emtricitabine (FTC), also known under the brand name, Truvada, has been shown to effectively prevent HIV transmission among sero-discordant partners (13, 14). In the Partners PrEP study among HIV uninfected women in sero-discordant partnerships, TDF-PrEP had 71% efficacy and TDF/FTC-PrEP had 66% efficacy; (3, 14, 15). High HIV incidence in AGYW necessitates action, and PrEP implementation is a practical intervention.

Although PrEP is effective, adherence has been poor among AGYW participating in PrEP RCTs: Sub-analyses of women in the Partners randomized control trial (RCT), showed that even among women with HIV risk factors such as high partner viral load count, unprotected sex, or diagnosis of a sexually transmitted infection (STI), PrEP retained efficacy (16). However, to maximize PrEP effectiveness as an HIV prevention tool, high adherence to regimens is required. Momentum to scale-up PrEP was suppressed when two large RCTs of PrEP among young women, VOICE and FEMPrEP, failed to show PrEP efficacy, due to low retention and low PrEP adherence (5, 6, 17, 18). A more recent meta-analysis of 5 PrEP studies in women estimated that PrEP would have had a protective effect, with a RR of 0.69 with PrEP if women had at least 75% adherence (19). As countries like Kenya [49] expand the availability and use of PrEP, it is imperative that efforts to scale-up PrEP in AGYW also focus on adherence.

Health system interactions may influence PrEP uptake and adherence among AGYW: PrEP studies often involve project-dedicated staff who commit to optimizing interactions with clients, providing in-depth and thoughtful HIV prevention counseling and PrEP messaging. Initiatives for PrEP use in AGYW involve programmatic expansion into the public health sector and require an understanding of user experiences and motivation of AGYW as well as optimization of health system interactions within an already over-extended system (Figure 2). Health systems interactions, led by HCWs lacking training, resources, skills, or empathy, have been shown to decrease AGYW uptake of sexual and reproductive health services (20-22). Among AGYW, stigma, HCW bias, and HCW discrimination have been reported to be common and major barriers to uptake of health care and HIV services, (23-25). These barriers may influence AGYW's attempt to seek and continue preventative services, like PrEP.

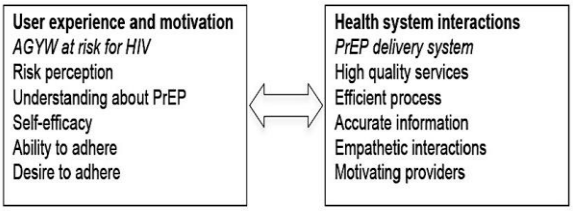

Figure 2. User experience and the health system interactions influence PrEP adherence

Standardized patient actors can accurately assess health service quality: Standardized patients (SPs) are actors who have been trained to portray patients in scripted, medically-themed scenarios for student and HCW evaluation and education. This style of training has been used since the 1960s in clinical and medical education (12). SPs have been used to develop and improve skills related to patient-centered communication: empathy, communication skills, and counseling for HCWs. As an evaluation tool, SPs are considered the gold-standard in measuring care quality (12) and can accurately assess the competencies of a provider in a variety of clinical and teaching settings. (14-17).

SP training programs can improve quality of care in low and middle-income countries (LMIC): In LMIC settings, SPs have been used to evaluate how services are delivered in practice. In a systematic review of 31 LMIC pharmacy studies, SPs helped identify whether providers were or were not adhering to prescription and diagnosis treatment guidelines (26). This review found that SPs were useful in describing counseling practices of pharmacists, however, few studies used SPs to provide feedback to HCWs. Global TB and STI program evaluations used SPs to demonstrate non-standard practices by clinical providers (27, 28). Additionally, SPs were effective in training nurses and midwives in obstetric care to improve provider self-efficacy in emergent obstetric situations (29)

A training intervention using SPs may improve the effectiveness of PrEP scale up for AGYW: Medical care involves transfer of information and skills in communication, cultural competence, and empathy. Use of SPs offers a pragmatic and effective way to improve HCW skills to facilitate PrEP counseling and delivery to AGYW. Ensuring AGYW take PrEP regularly decreases risk of acquiring HIV, interrupting the cycle of HIV transmission. Through this interruption, PrEP can ultimately reduce new HIV infections, bringing the world one step closer towards reaching the UNAIDS goal of 90-90-90 by 2020 (30).

1b. Rationale

High HIV incidence in AGYW demands an urgent response and PrEP implementation is a reasonable approach. As countries like South Africa (31) and Kenya (32) expand PrEP it is paramount that efforts to scale PrEP in AGYW do so in a manner that ensures adherence – otherwise these efforts are futile.

Offering PrEP to AGYW requires several challenging steps for busy HCWs, including incorporating discussion of HIV risk, providing information about PrEP, and encouraging PrEP adherence. Training health care workers for new programs typically incorporates didactic sessions but few practical tips on how to optimize interactions with clients. For clinicians working with adolescents, adolescent-friendly communication skills need to be trained. Medical care involves transfer of information and soft skills in communication, cultural competence, and empathy. Use of SPs, the gold standard for clinical training and assessment in high-resource settings, are a pragmatic and potentially effective way to improve HCW skills to facilitate PrEP delivery to AGYW. Clinical providers want to be 'youth friendly' but lack competence in this area, and often feel particularly unprepared for discussion of sexual risk with adolescents.

SPs have been widely used for medical education since the 1960s, both for training and licensing. In 2011, 90% of AAMC surveyed-US medical schools used SPs in medical training (33). A review of SP studies in 2016 found that 24 of 33 SP programs were effective in increasing clinical competence (34). Experiential learning leads to enhanced competence in motivational interviewing; SPs (high school students) have been useful in US settings to provide medical students experiential learning in communication with adolescents (35, 36). SPs have been shown to improve cultural competence in US providers (37). SPs can work with HCWs by acting out scenarios to help HCWs practice their communication strategies and be evaluated and provided with feedback regarding how to improve their abilities in counseling, information, and empathy.

Providing SPs to HCW to guide the process of navigating challenging scenarios, like working with AGYW to use and adhere to PrEP, can provide HCWs competency and confidence that makes their interactions with AGYW easier and more effective in practice.

There is substantial evidence that HCW interactions with SPs can improve service delivery and patient outcomes, though few data are available within the context of HIV prevention services among AGYW in African settings. Evaluating the effectiveness of SP education for HCWs within the context of PrEP use among AGYW populations will inform new training approaches to improve PrEP delivery practices and communication with AGYW in clinical settings. This study will address the gaps in delivering quality of PrEP services to AGYW through the following specific aims:

2. SPECIFIC AIMS

Aim 1: To assess quality of PrEP counseling and adherence to National AIDS and STI Control Programme (NASCOP) guidelines among HCWs delivering PrEP to AGYW in Kenya.

Aim 2: To implement and evaluate the effectiveness of an SP training intervention designed to improve HCW counseling and communication skills, and adherence to national guidelines, in delivery of PrEP to AGYW in Kenya.

3. STUDY OUTCOMES

The primary outcome will be quality of PrEP counseling, summarized by an SP checklist score at unannounced clinic visits that will assess communication (e.g. listening without interruption, encouraged questions) and adherence to national guidelines on PrEP counseling and delivery (e.g. risk assessment, counseling on key messages, correct medication recommended). The secondary outcome will be overall quality of provider communication skills with AGYW seeking PrEP services, measured by a score from SPs during the provider training intervention incorporating key domains including: ability to collect information, counseling and delivering information, rapport, and personal manner. Communications measures are adapted from the Kalamazoo Consensus Statement (38) and other published tools (39-41).

4. STUDY DESIGN

During the first phase (Aim 1) we will conduct a cross-sectional baseline assessment of PrEP counseling practices using unannounced SP actors as evaluators. SP actors are trained professional actors recruited from a Kenyan casting agency. They will be paid study staff, managed by our Study Coordinator. Before the study, actors will be trained in the SP methodology based on the study protocol. All SP actors will sign a confidentiality agreement and complete protection of human participants training before any contact with participants. Based on this assessment, we will develop and implement a clinical training program utilizing SP actors to improve adherence to national guidelines and communication skills. Finally, we will evaluate the training program through a parallel cluster-randomized trial of the SP training using repeat unannounced SP encounters at 24 health facilities purposively selected from all facilities in Western Kenya offering PrEP (Aim 2).

5. STUDY ENROLLMENT

5a. Population and Setting

The study will be implemented in 24 large public health facilities that provide PrEP care and counseling services to AGYW in Kisumu and other counties in Western Kenya. The facilities were purposively selected by the study team from among all facilities offering PrEP (37) based on factors such as size, location, and receptiveness of the facility to host research. The purposively selected study sites are: Chiga, Chulaimbo, Manywanda, Muhoroni, Nyalenda, Awasi, Koru, Ahero, Rabour, Lumumba, KCH, Migosi, Nightingale, Airport, Maseno, Bar Korwa, Railway, Rata, Nyan'goma, Nyalunya, Nyangande, Sondu, Ober-Kamoth, and Ojolla. At each site, the study will include HCWs who provide HIV care and PrEP services for AGYW. Inclusion and exclusion criteria are shown in Table 1, below.

5b. Eligibility criteria

Health Facility: Eligible facilities will include public health facilities that offer PrEP services and counseling to AGYW located within Western Kenya. Facilities with ongoing PrEP interventions where study staff will be excluded.

HCW participants: Eligible HCWs will be 18 years or older, current employees of one of the 24 facilities in the study, provide PrEP services to AGYW, and be able to provide informed consent. In Kenya, HCWs who provide PrEP therapy and counseling are most commonly trained nurses. The nurses are specifically trained in delivering PrEP per NASCOP guidelines.

Table 1. Inclusion Criteria

Population	Selection	N	Inclusion Criteria	Exclusion Criteria
Health Facilities	Facilities in Western County providing PrEP services for AGYW	24	Located in a county in Western Kenya Currently offering PrEP services	Sites where PrEP services are staffed by study staff
HCWs at selected facilities	HCWs working in any of the selected health facility sites	Up to 240	Age 18 or over Able to provide consent Current employee of one of the 24 selected facilities Currently providing PrEP services	Study staff seconded to the site as part of a trial or intervention

5c. Randomization

Randomization will occur at the cluster level: 24 facilities will be purposively selected from a list of all facilities in Western Kenya with PrEP services. We will use stratified randomization, through which 12 facilities will be allocated to the intervention and 12 will be assigned standard of care according to facility size, to ensure balance by arm. A UW biostatistician will generate the randomization assignment for each clinic.

5d. Recruitment

We will obtain permission from the NASCOP and local county and district officials to include these facilities in our study. At each clinic, we will obtain permission from the appropriate facility leadership before recruitment and receive a list of all potential HCW participants. All HCWs who meet inclusion criteria from both control and intervention groups will be recruited to participate in the study. A member of the study team will be stationed at the facility and approach potential participants to learn more about the study and provide informed consent. Based on previous studies, we estimate 10 HCWs per site, totaling approximately 240 HCWs.

5e. Participant withdrawal and replacement

Study facilities and participants may withdraw at any time. Reasons for a facility to withdraw may include closure or major changes in PrEP policies or procedures that would prevent or substantially limit ability to conduct the study. HCW participants may withdraw due to discomfort with the training, relocation, or leave of absence. The study team will record the timing and reasons for withdrawal of clinics or participants. Potential replacement of study facilities or HCW participants will be conducted but will not be required if it is not feasible because of design and logistical challenges.

6. STUDY PROCEDURES

6a. Stakeholder engagement

After obtaining NASCOP and local county and district official permission to enroll clinical study sites, the study team will meet with clinic leadership and managers to receive an overview of the study flow and procedures, and informed consent processes for participation (Figure 3).

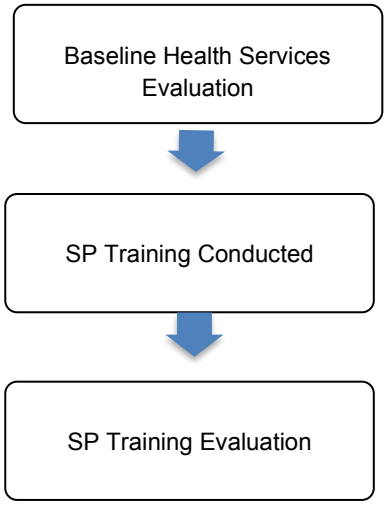

Figure 3. Study Schema

6b. Case script development and SP actor training

Qualitative themes from previously conducted AGYW IDIs and focus group discussions, national guidelines, and key informant experiences will inform development of standardized case scripts. We will train professional Kenyan actors matching the ethnicity and languages of the local area to role play AGYW PrEP scenarios for both the unannounced assessments and HCW training. All SP actors are hired study staff. SP actors will be selected by a Kenyan casting agency based on their ability as actresses and their age, ethnicity, and language characteristics which match AGYW visiting health facilities in Western Kenya. The SP actors will be trained in the SP methodology by an expert consultant hired onto this study for this purpose. The SP actors will be trained on the specific standardized case scripts by study staff who are familiar with scenarios of AGYW seeking PrEP in Western Kenya.

6c. Baseline health services evaluation

A health facility survey will be administered to the facility manager in each facility to obtain baseline site characteristics on staffing, guidelines, and PrEP services. Unannounced SP actors will present to all study sites as AGYW seeking PrEP or HIV health services for an estimated 2-3 encounters per clinic. During the clinic encounter, SPs will act out their scripted scenario with enrolled HCW. After the encounter, the study assistant will administer a post-consultation questionnaire with the SP and will also work with the health facility to remove the SP information from the clinic forms and registers. Results from the baseline assessment will inform the HCW training on PrEP service delivery.

6d. HCW SP Training on PrEP services

All HCW participants at intervention facilities will be invited to complete a 2-day training. The course will provide didactic sessions in communication skills, current PrEP guidelines, and counseling techniques, as well as role play sessions with the SPs. We aim to train all eligible HCWs at intervention facilities in small groups of 5-10. HCW-SP interactions will be video-recorded for training purposes. SPs will give verbal and written feedback on communication and counseling skills and will score HCWs using a standardized checklist. Facilitated group debriefings will take place at the end of each day, including review and discussion of selected videos. HCWs will complete a course evaluation and pre/post competency surveys. HCWs employed at the study facilities assigned to the control arm will not receive this training. They will perform their routine duties according to standard of care and will only take part in the unannounced SP assessments.

6e. Training evaluation

Once training is complete for all sites, unannounced SPs will repeat the assessment conducted during the baseline evaluation at all 24 intervention and control sites.

7. DATA COLLECTION

Health facility survey: This anonymous survey will be administered to a health facility manager at baseline to capture facility characteristics (number of staff, patient demographics, services provided, etc.), including turn-over of SP-trained HCWs, patient volume, and any relevant changes in HIV policies and procedures.

Unannounced SP checklist: A survey will be completed by each SP actor, following every clinical interaction with an HCW provider using electronic tablets. The surveys will be conducted at baseline and after the HCW training at all 24 sites. The tool will assess domains of counseling and communication skills, and adherence to national PrEP guidelines.

SP training checklist: Standardized SP checklists will be used to evaluate the HCW encounter with the SP actor. The SP will complete checklists based on individual scenarios to provide feedback for the HCW on their practice session and provide a score based on competencies met.

HCW surveys: HCW participants will complete surveys prior to and after the SP training to assess knowledge of and self-rated competency in provision of PrEP to AGYW, beliefs about AGYW and HIV, and basic demographic and work information.

HCW training evaluation surveys: Post-training surveys will be administered to HCW participates to obtain feedback on the quality, length, and relevance of the SP training.

8. STATISTICAL CONSIDERATIONS

8a. Sample Size and Power

Given a fixed number of clusters (24 facilities), we estimated the minimum number of SP encounters required to detect a 20 percentage-point difference in PrEP counselor competency score between intervention and control arms. Because it is uncertain what baseline PrEP competency would be, we estimated sample sizes to detect a 20-percentage point difference between the intervention and control arm varying the baseline competency percent, shown in Table 2 (following page). Under these assumptions, if PrEP competency is 20% in the control arm, we would need an estimated 192 total SP encounters (8 per site). Higher baseline competency would require a larger sample size to detect the same difference. Given this range, and logistical constraints of larger samples with this type of evaluation, the expected upper limit of SP encounters is 400.

Table 2. Sample sizes of SP encounters to detect a 20% difference in competency at 80% power, correlation coefficient (k) of 0.15, α=0.05 and 24 facilities

Control group competency %	Intervention group competency %	Cluster per arm (fixed)	SP encounters per cluster	Total SP encounters
0.2	0.4	12	8	192
0.3	0.5	12	10	240
0.4	0.6	12	11	264
0.5	0.7	12	12	288
0.6	0.8	12	13	312
0.7	0.9	12	30	720

8b. Analysis Plan

A CONSORT diagram will be used to show the number of facilities and HCWs by arm during the trial, numbers excluded, and reasons for exclusion. Baseline characteristics of each facility by intervention arm will be presented as descriptive statistics to assess whether balance of these factors was achieved through randomization using t-tests and McNemar's exact tests for continuous and dichotomous variables.

An intention-to-treat (ITT) analysis will be used to evaluate whether the SP training intervention resulted in higher competency scores at intervention compared to control facilities. The primary outcome will be at the individual level, adjusted for relevant baseline characteristics by arm and baseline evaluation scores. Generalized linear models (GLMM) with a Poisson distribution and log link, will be used to estimate rate ratios, and accounting for facility cluster as a random effect. Secondary analysis will be conducted using a similar GLMM modeling approach with provider overall communication quality score percent as the outcome. In addition, we will evaluate the intervention effect on individual components of PrEP competency and communication quality in separate GLMM regression models.

9. DATA MANAGEMENT

A dedicated data team will be responsible for the entry, management, and monitoring of study data, in accordance with standard operating procedures. The Nairobi data team will communicate frequently with the Seattle-based statistical team for reporting, data cleaning, study monitoring, and interim analyses. Study data will be uploaded to the secure study cloud server using REDCap. REDCap is a secure, web-based application designed to support data capture and management for research studies. The software provides 1) an intuitive interface for validated data entry; 2) automated export procedures for seamless data downloads; and 3) procedures for importing data from external sources.

9a. Data Capture and Storage Methods

Video-recordings: Videos from HCW participants in SP training who have consented to allow their videos to be used for further training purposes will be stored on a secure server for at least three years after completion of the study by the University of Washington.

Surveys and unannounced SP checklist: Health facility surveys and the unannounced SP checklist will be administered by study staff via electronic tablets using REDCap data collection software and uploaded daily during survey capture periods. Data will be transported via secure socket layer (SSL) and only accessible by authenticated users. Weekly reports will be generated to monitor study progress and troubleshoot problems. All computers, tablets, and individual study databases will be encrypted, and password protected.

SP training checklist: Data from the checklist will be shared with the HCW during the training session. The original paper copies of the checklist will be identified using a study ID number. They will be stored in a secured locked cabinet in a study office accessible only to study staff.

Data Custody and Retrieval: All data for this study will be under the custody of the Principal Investigators, Site PI, and authorized study staff. Data retrieval procedures will be similar for all types of data in this study. Authorized study staff members will download the datasets from the secure servers for routine quality checking and analyses. All downloaded data will be maintained on a secured, password-protected study computer. From these data sources, the analysts will create merged datasets for planned analyses.

Study Records Retention: Retention of study records will comply with UW, KNH, and federal requirements (http://f2.washington.edu/fm/recmgt/retentionschedules/gs/general/uwgsResearch#Research). All consents, study data and link between HCW participant identifiers and study ID codes will be retained following completion of the study for a period of time in accordance with UW and KNH requirements.

Data handling procedures: Members of the research team have completed required training in human subjects, including training in data handling and confidentiality. All data for this study will be under the custody of the Principal Investigators, Site Leader, and authorized study staff.

Security of electronic records: To protect participant identity, all data will be stored on password protected computers, accessible only to the study staff. Authorized study staff members will download the datasets from the secure servers for routine quality checking and analyses. All downloaded data will be maintained on

a secured, password-protected study computer. From these data sources, the analysts will create merged datasets for planned analyses.

10. ASSESSMENT OF SAFETY

10a. IRB monitoring

The IRB at the University of Washington (UW) and at the Kenya National Hospital Ethics Review Committee (KNH ERC). Will periodically review the study protocols and maintain ongoing oversight of the risks and benefits of the study and ensure compliance with institutional guidelines. Monitoring of adverse events will be done by PI and project staff and any problems will be recorded in a study database. Research and clinical staff will be trained to identify potential adverse events and instructed to report them immediately to the site PIs and in-country research director.

10b. Reporting adverse events or unanticipated events

In compliance with federal regulations and UW policy, the Principal Investigator will notify the UW Human Subjects Division (HSD) and or UW Institutional Review Board (IRB), Kenyan Ethics Committee, and relevant local Kenyan authorities (i.e. Ministry of Health) of any unanticipated problems within 10 business days. Adverse events and study procedure-specific adverse events are expected to be rare in this clinical training intervention. If any occur, they will be reported to the UW IRB and KNH ERC within 24 hours. Any breach or possible breach of confidentiality of any participants in this study will be reported to UW HSD and/or IRB within the timeframe established by these ethics committees.

10c. Potential adverse events and mitigation

Answering questions: We may ask questions that make participants feel embarrassed or uncomfortable. Some questions are about their beliefs, attitudes, and perceptions of providing counselling to AGYW about sexual history and health. In addition, provider participants in the intervention arm may feel discomfort sharing their views and training experiences during the group debriefing sessions.

To minimize the risk of embarrassment, participants will be reminded that they can choose whether to answer any question. Participant answers will be confidential. Participants in the training intervention will be assured that it is a safe and non-judgemental space to share their views and experiences.

Loss of Confidentiality: Others may learn that a participant is part of the study. We have procedures in place to protect confidentiality and will do everything possible to reduce this risk. HCWs who have consented to the study may be video recorded during SP encounters that take place in the training. There is a chance that others could find out about participants through these recordings. However, each SP training participant will have the opportunity to sign a waiver to allow use of the SP encounter video footage outside of the study (e.g., dissemination activities, examples for future SP trainings, online courses, conference presentations). Videos containing footage of any participant who has not signed the waiver will not be used outside of the training.

We will keep participant identity as research subjects confidential. Responses to questions will be kept private. No identifying information or any kind will be released to any other person or agency that is not working on this study without participant permission in writing. We will not publish or discuss in public anything that could identify participants. All of their information, including the link between participant name and code number will be kept in a secure location at the clinic only. Once the study is completed, we will maintain the link following Kenyatta National Hospital and University of Washington guidelines, after that period we will remove their name and all identifying information from the study files. Any publications of this study will not use their name or identify participants. All of the information will be confidential. However, if we learn that they intend to harm themselves or others, we must report that to the authorities. Although we will make every effort to

keep their information confidential, no system can be completely secure. It is possible that someone could find out a participant was in this study and could find out information about them.

10d. Study oversight

The trial data safety monitoring plan will be overseen by the Principal Investigators, Drs. Kohler and John-Stewart. An external oversight committee, appropriate to the level of risk for a trial of a training intervention, will be convened and meet regularly accordingly to written procedures to monitor recruitment, enrollment, adherence to protocol, and any potential social harms. The external committee will consist of experts in adolescent HIV prevention and treatment research and clinical practice. All program activities will be implemented through the standard routine PrEP clinical process. The protocol, data collection tools, and consent forms will be reviewed and approved by the UW IRB and the KNH ERC.

11. ETHICS/PROTECTION OF STUDY PARTICIPANTS

11a. Informed Consent Process

Health facility participation: To ensure appropriate permissions and access at the facility level, we will engage with the Kenyan Ministry of Health, relevant county health management and facility administration teams prior to entering health facilities. Each facility designee will provide the study team with a list of potentially eligible HCWs to participate in the training. Facility managers will be asked separately to provide informed consent to complete an anonymous survey on facility characteristics at the start and end of the study.

HCW participants: All HCW participants will provide written consent prior to study activities. HCW participants will sign a standard written informed consent form describing the study procedures and risks. Consent forms will be IRB-approved, and the participant will be required to read and review the document or have the document read to him or her. HCWs will be informed that they have the option to decline signing the consent. They will be informed that unannounced patient actors will present to their facility during the study, but they will not be told the specific time or date of SP visits. Participants will be informed that they are free to withdraw their permission at any time during the study. A copy of the informed consent document will be given to participants for their records. In the unlikely event of an HCW participating in an unannounced patient actor interaction prior to consent, any data collected from the interaction will be destroyed.

Waiver to release SP training videos: HCWs will also have the opportunity to sign waivers to authorize use of SP encounter videos for educational purposes by the study team (e.g. dissemination activities, examples for future SP trainings, online courses, conference presentations). Waivers will be signed at the end of the training. Only videos where participants have signed waivers will be used for these purposes. Videos where a participant has not signed the waiver will not be used beyond the training.

Exclusion of women or minorities: There are no exclusions of women or minorities for the HCW participants. Eligibility is based on age, occupation and employment status at the study facilities.

11b. Participant Confidentiality

Study staff will take strict measures to maintain confidentiality for all participants. No names will be recorded on data collection forms. HCW participants will be assigned unique study identification (ID) numbers. Participants will be assigned a non-identifiable study code upon enrollment. Study analysts will receive only coded data. The links to participant identifiers will be retained in a password-protected file on an encrypted computer. Data collected will be kept confidential and access restricted to study staff. All video-recordings of the SP encounters will be kept in an encrypted cloud server. Video data are potentially identifiable. Only

videos of HCWs who have signed release waivers will be stored after the two-day training. All other data will be kept in password-protected databases, in a locked study office, accessible only to study personnel.

11c. Risks and Benefits

Physical risks: There are no medical interventions associated with the study, therefore we anticipate no risk of serious physical harm to participating HCWs.

Psychosocial or other risks: Other potential study risks to the HCW participants include breach of confidentiality, emotional distress associated with the sensitive nature of HIV counseling for AGYW, and stress associated with group critique/feedback of videotaped training encounters.

Procedures to minimize psychological risks: All participants will be assured that their participation is voluntary and that they may withdraw from the study at any time. Trained facilitators will oversee debriefing sessions with HCWs. For HCW training attendees, each clinical training intervention will begin with a session on professional standards, expectations, and confidentiality, building an atmosphere of peer-support and collaboration. All HCW participants will agree to not share individual performance information from the SP trainings outside of the learning group.

Procedures to minimize other risks: Study staff will be trained to take all precautions to ensure confidentiality of participation and data collected and will have standardized operating procedures for ensuring data security. Risk of breach of confidentiality of study data is low, as all HCW data collected will not include names and will be located on a password protected server and encrypted prior to upload. Study data is not very sensitive in nature and focuses on facility-level characteristics and provider experiences during SP encounters. Study staff will be trained in the importance of confidentiality during human participants training prior to study implementation. We will not share individual-level HCW data with health facilities in order to minimize risk of a negative reaction by an employer if they choose to participate or not participate in this study. In the event of reported social harm, we have developed standard operating procedures for referrals to local social agencies that will be incorporated into the HCW training.

Direct benefits: HCWs will receive direct and immediate benefit in receipt of SP training to improve their skills in delivery of adolescent friendly HIV services and counseling. HCWs in previous studies have specifically requested this training.

Indirect benefits: The study can identify important information regarding AGYW adherence of PrEP to guide the best model for PrEP delivery which will benefit individuals in Kenya and other African countries with high HIV prevalence.

12. DISSEMINATION AND IMPACT

12a. Community dissemination

Results of the SP mystery shoppers and training program pilot evaluations will be shared with community groups, key stakeholders, HCWs and clinic program leaders. The SP training scenarios, curriculum, and approach will also be shared with Ministry of Health for consideration as a strategy to improve PrEP service quality, provider communication and counseling at public sector facilities in Kenya.

12b. Anticipated impact from the study

This study will provide detailed analyses of PrEP services in the context of PrEP counseling for AGYW in Kenya. These data are critical to understand programmatic effectiveness of new efforts to improve HCW adherence to guidelines and communication regarding PrEP for AGYW. Our study of unannounced SPs and SP training will provide evidence to support new interventions to improve PrEP counseling practices for AGYW, by improving communication with AGYW in PrEP service delivery. The Kenya Ministry of Health and National AIDS Control Program prioritizes evidence-based strategies for HIV prevention, and throughout the

course of the study, results will be shared with the Ministry of Health as they become available to maximize translational impact.

STUDY SCHEDULE

ACTIVITY	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	Q2 2020	Q3 2020	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022
Recruitment and selection of 24 health facility sites														
Facility and HCW consent														
Facility site evaluation survey														
Training of SP actors with case scripts														
Unannounced SP baseline assessment														
HCW SP training														
Unannounced SP assessment (post-training)														
Analysis and Dissemination														

REFERENCES

1. UNAIDS. On the Fast-Track to end AIDS by 2030: Focus on location andpopulation. Geneva, Switzertand: 2015.
2. Joint United Nations Programme on HIV/AIDS (UNAIDS). Get on the Fast Track to HIV: The lifecycle approach to HIV 2016. Available from: http://www.unaids.org/en/resources/documents/2016/get-on-the-fast-track.
3. Baeten JM, Donnell D, Ndase P, Mugo NR, Campbell JD, Wangisi J, Tappero JW, Bukusi EA, Cohen CR, Katabira E, Ronald A, Tumwesigye E, Were E, Fife KH, Kiarie J, Farquhar C, John-Stewart G, Kakia A, Odoyo J, Mucunguzi A, Nakku-Joloba E, Twesigye R, Ngure K, Apaka C, Tamooh H, Gabona F, Mujugira A, Panteleeff D, Thomas KK, Kidoguchi L, Krows M, Revall J, Morrison S, Haugen H, Emmanuel-Ogier M, Ondrejcek L, Coombs RW, Frenkel L, Hendrix C, Bumpus NN, Bangsberg D, Haberer JE, Stevens WS, Lingappa JR, Celum C. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. The New England journal of medicine. 2012;367(5):399-410. Epub 2012/07/13. doi: 10.1056/NEJMoa1108524. PubMed PMID: 22784037; PMCID: PMC3770474.
4. Celum C, Wald A, Lingappa JR, Magaret AS, Wang RS, Mugo N, Mujugira A, Baeten JM, Mullins JI, Hughes JP, Bukusi EA, Cohen CR, Katabira E, Ronald A, Kiarie J, Farquhar C, Stewart GJ, Makhema J, Essex M, Were E, Fife KH, de Bruyn G, Gray GE, McIntyre JA, Manongi R, Kapiga S, Coetzee D, Allen S, Inambao M, Kayitenkore K, Karita E, Kanweka W, Delany S, Rees H, Vwalika B, Stevens W, Campbell MS, Thomas KK, Coombs RW, Morrow R, Whittington WL, McElrath MJ, Barnes L, Ridzon R, Corey L. Acyclovir and transmission of HIV-1 from persons infected with HIV-1 and HSV-2. The New England journal of medicine. 2010;362(5):427-39. Epub 2010/01/22. doi: 10.1056/NEJMoa0904849. PubMed PMID: 20089951; PMCID: PMC2838503.
5. Marrazzo JM, Ramjee G, Richardson BA, Gomez K, Mgodi N, Nair G, Palanee T, Nakabiito C, van der Straten A, Noguchi L, Hendrix CW, Dai JY, Ganesh S, Mkhize B, Taljaard M, Parikh UM, Piper J, Masse B, Grossman C, Rooney J, Schwartz JL, Watts H, Marzinke MA, Hillier SL, McGowan IM, Chirenje ZM. Tenofovir-based preexposure prophylaxis for HIV infection among African women. The New England journal of medicine. 2015;372(6):509-18. Epub 2015/02/05. doi: 10.1056/NEJMoa1402269. PubMed PMID: 25651245; PMCID: PMC4341965.
6. Van Damme L, Corneli A, Ahmed K, Agot K, Lombaard J, Kapiga S, Malahleha M, Owino F, Manongi R, Onyango J, Temu L, Monedi MC, Mak'Oketch P, Makanda M, Reblin I, Makatu SE, Saylor L, Kiernan H, Kirkendale S, Wong C, Grant R, Kashuba A, Nanda K, Mandala J, Fransen K, Deese J, Crucitti T, Mastro TD, Taylor D. Preexposure Prophylaxis for HIV Infection among African Women. The New England journal of medicine. 2012;367(5):411-22. doi: 10.1056/NEJMoa1202614. PubMed PMID: 22784040; PMCID: PMC3687217.
7. Abdool Karim Q, Abdool Karim SS, Frohlich JA, Grobler AC, Baxter C, Mansoor LE, Kharsany AB, Sibeko S, Mlisana KP, Omar Z, Gengiah TN, Maarschalk S, Arulappan N, Mlotshwa M, Morris L, Taylor D, Group CT. Effectiveness and safety of tenofovir gel, an antiretroviral microbicide, for the prevention of HIV infection in women. Science. 2010;329(5996):1168-74. doi: 10.1126/science.1193748. PubMed PMID: 20643915; PMCID: 3001187.
8. Joint United Nations Programme on HIV/AIDS (UNAIDS). Guidance: HIV prevention among adolescent girls and young women 2016. Available from: http://www.unaids.org/sites/default/files/media_asset/UNAIDS_HIV_prevention_among_adolescent_girls_and_young_women.pdf.
9. Maughan-Brown B, Kenyon C, Lurie MN. Partner age differences and concurrency in South Africa: Implications for HIV-infection risk among young women. AIDS and behavior. 2014;18(12):2469-76. Epub 2014/07/23. doi: 10.1007/s10461-014-0828-6. PubMed PMID: 25047687; PMCID: PMC4451824.

10. Pettifor A, MacPhail C, Selin A, Gomez-Olive FX, Rosenberg M, Wagner RG, Mabuza W, Hughes JP, Suchindran C, Piwowar-Manning E, Wang J, Twine R, Daniel T, Andrew P, Laeyendecker O, Agyei Y, Tollman S, Kahn K. HPTN 068: A Randomized Control Trial of a Conditional Cash Transfer to Reduce HIV Infection in Young Women in South Africa-Study Design and Baseline Results. AIDS and behavior. 2016;20(9):1863-82. Epub 2016/02/20. doi: 10.1007/s10461-015-1270-0. PubMed PMID: 26891839; PMCID: PMC4990514.
11. Pettifor A, MacPhail C, Hughes JP, Selin A, Wang J, Gomez-Olive FX, Eshleman SH, Wagner RG, Mabuza W, Khoza N, Suchindran C, Mokoena I, Twine R, Andrew P, Townley E, Laeyendecker O, Agyei Y, Tollman S, Kahn K. The effect of a conditional cash transfer on HIV incidence in young women in rural South Africa (HPTN 068): a phase 3, randomised controlled trial. The Lancet Global health. 2016;4(12):e978-e88. Epub 2016/11/07. doi: 10.1016/s2214-109x(16)30253-4. PubMed PMID: 27815148; PMCID: PMC5626439.
12. De Neve JW, Fink G, Subramanian SV, Moyo S, Bor J. Length of secondary schooling and risk of HIV infection in Botswana: evidence from a natural experiment. The Lancet Global health. 2015;3(8):e470-e7. Epub 2015/07/03. doi: 10.1016/s2214-109x(15)00087-x. PubMed PMID: 26134875; PMCID: PMC4676715.
13. World Health Organization (WHO). Guidance on Pre-Exposure Oral Prophylaxis (PrEP) for Serodiscordant Couples, Men and Transgender Women Who Have Sex with Men at High Risk of HIV: Recommendations for Use in the Context of Demonstration Projects 2012. Available from: https://www.ncbi.nlm.nih.gov/books/NBK132003/.
14. Thomson KA, Baeten JM, Mugo NR, Bekker LG, Celum CL, Heffron R. Tenofovir-based oral preexposure prophylaxis prevents HIV infection among women. Current opinion in HIV and AIDS. 2016;11(1):18-26. Epub 2015/09/30. doi: 10.1097/coh.0000000000000207. PubMed PMID: 26417954; PMCID: PMC4705855.
15. Haberer JE, Baeten JM, Campbell J, Wangisi J, Katabira E, Ronald A, Tumwesigye E, Psaros C, Safren SA, Ware NC, Thomas KK, Donnell D, Krows M, Kidoguchi L, Celum C, Bangsberg DR. Adherence to antiretroviral prophylaxis for HIV prevention: a substudy cohort within a clinical trial of serodiscordant couples in East Africa. PLoS medicine. 2013;10(9):e1001511. doi: 10.1371/journal.pmed.1001511. PubMed PMID: 24058300; PMCID: 3769210.
16. Murnane PM, Celum C, Mugo N, Campbell JD, Donnell D, Bukusi E, Mujugira A, Tappero J, Kahle EM, Thomas KK, Baeten JM. Efficacy of preexposure prophylaxis for HIV-1 prevention among high-risk heterosexuals: subgroup analyses from a randomized trial. AIDS (London, England). 2013;27(13):2155-60. Epub 2014/01/05. doi: 10.1097/QAD.0b013e3283629037. PubMed PMID: 24384592; PMCID: PMC3882910.
17. Tobin SC. VOICE reveals the need to improve adherence in PrEP trials. AIDS (London, England). 2015;29(12):N9. Epub 2015/08/06. doi: 10.1097/qad.0000000000000693. PubMed PMID: 26244400.
18. Corneli AL, McKenna K, Perry B, Ahmed K, Agot K, Malamatsho F, Skhosana J, Odhiambo J, Van Damme L. The science of being a study participant: FEM-PrEP participants' explanations for overreporting adherence to the study pills and for the whereabouts of unused pills. Journal of acquired immune deficiency syndromes (1999). 2015;68(5):578-84. Epub 2015/03/12. doi: 10.1097/qai.0000000000000525. PubMed PMID: 25761233.
19. Hanscom B, Janes HE, Guarino PD, Huang Y, Brown ER, Chen YQ, Hammer SM, Gilbert PB, Donnell DJ. Brief Report: Preventing HIV-1 Infection in Women Using Oral Preexposure Prophylaxis: A Meta-analysis of Current Evidence. Journal of acquired immune deficiency syndromes (1999). 2016;73(5):606-8. Epub 2016/11/16. doi: 10.1097/qai.0000000000001160. PubMed PMID: 27846073; PMCID: PMC5175411.
20. Bender SS, Fulbright YK. Content analysis: a review of perceived barriers to sexual and reproductive health services by young people. The European journal of contraception & reproductive health care : the official journal of the European Society of Contraception. 2013;18(3):159-67. Epub 2013/03/27. doi: 10.3109/13625187.2013.776672. PubMed PMID: 23527736.

21. Godia PM, Olenja JM, Hofman JJ, van den Broek N. Young people's perception of sexual and reproductive health services in Kenya. BMC health services research. 2014;14:172. doi: 10.1186/1472-6963-14-172. PubMed PMID: 24731733; PMCID: 3996312.
22. Godia PM, Olenja JM, Lavussa JA, Quinney D, Hofman JJ, van den Broek N. Sexual reproductive health service provision to young people in Kenya; health service providers' experiences. BMC health services research. 2013;13:476. doi: 10.1186/1472-6963-13-476. PubMed PMID: 24229365; PMCID: 4225671.
23. Wagner AD, Mugo C, Bluemer-Miroite S, Mutiti PM, Wamalwa DC, Bukusi D, Neary J, Njuguna IN, O'Malley G, John-Stewart GC, Slyker JA, Kohler PK. Continuous quality improvement intervention for adolescent and young adult HIV testing services in Kenya improves HIV knowledge. AIDS (London, England). 2017;31 Suppl 3:S243-S52. doi: 10.1097/QAD.0000000000001531. PubMed PMID: 28665882; PMCID: 5497779.
24. Luseno WK, Iritani B, Zietz S, Maman S, Mbai, II, Otieno F, Ongili B, Hallfors DD. Experiences along the HIV care continuum: perspectives of Kenyan adolescents and caregivers. African journal of AIDS research : AJAR. 2017;16(3):241-50. Epub 2017/10/06. doi: 10.2989/16085906.2017.1365089. PubMed PMID: 28978294.
25. Joint United Nations Programme on HIV/AIDS (UNAIDS). On the fast-track to an AIDS-free generation 2016. Available from: http://www.unaids.org/sites/default/files/media_asset/GlobalPlan2016_en.pdf.
26. Xu T, de Almeida Neto AC, Moles RJ. A systematic review of simulated-patient methods used in community pharmacy to assess the provision of non-prescription medicines. The International journal of pharmacy practice. 2012;20(5):307-19. Epub 2012/09/08. doi: 10.1111/j.2042-7174.2012.00201.x. PubMed PMID: 22953770.
27. Satyanarayana S, Kwan A, Daniels B, Subbaraman R, McDowell A, Bergkvist S, Das RK, Das V, Das J, Pai M. Use of standardised patients to assess antibiotic dispensing for tuberculosis by pharmacies in urban India: a cross-sectional study. The Lancet Infectious diseases. 2016;16(11):1261-8. doi: 10.1016/S1473-3099(16)30215-8. PubMed PMID: 27568359; PMCID: 5067371.
28. Das J, Kwan A, Daniels B, Satyanarayana S, Subbaraman R, Bergkvist S, Das RK, Das V, Pai M. Use of standardised patients to assess quality of tuberculosis care: a pilot, cross-sectional study. The Lancet Infectious diseases. 2015;15(11):1305-13. doi: 10.1016/S1473-3099(15)00077-8. PubMed PMID: 26268690; PMCID: 4633317.
29. Cohen SR, Cragin L, Wong B, Walker DM. Self-Efficacy Change With Low-Tech, High-Fidelity Obstetric Simulation Training for Midwives and Nurses in Mexico. Clinical Simulation in Nursing,. 2012;8(1):e15-e24. doi: doi:10.1016/j.ecns.2010.05.004.
30. Joint United Nations Programme on HIV/AIDS (UNAIDS). 90-90-90 An ambitious treatment target to help end the AIDS epidemic 2018. Available from: http://www.unaids.org/sites/default/files/media_asset/90-90-90_en.pdf .
31. Bekker LG, Rebe K, Venter F, Maartens G, Moorhouse M, Conradie F, Wallis C, Black V, Harley B, Eakles R. Southern African guidelines on the safe use of pre-exposure prophylaxis in persons at risk of acquiring HIV-1 infection. South Afr J HIV Med. 2016;17(1):455. Epub 2016/03/15. doi: 10.4102/sajhivmed.v17i1.455. PubMed PMID: 29568613; PMCID: PMC5843155 may have inappropriately influenced them in writing this article.
32. Health Mo. Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV in Kenya2016.
33. Huang GC, Sacks H, Devita M, Reynolds R, Gammon W, Saleh M, Gliva-McConvey G, Owens T, Anderson J, Stillsmoking K, Cantrell M, Passiment M. Characteristics of simulation activities at North American medical schools and teaching hospitals: an AAMC-SSH-ASPE-AACN collaboration. Simulation in healthcare : journal of the Society for Simulation in Healthcare. 2012;7(6):329-33. Epub 2012/08/21. doi: 10.1097/SIH.0b013e318262007e. PubMed PMID: 22902605.

34. Williams B, Song JJY. Are simulated patients effective in facilitating development of clinical competence for healthcare students? A scoping review. Advances in simulation (London, England). 2016;1:6. Epub 2016/02/16. doi: 10.1186/s41077-016-0006-1. PubMed PMID: 29449975; PMCID: PMC5796606.
35. Cahill H, Coffey J, Sanci L. 'I wouldn't get that feedback from anywhere else': learning partnerships and the use of high school students as simulated patients to enhance medical students' communication skills. BMC Med Educ2015.
36. Edwards EJ, Stapleton P, Williams K, Ball L. Building skills, knowledge and confidence in eating and exercise behavior change: brief motivational interviewing training for healthcare providers. Patient education and counseling. 2015;98(5):674-6. Epub 2015/03/03. doi: 10.1016/j.pec.2015.02.006. PubMed PMID: 25727283.
37. Paroz S, Daele A, Viret F, Vadot S, Bonvin R, Bodenmann P. Cultural competence and simulated patients. The clinical teacher. 2016;13(5):369-73. Epub 2016/01/20. doi: 10.1111/tct.12466. PubMed PMID: 26783081.
38. Rider EA, Hinrichs MM, Lown BA. A model for communication skills assessment across the undergraduate curriculum. Med Teach. 2006;28(5):e127-34. doi: 10.1080/01421590600726540. PubMed PMID: 16973446.
39. Woods ER, Klein JD, Wingood GM, Rose ES, Wypij D, Harris SK, Diclemente RJ. Development of a new Adolescent Patient-Provider Interaction Scale (APPIS) for youth at risk for STDs/HIV. J Adolesc Health. 2006;38(6):753 e1-7. doi: 10.1016/j.jadohealth.2005.08.013. PubMed PMID: 16730606.
40. van Zanten M, Boulet JR, McKinley D. Using standardized patients to assess the interpersonal skills of physicians: six years' experience with a high-stakes certification examination. Health Commun. 2007;22(3):195-205. doi: 10.1080/10410230701626562. PubMed PMID: 17967142.
41. Pilgrim N, Jani N, Mathur S, Kahabuka C, Saria V, Makyao N, Apicella L, Pulerwitz J. Provider perspectives on PrEP for adolescent girls and young women in Tanzania: The role of provider biases and quality of care. PLoS One. 2018;13(4):e0196280. doi: 10.1371/journal.pone.0196280. PubMed PMID: 29702659; PMCID: PMC5922529.

APPENDICES