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: awaiting peer review]

Jane Mutegi1, Mary Mugambi2, Daniel Were1, Abednego Musau1, Aigelgel Kirumburu1, Mercy Kamau1, Brian Wakhutu1, Soud Tenga1, Geoffrey Odhyambo1, Manya Dotson3, Jason Reed3, Patricia Ong’ewn1

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

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 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...
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; Were D: 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

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Background and study rationale

Globally, almost 33% of new HIV infections occur among youth 15–24 years old. In 2019, an estimated 64 adolescents acquired HIV every hour culminating in an estimated 561,000 new HIV infections occurring worldwide. AIDS is the leading cause of morbidity and mortality among adolescents around the world; 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 acquisition. Demographic projections also suggest an impending “youth bulge” in developing countries where HIV infections are highest. 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 suppression. This progress has resulted in a reduction of the estimate of annual new HIV infections from 76,315 in 2006 to 36,000 in 2018. 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 infections. Recently, oral pre-exposure prophylaxis (PrEP) has been rolled out in many sub-Saharan African countries following World Health Organization’s (WHO) 2015 recommendation. Kenya issued guidelines promoting oral PrEP for HIV prevention in 2016 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 world. 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 problems. In Kenya, one in every five girls between 15–19 years is either pregnant or already a mother. 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 services. 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 them. 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 ineffectively. PrEP uptake among AGYW in Kenya has remained low even among those obviously at risk of acquiring HIV. In addition, the uptake of family planning (FP) services has remained low as evidenced by high rates of teenage pregnancies. Early lessons from PrEP implementation among AGYW in Africa also indicate low continuation rates, with many not returning for refills after a few weeks. 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 Kenya. The comparison counties were selected for their comparability to the intervention counties based on the following characteristics: comparable high population level 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...
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 (KII) 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:

i. **AGYW** – Females aged 15–24 years residing within the catchment area of the selected facilities.

ii. **General population** – Male household members aged 18–64 years and females aged 25–64 years residing within the catchment of the study health facilities.

iii. **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.

iv. **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
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) KIIIs 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.

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Table 1. Eligibility criteria for study participants.

<table>
<thead>
<tr>
<th>Participant category</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
</table>
| AGYW                 | • Consenting AGYW 18–24 years and 15–17-year-old mature minors\[^1\]  
• A resident of the selected study region | • Girls aged <17 with no evidence of emancipation  
• Unwilling to consent  
• Girls residing outside selected study county  
• Persons with cognitive disabilities |
| General Population   | • Male aged between 18–64 years  
• Female aged between 25–64 years  
• Resident within the study county | • 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 | • Service providers within the selected study sites | • Service providers who have worked in the facility for a period of less than one month |
| Key informants       | • Health managers at sub-county or county level in the geographical locations | • Managers who have served in the position for a period of less than one month  
• Unwilling to consent |

\[^1\] 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 income\[^1\].
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:

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

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; $\Delta$ 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 $\rho$ 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
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 distribution\(^19\), 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:

<table>
<thead>
<tr>
<th>General population:</th>
<th>AGYW:</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>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</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>For the survey-specified parameters</th>
<th>For awareness survey</th>
<th>For utilization survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formative parameter of key outcome (same in intervention and comparison counties)</td>
<td>0.60</td>
<td>0.22</td>
</tr>
<tr>
<td>Expected difference between comparison and intervention counties at endline</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>Significance level</td>
<td>0.05</td>
<td>0.05</td>
</tr>
<tr>
<td>Power</td>
<td>0.80</td>
<td>0.80</td>
</tr>
<tr>
<td>Number of clusters available (per arm)</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Intra-cluster correlation</td>
<td>0.03</td>
<td>0.03</td>
</tr>
<tr>
<td>Non-response and incomplete interviews adjustment</td>
<td>10%</td>
<td>10%</td>
</tr>
</tbody>
</table>

#### Average cluster size required

- General population:
  - 30

#### Sample size for each study group (formative and endline each)

- General population:
  - 270

#### Cumulative sample size

- General population:
  - 1,080

#### Projected number of households (adjusting for household refusals and unavailable household members)

- General population:
  - 720 automated 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.\n
### 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 distribution\(^19\), 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
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.

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

<table>
<thead>
<tr>
<th>Study Population</th>
<th>Intervention Counties</th>
<th>Comparison Counties</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Formative assessment</td>
<td>Endline assessment</td>
<td>Formative assessment</td>
</tr>
<tr>
<td><strong>Surveys</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AGYW</td>
<td>270</td>
<td>270</td>
<td>270</td>
</tr>
<tr>
<td>General population</td>
<td>270</td>
<td>270</td>
<td>270</td>
</tr>
<tr>
<td><strong>IDIs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IDI with AGYW</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td><strong>FGDs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FGD with AGYW</td>
<td>40</td>
<td>40</td>
<td>40</td>
</tr>
<tr>
<td>FGD with health service providers</td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td><strong>KII</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KII with county health managers</td>
<td>8</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td>618</td>
<td>618</td>
<td>618</td>
</tr>
</tbody>
</table>

*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 nationally.

<table>
<thead>
<tr>
<th>Description of population category</th>
<th>Number or %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Awareness Survey</strong></td>
<td></td>
</tr>
<tr>
<td>Total population size¹</td>
<td>47,564,296</td>
</tr>
<tr>
<td>General population (18–64 years)²</td>
<td>20,488,937</td>
</tr>
<tr>
<td>Proportion of general population (18–64 years)</td>
<td>43.1%</td>
</tr>
<tr>
<td>Estimated number of general population (18+ years) per household³</td>
<td>1.72</td>
</tr>
<tr>
<td><strong>Utilization Survey</strong></td>
<td></td>
</tr>
<tr>
<td>Total AGYW (15–24 years)</td>
<td>4,934,220</td>
</tr>
<tr>
<td>Proportion of AGYW (15–24 years)</td>
<td>10.4%</td>
</tr>
<tr>
<td>Estimated number of AGYW (15–24 years) per household³</td>
<td>0.41</td>
</tr>
</tbody>
</table>

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
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 list line. 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) software 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 guideline 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.

<table>
<thead>
<tr>
<th>Study</th>
<th>Content of the instrument</th>
<th>Frequency of data collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utilization survey for AGYW</td>
<td>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</td>
<td>Formative and endline</td>
</tr>
<tr>
<td>Awareness survey for general population</td>
<td>Socio-demographics characteristics, awareness and attitudes toward FP and HIV, knowledge and attitude toward PrEP</td>
<td>Formative and endline</td>
</tr>
<tr>
<td>FGDs with AGYW</td>
<td>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</td>
<td>Formative and endline</td>
</tr>
<tr>
<td>IDIs for AGYW</td>
<td>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</td>
<td>Formative and endline</td>
</tr>
<tr>
<td>FGDs with health providers</td>
<td>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</td>
<td>Formative and endline</td>
</tr>
<tr>
<td>KIIs with county health managers</td>
<td>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</td>
<td>Formative and endline</td>
</tr>
<tr>
<td>Routine PrEP and FP utilization data</td>
<td>Monthly uptake of services for FP and PrEP</td>
<td>Throughout intervention period</td>
</tr>
</tbody>
</table>

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 package. 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 model 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 Africa\(^1\). The high HIV incidence among young women meets the WHO eligibility criteria\(^2\) 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 importance\(^2\). Kenya has progressive national policies and guidelines that facilitate provision of PrEP\(^3\) and SRH\(^4\) for adolescents and young people. However, the low uptake of PrEP\(^5\), including in integrated settings\(^6\), and contraception\(^7\), points to a gap in the translation of these guidelines into effective interventions\(^8\).

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.

<table>
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<tbody>
<tr>
<td>Formative assessment (pre-intervention)</td>
<td>X</td>
<td>X</td>
<td></td>
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<tr>
<td>• Awareness survey</td>
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<tr>
<td>• Utilization survey</td>
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<tr>
<td>Qualitative research</td>
<td></td>
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<tr>
<td>Intervention rollout</td>
<td>X</td>
<td>X</td>
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<tr>
<td>• Recruitment and training of peer educators</td>
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<tr>
<td>Training of health care providers</td>
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<tr>
<td>Endline assessment (post intervention)</td>
<td></td>
<td>X</td>
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<tr>
<td>• Awareness survey</td>
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<tr>
<td>• Utilization survey</td>
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<tr>
<td>Qualitative research</td>
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<tr>
<td>Data processing, analysis and dissemination of results</td>
<td>X</td>
<td></td>
<td></td>
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</tbody>
</table>
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

7. NACC Kenya: KENPHIA 2018 PRELIMINARY REPORT. Reference Source