STUDY PROTOCOL

Evaluating user-centered interventions in optimizing utilization of HIV and pregnancy prevention services among adolescent girls and young women (AGYW) in Kenya: a study protocol [version 1; peer review: 3 approved with reservations]

Jane Mutege ¹, Mary Mugambi ², Daniel Were ¹, Abednego Musau¹, Aigelgel Kirumburu¹, Mercy Kamau¹, Brian Wakhutu¹, Soud Tenga¹, Geoffrey Odhyambo¹, Manya Dotson³, Jason Reed³, Patricia Ong'ewn ¹

¹Jilinde Project, Jhpiego, Nairobi, Nairobi, 00800 Nairobi, Kenya

²HIV prevention Department, National AIDs & STI Control Program, Nairobi, Nairobi, 00202 Nairobi, Kenya

³Jhpiego, Jhpiego, Baltimore, MD 21231 USA, 1615 Thames street,, USA

V1 First published: 19 Nov 2021, 5:172
<https://doi.org/10.12688/gatesopenres.13432.1>
 Latest published: 19 Nov 2021, 5:172
<https://doi.org/10.12688/gatesopenres.13432.1>

Abstract

Background: Globally, HIV/AIDS is the leading cause of morbidity and mortality among adolescents; sub-Saharan Africa contributes more than two-thirds of all HIV-related adolescent deaths. In Kenya, HIV incidence remains high among youth (15–24 years), with women disproportionately affected. Morbidity and mortality are compounded by a high rate of early and unwanted pregnancies. Existing prevention efforts to reduce youth vulnerabilities overwhelmingly focus on HIV alone, with limited efforts made to address concurrent factors that increase vulnerability of adolescent girls and young women (AGYW) to HIV infection and unplanned pregnancies. Jilinde, is a Bill and Melinda Gates Foundation funded large-scale project that supports the provision of pre-exposure prophylaxis (PrEP) in Kenya. This manuscript presents a protocol for a study that seeks to evaluate the effectiveness of a comprehensive package of user-centered interventions to optimize uptake of HIV and pregnancy prevention services among AGYW in four Kenyan counties.

Methods: The study employed a concurrent mixed-methods design including two parallel before and after population-based cross-sectional surveys, focus group discussions, and in-depth interviews. Study participants included 1,280 AGYW, 1,080 individuals from the general population, 80 health service providers, and 32 county health managers. The study involved a formative, implementation phase and

Open Peer Review

Approval Status

	1	2	3
version 1			
19 Nov 2021	view	view	view

1. **Ilene S. Speizer** , University of North Carolina, Chapel Hill, USA

2. **Jean de Dieu Tapsoba**, Fred Hutchinson Cancer Research Center, Seattle, USA

3. **Aoife M. Doyle** , London School of Hygiene and Tropical Medicine, London, UK

Any reports and responses or comments on the article can be found at the end of the article.

endline assessment. Survey data was collected using Research Electronic Data Capture and analyzed using regression modelling while adjusting for confounders. Qualitative data will be analyzed using grounded theory techniques using NVivo 12.0.

Discussion: This study will uncover useful insights on the effectiveness of user-centered interventions in increasing concurrent utilization of blended HIV and pregnancy prevention interventions in a routine low resource setting. The findings will be disseminated through technical briefs, manuscripts, conferences, and workshops. The consolidated evidence could inform the scale-up of integrated HIV prevention and sexual and reproductive health interventions targeting AGYW.

Keywords

HIV prevention, pre-exposure prophylaxis (PrEP), adolescent girls and young women (AGYW), pregnancy prevention, Integration

Corresponding author: Jane Mutegi (Jane.Mutegi@jhpiego.org)

Author roles: **Mutegi J:** Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Supervision, Validation, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing; **Mugambi M:** Conceptualization, Investigation, Methodology, Supervision, Writing – Review & Editing; **Were D:** Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Supervision, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing; **Musau A:** Conceptualization, Investigation, Methodology, Validation, Writing – Original Draft Preparation, Writing – Review & Editing; **Kirumburu A:** Conceptualization, Investigation, Methodology, Supervision, Validation, Writing – Original Draft Preparation, Writing – Review & Editing; **Kamau M:** Conceptualization, Investigation, Methodology, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **Wakhutu B:** Data Curation, Investigation, Software, Validation, Writing – Original Draft Preparation, Writing – Review & Editing; **Tenga S:** Conceptualization, Investigation, Methodology, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **Odhyambo G:** Conceptualization, Investigation, Methodology, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **Dotson M:** Conceptualization, Investigation, Validation, Writing – Original Draft Preparation, Writing – Review & Editing; **Reed J:** Conceptualization, Validation, Writing – Original Draft Preparation, Writing – Review & Editing; **Ong'ewn P:** Conceptualization, Investigation, Methodology, Project Administration, Supervision, Validation, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

Grant information: This work was supported by the Bill and Melinda Gates Foundation [OPP1146198].

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Copyright: © 2021 Mutegi J *et al.* This is an open access article distributed under the terms of the [Creative Commons Attribution License](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

How to cite this article: Mutegi J, Mugambi M, Were D *et al.* **Evaluating user-centered interventions in optimizing utilization of HIV and pregnancy prevention services among adolescent girls and young women (AGYW) in Kenya: a study protocol [version 1; peer review: 3 approved with reservations]** Gates Open Research 2021, 5:172 <https://doi.org/10.12688/gatesopenres.13432.1>

First published: 19 Nov 2021, 5:172 <https://doi.org/10.12688/gatesopenres.13432.1>

Background and study rationale

Globally, almost 33% of new HIV infections occur among youth 15–24 years old¹. In 2019, an estimated 64 adolescents acquired HIV every hour culminating in an estimated 561,000 new HIV infections occurring worldwide¹. AIDS is the leading cause of morbidity and mortality among adolescents around the world²; sub-Saharan Africa contributes more than two-thirds of all global AIDS-related adolescent deaths. The persistence of AIDS-related deaths among older adolescents and young women aged 15–24 is attributed to gender inequality-related social, cultural, economic, and human rights barriers, which disproportionately affect AGYW, and biological differences that result in elevated risk of HIV acquisition³. Demographic projections also suggest an impending “youth bulge” in developing countries where HIV infections are highest⁴. This underscores the need for HIV prevention efforts to focus on AGYW.

Kenya has made considerable strides in the fight against HIV; it has nearly achieved the UNAIDS 90-90-90 targets for adults 15–64 years at 79.5% for HIV testing, 96% for treatment, and 90.6% for viral suppression⁵. This progress has resulted in a reduction of the estimate of annual new HIV infections from 76,315 in 2006⁶ to 36,000 in 2018⁷. Despite the milestones achieved, HIV incidence remains high among young people ages 15–24 years who account for 55% of new infections among individuals older than 15 years and AGYW account for 33% of new infections⁸. Recently, oral pre-exposure prophylaxis (PrEP) has been rolled out in many sub-Saharan African countries following World Health Organization’s (WHO) 2015 recommendation⁹. Kenya issued guidelines promoting oral PrEP for HIV prevention in 2016¹⁰ and subsequently launched national scale-up in 2017.

Globally, at least 10 million unintended pregnancies occur each year among adolescent girls aged 15–19 years in the developing world¹¹. The complications during pregnancy and childbirth are the leading cause of death for girls 15–19 years. Of the estimated 5.6 million abortions that occur each year among adolescent girls aged 15–19 years, 3.9 million are unsafe, contributing to maternal mortality, morbidity, and lasting health problems¹¹. In Kenya, one in every five girls between 15–19 years is either pregnant or already a mother¹². The Evidence for Contraceptive and HIV Outcomes (ECHO) trial, which was conducted across communities expected to have high levels of HIV incidence including Kenya, revealed high levels of other sexually transmitted infections (STIs) among young women seeking contraceptive services¹³. However, HIV prevention efforts to date have overwhelmingly focused on HIV alone, with fewer efforts made to address concurrent factors that increase vulnerability.

While Kenya has made progress in HIV prevention and sexual and reproductive health (SRH) programming for adolescents and young persons, considerable gaps still exist. For instance, significant numbers of adolescents are not adequately reached by the interventions intended for them¹⁴. There has been progress in employing user-centered approaches including design mindset and skills to co-create interventions with young people with promising results in research studies. Unfortunately, there is

limited evidence whether these interventions can be implemented in routine, real-world settings in regular health systems and whether they can be scaled up and sustained. Further, interventions that have been shown to be ineffective continue to be implemented and interventions that have been shown to be effective are delivered ineffectively¹⁴. PrEP uptake among AGYW in Kenya has remained low even among those obviously at risk of acquiring HIV^{15,16}. In addition, the uptake of family planning (FP) services has remained low as evidenced by high rates of teenage pregnancies¹⁷. Early lessons from PrEP implementation among AGYW in Africa also indicate low continuation rates, with many not returning for refills after a few weeks^{18,19}. These gaps signal the need for a paradigm shift to adequately reach AGYW with HIV prevention and SRH services. It is on this basis that the Jilinde project, funded by the Bill and Melinda Gates Foundation, designed a study to evaluate the effectiveness of user-centered interventions in improving utilization of PrEP and pregnancy prevention services among AGYW in Nairobi, Mombasa, Nakuru, and Uasin Gishu counties in Kenya. In collaboration with the Ministry of Health, Jilinde has been scaling up oral PrEP through integration into routine health services in drop-in centers (DICEs) and public and private health facilities in 10 out of the 47 counties in Kenya. The project supports the provision of PrEP to key populations and AGYW in Kenya.

Intervention

The Jilinde project developed a package of user-centered interventions to optimize uptake and continuation of HIV and pregnancy prevention services. The package of interventions was developed through a co-creation process with AGYW based on the conceptualized journey map which describes the steps that an AGYW navigates while accessing PrEP and SRH services. This package addresses barriers at different steps of the journey to support uptake and continuation on services. The journey map has six steps: Step 1) hearing about PrEP and SRH services; Step 2) consulting friends and other sources, e.g., social media for more information; Step 3) accessing a service delivery point; Step 4) receiving services; Step 5) returning to the community; and Step 6) returning to the facility for follow-up visits. [Figure 1](#) illustrates the journey map and the different activities proposed for addressing challenges at each step.

Methods

Study setting

The study is being implemented in four counties, Nairobi and Mombasa as the intervention counties and Uasin Gishu and Nakuru counties are serving as the comparison counties. The intervention counties are the first and third highest urban cities with HIV incidence among youth aged 15–24 years in Kenya⁷. The comparison counties were selected for their comparability to the intervention counties based on the following characteristics: comparable high population level²⁰ and urban settings with informal settlements that have vulnerable AGYW.

Study design

This study employs a concurrent mixed-methods design to facilitate triangulation of findings between the quantitative

Figure 1. AGYW Journey map. Source: Jilinde Project.

and qualitative methods. The study was implemented in three phases—formative phase, implementation phase, and endline phase—conducted at different study points. The study objectives are: i) to assess changes of the level of awareness and attitudes of the community members and health workers toward HIV and pregnancy prevention services for AGYW; ii) to assess levels of comprehensive knowledge and utilization patterns for PrEP and pregnancy prevention services among AGYW; iii) to examine the barriers and facilitators of uptake of HIV and pregnancy prevention services among AGYW; and iv) to evaluate changes in uptake of integrated SRH and PrEP services among AGYW.

Quantitative data consists of two household surveys, one involving AGYW (utilization survey) and another the general population (awareness survey), and collection of routine data on utilization of HIV prevention and pregnancy prevention services abstracted from registers in 11 health facilities. Qualitative data consists of key informant interviews (KIIs) with relevant county health managers, focus group discussions (FGDs) with health service providers, and FGDs and in-depth interviews (IDIs) with AGYW. Quantitative and qualitative data analysis were conducted simultaneously comparing findings as they emerge. Comparison of formative and endline indicators will document changes during the study period. During the intervention phase, the proposed package of interventions was executed in Nairobi and Mombasa counties while the comparison counties continued with the current standard of care delivering HIV and pregnancy prevention services for AGYW. The study lasted for 12 months.

Participants

Study participants include AGYW, the general population (male and female), health service providers, and county health managers. Details of each of these study populations are outlined below:

- AGYW** – Females aged 15–24 years residing within the catchment area of the selected facilities.
- General population** – Male household members aged 18–64 years and females aged 25–64 years residing within the catchment of the study health facilities.
- Health service providers** – These include HIV testing services (HTS) providers, nurses, clinical officers, and medical officers working in the identified service delivery points for SRH and PrEP within the selected health facilities.
- County health managers** – County staff who oversee SRH and PrEP services for AGYW. They included the reproductive health (RH) coordinators, community strategy focal persons, adolescent and youth focal persons, and AIDS and STI coordinators based within the selected study counties.

Participant eligibility: The inclusion and exclusion criteria are detailed in [Table 1](#).

Outcomes

The overall expected outcomes of the package of interventions include increasing demand for services, supporting delivery

Table 1. Eligibility criteria for study participants.

Participant category	Inclusion criteria	Exclusion criteria
AGYW	<ul style="list-style-type: none"> Consenting AGYW 18–24 years and 15–17-year-old mature minors* A resident of the selected study region 	<ul style="list-style-type: none"> Girls aged <17 with no evidence of emancipation Unwilling to consent Girls residing outside selected study county Persons with cognitive disabilities
General Population	<ul style="list-style-type: none"> Male aged between 18–64 years Female aged between 25–64 years Resident within the study county 	<ul style="list-style-type: none"> Unwilling to participate Not a resident of the study county Persons with cognitive disabilities Persons with visible signs of alcohol or drugs intoxication at the time of the interview
Health service providers	<ul style="list-style-type: none"> Service providers within the selected study sites 	<ul style="list-style-type: none"> Service providers who have worked in the facility for a period of less than one month
Key informants	<ul style="list-style-type: none"> Health managers at sub-county or county level in the geographical locations 	<ul style="list-style-type: none"> Managers who have served in the position for a period of less than one month Unwilling to consent

* A mature minor is defined as a minor 15 years of age or older; living separate and apart from their parents or guardian, whether with or without the consent of a parent or guardian and regardless of the duration of the separate residence, and managing their own financial affairs, regardless of the source of income²¹.

of AGYW-responsive services, and strengthening use of data. The specific activities and their expected outcomes are summarized in [Figure 2](#).

Recruitment and consent

During the formative and endline phases, study participants were recruited using different procedures for the quantitative and qualitative components and populations.

Quantitative studies

a) Utilization survey: AGYW were recruited at the household level within the catchment areas of the study health facilities. Trained research assistants established eligibility using a recruitment script and, thereafter, administer consenting procedures in a private location within the precincts of the household. Those who agreed to participate in the study provided written consent and only one AGYW per household will be invited to participate in the survey.

b) Awareness survey: General population participants were recruited at the household level within the catchment area of study health facilities. Community health workers guided the trained research assistants to the selected households with an adult male or female. The research assistants used a recruitment script to invite the potential participants. Those who met the eligibility criteria and expressed interest provided a written consent to participate. Only one participant per household participated and the research team alternated between male and female participants to ensure a balanced sex representation.

Qualitative studies

a) FGDs and IDIs for AGYW: Participants were invited by facility staff who approached AGYW in their community using

a recruitment script. The AGYW were purposely selected to include those who had used PrEP, those who use contraceptives, and those who had neither used PrEP nor contraceptives. Consenting for FGDs was conducted as a group by a trained qualitative researcher on the day of the FGD, and those who agreed to participate provided written consent. Consent for the IDIs was administered individually in private.

b) FGDs for health providers: Participants were recruited through facility in-charges guided by a recruitment script. Providers who expressed interest were linked to the qualitative researchers who confirmed eligibility and invited participants for the FGDs. Consent was administered as a group on the day of the FGD, followed by individual written consent.

c) KII for county health managers: County health managers were approached by a qualitative researcher through a phone call or a face-to-face meeting and were invited to participate in a KII. If the manager accepted the invitation, the qualitative researcher scheduled a convenient time and agreed on the venue of the interview. Consenting procedures were conducted in a private location.

Sample size

Quantitative: The sample size for the utilization survey was powered to provide estimates of the difference of PrEP and pregnancy prevention services' utilization among AGYW aged 15–24 years. The sample size for the general population was powered to provide estimates of the difference in PrEP awareness between the intervention and comparison counties. The sample sizes for both surveys was powered to detect a 10 percentage point difference in the difference between the endline and formative assessment in the intervention relative to the comparison counties at 80% power and a 95% confidence

Figure 2. Summary of components of the user-centered intervention package and outcomes. Source: Jilinde Project.

interval. In both surveys participants were recruited from clusters consisting of several households in a community unit affiliated to the selected facilities. We assumed an average cluster yield of 30 participants meeting the study criteria and an intra-class correlation of 0.03, which resulted into a design effect (DE) of 1.87. After accounting for a 10% non-response, the sample size was adjusted to about 264–270 for each of the intervention and comparison counties. The cumulative sample size was 540 for each population type and also for each of the two data collection periods (formative and endline assessments) resulting into a total sample size of 1,080 AGYW and 1,080 general population participants. The formula for sample size calculation is:

$$m = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta} \right)^2 * P_1(1-P_2) + P_2(1-P_2) * [(1+(n-1)\rho)]}{\Delta^2} \quad 22,23$$

where P_1 is the probability of an event in the intervention group, and P_2 the probability of an event in the comparison group; Δ represents the difference in proportions, $P_1 - P_2$; and design effect = $1 + (n-1)\rho$ where n is the number of individuals per cluster and ρ the intra-class correlation.

A summary of the parameters and sample size estimates for the utilization and awareness surveys are summarized on Table 2

Qualitative study population: FGDs, IDIs, and KIIs were conducted during the formative and endline phases where the participants were purposively selected at community, health facility and county level. The study included eight FGDs among AGYW and four with health providers during the formative phase. Each FGD constituted an average of 10 participants. IDIs were conducted among 20 AGYW allocated equally to the study counties. Four health managers in

Table 2. Summary of the parameters for sample size estimation for the surveys involving AGYW and general population.

For the survey-specified parameters	For awareness survey	For utilization survey
Formative parameter of key outcome (same in intervention and comparison counties)	0.60	0.22
Expected difference between comparison and intervention counties at endline	10%	10%
Significance level	0.05	0.05
Power	0.80	0.80
Number of clusters available (per arm)	9	9
Intra-cluster correlation	0.03	0.03
Non-response and incomplete interviews adjustment	10%	10%
Cluster sample size		
Average cluster size required	30	30
Sample size for each study group (formative and endline each)	270	270
Cumulative sample size	1,080	1,080
Projected number of households (adjusting for household refusals and unavailable household members)	720	1800

each of the four counties were interviewed during the formative assessment. A similar number of FGDs, KIIs, and IDIs were conducted during the endline assessment to exhaustively saturate the themes related to each group of participants. A summary of the estimated sample sizes for the quantitative and qualitative data is presented in [Table 3](#).

Sampling procedures

We employed multi-stage sampling for the two surveys and purposive sampling for the FGDs, KIIs and IDIs.

Multi-stage sampling

This sampling approach included selection of clusters, households, and participants at the household level. The sampling procedure at formative and endline assessments were similar.

Step 1. Selection of the clusters

During formative, community units (CUs) affiliated with the selected health facilities were used as clusters. All CUs were listed to form a sampling frame and simple random sampling method used to select CUs/clusters to be involved in the study. Nine clusters were selected for the intervention and a similar number for the comparison counties.

Step 2. Selection of the households

Households for each selected cluster was line-listed by the study team with support from the CHVs in each CU as guided by the community health strategy team in each county. The updated list of households (with unique serial identifiers)

served as the sampling frame for the selection of households in the second stage. Random sampling was used to select 100 households in every cluster as described below:

Determining the number of households

Based on the 2019 census distribution¹⁹, we will compute the expected distribution of the population in the respective age categories, as shown in [Table 4](#).

Based on these computations, and assuming a household size of four, the number of households needed per population type is described below:

General population: It was estimated that we would be able to find at least one respondent in each household. Therefore, to reach the estimated sample size, we needed a ratio of 1:1 for the number of households to sample size. Considering that every cluster was assigned an average of 30 participants, it was possible to reach 30 participants in 30 households in a cluster. We included 10 additional households per cluster to account for household refusals and non-traceable eligible household members. Therefore, we required 40 households for each cluster. Using the sample size estimate, we needed 360 households to reach the required sample size for general population at both formative and endline phases.

AGYW: It was estimated that, at least one AGYW would be found in every three households. Therefore, in order to obtain the required sample size for the AGYW, we needed a ratio of 3:1

Table 3. Sample size estimated for surveys, FGDs, KIIs, and IDIs.

Study Population	Intervention Counties		Comparison Counties		Total
	Formative assessment	Endline assessment	Formative assessment	Endline assessment	
Surveys*					
AGYW	270	270	270	270	1,080
General population	270	270	270	270	1,080
IDIs *					
IDI with AGYW	10	10	10	10	40
FGDs*					
FGD with AGYW	40	40	40	40	160
FGD with health service providers	20	20	20	20	80
KIIs					
KII with county health managers	8	8	8	8	32
Totals	618	618	618	618	2,472

*The study participants for the formative and endline survey will not necessarily be the same people.

Table 4. Estimated distribution of population of males and females nationally¹.

Description of population category	Number or %
Awareness Survey	
Total population size ¹	47,564,296
General population (18–64 years) ²	20,488,937
Proportion of general population (18–64 years)	43.1%
Estimated number of general population (18+ years) per household ³	1.72
Utilization Survey	
Total AGYW (15–24 years)	4,934,220
Proportion of AGYW (15–24 years)	10.4%
Estimated number of AGYW (15–24 years) per household ³	0.41

¹ Based on the 2019 census

² The general population in this context is defined as women 25–64 years and men 18–64 years

³ The household size is 4, based on the 2019 census

for the number of households to sample size. Every cluster was assigned an average of 30 AGYW, hence it was to be possible to reach the 30 AGYW participants in 90 households per cluster based on the population distribution in Table 4. We included a reserve of 10 households to each cluster to account for

household refusals and non-traceable eligible household members and thus we required 100 households for each cluster. Using the sample size estimate, we needed to cover 900 households for the AGYW to reach the required sample size in each arm at both formative and endline assessments.

Step 3. Selection of the survey participants

The survey participants (AGYW and general population) were selected at the household level. For the AGYW, we visited all the households selected until we reached the sample size. For the general population, participants were drawn specifically from households with an odd number on the line list. Only one AGYW and one general population respondent participated in the survey per household. In case two or more eligible participants were found within a household, the study team used to paper-pick method where the participant who picks a “Yes” was interviewed. For the general population survey, the research team alternated between male and female participants to ensure a balanced sex representation.

Purposive sampling

This approach was used to sample participants for FGDs, KIIs, and IDIs:

- **FGDs for AGYW:** AGYW were purposely selected by peer educators or facility staff from the pool of AGYW affiliated with peer networks in the community that are linked to the health facilities.
- **FGDs for health service providers:** Health service providers were selected at the health facility level. The health facility in-charge assisted the qualitative researcher to identify all departments from which to draw 10 health service providers offering PrEP and SRH services.
- **IDIs for AGYW:** The AGYW participants were purposely selected by peer educators or facility staff from the pool of AGYW affiliated with peer networks that are linked to the health facilities.
- **KIIs for county health managers:** County health managers included the RH coordinators, adolescents and youth focal person, community strategy focal person, and AIDS and STI coordinators were interviewed.

Data collection

Diverse data collection procedures were employed to generate quantitative and qualitative data. The same procedures conducted at formative, were conducted at endline assessments. Surveys were conducted by trained research assistants at private locations within the precincts of participants' households. Data was collected using an interviewer-administered survey questionnaire in English or Kiswahili. Data was collected using Research Electronic Data Capture (REDCap) software²⁴ hosted on password-protected tablets and the data submitted to the server daily.

FGDs, IDIs, and KIIs were moderated by trained qualitative researchers using guides and the appropriate language (Swahili or English) for each target audience. Sessions were conducted in private rooms within public health facilities, community halls, or offices of the county health managers. The researchers took handwritten notes and audio recorded all the sessions. The handwritten notes and the downloaded

audio data files were properly labelled, encrypted, and securely stored in lockable cabinets and password secured computers. A brief demographic profile consisting of age, gender, education, marital status, and current living standards of the FGD, KII and IDI participants was also obtained.

Data extraction for service statistics

During the intervention phase, data on utilization of PrEP and family planning (FP) services was collected on a monthly basis from the health facilities in both the intervention and comparison counties through a data abstraction form.

Different data collection tools were used for each sub-study described above. Table 5 outlines the variables that were collected using each of the study tools.

Data quality assurance

To ensure data quality, tools and the methods for data collection were pre-tested before the actual study and necessary changes made. The data collectors were trained on the process to ensure quality data is captured. All the completed questionnaires were checked for completeness, legibility, and consistency and any errors noted corrected before uploading of the data to the server. Continuous on-the-job training for service providers and focal persons in charge of data in facilities, monthly data verification, data review meetings, and quarterly data assessments was done during the intervention phase, to ensure data quality was maintained.

Anticipated and unanticipated events

We did not anticipate that this study would cause any harm. However, there was minimal risk related to breach of confidentiality in case information discussed in the FGDs was shared by participants outside the research setting. Further, it was possible for participants to experience emotional distress, embarrassment, or discomfort discussing their sensitive information with the study team. We also identified that participants might have felt uncomfortable sharing their personal sexual and behavioral experiences. The study team carefully tracked the occurrence of any of such events.

Given that the study was conducted during the COVID-19 pandemic era, the study implemented Kenya medical Research institute guideline²⁵ and MOH guidelines to prevent and address any potential threat of transmission of the COVID-19 virus to study participants and staff. These includes: 1) provision of alcohol-based sanitizers, 2) enforcement of donning of three-ply masks by participants and staff, and 3) maintaining physical distancing precautions including conducting data collection in private outdoor spaces.

Data analysis

Quantitative data analysis

The outcomes of interest for this study include service utilization of PrEP and pregnancy prevention services among AGYW and knowledge and attitudes toward PrEP and contraceptives among the general population. For the service utilization, we will compare difference in the proportion of AGYW reporting

Table 5. Data collection for the various sub-studies.

Study	Content of the instrument	Frequency of data collection
Utilization survey for AGYW	Sociodemographic characteristics, knowledge of HIV and AIDs, sexual history and behavior, HIV risk perception, knowledge of PrEP, source of PrEP information and exposure, HIV prevention and PrEP self-efficacy, knowledge of FP, social support for PrEP, utilization of Family planning (FP) and PrEP	Formative and endline
Awareness survey for general population	Socio-demographics characteristics, awareness and attitudes toward FP and HIV, knowledge and attitude toward PrEP	Formative and endline
FGDs with AGYW	Knowledge on HIV, HIV prevention and SRH services, attitudes toward SRH and FP services, demand creation for PrEP and FP, service delivery experiences and preferences	Formative and endline
IDIs for AGYW	Risk perception and risk compensation, PrEP attributes, acceptability and potential use, gendered power dynamics, stigma and social acceptability, what their friends know about PrEP, service delivery and demand creation strategies and models	Formative and endline
FGDs with health providers	Knowledge on HIV prevention and SRH services, knowledge and attitude on PrEP, demand creation approaches for FP and PrEP, acceptability and accessibility of PrEP, optimizing service delivery	Formative and endline
KIIs with county health managers	Knowledge on HIV prevention and SRH services, knowledge and attitude on PrEP, demand creation approaches for FP and PrEP, acceptability and accessibility of PrEP, optimizing service delivery	Formative and endline
Routine PrEP and FP utilization data	Monthly uptake of services for FP and PrEP	Throughout intervention period

PrEP and contraceptive method use between the intervention and comparison counties, expecting a 10% difference between formative and endline assessment. We also expect a 10% difference in knowledge and attitudes in the general population in the intervention and comparison counties comparing formative and endline assessment.

Data reduction techniques will be used to summarize the observed variables for data collected through Likert scales for the knowledge and attitude questions into a few dimensions through latent variable modelling using the *ltm* R package²⁶. Component internal consistency and reliability used for computing the composite scores will be evaluated by calculating Cronbach's α . Pairwise associations corresponding to two-by-two contingency tables for all possible pairs will be computed and variables with a low association with other items will be dropped leaving variables with Cronbach's α of 0.78. Factor scores will then be generated by fitting the Rasch model²⁷ or multiple item response theory analysis for outcomes, which have more than two levels. Depending on the distribution of factor scores, a new outcome variable will be generated, which will be either dichotomous or ordinal and used in new analysis.

Descriptive analysis of quantitative variables will be conducted using measures of central tendency (mean, median) and measures of dispersion (range, standard deviation) as appropriate. We will then conduct an exploratory analysis to compare outcomes by sociodemographic, cultural, and economic characteristics (age, education, religion, marital status, wealth quintile, etc.) using the Rao-Scott chi-square test to determine

if there is any association. We will further check the balance between the intervention and comparison counties in terms of potential confounding factors. To determine the relative importance of these factors on the outcomes, generalized estimating equations, univariate and multivariate logistic regressions will be used to adjust for clustering within the clusters. Results from the regression analysis will be reported as odds ratio (OR) and 95% confidence intervals. All statistical analysis will be considered statistically significant if the *p*-value is less than 0.05.

Qualitative data analysis

Qualitative analysis will commence by verbatim transcription of the audio-recordings from the FGDs, KIIs, and IDIs. Data collected in Swahili will be translated to English and back translated to confirm accuracy of the meanings during translation. The transcripts will be compared with the typed handwritten notes for concurrence. The data will be imported to NVivo 11.0 for analysis. First, open coding will be conducted to unearth all the emergent codes from the data. This will be augmented by a priori codebook derived from the qualitative guides. A master codebook will then be developed to make sure the codes are applied consistently but also allow the qualitative analysts to propose new codes as they emerge. Next, all the data will be coded using the master codebook. Thereafter, axial coding will be conducted using the constant comparison method to identify linkages and relationships in the data, and begin structuring the data according to emerging concepts. Finally, we will conduct selective coding using constant comparison techniques to organize the findings in an organized framework, drawing on the research questions, existing literature, and

seeing what new relationships of phenomena emerging from the data.

Dissemination of study results

The study team plans to disseminate the findings to in-country stakeholders at both the national and county level. The study findings will inform the in-country stakeholders on the opportunities and adaptations required to effectively integrate oral PrEP and SRH services. Further, the team plans to disseminate globally through regional and international conferences, webinars, and peer reviewed manuscripts. The study will contribute to the body of knowledge on whether integrated oral PrEP and SRH service delivery improves PrEP and SRH outcomes among AGYW.

Ethical approval

Ethical approval to conduct this study was obtained from the Kenya Medical Research Institute Scientific Ethics Review Unit (NON-KEMRI 700), and the Johns Hopkins Bloomberg School of Public Health Institutional Review Board (IRB000013293). A research permit was obtained from the National Commission for Science, Technology and Innovation.

Study status and implementation timeline

Collection of formative data began in November 2020 and was completed in January 2021. Recruitment and training of youth peer educators to conduct peer mobilization were conducted in January 2021. The youth peer educators began mobilizing AGYW clients in January 2021. Training of health care providers from the study sites to offer the intervention was conducted in January and February 2021. Whereas the intervention sites were already providing oral PrEP and SRH services prior to this intervention, the sites began offering

the revamped and integrated service package in January 2021. The first set of clients in the intervention sites received services in January 2021 (Table 6).

Discussion

There is an unequivocal need for integrated HIV prevention, contraception, and SRH services for young women in sub-Saharan Africa¹³. The high HIV incidence among young women meets the WHO eligibility criteria²⁸ and warrants access to oral PrEP, and the high unmet need for contraception necessitates interventions to increase access to modern contraception methods. Delivering high quality and integrated PrEP and SRH services that are acceptable, client-centered, and confidential for AGYW is of utmost public health importance²⁹. Kenya has progressive national policies and guidelines that facilitate provision of PrEP³⁰ and SRH³¹ for adolescents and young people. However, the low uptake of PrEP¹⁵, including in integrated settings³², and contraception³³, points to a gap in the translation of these guidelines into effective interventions³⁴.

This study evaluated the effectiveness of delivering user-centered HIV and pregnancy prevention interventions using a client journey map approach. Implementation of this study will contribute to the global body of evidence on whether delivering integrated PrEP and pregnancy prevention services leads to improved uptake of both PrEP and pregnancy prevention services among AGYW. Findings from the qualitative analysis will provide in-depth information on the barriers and facilitators to the uptake of HIV and pregnancy prevention services. This analysis will be useful in developing interventions and recommendations to address these barriers, while leveraging opportunities. The study will also provide information on the level of comprehensive knowledge about PrEP and SRH

Table 6. Study implementation status summary.

Activity	November– December 2020	January 2021	February– July 2021	August 2021	September – December 2021
Formative assessment (pre-intervention) • Awareness survey • Utilization survey Qualitative research	X	X			
Intervention rollout • Recruitment and training of peer educators Training of health care providers		X	X		
Endline assessment (post intervention) • Awareness survey • Utilization survey Qualitative research				X	
Data processing, analysis and dissemination of results					X

among AGYW, utilization patterns for these services when offered as an integrated package, and how the services can be improved. In addition, the study will provide evidence on the levels of awareness and attitudes of community members and health workers toward HIV and pregnancy prevention services for AGYW. This will inform recommendations on specific interventions that can contribute toward creating an enabling environment that will increase utilization of these services by AGYW. Overall, implementation of this

study is expected to contribute toward improved utilization of HIV prevention and SRH interventions among AGYW in the intervention sites. Further, the study will generate actionable evidence that will inform stakeholders and contribute to policy and operational decisions on whether to adopt this model in the scale-up of integrated delivery of these services.

Data availability

No data are associated with this article.

References

- Vicari M, Oliveras C, Gleeson H, *et al.*: **Meaningful engagement of adolescents and young people in national and local HIV programming.** World Health Organization; 2019.
[Reference Source](#)
- WHO: **Global health estimates 2015: deaths by cause, age, sex, by country and by region, 2000-2015.** World Health Organization Geneva; 2016.
- The Global Fund: **Technical Evaluation Reference Group Position paper – Adolescent Girls and Young Women in HIV.** 2019.
- Idele P, Gillespie A, Porth T, *et al.*: **Epidemiology of HIV and AIDS Among Adolescents: Current Status, Inequities, and Data Gaps.** *J Acquir Immune Defic Syndr.* 2014; **66** Suppl 2: S144–53.
[PubMed Abstract](#) | [Publisher Full Text](#)
- UNAIDS: **Data 2020.** Program HIV/AIDS, 2020; 1–248.
[Reference Source](#)
- National AIDS Control Council (NACC): **Kenya HIV prevention response and modes of transmission (MOT) analysis.** 2009.
[Reference Source](#)
- NACC Kenya: **KENPHIA 2018 PRELIMINARY REPORT.**
[Reference Source](#)
- NACC Kenya: **Kenya hiv estimates.** 2018.
[Reference Source](#)
- World Health Organization: **Pre-exposure prophylaxis (PrEP). WHO expands recommendation on oral PrEP of HIV infection.** World Heal Organ, 2015; 2.
[Reference Source](#)
- Ministry of Health NA& SCP: **Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya.** 2018.
[Reference Source](#)
- WHO: **Adolescent pregnancy.** WHO.
[Reference Source](#)
- Kenya National Bureau of Statistics, Ministry of Health/Kenya, National AIDS Control Council/Kenya, *et al.*: **Kenya Demographic and Health Survey 2014.** Rockville, MD, USA; 2015.
[Reference Source](#)
- Evidence for Contraceptive Options and HIV Outcomes (ECHO) Trial Consortium: **HIV incidence among women using intramuscular depot medroxyprogesterone acetate, a copper intrauterine device, or a levonorgestrel implant for contraception: a randomised, multicentre, open-label trial.** *Lancet.* 2019; **394**(10195): 303–13.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Chandra-Mouli V, Lane C, Wong S: **What Does Not Work in Adolescent Sexual and Reproductive Health: A Review of Evidence on Interventions Commonly Accepted as Best Practices.** *Glob Health Sci Pract.* 2015; **3**(3): 333–40.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Oluoch LM, Roxby A, Wald A, *et al.*: **Low Uptake of Pre-exposure Prophylaxis among Kenyan Adolescent Girls at Risk of HIV.** *Conf Retroviruses Opportunistic Infect.* 2019; **3**.
[Reference Source](#)
- Mugwanya KK, Pintye J, Kinuthia J, *et al.*: **Integrating preexposure prophylaxis delivery in routine family planning clinics: A feasibility programmatic evaluation in Kenya.** Geng EH, editor. *PLoS Med.* 2019; **16**(9): e1002885.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Rutgers University, Republic of Kenya: **Fact Sheet: Teenage Pregnancy, Kenya.** 2017.
- Koss CA, Charlebois ED, Ayieko J, *et al.*: **Uptake, engagement, and adherence to pre-exposure prophylaxis offered after population HIV testing in rural Kenya and Uganda: 72-week interim analysis of observational data from the SEARCH study.** *Lancet HIV.* 2020; **7**(4): e249–61.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Were D, Musau A, Muteji J, *et al.*: **Using a HIV prevention cascade for identifying missed opportunities in PrEP delivery in Kenya: results from a programmatic surveillance study.** *J Int AIDS Soc.* 2020; **23** Suppl 3(Suppl 3): e25537.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Kenya National Bureau of Statistics: **2019 KENYA POPULATION AND HOUSING CENSUS VOLUME I: POPULATION BY COUNTY AND SUB-COUNTY.** 2019; 1.
- National AIDS and STI Control Programme (NASCOP), Kenya Medical Research Institute (KEMRI): **Guidelines for Conducting Adolescent HIV Sexual and Reproductive Health Research in Kenya.** Gov Kenya, 2015; 48.
- Hemming K, Girling AJ, Sitch AJ, *et al.*: **Sample size calculations for cluster randomised controlled trials with a fixed number of clusters.** *BMC Med Res Methodol.* 2011; **11**(1): 102.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Hemming K, Girling AJ, Sitch AJ, *et al.*: **Erratum to: Sample size calculations for cluster randomised controlled trials with a fixed number of clusters.** *BMC Med Res Methodol.* 2017; **17**(1): 8.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Harris PA, Taylor R, Thielke R, *et al.*: **Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support.** *J Biomed Inform.* 2009; **42**(2): 377–81.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- KEMRI: **KEMRI SERU Guidelines for the conduct of research during the covid19 pandemic in Kenya.** Vol. Version 1. 2020.
- Rizopoulos D: **Item: An R package for latent variable modeling and item response theory analyses.** *J Stat Softw.* 2006; **17**(5): 1–25.
[Publisher Full Text](#)
- Andrich D: **Rasch Models for Measurement.** Thousand Oaks, California; 1988.
[Reference Source](#)
- WHO: **WHO expands recommendation on oral pre-exposure prophylaxis of HIV infection (PrEP).** World Heal Organ, 2015; 2.
[Reference Source](#)
- WHO U and U: **Hormonal contraceptive methods and HIV acquisition in women: Joint Statement.** 2019.
[Reference Source](#)
- Ministry of Health N: **Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya.** 2016.
- Ministry of Health Kenya: **National Adolescent Sexual and Reproductive Health Policy, 2015.** *Natl Adolesc Sex Reprod Heal Policy.* 2015; 1–37.
[Reference Source](#)
- Sila J, Larsen AM, Kinuthia J, *et al.*: **High Awareness, Yet Low Uptake, of Pre-Exposure Prophylaxis Among Adolescent Girls and Young Women Within Family Planning Clinics in Kenya.** *AIDS Patient Care STDS.* 2020; **34**(8): 336–43.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Gichangi P, Agwanda A, Thiongo M, *et al.*: **Assessing (in) equalities in contraceptives use and family planning demand satisfied with modern contraceptives in Kenya.** 2020.
[Publisher Full Text](#)
- NCPD: **Kenya's Adolescent Reproductive Health and Development policy: Implementation Assessment Report.** 2013; 40.
[Reference Source](#)

Open Peer Review

Current Peer Review Status: ? ? ?

Version 1

Reviewer Report 29 July 2022

<https://doi.org/10.21956/gatesopenres.14687.r32169>

© 2022 Doyle A. This is an open access peer review report distributed under the terms of the [Creative Commons Attribution License](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Aoife M. Doyle

Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, London, UK

This manuscript describes the protocol for a study to evaluate the effectiveness of a comprehensive package of user-centered interventions to optimised uptake of HIV and pregnancy prevention services among AGYW in four Kenyan counties.

The manuscript provides a good overview of the planned research. Some areas require further clarity as detailed below.

Major comments:

- The primary and secondary outcomes of the quantitative studies are unclear and poorly defined. While a lot of useful detail is provided on the proposed analysis, it was not clear what analysis would be used to determine if the intervention had been effective.
- More detail on the interventions are required.
- The discussion section should include the strengths and limitations of the proposed study.
- The tense used through the abstract and manuscript varies between past and future. It would help the reader if a consistent tense was used throughout.

Specific comments:

Abstract:

- HIV/AIDS is not the leading cause of morbidity and mortality among adolescents. See: Global Health Estimates for 2019, World Health Organization.
<https://www.who.int/data/maternal-newborn-child-adolescent-ageing>
- The different phases of the study are mentioned several times but the difference between the phases is unclear. Could 'formative' be described as 'baseline'?

Background:

- AIDS is not the leading cause of morbidity and mortality among adolescents around the world (see reference above for up to date estimates on leading causes of mortality and morbidity).
- *"However, HIV prevention efforts to date have overwhelmingly focused on HIV alone, with fewer efforts made to address concurrent factors that increase vulnerability."*
Can you clarify what you mean here by "concurrent factors that increase vulnerability"? Also, there have been many initiatives that address the structural drivers of HIV - see this recent review for some examples: Stoner *et al.* (2021¹).
- Please explain or give a reference for the term 'design mindset'.
- *"Unfortunately, there is limited evidence whether these interventions can be implemented in routine, real-world settings in regular health systems and whether they can be scaled up and sustained."*
Please clarify if you are referring to the interventions that emerge from these design processes or the design methodologies themselves.
- The background section would be strengthened by a sentence or two on why the delivery of PrEP and pregnancy prevention services should be integrated.

Methods:

- The study objectives and outcomes don't align very well. Please clarify what the primary and secondary outcomes are. Some of the expected outcomes (Figure 2) are not listed in the methods/analysis section e.g. demand (how will this be captured?), adherence and continuation, data use for quality improvement, PrEP and SRH services normalised in the community, increased access points for PrEP and SRH services, integration, increased capacity of health care providers.
- How are cognitive disabilities assessed (exclusion criteria in Table 1)?
- The description of sample recruitment (page 5) and sampling methodology (page 7) should be combined as many of the questions that the reader will have when reading the text on page 5 are answered by the details provided on page 7.
- Baseline prevalence of primary outcome - what data source did you use to inform the estimate of 22%?
- Please explain what a 'community unit' is? Is this a pre-existing structure or one created for the purposes of the study?
- Sampling of households: *"For the general population, participants were drawn specifically from households with an odd number on the line list."* This does not seem consistent with the earlier statement *"Random sampling was used to select 100 households in every cluster as described below"*. Please comment on the potential for biased sampling as it appears that households near the top of the household line listing will be more likely to be included in the surveys.

Data analysis:

- The primary outcomes "*Proportion of AGYW reporting PrEP and contraceptive method use*" and "*knowledge and attitudes*" need to be more clearly defined including specification of the questions used.
- "*Data reduction techniques will be used to summarize the observed variables for data collected through Likert scales for the knowledge and attitude questions into a few dimensions through latent variable modelling using the ltm R package*²⁶." This sentence is unclear.
- Will you use weights during your analysis as your sampling methodology will not lead to a self-weighting sample?
- Will an individual girls exposure to the intervention be captured and used in the analysis?
- Routine PrEP and FP utilisation data - not clear how these will be used. Routine data will be collected from 11 health facilities but the survey includes the catchment areas of 9 health facilities. Please clarify why these numbers differ.
- "*All statistical analysis will be considered statistically significant if the p-value is less than 0.05.*" There is a move away from focusing on a single p-value cut-off for 'significance' and more towards looking at the overall strength of evidence.
- Data availability - will the anonymised data be made publicly available after the study?

Tables and Figures:

- Figure 1 – This is a helpful diagram to help understand the journey map and interventions. However, the text within each box is too small to read. Could this be simplified and/or included as a full page diagram in an appendix?
- Figure 2 - text too small to read.
- Table 1 - exclusion criteria for healthcare workers should also have 'unwilling to consent'.

References

1. Stoner MCD, Kilburn K, Godfrey-Faussett P, Ghys P, et al.: Cash transfers for HIV prevention: A systematic review. *PLoS Med.* **18** (11): e1003866 [PubMed Abstract](#) | [Publisher Full Text](#)

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Epidemiology, adolescent health, intervention evaluation, sexual and reproductive health, HIV

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 11 July 2022

<https://doi.org/10.21956/gatesopenres.14687.r32098>

© 2022 Tapsoba J. This is an open access peer review report distributed under the terms of the [Creative Commons Attribution License](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Jean de Dieu Tapsoba

Vaccine and Infectious Diseases Division, Fred Hutchinson Cancer Research Center, Seattle, WA, USA

This manuscript describes the protocol of a study aiming to evaluate user-centered interventions to increase utilization of HIV and pregnancy prevention services among adolescent girls and young women (AGYW) in Kenya. This is an important topic. However, more details about the proposed methods are needed to make the manuscript more useful to the readers. My specific comments are given below.

- It is not clear how comparable the intervention and control counties are in terms of percent of the population that are AGYW and baseline rates of PrEP and contraceptive method use among AGYW.
- It is mentioned in the manuscript that community units affiliated with the selected health facilities were used as clusters. But there is no detail about the selection of the study health facilities and how the community units were defined. Also, it will be helpful to provide the number of selected health facilities and clusters for each of the intervention and comparison counties.
- The study population for AGYW needs clarification. The target population for AGYW seems to be AGYW 15-24 years residing within the catchment area of the selected health facilities. However, for AGYW 15-17 years the study only includes those who are “mature minors” (those with no evidence of “emancipation” are apparently excluded) based on the study eligibility criteria. This could limit the interpretation and generalizability of the study findings.
- More details about the assumptions on the baseline rates of PrEP and contraceptive

method use among AGYW for the power and sample size calculations are needed.

- The authors need to clarify whether AGYW enrolled at the “formative” phase were longitudinally followed up through the “endline” phase of the study. Did the “endline” assessment involve new selections of study health facilities, clusters, households and participants?
- It is not clear how PrEP use and contraceptive method use were defined. Also, more details about the data collected on PrEP use and contraceptive method use by the survey questionnaires are needed.
- The authors need to provide clarification about the denominator for the calculation of the proportion of AGYW reporting PrEP and contraceptive use. It is unclear if it includes all AGYW (regardless of HIV status or current pregnancy).

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Statistics; HIV prevention clinical trial and analysis

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 27 June 2022

<https://doi.org/10.21956/gatesopenres.14687.r32172>

© 2022 Speizer I. This is an open access peer review report distributed under the terms of the [Creative Commons Attribution License](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Ilene S. Speizer

Department of Maternal and Child Health, Carolina Population Center, Gillings School of Global

Public Health, University of North Carolina, Chapel Hill, NC, USA

This protocol paper provides an overview of the different study components of an HIV and pregnancy prevention program for adolescent girls and young women in Kenya. For the most part, the paper is comprehensive and gives important details on the study design that will be helpful for others trying to replicate the findings (or later use the data). Some clarifications would be helpful for a reader to better understand the paper; these are identified below.

1. From the description of the intervention, it is not completely clear how the intervention examined in this paper differs from the broader/longer Jilinde Project. I went to the Jilinde Project website to get some more details but even reviewing that did not clarify some key factors:
 - What is specifically being tested in this intervention? Is it all of the components in the Journey Map and if so, was there enough time to roll all these out? In the “Study status and implementation timeline” not all of the components are addressed.
 - How was the “user-centered design” intervention developed? Is it from the data in this paper or from the earlier project? It seems that the earlier work developed the Journey Map but more information on that process would be useful.
 - How long does the intervention being examined last (from Table 6 it looks like about 7 months but given that Jilinde has been going on for a while, perhaps it is longer)? If it is only 7 months, I am not sure why you need such comprehensive data since not much will change in that short period.
2. I also think there needs to be some clarifications about the data including the following:
 - How were the formative data used to inform the intervention? Not sure that there is time to use it as “formative” and thus, I think it is simply “baseline” data.
 - Why were the four counties selected for the study, given that the broader program was in 10 counties. Were the comparison counties part of the original 10 counties?
 - It says that “the study lasted for 12 months” but it is not clear if this is the period that included formative data collection, intervention, and endline data collection. If so, it is hard to imagine how the data were used to inform programming (see point 2a above) and that this was implemented long enough to have any effects (see point 1c above).
 - For the description of recruitment, some of the relevant information I wanted about the samples was included in later tables (e.g., whether the sample was randomly selected) and it might be good to refer to those tables earlier. Also, for the FGDs with the health care providers, it wasn’t clear if these FGDs happened with providers from the same facility or if providers across different facilities formed a group.
 - In the sampling procedures discussion it was not clear on the relationship between community units and clusters. It would be good to clarify this and be consistent with the language used. Also, were the clusters/households reselected at endline? And did you select different clusters for the AGYW survey and for the general population

survey? Since all households were eligible, I would think you would want different clusters but this wasn't clear.

- Table 5 is useful and might be good to refer to earlier. That said, it is not clear how some of the data sources will be used (e.g., KII and routine data) and how the full benefits of this mixed-methods study will be gained.
3. The discussion section focuses on how the findings will be useful but it seems to mostly be talking about the formative results rather than the full evaluation results. If it were including evaluation results, it might include a discussion of effectiveness, feasibility, coverage, sustainability, and scale-up.
4. A last point that I struggled with. As a protocol paper, it seemed like the paper should be discussing a future/planned study. That said, in this case, the data are all collected, and thus it left me wanting more information (i.e., baseline results, etc.). This challenge was highlighted throughout the paper where the tenses were inconsistent. At times the authors say "we will" do something whereas other times it was "we did" something. This makes it hard to follow and made me wonder if it might be better to provide a protocol paper that includes the baseline sample information so that it is more informative than just a description of the samples, given that the data are already available.

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Evaluation research, AGYW sexual and reproductive health, fertility and family planning, HIV prevention

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.