Assessment of adolescents HIV care in large HIV Treatment Programs in Kenya

A Protocol Prepared by

Ministry of Health, Kenya
University of Washington
Centers for Disease Control and Prevention, Kenya
Kenyatta National Hospital
and
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<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ALHIV</td>
<td>Adolescents living with HIV</td>
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<tr>
<td>APS</td>
<td>Adolescent Package of Services</td>
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<tr>
<td>ART</td>
<td>Antiretroviral Therapy</td>
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<td>ARVs</td>
<td>Antiretroviral drugs</td>
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<tr>
<td>BIPAI</td>
<td>Baylor International Pediatric AIDS Initiative</td>
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<tr>
<td>CCC</td>
<td>Comprehensive Care Clinic</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<tr>
<td>CRF</td>
<td>Case Report Form</td>
</tr>
<tr>
<td>ERC</td>
<td>Ethics Review Committee</td>
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<td>EMR</td>
<td>Electronic medical records</td>
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<tr>
<td>FGD</td>
<td>Focus group discussion</td>
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<td>FHI</td>
<td>Family Health International</td>
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<tr>
<td>FP</td>
<td>Family Planning</td>
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<tr>
<td>HAART</td>
<td>Highly active antiretroviral therapy</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>IDI</td>
<td>Individual Interview</td>
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<tr>
<td>IQR</td>
<td>Interquartile Range</td>
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<td>IRB</td>
<td>Institutional Review Board</td>
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<td>I-TECH</td>
<td>International Training &amp; Education Center for Health</td>
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<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
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<td>KEMRI</td>
<td>Kenya Medical Research Institute</td>
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<tr>
<td>KNH</td>
<td>Kenyatta National Hospital</td>
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<tr>
<td>MOH</td>
<td>Ministry of Health</td>
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<tr>
<td>MTCT</td>
<td>Mother-to-Child Transmission</td>
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<td>NASCOP</td>
<td>National AIDS and STI Control Program</td>
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<td>PMTCT</td>
<td>Prevention of Mother-to-Child Transmission</td>
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<td>SRH</td>
<td>Sexual and Reproductive Health</td>
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<td>SRHE</td>
<td>Sexual and Reproductive Health Education</td>
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<td>SSA</td>
<td>Sub-Saharan Africa</td>
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<td>STI</td>
<td>Sexually Transmitted Infection</td>
</tr>
<tr>
<td>UON</td>
<td>University of Nairobi</td>
</tr>
<tr>
<td>UW</td>
<td>University of Washington</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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**Sponsor:** Division of Global HIV/AIDS (DGHA), US Centers for Disease Control and Prevention (CDC), Kenya
CoAg Title: Coptic Hospital/UW Collaborative HIV Care Program
CoAg Number: U2GPS002047
ABSTRACT

With the advent of successful pediatric HIV treatment programs, more HIV-infected children are living into adolescence, thus uptake of care and adherence to treatment will be an increasing need. Adolescents require specialized care because adolescence is attended by unique physiological, developmental, and psychosocial changes that could potentially confound preexisting stressors associated with HIV infection. Unfortunately, there has been less programmatic focus on adolescent HIV care. In response to the need for a systematic format for provision of adolescent HIV and reproductive services, the Kenya Ministry of Health (MOH) has begun development of a comprehensive package of clinical and psychological services for adolescents, known as the Adolescent Package of Services (APS). This package includes an adolescent care booklet developed by the Kenyan MOH (2013); a standardized checklist regarding adolescent services; and health provider training materials, including disclosure guidelines, sexual and reproductive health education, HIV care, and reproductive health services. Gradual roll-out of the APS has started but uptake by clinics, and acceptability and feasibility of the APS materials have not yet been assessed. The primary objective of this evaluation is to use mixed methods approaches to assess uptake, acceptability, and feasibility of APS; and to identify baseline rates and correlates of key health indicators for HIV-infected adolescents. Specifically, we will conduct a facility assessment of services and trainings in provision of adolescent care and uptake of APS at 102 clinics. We will determine the numbers of adolescents seeking care, services offered to adolescents, and trainings health providers received in providing adolescent services. We will also conduct a clinic-based retrospective records assessment of HIV-specific and sexual and reproductive health outcomes in up to 7000 HIV-infected adolescents using abstracted electronic medical record (EMR) and adolescent checklist data from the 102 clinics participating in the facility assessment. Finally, we will perform a stakeholder assessment of feasibility and acceptability of APS by conducting interviews and focus groups with 50 health providers, 50 adolescents, and 50 of their primary caregivers from clinics already trained in APS. This evaluation will inform the continued roll out of the national program on adolescent health outcomes, acceptability and feasibility of the APS in Kenyan clinics.
LAY ABSTRACT

According to the 2012 UNAIDS Global report, there are currently 2.1 million adolescents living with HIV and an additional 300,000 adolescents are newly infected with HIV each year. Inadequate provision of accessible and acceptable HIV testing, counseling, and treatment services is cited as a barrier to uptake of and retention in HIV care among adolescents. In response to the need for improved HIV and reproductive services for adolescents, the MOH, with support from collaborating partners, has developed the adolescent package of services. The adolescent package of services, or APS, is a healthcare provider guide designed to improve health services offered to adolescents. The package targets provision of care to all adolescents, but places a specific emphasis on HIV-infected adolescents. The goal of this project is to assess uptake and acceptability of APS by health clinics/providers, and to assess adolescent health outcomes. Specifically, we want to use a mixed methods design to review services and trainings for adolescent care and uptake of APS at Kenyan public health clinics, determine baseline rates of key adolescent HIV outcomes, and conduct an assessment of feasibility and acceptability of APS by talking with health providers, caregivers and adolescents about HIV services offered at their clinics. The results from this evaluation can help inform the MOH and other implementing partners on the continued roll out of the national program.
1.0 BACKGROUND

1.1 Adolescent HIV
The World Health Organization defines adolescents as individuals aged 10-19 years and youth as those aged 15-24 years (1). In 2012, an estimated 2.1 million adolescents were living with HIV (2), and 300,000 adolescents were newly infected. Sub-Saharan Africa (SSA) is home to 80% of adolescents and youth living with HIV (4). In 2010, 1.3 million HIV infected adolescents lived in Eastern and Southern Africa. Kenya alone accounted for 7% of all adolescent HIV infections globally (5). In 2012, 13,000 children acquired HIV vertically and 104,000 children aged 18 months to 14 years were already living with HIV in Kenya (6, 7). With the advent of successful pediatric HIV treatment programs, more infected children are living into adolescence, thus uptake of care and adherence to treatment will be an increasing need (5, 8, 9). Adolescents require specialized care because adolescence is attended by unique physiological, developmental, and psychosocial changes that could potentially confound preexisting stressors associated with HIV infection (10-12). Unfortunately, there has been less programmatic focus on adolescent HIV care (2, 7, 13). There is need for more investment in evidence-based interventions that promote adolescent uptake of HIV care and reproductive services (7). From 2001 to 2012, adolescents are the only age group in which HIV-related deaths have increased (2), increasing by 50% compared to a 30% decrease in other age groups (10).

1.2 Adolescent HIV disclosure
Disclosure of HIV status is imperative for optimum treatment uptake and adherence to ART regimens among adolescents (12, 14-18). Furthermore, late, abrupt or inadvertent disclosure often has significant adverse effects on the child’s emotional and physical health including diminished trust in healthcare workers (HCWs) and caregivers, reduced adherence, increased rates of opportunistic infections, and fatalistic or suicidal mentalities. Disclosure should be a guided step-by-step process, progressing from partial to full disclosure depending on caregiver readiness and child’s maturity (19, 20). Full disclosure is defined as sharing HIV-specific information with the adolescent and naming the virus as “HIV.” In contrast, partial disclosure is defined as providing the adolescent with non-specific health information regarding their infection to account for clinic visits and the need for medication (21). Unfortunately, most adolescents living with HIV do not know their status in SSA (20-27). Kenya ART treatment guidelines stipulate that full disclosure occur by age 8 (28). In preliminary retrospective analyses of program data by CDC-Kenya, adolescent HIV disclosure was associated with improved retention and reduced mortality (29). Disclosure is a challenging process that requires a high level of support and guidance (10, 17, 30-33). However, rates of disclosure throughout adolescents in Kenya are not well known.

1.3 Adolescent sexual risk behavior
Prevalence of adolescent HIV and reproductive health knowledge and condom use is low (13, 34, 35). Lack of knowledge is likely due to a lack of programs and trainings for sharing reproductive and sexual health information with adolescents. In addition, adolescents are at high risk for risky sexual behavior, sexually transmitted infections (STIs), pregnancy, and pregnancy-related complications (13, 35). In 2008-2009, only 13% of sexually active adolescents used modern contraceptive methods. Given high rates of HIV transmission among adolescents and young adults, and their lack of sexual and reproductive health knowledge, there is ongoing need to increase comprehensive sexual health knowledge and access to reproductive health services for adolescents (3).

1.4 Current health programs for Adolescents living with HIV in Kenya
Though HIV and reproductive health services are widely available there are few designated adolescent facilities or services in Kenya (36). A substantial number of adolescents living with
HIV are not able to readily access sexual and reproductive health (SRH) services, leaving them at risk for STI infections, HIV re-infection, and pregnancy (28, 37). According to a report by FHI 360, although HIV programs include family planning services, these primarily target adults (36). In addition, the majority of infected adolescents are unaware of their status and HIV disclosure trainings and guidelines for health providers on disclosure to adolescents in Kenya are limited. Therefore, a nationally developed package of services for adolescents, that integrates HIV disclosure and reproductive health and can be uniformly implemented in public and private health facilities, is necessary.

1.5 Program innovation to be evaluated and the programmatic gap it will address
In response to the need for a systematic format for disclosure of HIV to HIV-infected adolescents in Kenya and provision of adolescent HIV and reproductive services, CDC and other partners supported the Kenya MOH to begin development of a comprehensive package of clinical and psychological services for adolescents known as the Adolescent Package of Services (APS). This package includes an adolescent care booklet developed by the Kenyan MOH (2013), a standardized checklist regarding adolescent services, health provider training materials, including disclosure guidelines and sexual and reproductive health education (SRHE), HIV care, and reproductive health services. The booklet details adolescent-specific clinical and psychosocial evaluation processes. The MOH-designed adolescent checklist is used to chart services offered to HIV-infected adolescents and adolescent outcomes. Gradual roll-out of the APS has started but uptake by clinics, and acceptability and feasibility of the materials has not yet been assessed.

1.6 Description of the Adolescent Package of Services
The APS entails components that have been developed by the MOH and those still undergoing development and refinement. Below is a detailed description of developed APS components:

1. Adolescent Care Booklet: Provides information on adolescent growth, development, HIV care, treatment and psychosocial management (Appendix 22)
2. Adolescent checklist: This is a data capture tool that is completed by the provider at each adolescent visit. It allows recording of services provided and milestones made toward partial or full HIV disclosure (Appendix 2)
3. Provision of HIV services: adherence counselling, HIV treatment, transition to adult clinic at >14 years of age, monitoring for and management of drug resistance
4. Provision of reproductive health services particularly condoms, contraception, pregnancy testing, STI screening and management, partner HIV testing
5. Health provider training including in-person case-based trainings and provision of materials (Appendix 23)

2.0 JUSTIFICATION
Multiple studies in Africa have described the challenges with adolescent HIV disclosure as a component of HIV care and treatment. There is an increasing awareness of the complexities around HIV disclosure to infected adolescents, the unique physiologic and psychological needs of HIV-infected adolescents, and the need for comprehensive adolescent HIV services that address disclosure, sexual risk behavior, and adherence to antiretroviral therapy. The objectives of this evaluation are to assess uptake and acceptability of APS and determine baseline rates and correlates of key adolescent health indicators. Results from this evaluation will identify gaps in training and implementation that need to be addressed moving forward.
3.0 EVALUATION OBJECTIVES

GENERAL OBJECTIVE:
To assess baseline health indicators among adolescents, determine which adolescent services are currently offered in health facilities, and evaluate the acceptability of the MOH APS.

SPECIFIC OBJECTIVES:
Objective 1: To assess HIV-specific and sexual and reproductive health outcomes in HIV-infected adolescents. We will perform a retrospective records review from a randomly drawn sample of clinics with electronic medical record (EMR) systems in place to determine current health indicator outcomes in adolescents. All data for this objective will be obtained from already existing EMR data and the adolescent checklist. This assessment will provide an important national baseline for adolescent health outcomes to which future studies evaluating the impact of adolescent interventions can be compared.

Primary outcome:
Baseline rates and correlates of the adolescent outcomes of retention in care and clinical HIV indicators (including viral suppression, CD4 count, and hospitalizations).

Secondary outcomes:
Baseline rates and correlates for disclosure, sexual and reproductive health outcomes in HIV-infected adolescents including STI screening, pregnancy rates, and uptake of contraception services.

Objective 2: To describe current SRHE and HIV-specific health provider services available and offered to adolescents using baseline health facility surveys. Baseline survey information will provide opportunity to understand current status and diversity of available adolescent-friendly services and awareness among health providers.

Objective 3: To determine the feasibility and acceptability of APS using focus group discussions and individual interviews with health providers, adolescents and caregivers of adolescents following roll out of APS. Focus group discussions (FGDs) and in-depth interviews (IDIs) will assess personal experiences with the implementation of APS. Better understanding health provider and patient experiences will provide opportunity for lessons learned and continued refinement of the intervention.

4.0 EVALUATION DESIGN AND METHODOLOGY

Design: The proposed evaluation is a mixed methods evaluation that will include a retrospective records review of adolescent HIV and SRHE outcomes, health facility surveys, health provider focus group discussions, and adolescent and caregiver in-depth interviews. A schematic of the assessment project details can be found in appendix 1.

Health Facility Baseline Surveys: A baseline survey will be administered to a facility manager or his/her designee in 102 HIV clinics selected among clinics with EMR systems in place. We will include a mixture of small, medium and large clinics.

Retrospective Records Review: This retrospective records review will utilize routine clinic program data, including the new APS checklist (appendix 2) when available, to assess adolescent HIV and reproductive health outcomes for up to 7000 adolescents enrolled in HIV care. We will determine rates and correlates of important HIV and SRH outcomes in HIV-infected adolescents.
A list of the demographic and HIV- and SRH-specific adolescent health outcomes being assessed can be found in appendix 3.

**Focus Group Discussions:** We will conduct a total of six FGDs with health providers (doctors, nurses, clinical officers, counselors). Participants will be selected from among APS-implementing clinics. Focus groups are useful in fostering rich discussion between group members. Participants’ comments stimulate the thinking and responses of others. Additionally, focus group discussions help to elicit divergent or convergent viewpoints among participants (38). Focus groups will be used to understand provider experiences providing adolescent services to HIV-infected adolescents and perspectives on usability and acceptability of APS among health providers and recommendations for improvement.

**Adolescent and Caregiver In-depth Interviews:** We will conduct up to 50 IDIs with adolescents and up to 50 IDIs with caregivers receiving care from APS implementing clinics to better understand their experiences receiving care from public health facilities after introduction of the APS.

We postulate that mixing qualitative and quantitative evaluation will provide opportunity for triangulation and convergence of findings. Triangulation is the combination of multiple methodologies in the study of a phenomenon (39). Multiple viewpoints of the same phenomenon increase accuracy of evaluation because convergence/agreement of multiple findings enhances validity of results (39).

**(i) Evaluation sites**
We will select up to 102 public clinics that are currently providing HIV services to adolescents to participate in baseline facility surveys and clinical outcomes assessments. The evaluation will include a stratified random sample of clinics. The sampling frame of all national facilities currently using EMR will be utilized in this approach. The sampling frame will also incorporate clinic size and include an even number of small, medium, and large volume clinics.

Focus group discussions will be conducted with healthcare providers and in-depth interviews will be conducted with adolescents and caregivers receiving care in a subset of APS-implementing clinics. For interviews and focus groups, clinics will be randomly selected from among the APS-implementing clinics included in the baseline survey and clinical outcomes assessment. To capture variability in services offered by clinic size, we will design our sampling frame to purposively select to include 2 small, 2 medium and 2 large clinics as sites for interviews and focus groups.

**(ii) Populations**
Stratified random sampling will be used to select up to 102 clinics based on clinic volume. The sampling frame of all national facilities currently using EMR will be utilized in this approach. We will exclude clinics with less than 300 HIV clients and divide the remaining clinics equally into tertiles. The tertiles will represent the small, medium, and large clinic sizes. Within each stratum, the clinics will be chosen using equal probability sampling and we will select 34 clinics per stratum. In-depth interviews will be done with up to 50 adolescents aged 14-19 years and up to 50 caregivers at APS-implementing sites from a range of clinic sizes. For the FGDs, due to the potentially small number of providers per site, we might combine providers from different sites to create groups of 5-10 participants per FGD. Up to 50 health providers (up to 10 per FGD) who offer care to adolescents living with HIV will be purposively sampled for FGDs. Based on previous experiences conducting interviews with health providers, children and caregivers in Kenya, we
anticipate that up to six FGDs, and up to 50 individual interviews with adolescents and caregivers, will be sufficient to reach data saturation (40).

### Inclusion and exclusion criteria

<table>
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<tr>
<th>Inclusion criteria</th>
<th>Facility survey</th>
<th>Retrospective records review</th>
<th>Adolescent interview</th>
<th>Provider FGDs</th>
<th>Caregiver interview</th>
</tr>
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<tr>
<td>&gt;10 HIV-infected adolescents (aged 10-19) or &gt;500 HIV+ clients enrolled in routine care; Existing electronic medical records (EMR) system Informed written permission obtained from clinics’ administrative teams</td>
<td>Aged 10-19 years of age Attended clinic ≥1 time after January 1, 2015 Attended clinic included in facility survey</td>
<td>Aware of HIV status; Enrolled in APS trained facility; 14-19 years of age Provide written assent or consent as age appropriate; Able to communicate in English, Kiswahili, Sheng or other relevant languages based on where activities are being conducted</td>
<td>Involved in adolescent HIV care; Provide care at APS trained facility; Provide informed written consent; Willing to attend scheduled focus group</td>
<td></td>
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<tr>
<td>Unable to collect data via EMR from the National Data Warehouse</td>
<td>None</td>
<td>None</td>
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### (iii) Sampling

#### Facility Surveys and Adolescent Outcomes Assessment

We will base our sample size on MOH facilities with EMR systems in place and current estimates of adolescent client volumes based on total HIV clients in care. We propose an evaluation with 102 clinic clusters, 34 per clinic cluster, and a maximum total sample size of 5,000 adolescents. For the retrospective records review, EMR records for all adolescents aged 10-19 from selected clinics will be included in the analysis. All adolescents who have at least one visit on or after January 1, 2015 will have their medical records pulled.

Based on previous data we will be able to identify 50 adolescents per clinic. Assuming a prevalence of 60%, an intra-class coefficient (ICC) of 0.05 and a clinic size of 50 we would need to select 102 clinics for estimating the expected proportion with a 2.5% absolute precision and 95% confidence. With an estimated minimum sample size of 5,000 adolescents who are enrolled in HIV care during the previous 12-24 months, the precision of the estimates across possible ranges (50%-90%) of prevalence of retention in care or viral load suppression will range from ±2.6% to ±1.5%. Thus, our study will have high precision in estimating the prevalence of retention in care and HIV viral load suppression, providing valuable input for understanding impact of interventions aimed at improving these adolescent HIV outcomes.

<p>| Precision estimates for prevalence of retention and viral load suppression in HIV-infected adolescents |</p>
<table>
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<tr>
<th>Indicator</th>
<th>Adolescents evaluated</th>
<th>Observed Prevalence</th>
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<td>Retention or suppressed viral load</td>
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<td>47.4-52.6%</td>
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<td>+/-1.5%</td>
</tr>
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Provider Focus Group Discussions
We will select healthcare providers from 6 APS-implementing clinics for FGDs. Clinics will be selected randomly from among those clinics involved in the facility survey that have had APS training. A total of 5-10 providers will be selected purposively from each site for a total of up to 50 health providers. We will specifically select healthcare providers who provide services for adolescents. To identify specific providers, we will approach the clinic supervisors at selected clinics to inform them of study. The clinic supervisors will identify health providers who work with adolescents and will refer interested healthcare workers to the research coordinator or interviewer. The research coordinator or interviewer will meet with healthcare workers, describe the study in more detail, and schedule interested healthcare workers for participation in the focus group discussion. For each clinic, if more than 10 participants are interested in participating, we will select those participating so that we have a broad range of health provider cadre’s represented. We believe this will give us adequate numbers to attain saturation during data collection and enough diversity in health provider cadre to ensure different perspectives are accurately represented.

Adolescent and Caregiver IDIs
We will conduct surveys with up to 50 adolescents (up to 10 per site at 6 sites) and up to 50 caregivers (up to 10 per site at 6 sites) at a random sample of APS implementing clinics selected from among those participating in the facility surveys and adolescent outcomes assessment. To capture variability in services offered by clinic size, we will specifically include 2 small, 2 medium and 2 large clinics as sites for interviews and focus groups. Participants within clinics will be randomly selected to participate. Clinic providers will assist in identifying and referring caregivers and adolescents who are aware of their HIV status. Eligibility of adolescents will be confirmed by reviewing their chart for documentation of disclosure. It will not be required that the adolescent and their caregiver both participate as a dyad.

5.0 PROCEDURES

a) Description of data to be collected
Health facility survey data: will be collected using Case Report Forms (CRFs) that will be administered orally over the phone or in person to the facility manager or his/her designee. See attached appendix 7 for the baseline survey CRF.

Adolescent outcomes assessment data: Routine clinic data will be abstracted from the EMR system and from the APS checklist paper forms when available. The EMR will contain data from the patient charts tracking routine services offered and laboratory measurements collected. EMR data will be abstracted from the National Data Warehouse. If clinic specific data is not available from the National Data Warehouse, hired technicians will travel to individual clinic sites to extract EMR data directly. Data from the APS checklist will be collected via the EMR system at sites with integrated electronic management of APS and via extracting data from paper forms within patient
charts for clinics without integrated APS checklist data collection in place. Additional data regarding adolescent health and adherence will be obtained from pharmacy records and laboratory records already incorporated into the EMR system. A list of variables that will be collected is attached as appendix 3.

Focus Group Discussion data: Focus group discussions will be conducted with the aid of a flexible semi-structured FGD guide. A draft guide is attached as appendix 10. The attached guide provides example open-ended questions. Discussion questions will focus on the services offered to adolescents through the APS and personal experiences with APS training and service provision. Discussion guides will be validated by piloting practicing the guides with a small subset of potential participants and/or study staff following initial IRB and ERC approval. During the piloting phase, interviewers and discussion leaders for each site will have the opportunity to practice asking and phrasing questions, determine whether the organization order of the guides are appropriate, and whether there is ample time to ask all of the questions posed in the draft guides. Following piloting of draft guides, final interview guides will be developed that include optimal phrasing, timing and ordering of discussion questions. The basic content included in the guides will not change between the pilot and final versions of the guides. Health providers will also complete short surveys to collect basic demographic information at the beginning of the interview. A draft survey is available as appendix 6.

Adolescent and Caregiver interviews: Individual interviews will be conducted using semi-structured interview guides. Adolescent interview questions will focus on personal experiences with HIV disclosure, seeking and receiving HIV treatment and care services, and seeking and receiving sexual and reproductive health services. Caregiver interview guides will focus on eliciting personal experiences of those involved in caring for HIV-infected adolescents centered on the topic areas of disclosure, HIV testing and treatment services, and sexual and reproductive health services. Interview guides will also include questions about the acceptability of APS. Adolescents and caregivers will complete short surveys to collect basic demographic information at the beginning of the interview. Draft surveys are available as appendices 4 and 5 and draft interview guides are available as appendices 8 and 9.

b) Recruitment procedures

Potential clinics will be recruited by sending letters to County health management teams to request for access and a formal letter of support to enroll these clinics (appendix 11). After county-level approval, we will send letters to administrative teams of randomly selected clinics. The letter will have information on the objectives of the evaluation and will include a formal request for the clinic to be part of the evaluation. This will be sent with a letter of support from the respective County Health Management Teams. Written permission to participate in the evaluation will be obtained from administrative authorities at health facilities of interest.

Health Facility Survey: For the health facility survey, we will ask the facility manager at each facility to identify an appropriate person to participate in a facility survey. We will either call or visit eligible health facilities to make this request. The participant will be either the facility manager or a designee identified by the facility manager (such as a provider who is involved in adolescent HIV care). A script outlining talking points for recruitment is attached as appendix 12. The facility survey will be conducted by phone. Prior to the phone interview, we will make a phone call or personal visit to the facility. The purpose of this call or visit will be to discuss the study procedures and review the consent form with the potential participant. Potential participants will also be given a time to ask any questions they might have about the study. If the facility manager or designee agrees to participate, study staff will schedule a time at a later date to complete the facility
questionnaire. During this initial call, we will also obtain an email address for the participant to send the consent and questionnaire for their review prior to our phone or in-person scheduled time for conducting the survey interview. If the facility manager or designee does not have access to email, the study questionnaire and consent form will be mailed by G4S courier service to the individual. Sending the consent and questionnaire to the facility point-person beforehand will give him/her ample time to prepare for the survey interview and sign and return a written consent form prior to the survey time. Participants with email will return the signed written consent form via email while those without email may return the signed consent form via G4S courier services. All survey participants will be reimbursed 500 KSH to cover the shipping costs or internet access data charges for returning consent forms. Refusal to participate in the survey will have no impact or repercussions for the health provider. In the event that a selected health provider is unable or unwilling to complete the baseline survey, they may refer the study staff member to another health provider in the facility that meets the eligibility criteria. Written consent will be given to conduct the survey.

Adolescent outcomes assessment: For obtaining data from participating clinics, a data technician employed by the National Data Warehouse will create a query to extract all specified variables (Appendix 8) for all clients between the ages of 10 and 19 from the EMR. All EMR records are stored centrally by the Ministry of Health in the National Data Warehouse. The query will pull records for all adolescents ages 10-19 years who have at least 1 visit on or following January 1, 2015 and attend a clinic selected to participate in the facility survey. This will include all data on each adolescent from January 1, 2015 up until the date when data is abstracted but not later than December 31, 2016. We will not obtain individual consent for pulling adolescent records from the EMR and will pull only de-identified data from the EMR. We will obtain a waiver of consent to obtain this information.

Focus group discussions: For the qualitative evaluation, health providers from APS-implementing clinics will be purposively sampled. All health providers (medical officers, nurses, physicians, counselors and psychologists) who currently work with HIV positive adolescents will be told about the study by study team personnel and offered the opportunity to participate. Specifically, study staff will visit the clinic and meet with health providers involved in the care of HIV infected adolescents and will verbally inform them of the study. A script outlining talking points for recruitment is attached as appendix 24. Those willing and eligible to participate will be asked to give written consent to be part of a focus group discussion and have the discussion audio recorded. It will be emphasized that participation is completely voluntary and failure to participate will have no repercussions on the provider’s employment. They will be asked to sign a written consent form. They will read through the consent form on their own. One of the study personnel will then go through it with them verbally and answer any questions they might have. Those who consent will participate in focus group discussion conducted by the study staff.

For IDIs, evaluation staff will recruit eligible adolescents or caregivers from pediatric/adolescent clinics or CCC settings. Routine clinical staff will help with recruitment. They will contact eligible adolescents and/or their caregivers to briefly describe tell them about the study. Caregivers and adolescents who are interested will be invited for eligibility assessment and participation. It will be emphasized that participation is completely voluntary. Eligible participants will undergo the informed consent (caregivers and/or adolescents ≥18 years of age) or assent process (adolescents ages 14-17). The age of majority in Kenya is 18 years of age. Adolescents enrolled that are 18 years of age or older will provide their own adult consent, without the need for parental consent. Adolescents who are between the ages of 14 and 17 will provide written assent and their parent or primary caregiver will provide written informed consent.
Specifically, adolescents who are 18 years of age or older, or caregivers of adolescents who are between 14 and 17 years of age, who are eligible to participate, will be identified by the HIV counselors and clinicians within their respective clinics and will be told about the study during a routine clinic visit or by a phone call from the provider. HIV counselors and clinicians involved in routine clinical care at selected clinics will be given a recruitment script with talking points to help guide them on what to say. A script outlining talking points for recruitment is attached as appendix 25. Adolescents, or caregivers of adolescents, who are interested in participating or having their adolescent participate, will be asked to either stay late that day or come to the clinic on a specific selected date to sign consent forms and participate in an individual interview.

When the potential participant arrives on the date of the interview, the adolescent or caregiver/adolescent team will go through a consent/assent process. During this time they will be informed of more details of the study purposes and procedures. Caregivers will be told that participation in the study will not affect their child’s or their own personal care at their clinic.

Adolescents younger than age 18 cannot provide informed consent but will be asked to provide assent. For adolescents younger than age 18, an age appropriate explanation of the study purpose and procedures will be given to the adolescent and the adolescent will be asked to give their assent to participate. In addition, the parent or legal guardian of the adolescent must provide consent on the child’s behalf. Caregivers willing and eligible to have their adolescent participate will be asked to sign a written consent form. Adolescents and caregivers will each read through the consent or assent form on their own and one of the study personnel will then go through it with them verbally. Those adolescents whose caregivers provide consent and who themselves give assent will become enrolled in the study and participate in an individual interview with study staff. This could be after one of their routine clinic visits or on a separate date.

Parents or caregivers with adolescents between the ages of 10 and 17 who are on regular follow up at the clinic will be eligible for the study. Parents or caregivers who are eligible to participate in the study will be identified by regular clinic staff (physicians, counselors, psychologists) during routine clinic visits or by reviewing patient charts and calling eligible caregivers. Routine clinic staff will be given a recruitment script with talking points to help guide them on what to say. A script outlining talking points for recruitment is attached as appendix 26. Caregivers will be told of the study in confidence without the knowledge of their adolescent. To ensure this confidentiality, caregivers will be told of the study only when meeting individually with the healthcare worker or over the phone. Caregivers will be told that participation in the study will not affect their child’s or their own personal care at the clinic. Caregivers interested in participating will be asked to return to the clinic to meet with study staff if recruited over the phone or sent directly to study staff if recruited during routine clinic visits for a more detailed description of the study and to obtain consent to participate. If the caregiver is interested in participating, the study staff will take them through the consent process. Those who provide consent are eligible to participate.

Caregivers willing and eligible to participate will be asked to sign a written consent form. They will read through the consent form on their own. One of the study personnel will then go through it with them verbally. Those who provide consent are eligible to participate in one of the study interviews.

Consent forms for all participants are attached as appendices (Appendix 13-19).

c) Facility Survey Procedures
Evaluation staff will call or visit each selected clinic and ask to speak with the facility manager or his/her designee (a provider who offers adolescent HIV/reproductive health services). Only
information on the cadre of health provider, age, sex and years of experience will be recorded; no other personal demographic information will be captured from health providers. The survey will be administered after obtaining written consent. To minimize disruption of participation in routine clinic activities, the survey will be conducted during a pre-arranged appointment time convenient for the participant. The questionnaire will be administrated over the phone or in person and will take approximately 20-30 minutes to complete. The provider will be required to have access to a quiet, private location during the time of the interview and will be asked to identify another time for the interview to take place if a quiet private location is unavailable during the time or recruitment or their previously pre-arranged time. No reimbursement will be provided other than for reimbursing costs associated with mailing consent forms to the main office in Nairobi. Once the survey interview is completed, hardcopies of survey responses will be stored without links to any identifiers, i.e. anonymously, in a locked cabinet in the UW KEMRI offices in Nairobi for up to six years. We will gather information on available adolescent friendly services. Information on the following topical areas will be obtained: number of adolescents in HIV care; adolescent HIV and reproductive services provided; health care provider training; presence and content of disclosure and SRHE guidelines; viral load testing procedures and ART provision, number of clinicians responsible for SRHE and HIV testing among adolescents; availability of peer groups; and important services lacking in clinics.

d) Adolescent Outcomes Assessment Procedures
Data will be collected from the National Data Warehouse in Kenya, a centralized location storing EMR data for all clinics in Kenya currently using an EMR system for collecting and storing patient information. We will obtain basic demographic and HIV-specific clinical care outcomes as detailed in appendix 3. Other services that will be assessed include: SRHE, sexual activity assessment; STI screening; contraception and condom supply for sexually active adolescents; pregnancy status assessment; ART adherence; annual viral load tests; and transition to adult clinic for those >14 years. This information will be charted as part of routine care in the MOH-designed adolescent checklist and EMR patient charts. Data pulled from the EMR will be downloaded or copied by data officers from Palladium, the group responsible for coordinating the National Data Warehouse.

Data stored in the National Data Warehouse are de-identified patient data containing health facility code, unique patient number (numeric code used in CCCs), sex, DOB, and other attributes. We will not collect the unique patient identifiers for this evaluation but will have the data officer facilitating data collection generate a new set of unique IDs not associated with their actual unique ID. Prior to data abstraction from the National Data Warehouse, permission to use the data will be obtained from Dr. Martin Sirengo, head of NASCOP, a collaborator on this evaluation. NASCOP can then make a request on behalf of the research team to Palladium (its technical assistance partner) to pull the study data from the NDW. They would presumably encrypt the data file and then transmit it to the research team. Because the data are de-identified data which were originally collected for the primary purpose of patient care, and the study is using the data in a secondary manner, we will not seek permission from the individual patients, facilities, or county health authorities to use the data. Instead, we will request a waiver of consent from local and UW IRBs for the use of this data.

Once obtained, the study team will follow UW-recommended procedures for transmission, storage, and access to data files. In alignment with these procedures, data will be stored on a password protected computer and data will be backed up daily to a password protected external hard disk located in the study data office and to a secure website. Backing up to a local external hard drive will enable rapid restoration of files in case of computer malfunction, and backing up
to the external website will ensure safety of the data in case of accent/fire/theft at the study data office.

e) **Focus Group Discussion Survey procedures**

Because FGDs may be conducted with providers recruited from different facilities, focus group discussions will be conducted at a centralized hotel or community center venue that has a quiet private meeting room. During FGDs, participants will meet with trained moderators and note takers in private rooms. With consent from participants, discussions will be audio-recorded. The moderators will describe the procedure for discussions and establish group norms for participation. Participants will be requested to keep the discussions confidential and talk to evaluation staff about the FGD procedures or ask questions. They will receive unique identification numbers and will not be addressed with their real names during discussions so as to maintain confidentiality. They will also complete a short demographic form to collect socio-demographic information and information on their background in providing clinical care. Their socio-demographic information will be recorded in separate forms from the interview data. Thereafter, FGDs will run for 1½ - 2 hours.

Discussions will be led by a trained facilitator using a semi-structured flexible data collection guide written in Kiswahili, Sheng, English or other language appropriate for the location where activities are taking place. The moderator will guide the flow of discussion and will document topics that generate the most discussion, participants’ attitudes, non-verbal gestures, body language, and interactions among group members. To ensure that no data are lost, notes will also be taken by a note taker during the interview. The note-taker will record; date, venue, participant information, unique identification numbers, and track participant responses. Neither the transcribed notes from the interviews nor the facilitator notes from the focus groups will include any personal identifiers other than the participant’s first name. Following participation in the FGD, participants will receive KES. 1000 ($11) as a token of appreciation for participation. Data will be transcribed verbatim to English and compared with audio-recordings to fill in missing information. A portion of translated transcripts will be back-translated to ensure accuracy. Collected transcript data will be de-identified and will be retained for up to six years. The audio recordings of focus group discussions will be destroyed after study participation and data analysis has been completed and no later than 5 years after the interview or focus group took place.

English transcripts will be uploaded to a password protected secure website for back-up. ATLAS.ti will be used for analysis.

f) **Adolescent and Caregiver IDI procedures**

IDIs will be conducted by a trained interviewer using a semi-structured flexible interview guide and will take approximately 60 minutes to complete. With consent from participants, discussions will be audio-recorded. At the beginning of the interview, interviewers will describe the goal of the interview and information about participation, including the ability to skip questions and the confidentiality of information shared. Prior to conducting the interview, interviewers will help the participant complete a short demographic form to collect socio-demographic information about the adolescent. Reimbursement for transportation costs, up to 500 KSH per participant, will be provided. Socio-demographic and interview data will be handled with the same approach as described above for the FGDs.

g) **Training Procedures**

Drs. McGrath, Beima-Sofie and Singa will supervise training of all study teams. This training will include training on study procedures, providing details of the purposes and procedures of the
study, good clinical practice (GCP), and human subjects training. Specifically, this will include training on interviewing, research confidentiality and participants’ rights, obtaining informed consent, completion of CRFs, record keeping, obtaining register data, evaluation of data, and quality assurance of entered data. Following the training, Drs. Singa and McGrath, in collaboration with Seattle-based staff, will help oversee the project staff and direct any additional follow-up study specific training.

h) Limitations

We recognize that clinics utilizing EMR systems for capturing patient information may not be representative of all clinics in Kenya and that selecting only sites with EMR systems in place may limit the generalizability of our findings. To minimize this limitation, we are collecting facility level data from the clinics that can be compared to facility level data from clinics without EMR systems in place to get a comparison of how similar or different clinics with and without EMR systems are in terms of these baseline data.

The strength of this proposal is the ability of qualitative methods to uncover detailed information about questions of interest. However, due to the nature of qualitative research methods, there will only be a small number of focus group discussions and interviews conducted, limiting the generalizability of the data collected. Although findings may not be generalizable to a larger audience, we believe that our results can help improve the current knowledge on the use and acceptability of APS and other adolescent services. In addition, to minimize this limitation, we will hire trained facilitators to optimize information elicited from these focus group discussions and interviews.

6.0 DATA MANAGEMENT

a) Data storage and disposition

Paper copies of data collected for the project will be entered into an electronic database; binders containing data will be stored in a locked cabinet in the UW KEMRI office in Nairobi and on a password protected computer. Audio recordings will be stored securely until they can be downloaded onto a computer at the research site. After audio files are downloaded they will be erased from the digital recorders, which will occur within 4-8 weeks of the focus group discussion or interview. All audio files will be stored in password protected files.

We only will collect personal identifiers for the purposes of identifying and contacting participants about the study. This information will include the names and telephone numbers for those identified as interested in participating in the study interviews (caregivers and adolescents) or focus group discussions (healthcare providers). We will also collect names and contact information for the clinic representatives participating in the facility surveys. This information will be used to contact participants to remind them of their upcoming focus group discussion, interview or survey time and also to contact them if they fail to appear for their scheduled focus group discussion or interview or unreachable during their scheduled survey time. This information will also be used to contact them again to verify the accuracy of the information collected or to elaborate on certain points raised in the discussion or survey following the completion of the interview, focus group discussion or survey if they select an option to be re-contacted on the consent form. We will not record identifiers, such as patient unique numbers.

All participants will be assigned a study identification number (ID) that is delinked and independent of their name and telephone number. For participants involved in interviews, focus groups and
surveys, participant identifiers, such as name and phone number, will be linked to their study ID. This link will be stored in a separate binder from their study data. This binder will be stored in a locked cabinet separately from all other data. Only necessary study staff will have access to this linkage binder.

A limited number of study staff will have access to patient identifiers and will not share this information with other study staff or with others outside of this study. Links between patient identifiers and unique study IDs will be kept for a maximum period of 5 years (December 2021) after the interview or focus group took place, at which time the link between patient IDs and identifiers will be destroyed. All consent forms will be kept in locked offices and file cabinets, and will be in separate files from data with identifiers.

We will not collect identifiers for the adolescent outcomes evaluation. This includes patient contact information such as address or phone number, name, and/or dates of birth/death. We will still collect date specific information. However, date information will be anonymized by shifting all date data collected by the EMR system by a random number of days. This will preserve the relationship between dates in the patient’s file but will limit the identifiable information shared with the study team. The number of days used for the date shift will be known only to the person responsible for compiling the data from the National Data Warehouse and delivering it to the study team.

All evaluation computers, other electronic data storage gadgets, and records will be stored in a secure room with access limited only to authorized personnel. All electronic databases used in this evaluation will be protected by procedures consistent with applicable laws, directives, policies, regulations, and standards in Kenya, where the data will be managed. Data held in U.S. Government offices will be subject to applicable U.S. law. Databases will not include patient identifiers and will be encrypted and password protected. Data will be backed up daily to an external hard disk located in the evaluation office in Nairobi, and to the UW mainframe “HOMER” via secure ftp. Backing up to a local external hard drive will enable rapid restoration of files in case of computer malfunction, and backing up to the external server HOMER will ensure safety of the data in case of accident/fire/theft at the evaluation data office. No data collected or abstracted from the database will contain personally identifiable information. De-identified data from this evaluation will be retained indefinitely.

b) Data entry, transcription and management
A Data Manager and Data Clerk in Nairobi will develop data entry standard operating procedures, oversee data quality, verification, range checks and procedures and coordinate merging data from all sites. The data manager will supervise the transition from data collection to data storage and ensure no duplicate entries or data errors. The database will be designed with variable range limits to minimize the possibility of inaccurate entries. Correct data entry will be validated by line-listing entered data against evaluation questionnaire.

Facility-level or patient-level outcomes will be obtained from training records or the checklist, patient charts, and electronic medical records respectively. Electronic medical records will be accessed from either facility or national-level. Data collection will be routine and all data will be transferred into a secure electronic evaluation database. Access to data for the analytical and program staff will be password protected. Only members of the research team will have access to the data. Data entry will be done by trained health providers, data specialists, and facility staff who are familiar with use of evaluation databases as well as with protection of human subjects. Prior to accessing any evaluation data, evaluation staff will be asked to sign a Data Use and Confidentiality Agreement (Appendix 20).
To ensure data quality, focus group discussions and interviews will be immediately translated and transcribed. We will set a maximum number of focus group discussions (1/study staff person/week) and interviews (4/study staff person/week) to ensure that the data collection and data transcription are occurring simultaneously and the unique characteristics of each focus group and interview are preserved before additional focus group discussions and interviews are conducted. All focus group discussions and interviews will be audio-recorded and transcribed verbatim. The audio recording and direct verbatim transcription will ensure that the discussion is recorded as accurately as possible. For each focus group discussion and interview, a contracted transcriptionist will transcribe the interview. A second researcher or study staff member will listen to segments of the audio recording and ensure that the transcription is accurate. In addition, transcripts and notes from focus group discussions and interviews will be reviewed by a trained social scientist to ensure that the approved protocol procedures are being followed.

c) Statistical analysis
Descriptive analyses
We will report the median and IQR clinic adolescent patient volume, number of trained health providers, and proportions of facilities with availability of APS tools such as disclosure and SRHE guidelines, and presence of any adolescent-specific service (peer groups, clinics etc.) For APS implementing facilities, we will perform descriptive analysis on disclosure status and receipt of APS services. Descriptive adolescent information will include socio-demographic characteristics, retention in care, and health status outcomes including adherence, viral load and CD4 count as well as adolescent disclosure, sexual and reproductive health outcomes. For both clinic level and adolescent level rates, we will use survey data analysis techniques to weight the estimates based on our stratified random sampling scheme. Correlates of adolescent outcomes of retention in care and clinic HIV indicators and adolescent disclosure, sexual and reproductive health outcomes will be analyzed using logistic regression. Multivariate logistic regression will be used to account for confounding. For adolescent level comparisons, we will use Generalized Estimating Equations (GEE) to account for the correlation within a clinic.

Qualitative data
Focus Group Discussions and In-depth Interviews will be analyzed using thematic network analysis and descriptive content analysis techniques to characterize and map the network of themes regarding the main topics of discussion. Content analysis and thematic description entail an iterative process of reading and coding the transcripts as the interviews and focus group discussion are completed, then re-reading the codes across the set transcripts to identify a network of related themes. A codebook will be developed for use by at least two coders who will analyze and validate the data.

d) Data ownership
The proposed project is a collaborative effort between investigators at the University of Washington, Kenya Ministry of Health, KEMRI/UON, and CDC. The University of Washington Kenya Ministry of Health, and KEMRI/UON will jointly share ownership of the data. Collected de-identified data will also be shared with the CDC. Authorship on publications, conference presentations, abstracts and other materials generated from this evaluation will reflect contribution to design, execution and analysis of the evaluation.

e) Data Release/Sharing Policy
In accordance with collaborating institutions, the data manager will develop procedures to ensure a standardized policy regarding data release/sharing following completion of data collection. It may be possible to establish a data-release review board to authorize public use of the data. Prior
to release/approval of data sharing, external parties must submit an outline of proposed analyses including background, specific aims, analysis methods, and timeline/procedures for dissemination of results. Further, all proposed analyses using the delinked, de-identified data must be accompanied by ethical approvals from appropriate institutional review boards or ethical review committees. Before release/sharing of data, all phases of data collection, design, analysis, storage, confidentiality, and dissemination will be evaluated for quality by evaluation co-investigators. All external parties will sign a public use data agreement prior to release/access of data.

7.0 EVALUATION TIMELINE
This project will take approximately 5 months to complete. We will allow 1 month for preparation including ethical approvals and training, 2 months for field activities and data collection, 2 months for analyses and mentored manuscript development.

8.0 ETHICAL CONSIDERATIONS

a) Human Subjects
This is a public health evaluation that will involve data analyses in Nairobi, Kenya and Seattle, Washington. Additionally, the evaluation will be conducted in collaboration with the KEMRI, Ministry of Health, CDC, and University of Washington. The Institutional Review Board (IRB) at the University of Washington and the Kenya Medical Research Institute (KEMRI) Ethical Review Committee (ERC) will review this evaluation. The protocol will also be submitted to CDC for scientific and ethical review. Since adolescents will be interviewed, the UN policy guidelines will be adhered to in order to ensure that adolescents are protected (Appendix 21)

(i) Risk to subjects
The possible risks are minimal though not less than what would be expected in routine settings. Key risks include:
- Breach of confidentiality if abstracted data is accessed by unauthorized individuals.
  i. We will conduct FGDs with health providers: there is a risk of loss of confidentiality if participants divulge the discussion or participant opinions to others outside the study.
  ii. We will conduct IDIs with caregivers and adolescents. Questions and issues discussed during interviews and counseling may be perceived as personal and sensitive and may cause psychological stress or discomfort for the participant.
    - By taking part in the interviews, others in the clinic may deduce that the caregivers and adolescents HIV+ status and introduce stigma.
    - Adolescents particularly may feel shy or embarrassed to share their personal information. They may feel coerced to participate.

(ii) Adequacy of protection against risks
- Evaluation databases will not contain patient names or identifiers and will be encrypted and password protected. All field staff that carry out evaluation procedures will undergo training on research ethics prior to intervention.
- FGDs: We will encourage participants to keep all discussions confidential and to discuss the evaluation only with study staff.
- To reduce HIV stigma associated with others in the clinic finding out an adolescent or caregiver might be HIV positive: We will ensure a private location for all interviews. We will also only recruit participants who are aware of possible disclosure of their HIV status or their
adolescent’s HIV status to others in the clinic by participating in the study and remain willing to participate.

- In order to minimize coercion, we will assure participants that there will be no negative consequences for declining to participate. Multiple “opt-out” options will be available for participants at consent, enrollment and participatory phases of evaluation.
- In order to minimize potential risks of stresses and discomfort associated with participating in interviews discussing sensitive topic areas, we will make sure to explain to each participant that they are not required to answer any question that makes them uncomfortable or do not want to answer and that they are able to withdraw from the study at any point in time.

(iii) Potential benefits of the proposed research to the subjects and others
This project evaluates an intervention to promote disclosure and optimize HIV management in adolescent groups. Disclosure and adolescent specific services have also been shown to improve uptake of HIV care and retention with implications on clinical outcomes of patients. This intervention will empower caregivers and increase provider skills to facilitate HIV disclosure and adolescents will receive the necessary support to cope with their HIV diagnosis. This is in contrast to current disclosure which is predominantly unplanned and occurs when adolescents are not adequately prepared. This could have negative psychological and emotional effects. This knowledge will also help inform the MOH, policy makers, and program implementers on promising strategies for improving adolescent HIV care.

(iv) Maintaining confidentiality of information
Delinked and de-identified data will be released by all institutions (UW, MOH, KEMRI/UON, CDC) for public use after the data has been collected, scrutinized for errors, validated, shared with any partners in data collection, and evaluation results are published. More specifically, de-identified data will not include any information that can be used to identify an individual. Identifiers to be excluded include: names, birth date, clinic visit date, biometric identifiers, and any other unique identifying number or code.

(v) Informed consent
This intervention will be at facility level therefore, informed consent will be sought from relevant county health management teams and facility administration teams. Because we will be collecting routinely collected demographic and outcome data as part of an MOH-supported evaluation, we will not seek individual patient consent. However, we will obtain individual participant consent for the FGDs and IDIs.

Collaborating sites
The evaluation will be conducted in collaboration with the KEMRI, Ministry of Health, CDC, and University of Washington. The evaluation will be reviewed by the KEMRI ERC and University of Washington IRB, and will not be started before approvals are obtained from all organizational review boards. For this specific evaluation, CDC collaborators will not be directly involved in fieldwork, data collection, evaluation recruitment or consenting processes, and CDC will not have access to identifiable data. Data analysis performed by CDC co-investigators and personnel will be performed using only de-identified data.

Study monitoring
As the study sponsor, the CDC may conduct monitoring or auditing of study activities to ensure the scientific integrity of the study and to ensure the rights and protection of study participants. Monitoring and auditing activities may be conducted by:
• CDC staff (“internal”)
• authorized representatives of CDC (e.g., a contracted party considered to be “external”)
• both internal and external parties

Monitoring or auditing may be performed by means of on-site visits to the Investigator’s facilities or through other communications such as telephone calls or written correspondence. The visits will be scheduled at mutually agreeable times, and the frequency of visits will be at the discretion of CDC. During the visit, any study-related materials may be reviewed and the Investigator along with study staff should be available for discussion of findings.

The study may also be subject to inspection by regulatory authorities (national or foreign) as well as the International Ethics Committees/Institutional Review Boards to review compliance and regulatory requirements.

Conflicts of interest

We acknowledge the potential for conflict of interest with NASCOP involvement is real as they supervise implementation of PMTCT programs. While this is a potential source of conflict, we believe that limiting NASCOP’s involvement in the protocol development phase mitigates this issue. NASCOP will not be directly involved in data collection or analyses, which are the key areas in which their interests could potentially influence interpretation of results. NASCOP will be asked to remain impartial to the presentation of findings and will not influence the scientific interpretation of results.

Dissemination plans

This evaluation will provide important information for public-health decision makers. The results of the evaluation will be presented to the Ministry of Health and National AIDS and STI Control Program (NASCOP) of Kenya and KEMRI. An oral debriefing and a written summary report will be provided by Ministry of Health and CDC staff jointly for participating clinics/health care providers and other stakeholders. Results from this evaluation will also be presented at national, regional, and international meetings, and submitted to international peer-reviewed journals. It is expected that the results of the evaluation will inform adolescent HIV programs about ways to improve uptake of services and retention in care, including revisions to the training and provision of APS, within Kenya and other resource-constrained countries.

9.0 EXPECTED APPLICATION OF RESULTS

This evaluation will inform the continued roll out of the national program on adolescent health outcomes and determine the acceptability and feasibility of the APS in Kenyan clinics.

10.0 REFERENCES


12. WHO. Strengthening the health sector response to care, support, treatment and prevention for young people living with HIV. 2006.


11.0 EVALUATION BUDGET
This proposal is CDC-funded. The budget for the evaluation supports staff, equipment, and supplies that will be used for the evaluation. Figures below reflect the currently proposed evaluation’s 18 month budget.

A) PERSONNEL- SALARIES AND DISBURSEMENTS: $138,271
B) PATIENT COSTS: NOT APPLICABLE
C) SUPPLIES AND EQUIPMENT: $20,278
D) ANIMAL ACQUISITION: NOT APPLICABLE
E) TRAVEL AND ACCOMODATION: $41,400
F) TRANSPORT (VEHICLES, REPAIR, FUEL): NOT APPLICABLE
G) OTHER EXPENSES (Communication cost, photocopy, it, Shipping, Qualitative research ETC): $15,000
H) CONSORTIUM/CONTRACTUAL COSTS-KEMRI; University of Texas: $47,744
I) CONSULTANCY IF APPLICABLE: $45,000
J) MISCELLANEOUS: NOT APPLICABLE
K) CONTINGENCY (%): NOT APPLICABLE

11.1 BUDGET JUSTIFICATION
This is an MOH/ CDC program intervention that will be funded and supported through CDC. Given that we will not be involved in the program’s day to day running or implementation, we will not be responsible for funding of transport/ vehicles, supplies and equipment, or patient costs. These costs will be covered by CDC and MOH. Our role will primarily be program setup and evaluation. We will cover associated costs for personnel, communication, IT, qualitative procedures and contractual costs which are outlined above.

12.0 INVESTIGATOR RESPONSIBILITIES
The UW team will be involved in the designing and planning of this proposed program evaluation. The team will develop training and study-related material and streamline submission of the protocol for IRB and KEMRI ERC review. The UW team will also oversee statistical procedures, program evaluation coordination, conduct analyses and manuscript development in collaboration with other partners.

Kenyatta National Hospital will be responsible for coordinating field teams in conjunction with KEMRI team. KNH will also provide additional oversight in data collection, data management, and manuscript development.

KEMRI team will oversee the subcontract at KEMRI for this program evaluation. In addition, KEMRI will manage data staff hiring and training, and ensure that staff and study procedures are in place and being followed.
ATTACHED:
   i. Overview of Evaluation: APPENDIX 1
   ii. Adolescent Checklist: APPENDIX 2
   iii. Data Collection Tools: APPENDICES 3-10
   iv. Letter to County Health Management teams: APPENDIX 11
   v. Informed Consent Forms: APPENDICES 13-19
   vi. Recruitment Scripts: APPENDIX 12, APPENDICES 24-26
   vii. Data Use Confidentiality Agreement: APPENDIX 20
   viii. Protocol Guidance Development for Surveillance, Research or Programs that Include Children who are Sex Workers, Trafficked or Victims of Violence: APPENDIX 21
   ix. APS book and training materials: APPENDIX 22-23