

The ATTACH Study:

Adolescent Transition To Adult Care for HIV-infected adolescents in Kenya
(ATTACH)



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LIST OF ABBREVIATIONS AND ACRONYMS

AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
ACP	American College of Physicians
ACT	Accelerating Children's HIV/AIDS Treatment
AIDS	Acquired Immunodeficiency Syndrome
ATP	Adolescent Transition Package
ART	Antiretroviral therapy
CCC	Comprehensive care clinic
CIPHER	Collaborative Initiative for HIV Education and Research
EMR	Electronic Medical Records
FACES	Family AIDS Care and Education Services
FGD	Focus Group Discussion
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
IeDEA	International Epidemiologic Databases to Evaluate AIDS
IDI	In-depth interview
KNH	Kenyatta National Hospital
LVCT	Liverpool Voluntary Counseling and Testing
MoH	Ministry of Health
NASCOP	National AIDS and STI Control Program
PEPFAR	President's Emergency Plan for AIDS Relief
RCT	Randomized controlled trial
SOC	Standard of Care
TRQ	Transition Readiness Questionnaire
UNAIDS	The Joint United Nations Programme on HIV/AIDS
US	United States
UW	University of Washington
WHO	World Health Organization

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PROTOCOL SUMMARY

Design

This implementation science research study aims to understand and implement best practices for adolescent “*transition*” from pediatric HIV care to autonomous adult care in Kenya.

To do this we will evaluate current transition procedures and rates in a large sample of HIV treatment programs, and will adapt, implement, and evaluate an Adolescent Transition Package (ATP) that combines existing transition tool and disclosure tools that have been validated in other populations.

The study will involve data abstraction and facility surveys to determine transition practices and co-factors of effective transition (AIM 1), adapting and optimizing a transition tool (AIM 2) and implementation and evaluation of the transition tool and a validated disclosure booklet (Adolescent transition package [ATP]) in a cluster RCT (AIM 3).

Population

Aim 1: Facility heads at a random sample of Kenyan clinics and routinely collected programmatic data on HIV-infected adolescents from the same clinics. Aim 2: Health Care Workers (HCWs) currently employed in HIV care services, HIV-infected adolescents and youth ages 14-24 years, caregivers of HIV-infected adolescents, facility administrators and policy makers at the national, county and program level. Aim 3: HIV-infected adolescents and youth ages 10-24 years and HCWs providing adolescent HIV care.

Sample size

Aim 1: 102 clinics providing HIV care in Kenya. Aim 2: 24 focus group discussions with adolescents and caregivers, and 68 interviews with health care workers, hospital administrators and policy makers; workshop with 12 HCWs. Aim 3: 20 clinics providing HIV care (10 randomized to receive the ATP and 10 standard of care [SOC]); Early-trial: Repeated surveys and FGDs with 200 implementing HCWs, 400 pre-trial surveys with adolescents; 200 pre-trial surveys with HCWs; During Trial: Repeated (6-monthly surveys) with up to 4000 adolescents; Post-trial: 96 interviews with adolescents and 48 in-depth interviews with HCWs, 400 post-trial surveys with adolescents and 200 post-trial surveys with HCWs.

Treatment

Aim 3: 10 clinics will receive the Adolescent transition package

Study sites:

Aim 1: Random sample of HIV clinics in Kenya. Aim 2: Interviews and focus groups at a sub-set of clinics participating in Aim 1, working group with HCWs from throughout Kenya. Aim 3: 20 HIV clinics in Nairobi, Homabay, Kajiado and Nakuru Counties.

Study Duration:

5 Years

SECTION 1: BACKGROUND INFORMATION AND LITERATURE REVIEW

1a. Background Information

With recent impetus to increase pediatric HIV diagnosis and treatment, an expanding number of HIV-infected children will reach adolescence and need to transition to adult HIV care. As has been seen with a variety of chronic diseases, there are challenges as children transition from pediatric to adult HIV care. Transitional care tools have evolved to help children, caregivers, and providers systematically optimize transition for children with chronic diseases in a variety of disease scenarios. These are largely untested or not used in settings with high HIV prevalence.

In Kenya, in large urban HIV Treatment Centers, children are seen in dedicated pediatric HIV clinics and transition to the separate adult HIV clinic at ~15-24 years of age. In other HIV Treatment Programs, children are seen on pediatric *days* with a team that may be identical or overlap considerably with the team providing care on separate adult care days. Finally, some clinics utilize the same team and days to offer care to children and adults, with a transition involved when a child no longer needs a caregiver/parent at visits and starts to receive independent care. In all scenarios, adult HIV care demands a higher level of autonomy and is associated with less specialized support than pediatric HIV care. **Well-conceived transitional models are needed because adolescents and young adults are a particularly vulnerable group. Adolescent HIV retention in care is lower than in adults, and adolescents have had increasing HIV-related mortality in contrast to declining mortality risk in adults.** This underscores the need for enhanced transitional care between pediatric and adult models of care.

In order for children to assume their own care, there must be accurate, well-conducted, and timely disclosure of their HIV status. However, in Kenya, we and others have noted that a large proportion of HIV-infected children have not been formally told they have HIV (disclosed) because of concerns of inadvertent disclosure to others, parental guilt regarding transmission, or concerns that the child will be unable to cope. Informing a child of any chronic illness is challenging because of a child's developmental limitations or because caregivers desire to protect children from negative consequences. However, delayed or poor disclosure practices can result in persistent mistrust of the health system. **Without disclosure, transition to adult HIV care cannot occur.** Disclosure to the child may also improve treatment adherence, physical health outcomes, and psychological adjustment to illness and family relationships. Programs are starting to address disclosure of HIV status to children, however, there are few systematic tools for disclosure and limited evaluation of impact of these tools. There is therefore an urgent need to develop interventions to assist HCWs with the challenging, but crucial process of HIV disclosure to children and adolescents.

Transitional care is a complementary urgent priority for aging children with HIV. **With poor disclosure and transitional care, adolescents will have higher morbidity, mortality, and risk of onward transmission.** There are huge gaps in HIV transitional care evidence-base – including the lack of a clear definition of transition, lack of evidence for effective transition tools, and challenges with integration of data from systems built separately for adults and children. We propose to evaluate rates and cofactors of effective transition in HIV Treatment Programs in Kenya and to adapt, implement, and evaluate an **Adolescent Transition Package** that combines an adapted US-based transition tool and a disclosure tool associated with improved disclosure outcomes in Namibia.

1b. Literature Review

Pediatric antiretroviral treatment (ART) coverage is rapidly expanding and children are surviving to adulthood

An estimated 2.6 million children under 15 years old are HIV-infected worldwide, almost 90% in Africa (UNAIDS 2015)[1]. To date, pediatric ART coverage has lagged behind adult coverage – the WHO estimated that only 32% of HIV-infected children <14 years old received ART in 2014 compared to 41% of HIV-infected adults[2]. To address this gap, the Accelerating Children's HIV/AIDS Treatment (ACT) program of PEPFAR, a \$200 million initiative, was initiated in 2014 to provide ART for 300,000 children with HIV in Africa[3]. Access to antiretroviral therapy (ART) has already improved survival of HIV-infected children and the ACT initiative will result in an increasing number of HIV-infected ART-treated children reaching adolescence and early adulthood [4-7].

Adolescents with HIV have unique needs and high risk for poor outcomes

An estimated 2.0 million adolescents (10-19 years old) worldwide are HIV-infected, and 220,000 adolescents aged 15-19 years old were newly infected in 2014. The majority (62%) of newly infected adolescents were female[8]. Unfortunately, global estimates of adolescent HIV and ART coverage are lacking because individuals between 10-15 years of age are considered children and those >15 years of age are considered adults. This makes it difficult to derive estimates for the group of adolescents and young adults between 10-24 years of age. In Kenya, an estimated 140,000 adolescents are HIV-infected, however, data are scant regarding adolescent ART coverage[8]. In a recent programmatic analysis of 22,832 adolescents and young adults aged 10-24 receiving ART in Kenya, young adolescents (aged 10-14) had a significantly lower CD4 at enrollment into HIV care than youth aged 15-24[9]. However, 15-24 year old youth had 2-fold higher loss to follow-up than younger adolescents. In another study of global trends, adolescents aged 10-19 years were noted to have a 50% increase in HIV-related mortality between 2005-2012 compared to a 32% decrease in non-adolescents during this same period[10]. This may be due to long-term complications from perinatally acquired infection or to poor adherence or motivation to continue in care. It is also possible that poor transition between pediatric to adult HIV treatment programs may contribute to poor adolescent outcomes.

Effective transition of children with HIV to self-directed health care requires disclosure of their diagnosis, however, pediatric HIV disclosure remains a challenge

In order for children to assume their own care, there must be accurate, well-conducted, and timely disclosure of their HIV status. Informing a child of any chronic illness is challenging because of a child's developmental limitations or because caregivers desire to protect children from negative consequences[11]. The complexities of disclosure are amplified for pediatric HIV because rather than affecting only the child, HIV is often a family infection and includes concerns about stigma and transmissibility [12-14]. Caregivers and HCWs are tasked with informing HIV-infected children that they have a chronic, potentially life-threatening, highly stigmatized disease during a critical time in the child's or adolescent's physical and psychosocial development.

Studies in African countries have noted low rates of disclosure ranging from 3-41%, including studies of older children and adolescents [15-22]. US and European programs report rates of disclosure ranging from 17-75% [23-30]. Median ages of disclosure for children in US and European studies (7.5-10 years) are lower than in studies from Africa (8.7-15 years)[16, 23, 27-33]. Rates of disclosure in Africa remain low even in programs where the majority of children (73-85%) are receiving ART [16, 21, 32]. Disclosure of HIV status requires that children comprehend information regarding the diagnosis and its implications. Thus, the age, cognitive development, and level of education of a child can significantly influence timing of disclosure [17, 21, 26-28, 32, 34].

Because pediatric HIV may result in neurocognitive impairments, emotional/cognitive maturity may be delayed therefore also delaying disclosure. In addition, caregivers are often reluctant to inform children of their HIV diagnosis because of concerns regarding inadvertent disclosure of the family's HIV status, perceptions of the child's inability to cope with results, and guilt regarding transmission [35-40]. Caregivers may have witnessed children lose friends and social standing when their status became known [41, 42]. Caregivers, who are often also infected with HIV, may have had difficulty when they learned their own HIV status, which then impacts their perception of the benefits of disclosure. Previous studies have demonstrated that the HIV serostatus of the caregiver is a key factor in disclosure [17, 28]. Among HIV positive caregivers, studies in Europe, South Africa, and Ethiopia observed that caregivers who had disclosed their own status were more likely to have also disclosed the child's status to the child [17, 19, 27].

Despite these challenges, disclosure to the child may improve treatment adherence, physical health outcomes, and psychological adjustment to illness and family relationships.[43-46] Furthermore, late, abrupt or inadvertent disclosure often has significant adverse effects on the child's emotional and physical health including diminished trust in Health Care Workers (HCWs) and caregivers, reduced adherence, increased rates of opportunistic infections, and fatalistic or suicidal mentalities. A 2014 national study in Kenya showed that adolescents who know their status had significantly lower rates of mortality and higher retention in HIV treatment programs[47]. Knowledge of HIV status has a potential public health benefit in that infected adolescents who know their HIV status may be more likely to use available HIV preventive interventions. The World Health Organization (WHO) and Kenyan guidelines recommend that school-aged children be fully informed of their HIV diagnosis and younger children told partial information about their diagnosis[48]. However, neither set of guidelines provides specific approaches for implementing disclosure in practice, nor do they accurately address the real world challenges HCWs and caregivers are encountering [48-50].

Adapting validated disclosure interventions may improve disclosure rates and experiences for HIV-infected adolescents

There is an urgent need to develop interventions to assist HCWs with the challenging, but crucial process of HIV disclosure to children and adolescents. We evaluated a disclosure tool used nationally in pediatric HIV treatment and care programs in Namibia and saw improved confidence in and comfort with disclosure in HCWs and caregivers, and improved knowledge and clinical outcomes in children exposed to the intervention[51]. The disclosure intervention is intended to be used with children aged 6-18. The centerpiece of the intervention is a 5-chapter cartoon book which uses empowering language and metaphors of body soldiers being strengthened by medicine (ARVs) and keeping the "bad guys" (HIV virus) asleep. The further the child progresses in reading the book, the more information about his or her disease and the role of medications is revealed. It is not until Chapter 5 that the words "HIV" or "ARV" are mentioned. A portion of the book is read, or re-read, at each visit by a HCW until the caregiver and child are ready to read Chapter 5 in which full disclosure occurs. The chapters are read in a highly interactive manner with each one taking approximately 5-10 minutes to complete the first time it is read. A disclosure form is attached to the patient care booklet on which the HCW notes how far in the disclosure book the child has gone at each visit and why the child thinks they are taking medicine. These notations help HCWs check comprehension and strengthen continuity across visits. A readiness assessment form helps HCWs assess the child's and family's readiness to engage in the full disclosure process. The intervention also includes HCW training on pediatric disclosure and the intervention tools. The Namibian disclosure intervention provides a helpful tool that could be adapted and used in other settings to improve rates and experiences with HIV disclosure.

Transition models are in standard use for varied diseases

The model for transitional care recommended by the American Academy of Pediatrics (AAP), American Academy of Family Physicians (AAFP), and American College of Physicians (ACP) is based on expert consensus and initiates discussion of transition at 12 years of age and includes standardized age-triggered actions to enhance transition[52]. General resources to guide transition aligned with the AAP, AAFP, and ACP Clinical Report on Transition have been recently developed by the Got Transition/Center for Health Transition Improvement (<http://www.gottransition.org>). These include 6 Core Elements: 1)Transition Policy, 2)Transition Tracking and Monitoring, 3)Transition Readiness, 4)Transition Planning/Integration into Adult Approach to Care, 5)Transfer to Adult Approach to Care, 6)Transfer Complete, Ongoing Adult Approach to Care. The guidance incorporates a framework that includes child, caregiver and HCW readiness for transition and involves a several year process with repeated iterative planning towards transition. This model is useful both for children who switch from pediatric to adult health care providers and for children who retain their provider but transition to an adult approach to care. In both models children need to transition to independent care when they reach adulthood. Regardless of program structure, it is important to systematically incorporate transition planning with input from primary caregivers, adolescents, and HCWs to ensure a smooth transition to autonomous care.

Transitional care models are not yet well-defined for HIV

As many children survive to adulthood with a variety of chronic diseases, models of transitional care have evolved to address the challenges of navigating transition. Recently Zhang and colleagues conducted a systematic review of transitional care models; the review identified 10 transition tools, 7 of which were disease specific, only 1 of which addressed HIV[53]. The HIV model utilized the Transition Readiness Questionnaire (TRQ), which included 21 questions to assess readiness for transition. The TRQ score improved following a transition program. However, it is not known if the TRQ was useful in predicting transition readiness. All published transitional care tools in the systematic review were from US or high-resource settings and none have been evaluated for impact on transition outcomes. The results of the systematic review illustrate the need for transition tool use and assessment in high HIV prevalence settings, such as Africa. The Collaborative Initiative for Pediatric HIV Education and Research (CIPHER) of the International AIDS Society and the leDEA Coordinating Center Vanderbilt University convened a workshop in 2015 to focus on adolescent HIV transition[54]. As part of the workshop, Soeters and colleagues summarized data from 218 facilities in 23 countries, focusing on adolescent HIV services. In this WHO supported survey, an estimated 51% of facilities included some process to guide 'transition' and the mean age of transition was 18 years of age. Most clinics had clinic days dedicated to either adult or pediatric services. The 2015 CIPHER Adolescent Transition Report highlighted huge gaps in transitional care evidence-base – including the lack of a clear definition of transition, lack of evidence for effective transition tools, and challenges with integration of data from systems built separately for adults and children[54].

1c. Rationale

As many HIV-infected children on ART survive to adulthood in sub-Saharan Africa, improving systems for disclosure and transition to adult care is a high priority. There is need for better data on transition in high volume HIV clinics in Africa, and these clinics require feasible and effective systematic approaches to improve disclosure and transition. A disclosure tool used in Namibia demonstrates effectiveness and acceptability and could be adapted for use in other settings. In addition, the Got Transition model, which was developed following broad expert consensus and programmatic evaluation in US settings, has a clear framework and useful resources relevant to pediatric HIV transition in Africa. Combining these interventions using an implementation science approach (program evaluation, adaptation and a cluster RCT) has potential to provide high quality

evidence for broader use of these approaches and to improve long-term outcomes for adolescents with HIV.

SECTION 2: OBJECTIVES

2a. Study Objective

This study aims to evaluate rates and co-factors of effective transition in HIV treatment programs in Kenya and to adapt, implement, and evaluate an Adolescent Transition Package (ATP) that combines an adapted US-based transition tool and a disclosure tool associated with improved disclosure outcomes in Namibia.

2b. Specific Objectives

Aim 1: To use programmatic data (KenyaEMR and paper files) to estimate prevalence of transition and disclosure, age at transition and disclosure, and individual-level co-factors of effective transition from pediatric to adult HIV care and retention and HIV disclosure among 10-24 year olds. To determine transition practices in Kenyan clinics using a facility survey.

Effective transition will be defined as enrollment into adult care within 6 months of exiting the pediatric care and continued clinical follow-up for at least 6 months thereafter, as evidenced by a second clinic visit recorded in the EMR.

Hypothesis: Transition will occur at varied ages (median 18 years); effective transition and earlier transition age will be associated with the presence of a transition plan and adolescent friendly services at the facility, later age at child HIV diagnosis, earlier age of HIV disclosure, parent on ART, better health status of the child at enrollment into HIV care and at transfer (CD4, WHO stage, viral load), pregnancy or marital status of the adolescent, and evidence of consistent adherence and retention prior to transition.

Approach: *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 adolescent health data for this objective will be obtained from existing medical record data, including EMR data, paper records, and the adolescent checklist. Concurrent with data abstraction, we will conduct facility surveys to determine pediatric clinic model (separate days or integrated), presence and type of transition planning approach, recommended age for transition, and available adolescent and transition services.*

Secondary Analysis: To determine baseline rates and correlates of other key health indicators for adolescents with HIV, including viral suppression, CD4 count, ARV regimens and switch to second line therapy, adherence, and other sociodemographic, physical and mental health information captured in existing medical records. Information from this secondary analysis can help inform other factors delaying or influencing disclosure and transition readiness and occurrence.

Aim 2: To adapt and optimize a transition tool (Got Transition; <http://www.gottransition.org/>) developed in the US, for use Kenyan HIV clinics based on adolescent, caregiver, HCW, clinic and country administrator, and policy maker perspectives.

Hypothesis: The US 'Got Transition' tool will be adaptable and relevant for pediatric HIV transition in Kenya.

Approach: *We will conduct semi-structured focus group discussions with adolescents and caregivers and individual interviews with HCWs, facility administrators and policy makers to*

understand experiences, challenges and potential solutions for transition and use this information to adapt and refine the transition tool. We will hold a working group meeting with purposively selected HCWs to further adapt the transition tool.

Aim 3: To evaluate the Adolescent Transition Package (ATP) in a cluster randomized trial of 20 clinics (10 with ATP and 10 with Standard of Care (SOC) processes). The Adolescent Transition Package (ATP) will contain a validated disclosure tool and the optimized transition tool from Aim 2.

Hypothesis: ATP will increase proportion of younger adolescents with disclosure, will result in earlier disclosure, will increase proportion of older youth ready to transition to adult care and improve satisfaction with transition.

Approach: *We will randomize 20 clinics to receive the ATP or no intervention (SOC) and compare disclosure and appropriate transition using pre-specified milestones among a group of adolescents with heterogeneous ages. During early implementation, we will monitor fidelity to the intervention using modified plan-do-study-act (PDSA) cycles. We will track implementation outcomes and factors influencing implementation during the initial ATP implementation phase (6 months). During this time, the study team will discuss and support changes to refine the tool as needed at each facility. Following the initial implementation period, HCWs will take part in focus group discussions to share their suggestions for optimizing the transition tool based on their experience. Understanding personal experiences with the tool will provide an opportunity for lessons learned and continued refinement of the intervention. At the end of the study, we will qualitatively evaluate acceptability, appropriateness and feasibility of the ATP by conducting interviews and FGDs with all HCWs from implementing sites and adolescents from a sub-set of intervention sites, purposively selecting to include participants from high and low performing facilities. We will also conduct pre-trial and post-trial surveys with adolescents and HCWs to quantitatively assess acceptability, appropriateness, feasibility of the ATP and implementation intervention fidelity. At 6-monthly intervals, we will collect readiness assessment information from adolescents in participating clinics.*

SECTION 3: STUDY OUTCOMES

Aim 1

- Prevalence of transition
- Age at transition
- Co-factors for retention
- Age at disclosure
- Co-factors of disclosure
- Individual level co-factors of effective transition
- Facility level co-factors of effective transition

Aim 2

- Adapted transition tool

Aim 3

- The primary outcome is **disclosure** among non-disclosed adolescents and **effective transition and transition readiness** among disclosed adolescents

- Disclosure will be defined as no, partial or complete disclosure. Time to disclosure and age at disclosure will also be assessed.
- Effective transition with retention in care will be defined as completing a visit on the adult day or completing a visit without a caregiver and repeat visits continuing for at least 6 months after transition.
- Transition readiness will be defined as change in response to readiness assessment questions administered every 6 months
 - We will also evaluate other key behavioral indicators of transition identified in AIM 2 as being associated with successful transition and included in transition study tools such as clinic attendance without a caregiver present, complete comprehension of ARVs and importance of adherence, and knowledge of and future plan for HIV management. Time to and age at effective transition will also be assessed.

The intervention period is not long enough to observe all adolescents passing from disclosure to effective transition; however, the use of milestone-specific outcomes among a group of adolescents within a heterogeneous stage of transition allows assessment of the full transition process. Adolescents will be observed during the portion of the transition process that they undergo, and milestone-specific achievement within their transition stage will be assessed. For example, an adolescent who is undisclosed at the beginning of the study will be assessed for whether they have completed no, partial, or full disclosure by the end of the study. Fully disclosed adolescents will be assessed for their progression to independent care within the adult system. The specific indicators for progressing beyond disclosure will be based on the adaptation of the Got Transition tool in aim 2. The first 6 months of the intervention will be considered a “catch up” period; while outcomes will be compared during the full study period, a sub-group analysis is planned for the first 6 months to see if the effect of the intervention is greater during the “catch-up” period.

- Secondary outcomes
 - Overall viral suppression
 - Overall retention
 - HCW and adolescent satisfaction with the transition process
 - Selected cost measures to be used in future cost-modeling
 - Age at and time to reaching transition specific-milestones
 - Acceptability and feasibility of the intervention
 - Intervention adaptation and fidelity to intervention implementation
 - Penetration and adoption of the ATP during implementation

Table 1 summaries the outcomes, metrics and data sources for aim 3.

Table 1: Outcome, metric and data source

Analysis Type	Group	Outcomes	Outcome metric *	Data source
Quantitative	Non-disclosed adolescents	Disclosure	Proportion initiated disclosure intervention	Disclosure checklist

			Proportion reached complete disclosure	
			Age at and time to disclosure	
			Satisfaction with disclosure	Post-trial surveys
Quantitative	Disclosed adolescents	Transition and readiness	Change in transition readiness over time	Transition readiness assessment
			Proportion of adolescents who initiate and exit pediatric care	Transition checklist
			Proportion with effective transition	
			Age at and time to transition	
			Satisfaction with transition	Post-trial surveys
Qualitative and Quantitative	Adolescents and HCWs	ATP Implementation	Acceptability of ATP	In-depth interviews, FGDs, and pre, during and post-trial surveys
			Feasibility of ATP	
			Appropriateness of ATP	
			Intervention Adaptation and Fidelity	
			Penetration and Adoption of the ATP	

*Additional transition process indicators and data sources will be included after the adaptation of the transition tool. For example we will identify specific outcomes from the adapted tools to track the transition process before full transition occurs.

SECTION 4: STUDY DESIGN

Design Overview: We will use mixed methods approach to describe current processes, adapt intervention tools and implement a package of tools for adolescent transition to adult care. Our methods include 3 distinct processes over formative and evaluative phases (Figure 1a):

Formative phase:

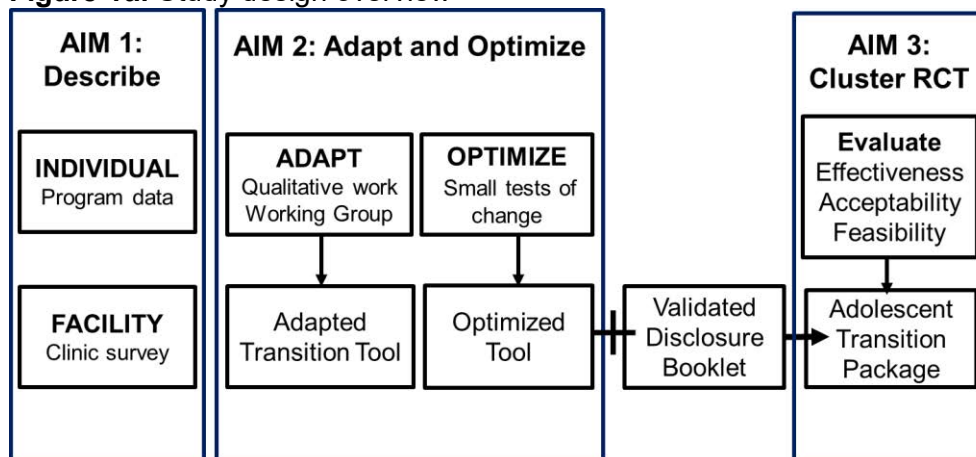
- 1) A retrospective records review of adolescent HIV outcomes and health facility surveys assessing current transition practices and gaps

2) Policy maker, hospital and county administrator, HCW, caregiver and adolescent interviews and focus groups, and a HCW working group meeting to develop, adapt, and refine the transition tool

Evaluative phase:

3) A cluster RCT to evaluate effectiveness, acceptability, appropriateness, feasibility, and intervention fidelity of the ATP intervention.

Figure 1a: Study design overview



Aim 1:

Retrospective Records Review: This retrospective records review will utilize routine clinic program data, including the Adolescent package of Services (APS) checklist, recently rolled out in Kenya, when available, to assess adolescent HIV health outcomes related to transition for up to 15000 adolescents enrolled in HIV care at participating facilities. We will determine rates and correlates of important transition outcomes in HIV-infected adolescents.

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

Aim 2:

Adaptation Interviews and focus groups: We will conduct 8 focus group discussions with caregivers of HIV-infected adolescents, 16 focus group discussions with adolescents and youth, 38 IDIs with HCWs from 6-10 clinics participating in the facility survey and 30 IDIs with hospital administrators or policy makers at national and county level. Clinic sites will be purposively selected from among those included in the facility survey (Aim 1). We will use stratified purposive sampling to recruit adolescents and caregivers of adolescents to capture adolescents who have and have not yet transitioned to adult care. We will use purposive sampling to include clinics with varying models of providing care for youth, including models where the same providers care for adults and youth, and models where different providers care for adults and youth. We will use information from the facility survey to identify different care models. We will use purposive sampling to recruit HCWs, policy makers and hospital administrators who can speak most knowledgably about adolescent HIV care. HCWs will also be recruited to include representation from clinics with different models of care. Interviews will be conducted with policy makers, HCWs and hospital administrators to accommodate busy schedules and ensure participation. We will purposively select policy-makers involved in assisting with development or implementation of

adolescent HIV care and treatment policies in Kenya. Interviews can provide rich data about personal experiences and rationale informing decision-making. Focus group discussion can provide important information on the range of experiences and beliefs in thinking about a topic and group discussion can help stimulate thinking by other group members. Focus group discussions with adolescents and their caregivers will provide information on experiences receiving HIV care for the adolescent and opinions on support and strategies for transition.

Working Group Meeting: We will host a 2 day working group meeting with a purposively selected group of an estimated 40 HCWs and policy makers to inform the adaptation of the Got Transition tool. We will present analyzed interview data to HCWs and use a targeted agenda to adapt tools for use in Kenyan clinics, ensuring adapted tools incorporate the views of all stakeholders. Selected HCWs will have expertise in caring for HIV-infected adolescents in varied settings throughout Kenya.

Aim 3

We will conduct a cluster RCT to evaluate a combined disclosure intervention and adapted transition tool (ATP) to increase disclosure among young adolescents and improve effective transition to adult care for pediatric patients. Cluster RCTs are well-suited to interventions that occur at the clinic, rather than individual level. The randomization at a clinic level allows for the traditional benefits of randomization. We will include a total of 20 clinics in the RCT, 10 receiving standard of care and 10 receiving the intervention and compare disclosure and transition outcomes between the 2 arms. We will periodically abstract routinely collected medical record information to determine proportions of adolescents with full disclosure and transitioned to adult care in addition to routinely extracting data from study data collection tools. We will conduct pre-study baseline surveys with adolescents and HCWs. We will also monitor initial implementation using modified plan-do-study-act cycles and surveys and FGDs with implementing HCWs. At the end of the study, we will conduct qualitative interviews and focus groups with adolescents and HCWs in the intervention sites and post-study surveys with adolescents and HCW to assess acceptability, appropriateness, feasibility, and intervention fidelity of the tools. Throughout the study, at 6-monthly intervals, we will collect readiness assessment data from adolescents and young adults ages 15-24 who have attained full disclosure.

SECTION 5: STUDY SITES AND POPULATIONS

5a. Study sites

Aim 1: We will perform facility surveys and abstract routinely collected programmatic data at 102 clinics in Kenya utilizing EMR systems. Clinics will be randomly selected from among clinics with EMR.

Aim 2: We will recruit HCWs from clinics throughout Kenya for the working group meeting. We will select caregivers of HIV-infected adolescents, HIV-infected adolescents, and HCWs from KNH and 6-10 facilities participating in AIM 1 for individual interviews and focus groups. We will invite policy makers from national and county level institutions and hospital administrators from facilities participating in Aim 1.

Aim 3: We will enroll 20 clinics located in Nairobi, Homabay, Kajiado and Nakuru counties. Adolescents and HCWs in intervention sites will participate in post-trial interviews, HCWs from intervention sites will participate in pre and post-trial surveys, PDSA cycles and FGDs, and a

sample of adolescents in all sites will participate in pre and post-trial surveys. Adolescents and young adults will also participate in 6-monthly readiness assessment surveys.

5b. Study population

AIM 1:

Facility Survey: 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 patients in HIV care, given that the number of adolescents attending the clinic would be small and hard to evaluate, 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. One or two designees per facility will be enrolled to complete the facility survey.

Retrospective Records Review: The study will include extraction of routinely collected health records of up to 15,000 adolescents aged 10-24, currently engaged in HIV care in Kenya and attending the facilities included in the facility survey.

AIM 2:

Adaptation Interviews (Table 2): We will conduct 16 focus group discussions with HIV infected adolescents aged 14-24 years, 8 focus group discussions with caregivers of HIV infected adolescents aged 14-24 years, 38 interviews with HCWs providing pediatric and adolescent HIV care, and 30 hospital administrators and policy makers identified by national and local health administration offices. We will recruit adolescents, primary caregivers and HCWs from KNH and 6-10 facilities that participated in Aim 1.

Working Group Meeting: For this aim of the study, we will enroll approximately 40 HCWs from clinics throughout Kenya providing HIV care for adolescents.

Table 2: Purposive sampling scheme and data collection details for Aim 2

Focus Groups and Interviews to DEVELOP										Working Group to ADAPT/REIVSE	
Already Transitioned HIV-Infected Adolescents: Ages 16-24 years (N=48 adolescents)					Healthcare Workers (N=38 healthcare workers)					Policy-makers & Administrators	Healthcare workers
Sampling Categories		Clinic Design			Sampling Categories		Clinic Design				
		Same providers; same day/clinic	Same providers; different day/clinic	Different providers; different day/clinic			Same providers; same day/clinic	Same providers; different day/clinic	Different providers; different day/clinic		
Transition Tools	Yes	N/A	2 FGDs (5-6 adolescents in each)	2 FGDs (5-6 adolescents in each)	Transition Tools	Yes	6 IDIs	6 IDIs	10 IDIs	N = 30	N = 40
	No	N/A	2 FGDs (5-6 adolescents in each)	2 FGDs (5-6 adolescents in each)		No	N/A	6 IDIs	10 IDIs		
Disclosed but Not Transitioned HIV-Infected Adolescents: Ages 14-19 years (N=48 adolescents)					Caregivers of HIV-Infected Adolescents: Ages 14-24 years (N=48 caregivers)					National and County Ministry of Health representatives, Facility administrators	2-day workshop with experienced HCWs and policy makers involved in HIV treatment and care provision
Sampling Categories		Clinic Design			Sampling Categories		Clinic Design				
		Same providers; same day/clinic	Same providers; different day/clinic	Different providers; different day/clinic			Same providers; same day/clinic	Same providers; different day/clinic	Different providers; different day/clinic		
Transition Tools	Yes	N/A	2 FGDs (5-6 adolescents in each)	2 FGDs (5-6 adolescents in each)	Transition Tools	Yes	N/A	2 FGDs (5-6 caregivers in each)	2 FGDs (5-6 caregivers in each)		
	No	N/A	2 FGDs (5-6 adolescents in each)	2 FGDs (5-6 adolescents in each)		No	N/A	2 FGDs (5-6 caregivers in each)	2 FGDs (5-6 caregivers in each)		

AIM 3:

We will enroll 20 facilities to participate in the cluster RCT. The intervention will involve working with and training HCWs at selected facilities and abstracting routinely collected programmatic data for HIV-infected adolescents aged 10-24 years attending the selected clinics (Table 3). We will also routinely abstract data from intervention tools being used at the facilities. We anticipate including up to 200 HCWs per intervention arm in the HCW training and intervention implementation and up to 2000 adolescents per arm. We will also enroll 400 adolescents and 200 HCWs to complete pre-trial surveys and 400 adolescents and 200 HCWs to complete post-trial surveys. HCWs from implementing sites will also participate in repeated surveys and planning meetings twice per month during the first 6 months of implementation of the ATP. We will conduct semi-structured interviews with up to 96 adolescents and 48 HCWs from a subset of 6 clinics included in the intervention arm of the trial. We will also complete FGDs with all HCWs from implementing facilities at 6 months into and at the end of the trial. At 6-monthly intervals, we will collect readiness assessment data from adolescents and young adults ages 15-24 years who have attained full disclosure.

Program data abstraction: We will abstract program level data at baseline, and throughout the RCT to assess outcomes. Table 3 summarizes enrollment characteristics and data collection tools in the RCT arms.

Table 3: Details of cluster RCT design, enrollment and data collection

	Control arm	Intervention arm
Required Facility Characteristic	>300 clients in HIV care	>300 clients in HIV care
Estimated number of clients aged 10-24 per clinic	50-500	50-500
Minimum number of clients aged 10-24 per RCT arm	2000	2000
Procedures	Standard clinic procedures	Adolescent transition package
Disclosure checklist	√	√
Transition checklist	√	√
Process indicators	-	Disclosure milestones Transition milestones HCW, caregiver and client satisfaction
Maximum number of adolescents completing pre-trial surveys	200	200
Maximum number of HCWs completing pre-trial surveys		200
Maximum number of HCWs participating in repeated surveys and planning meetings		200
Maximum number of HCWs participating FGDs at 6 months		200
Maximum number of adolescents completing readiness assessment form	2000	2000
Maximum number of adolescents completing post-trial surveys	200	200
Maximum number of HCWs completing post-trial surveys	-	200
Adolescents completing IDIs	-	96
HCWs completing post-trial IDIs	-	48
HCWs completing post-trial FGDs		200

Justification for involvement of adolescents: In sub-Saharan Africa, HIV-infected adolescents are at high risk of loss to follow-up and poor adherence resulting to poor outcomes. The purpose of this research is to improve adolescent HIV disclosure processes and transition to adult care, therefore improving retention in care and morbidity and mortality outcomes in HIV-infected adolescents. Collection of data about adolescents and from adolescents is necessary to determine the effectiveness of this intervention aimed at improving adolescent HIV care.

5c. Participant inclusion criteria

To be eligible for this study, an individual or clinic must meet the criteria listed in Table 4 below. Additional details related to participant inclusion are outlined below.

Aim 1:

To participate in Aim 1, facility leadership must be willing to serve as a study site. Clinics selected for Aim 1 must have an EMR system in place and be above 300 total patients in HIV care at the site. HCW designees completing facility surveys must be ≥ 18 years of age, employed at the facility for ≥ 1 year, and involved in adolescent or pediatric HIV care. Adolescent data that will be abstracted from routinely collected medical records will include information on adolescent medical care and demographic information for all adolescents ages 10-24 attending facilities included in the facility survey.

Aim 2:

Adolescents participating in focus group discussions must be aged 14-24 years old and must know that they are HIV positive and have attended HIV care for at least 1 year. Caregivers participating in focus group discussions must be ≥ 18 years of age and the primary caregiver of an adolescent ages 14-24 years old. HCWs participating in interviews should be employed at trial sites for at least 6 months prior to the interview date and provide clinical or counselling services to HIV-infected adolescents. Policy makers must be ≥ 18 years of age and employed at the national, county or HIV implementing partner (NGOs or Universities) organization in a policy making role. Hospital administrators must be ≥ 18 years of age and serve at an administrative and local policy making level within facilities.

Aim 3:

To participate in the RCT, facility leadership must be willing to implement the intervention. Clinics already actively using transition or disclosure tools will be excluded. Adolescent records will be abstracted for all 10-24 year olds enrolled in HIV care at participating facilities. In addition, every 6 months, we will collect readiness assessment data from adolescents and young adults ages 15-24 years who have attained full disclosure. Adolescents will give consent or assent to participate in readiness assessments. HCWs who complete interviews, focus groups or surveys must be ≥ 18 years of age and employed at trial sites during the intervention period and providing clinical services to adolescents. Adolescents who complete the interviews must be ≥ 18 years or must have caregiver consent to participate if less than 18 years. Adolescents who participate in interviews must know their HIV status. Adolescents who complete the pre-trial and post-trial surveys must give oral consent or assent for participation, and be between the ages of 12 and 24 years of age and know their HIV status.

5d. Site/participant exclusion criteria

Facilities will be excluded if they do not meet inclusion criteria. A facility may also be excluded if anything would prevent the complete conduct of the intervention at that site and/or the collection of outcome measures. An example of this would be if a separate transition intervention was being developed at the site concurrent to our study.

An individual who meets any of the following criteria will be excluded from participation in this study: Conditions that would place the individual at increased risk or preclude the individual's full compliance with or completion of the study.

Table 4. Inclusion Criteria for all participants/clinics

	Population	Sampling	N	Inclusion Criteria
AIM 1: Program data abstraction				
Facility Survey Site	HIV care clinics	Selected randomly from clinics with EMR systems in place and >300 patients in HIV care	102	EMR system in place >300 patients in HIV care
Facility Survey Designee	HCW	Selected as representative for clinic to complete facility survey; will enroll 1-2 HCWs to help complete the survey per study site	102 sites	≥18 years of age Employed at facility in clinical care for at least 6 months and/or have a 1 year contract (i.e. not temporary staff) Provides clinical services to adolescents
Retrospective Records Review	Adolescents ages 10-24	All adolescents from the 102 selected facilities	Up to 15,000	-Aged 10-24 years of age -Attended clinic ≥1 time after January 1, 2016 -Attended clinic included in facility survey
Aim 2: ADAPT and OPTIMIZE				
Working Group	HCWs	Purposively selected from HCWs providing adolescent care	40 for Working Group	-≥18 years of age -Employed at clinic in Kenya -Employed in clinical care for at least 6 months and/or have a 1 year contract (i.e. not temporary staff) -Provides clinical services to adolescents
Adaptation IDI and FGDs	Adolescents (aged 14-24 years)	Adolescents in HIV care (8 FGDs for adolescents who have not completed transition, 8 FGDs for adolescents who have completed transition)	16 FGDs and 96 adolescents total (from clinics with different models of care)	-Ages 14-24 -Seeking treatment services at facilities assessed in Aim 1 -Knows that they have HIV -Attended clinic for at least 1 year
	Caregivers of HIV-infected adolescents aged 14-24 years	Caregivers of adolescents who have and have not completed transition	8 FGDs and 48 caregivers total (from clinics with different models of care)	-≥18 years of age -Seeking treatment services at facilities assessed in Aim 1 -Caregiver of adolescent age 14-24 years seeking treatment at selected site -Adolescent has attended clinics for at least 1 year

	HCWs	Interviews with HCWs involved in pediatric/adolescent HIV care	38 (selected from clinics with different models of care)	≥18 years of age -Provide clinical services to HIV-infected children and adolescents -Employed at facility in clinical care for at least 6 months and/or have a 1 year contract (i.e. not temporary staff)
	Policy maker and administrator heads	Policy makers at National and County level and HIV care partners or administrator head at facilities offering HIV care	30 interviews	≥18 years of age -Employed by Ministry of Health at National or County level or a HIV care partner, at a level that involves policy making or in an administrative position at facilities offering HIV care
Aim 3: RCT				
Cluster RCT	Clinic clusters	Selected from clinics with >500 clients in care	20 clinics	-≥50 adolescents currently in HIV care -EMR data system -Facility leadership willing to take up intervention at their sites -Not actively already using transition or disclosure tools
Pre-trial surveys	Adolescent	Selected from intervention and control sites	400 surveys	- Between 12 and 24 years of age -Willing to complete anonymous survey - Knows HIV status
	HCW	Selected from intervention sites	200 surveys	-≥18 years of age -Working in intervention clinics during the intervention -Providing adolescent HIV care
Intervention Implementation Monitoring	HCW	Selected from intervention sites	Repeated surveys every 2 weeks	-≥18 years of age -Working in intervention clinics during the first 6 months of intervention implementation -Providing adolescent HIV care
			Repeated planning sessions every 2 weeks	-≥18 years of age -Working in intervention clinics during the first 6 months of intervention implementation -Providing adolescent HIV care
			10 FGDs (1/intervention facility)	-≥18 years of age -Working in intervention clinics during the first 6 months of intervention implementation -Providing adolescent HIV care
Post-trial IDIs and FGDs	Adolescents who have completed disclosure process	6-10 selected from intervention sites	48 (from a subset of 6 clinics)	-Attained full HIV disclosure during the intervention period -Between 14 and 24 years of age
	Adolescents who have completed	6-10 selected from intervention sites	48 (from a subset of 6 clinics)	-Transitioned to adult care during the intervention period -Between 14 and 24 years of age

	transition process			
	HCW	5-10 HCW selected from each selected intervention site	40 IDI (from a subset of 6 clinics)	-≥18 years of age -Working in intervention clinics during the intervention -Providing adolescent HIV care
		All HCWs from intervention sites	10 FGDs (1/facility)	-≥18 years of age -Working in intervention clinics during the intervention -Providing adolescent HIV care
Post-trial surveys	Adolescent	Selected from intervention and control sites	400 surveys	- Between 12 and 24 years of age -Willing to complete anonymous survey - Knows HIV status
	HCW	Selected from intervention sites	200	-≥18 years of age -Working in intervention clinics for at least 6 months during the intervention -Providing adolescent HIV care
Readiness assessment surveys	Adolescents ages 15-24 years	Selected from all 20 selected facilities	Up to 4000 (2000 per arm)	-Aged 15-24 years of age -Willing to complete survey - Knows HIV status
Retrospective Records Review	Adolescents ages 10-24	All adolescents from the 20 selected facilities	Up to 4000 (2000 per arm)	-Aged 10-24 years of age -Attended clinic ≥1 time during the RCT timeline

5e. Randomization procedures

For the RCT, 20 clinics will be randomized to receive the ATP intervention or no intervention (SOC). Depending on the heterogeneity of baseline facility factors, restricted randomization may be used to ensure an equal distribution of potentially confounding factors. Dr. Richardson (Biostatistician) will generate the randomization assignment.

5f. Masking procedures

Because this is a clinic-level intervention using a pragmatic trial design, there will be no masking procedures.

5g. Participant Withdrawal

Participants or clinics may withdraw from the study at any time or the investigator may terminate a participant's or clinic's participation.

Reasons for withdrawal

Reasons for a study clinic to withdraw may include: clinic closure or major changes in HIV care policies, procedures, or organizational structures that would prevent or substantially limit our ability to conduct this study.

Reasons for HCW, policy maker or hospital administrator participant withdrawal may include: discomfort or distress during the focus group discussion, interview, lack of time to participate, or job termination or relocation.

Reasons for an adolescent participant or caregiver not to complete the in-depth interviews or focus group discussions may include, lack of time, discomfort, or disinterest in answering the questions.

An investigator may terminate a participants' or clinic involvement in the study if any medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant or clinic.

Handling of participant withdrawals

The study team will track the withdrawal of any clinic or participant during the trial. The timing and reasons for withdrawal will be recorded, and reported to the PI. HCW participants may withdraw at any time without affecting their regular job. Adolescent and caregiver participants may withdraw at any time without affecting their access to services at the clinic. The study team will record the timing and reasons for withdrawal of individual adolescent, caregiver or HCW participants. The participant will be thanked for their time in the study and not contacted further by the study team.

SECTION 6: STUDY INTERVENTION

The Adolescent Transition Package (ATP) will include two components. The validated Namibia comic book for disclosure (to be used with children over 10 years of age) and an adapted US transition toolkit (“Got Transition”).

The disclosure tool includes a cartoon book, readiness and tracking tools used in clinic and a HCW training. The intervention progresses from incomplete to complete disclosure using a narrative about soldiers fighting the battle of infection as the rationale for taking medicine. This tool has been validated for use in Namibia.

The Got Transition model is based on health care perspectives of adolescents, caregivers, and providers and program evaluations in the US. It has 6 core elements that were iteratively developed and offer a standardized approach that can be used in varied settings (Table 5). The Core Elements address inter-related health systems components relevant to diverse HIV programs in Kenya. The Transition tools for the ATP include a transition flipchart, readiness assessment, and transition progress tracking tool. In addition, the study team will develop training materials to support the implementation of the transition tools.

Table 5: Core elements of the Got Transition Program

6 Core Elements of Got Transition Program	
	Selected key concepts
Transition policy	Develop clinic policy on transition Educate and post policy
Transition tracking and monitoring	Criteria for identifying eligible adolescents Tracking registry/tool development
Transition readiness	Regular transition discussions starting age 14 Develop prioritized actions (joint adolescent/caregiver)
Transition planning	Regular planning, goals re: timing of transition
Transfer of care	Confirm date, assess self-care readiness
Transfer completion	Elicit feedback regarding transfer, follow-up retention

The validated Namibia booklet and the Got Transition tool can be found in the appendices.

Each clinic team in the intervention sites will implement the tools guided by the study team with twice-monthly check-ins and evaluation. The twice-monthly check-ins will use modified PDSA cycle materials to facilitate feedback and adaptations to optimize ATP implementation.

The study will aim to optimize implementation of ATP over a 6-month period at each intervention site with continued clinic support throughout the course of implementation and measure the effect of the well-implemented ATP on transition outcomes over a 2-year period.

SECTION 7: STUDY PROCEDURES

Overview:

Study procedures consist of:

Aim 1: A programmatic data capture and facility survey describe phase aimed at identifying baseline rates of transition and HIV treatment and care outcomes, current HIV treatment and care procedures and policies, and barriers and facilitators to successful transition.

Aim 2: An adapt phase aimed at adapting an adolescent transition tool.

Aim 3: An RCT phase aimed at testing effectiveness of an adolescent transition package (consisting of a validated disclosure booklet and adapted transition tool), with simultaneous qualitative and quantitative evaluation of the intervention effectiveness and implementation context.

7a. Programmatic data analysis and facility surveys

Potential clinics will be identified by facility lists obtained from the Kenyan MOH. The MOH will provide the team with a list of clinics using EMR and the size of the patient population at each clinic. A random sample of clinics will be selected, based on clinic size, from among all potentially eligible clinics. Use of EMR will be confirmed for each potentially eligible clinic randomized for inclusion and new clinics will be substituted in for clinics lacking EMR. Eligible clinics will be recruited by the study team by sending letters to County health directors to request for access and a formal letter of support to enroll these clinics. 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 Director. Oral agreement to participate in this aspect of the study will be obtained from administrative authorities at health facilities of interest.

Programmatic data analysis

Recruitment and Enrollment

For each clinic that agrees to participate, routine clinic data will be abstracted from the EMR system and from paper forms when EMR systems are not available. The medical records collected from the patient charts will include data tracking routine services offered and laboratory measurements collected. EMR or other medical record data will be abstracted directly from clinics or from implementing partners, whichever is most convenient for the clinic. If data staff at the partner organization or at the clinic are unable to extract the data on their own, hired technicians or study staff will travel to sites and assist with data abstraction directly. All medical records for adolescents ages 10-24 attending the clinic at least 1 time between January 1, 2016 and the date of data abstraction (but not later than December 31, 2017) will be pulled.

Data Collection Procedures:

For EMR data, data will be extracted by running a standardized query of the EMR database. The query will pull serial records for all adolescents ages 10-24 years who have at least 1 visit on or following January 1, 2016 and attend a clinic selected to participate in the facility survey. This will include all data on each adolescent from January 1, 2016 up until the date when data is abstracted but not later than December 31, 2017. We will not obtain individual consent for pulling adolescent records from the EMR. We will obtain a waiver of consent to obtain this information. Data collected will obtain basic demographic and HIV-specific clinical care outcomes as detailed in the attached file listing variables to be collected. This information is

already charted as part of routine care. For paper records, data will be abstracted using Case Report Forms (CRFs) and Open Data Kit (ODK) or REDCap. We will abstract selected variables from the EMR and paper based records including: client age at enrollment, caregiver type, sex, date/age of HIV diagnosis, CD4 count or percent, date of ART initiation, attendance at pediatric or adult clinic day (data obtained from facility survey and calculated by visit dates), and presence of caregiver at the visit (in EMR counseling notes). Serial data will be obtained on follow-up at the clinic. A list of variables that will be collected is attached.

Patient data collected will contain health facility code, unique patient number (numeric code used in CCCs), sex, DOB, and other attributes. Once collected, we will remove patient IDs from all data and replace them with our own unique patient identifiers. Once all data from a facility is collected, we will not save the original data files with patient identifiers. Data will be handed to the team via encrypted hard drives and flash drives or securely through approved online data storage systems (One Drive for Business, Catalyst). Because the data was 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 to use the data. Instead, we will request a waiver of consent from KNH ERC 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 secure website and data will be backed up daily to a password protected external hard disk located in the study data office. 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 fire/theft at the study data office.

Facility surveys

Recruitment and enrollment:

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. The facility survey will be conducted by phone or in person. Prior to the phone or in person 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 or visit, 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 and participating via phone will return the signed written consent form via email or text message while those without email or access to a phone may return the signed consent form via G4S courier services. All survey participants will be reimbursed 1000 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.

Data Collection Procedures:

During the facility survey we will collect information on the following: clinic staffing, clinic volume and space, pediatric clinic model (separate days or integrated), presence and type of transition planning approach, recommended age for transition, and available adolescent and transition services. We will also gather information on available adolescent friendly services, number of adolescents in HIV care; adolescent HIV services provided; health care provider training; presence and content of disclosure and transition guidelines; ART provision, availability of peer groups; mental health assessment processes, and important services lacking in clinics. A draft form of the facility survey is attached. We request permission to modify this form to make minor changes in the wording of questions to read more appropriately or clarify confusing statements, or make minor changes and formatting of questions. These minor changes will not affect the general content of information being collected. Any questions asking for collection of new content areas will be submitted for approval as a modification.

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 services). We will capture basic demographic information on the cadre of health provider including age, sex and years of experience. In a separate file we will record the health provider's name and contact information for purposes of scheduling the survey and mailing the consent materials. This information will not be stored with the data collected during the survey but will be linked to the provider in a separate link log document.

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 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 of recruitment or their previously pre-arranged time. No reimbursement will be provided other than for reimbursing costs associated with mailing or emailing consent forms to the main office in Nairobi at 1000 KSH/participant. 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 Kenya Pediatric Studies offices in Nairobi for up to six years.

7b. Adapt and Optimize phase

This phase will consist of 2 steps: The **adapt step** consisting of in-depth interviews (IDI), focus group discussions (FGDs), and a HCW working group to adapt and refine the transition tool.

Adapt phase interviews

Recruitment and enrollment

A member of the study team will be stationed at the clinics to recruit HCWs, adolescents and caregivers and schedule interviews.

For focus group discussions, evaluation staff will recruit eligible adolescents or caregivers from pediatric/adolescent clinics or CCC settings. Routine clinical staff will help with recruitment. Routine clinic staff will review patient charts and identify eligible adolescents and their caregivers. They will use patient charts to identify adolescents who meet the age criteria and know their HIV status. They will select adolescents who have and have not yet transitioned to adult care, as noted in their files. They will contact eligible adolescents and/or their caregivers to briefly tell them about

the study. Caregivers and adolescents who are interested will be invited for participation and asked to meet with study staff. It will be emphasized that participation is completely voluntary. Adolescents and caregivers will be recruited for these focus group discussions until up to 96 adolescents have participated in 16 FGDs and 48 caregivers have participated in 8 FGDs, following the stratification pattern described in Table 2. Stratification for focus groups will include: whether or not they/ their children have completed the transition process, and the clinic model of care. 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 who 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 a routine provider. Because adolescents typically only visit the clinic every 3 months, providers will need to call adolescents (≥ 18) or their caregivers (adolescents ages 14-17) specifically for the purpose of recruiting them into the study. 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 an appendix. Adolescents aged 18 or older, or caregivers of adolescents ages 14-17, who are interested in participating or having their adolescent participate, will be asked to either stay after their visit (if already there for an appointment) or come to the clinic on a specific selected date to sign consent forms and participate in a FGD.

When the potential participant arrives on the date of the FGD, the adolescent or caregiver/adolescent team will meet with study staff to go through a consent/assent process. Prior to conducting consent and beginning each FGD, study staff will confirm that the adolescent knows their HIV status by asking “why do you come to this clinic” and/or “why do you take medications” and “how old are you.” Adolescents and caregivers who are eligible will begin the consent/assent process. During the consent process, 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 who meet the screening criteria and provide informed consent will be enrolled in the study.

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 a FGD 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 14 and 24 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 an appendix. 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. Prior to conducting consent and beginning each caregiver FGD, study staff will confirm that the caregiver is the primary guardian of an HIV-infected adolescent by asking "why does your child come to this clinic" and "how old is the child you bring to this clinic" and "are you this child's primary guardian." Those who provide consent and meet screening criteria 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 FGDs.

Consent forms for all participants are attached as appendices.

HCWs from selected 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 an appendix. Those willing and eligible to participate will be asked to give written consent to be part of an individual interview and have the discussion audio recorded. It will be emphasized that participation is completely voluntary and opting not 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 an individual interview conducted by the study staff.

Policy makers and hospital administrators will be purposively selected based on knowledge of their involvement in public office or employment within the hospital. Study staff will use public databases and other in-country resources to identify potential participants. Potential participants will be contacted by phone, email or in person by study staff to schedule interviews. A script outlining talking points for recruitment is attached as an appendix. Those willing and eligible to participate will be asked to give written consent to be part of an individual interview and have the discussion audio recorded. It will be emphasized that participation is completely voluntary and opting not to participate will have no repercussions on the policy maker's or administrator'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 an individual interview conducted by the study staff.

All participants will provide their contact information (phone, name, email if necessary) for follow-up until interview is conducted.

Data Collection Procedures:

Interviews:

We will conduct 16 focus group discussions with HIV-infected adolescents aged 14-24 years, 8 focus group discussions with caregivers of HIV-infected adolescents age 14-24 years, 38 interviews with HCWs caring for HIV-infected adolescents and 30 policy makers and healthcare administrators. During each IDI or FGD, participants will share their experiences receiving clinical care for HIV and with disclosure and transition processes at their clinics and provide feedback on areas that could be improved or strengthened. Draft guides for all interviews and focus group discussions are attached as appendices. The attached guides provide example open-ended questions. Adolescent focus group discussion questions will focus on experiences with HIV disclosure and/or transition and seeking and receiving HIV treatment and care 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, support, and treatment services, and transition. For HCWs, discussion questions will focus on the services offered to adolescents at their facility and personal experiences with service provision to adolescents. For policy makers and administrators, discussion questions will focus on their views on what they envision as good transition practices, what would work in their setting, how this would work, and to share their experiences on challenges and successes at national or county policy level and facility level. We may also present the transition tool to the participants and ask them to provide direct feedback on the tools regarding cultural relevance and acceptability, programmatic or logistical concerns, as well as offer creative solutions for innovation.

Discussion guides will be validated by piloting the guides with study staff following initial IRB and ERC approval. During the piloting phase, interviewers and discussion leaders 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. Guides will be submitted as modifications if the content of the interview questions change during the pilot and final guide development phase.

IDIs and FGDs will be conducted by a trained interviewer with previous experience in interviewing different populations, using a semi-structured flexible guide and will take approximately 60 minutes to 2 hours to complete. IDIs and FGDs will be conducted in Kiswahili, Luo, English or other language appropriate for the location where activities are taking place. With consent from participants, discussions will be audio-recorded. At the beginning of the interview or FGD, interviewers will describe the goal of the interview or discussion and information about participation, including the ability to skip questions and the confidentiality of information shared. Prior to conducting the interview or FGD, interviewers will help the participant complete a short demographic form to collect socio-demographic information about the participant. Demographic surveys are attached as appendices. During the interview or FGD, the interviewer will guide the

flow of discussion and will take notes to document participants' attitudes, non-verbal gestures, body language, and responses. The audio file may include the participant's first name (not full name). Neither the transcribed notes from the interviews or FGDs, or transcripts, will include any personal identifiers, including the participant's first name. If present in the audio recording, the participant's name will be removed during transcription. For caregivers and adolescents, reimbursement for transportation costs, up to KES 600 (\$6-7) per participant and if applicable, their guardian, will be provided. After completing their interviews, HCW participants will receive KES. 1000 (\$11) as reimbursement for their time. Participants may also receive light refreshments while they are participating in the interview or FGD. 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. The audio recordings of discussions will be destroyed after study participation and data analysis has been completed and no later than 6 years after the interview or FGD took place. Audio files and English transcripts will be uploaded to a password protected secure website for back-up. ATLAS.ti will be used for data management and analysis.

Interview list of procedures:

- a) Invitation to participate in in-depth interview or focus group discussion
- b) Collection of locator information (phone number) and scheduling interview
- c) Written informed consent from participants aged ≥ 18 years or caregiver consent and assent from adolescent if under 18 years
- d) Complete demographic survey with study staff
- e) Conduct in-depth interview or focus group discussion with study staff

Adapt Phase Working Group Meeting

Recruitment and Enrollment:

We will conduct a 2 day working meeting with an estimated 40 selected HCWs and policy makers from throughout Kenya with expertise in caring for HIV infected children and adolescents. HCWs with significant experience in assisting with HIV treatment and care for HIV infected adolescents will be purposively recruited from high performing clinics from Aim 1 with already existing transition policies and practices in place and/or adolescent friendly services and programs or through referral from policy makers and administrators interviewed in aim 2. We may also recruit healthcare workers known for their work in adolescent HIV treatment and care through reviewing peer-reviewed published articles or presentations at scientific meetings.

HCWs and policy makers participating in the working group will be purposively selected and contacted by phone, email or in person by the study coordinator. They will be told the details of the working group, including its purpose and scope of work. A script outlining talking points used for recruitment is attached as an appendix. Those willing and eligible to participate will be asked to give written consent to be part of the working group and have the discussions audio recorded and information about the process written up into a publishable manuscript. It will be emphasized that participation is completely voluntary and opting not to participate will have no repercussions on the HCWs employment. 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 a 2 day workshop with study staff to refine and adapt the

transition tools. All participants will provide their contact information (phone, name, email if necessary) for follow-up until the working group meeting is conducted.

Working meeting

The workshop will be led by study team members. During the workshop, we will first present synthesized data from the in-depth interviews. HCWs will also be presented with working summaries of the synthesized data to refer to throughout the workshop to ensure that the views of all stake-holders will be incorporated as much as is possible in the adapted tool. We will then introduce the Got Transition tool to the HCWs and discuss in detail each of the sections of the tool including: core elements, key concepts, data collection tools, and both qualitative and quantitative evaluation tools. The purpose of introducing the tool to the HCWs will be to create a framework from which they can develop core elements, concepts, data collection tools and evaluative measures that are suitable for their setting. HCWs will be encouraged to think about what would work in their work setting, while incorporating the views of stakeholders, rather than working from what is presented in the tool. HCWs and study team members will work to develop the core elements and key concepts as a group, we may then split the HCWs to smaller groups to refine, and develop data collection tools which will then be presented to the whole group and refined as needed. HCWs will be encouraged to be participatory and as practical as possible, and to develop the most inclusive and simplest tools that would work in the largest number of facilities in Kenya. Once a draft tool has been developed, it will be presented to the whole group and iteratively refined. We will provide reimbursement for transportation costs, accommodation and meals during the workshop and provide a per-diem allowance equal to current rates used by organizations or facilities where the HCWs work.

The workshop agenda will be developed by the study team, and daily discussions will be led by a combination of study team members and invited working group participants.

Data Collection Procedures:

Prior to the working group meeting, HCWs will complete a short demographic form to collect socio-demographic information. Demographic surveys are attached as appendices. Neither the transcribed notes from the workshop or transcripts will include any personal identifiers other than the participant's first name. 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. The audio recordings of discussions will be destroyed after study participation and data analysis has been completed and no later than 6 years after the workshop took place. Audio files and English transcripts will be uploaded to a password protected secure website for back-up. ATLAS.ti will be used for data management and analysis.

List of procedures for workshop

Listed below are all the required procedures.

- a) Invitation to participate in HCW working group meeting
- b) Collect locator information (phone number) and schedule meeting dates
- c) Provide a copy of the transition tool to review prior to the meeting
- d) Present results of the in-depth interview
- e) Provide summary document of synthesized data
- f) Discussion on the Got transition tool: The discussion will focus on the following key areas
 - i. Core elements
 - ii. Key concepts for each core element
 - iii. Draft tools or measures for key concepts

- iv. Assessment of transition activities in clinics (tools and procedures)
- g) Group discussion on key elements and concepts
- h) Small group discussions to develop tools and refine core elements and key concepts
- i) Whole group presentations on all transition tool items, with iterative refinement
- j) Presentation of refined tool

7c. Cluster Randomized Controlled Trial (RCT)

Recruitment and Enrollment:

The study team will identify 20 clinics in Nairobi, Homabay, Kajiado or Nakuru counties that meet study eligibility criteria. These clinics may be part of those selected for aim 1 or new clinics not included in aim 1. We will use information from the facility survey to help with selection of clinics. For any selected clinic that was not part of aim 1, we will conduct the facility survey done in aim 1 before randomization using the same procedures discussed in aim 1. This will ensure we have the same clinic baseline information available for all 20 clinics participating in the RCT. Prior to initiation of the trial, we will conduct pre-trial anonymous surveys with adolescents at both intervention and control sites. We will also conduct pre-trial surveys with all HCWs from intervention sites.

We will receive permission from county administrative teams and HIV care partners to enroll these clinics. We will then send letters to administrative teams of the selected clinics. The letter will have information on the objectives of the study and will include a formal request for the clinic to be part of the intervention. The study team will meet with clinic leadership and managers and provide more information on the study. Clinic leadership and staff in the adolescent clinic will give oral consent for the clinic to participate in the study.

Twenty clinics will be selected based on location, size, use of EMR, willingness to participate in the RCT and taking into consideration other transition interventions ongoing at the site based on information collected in the facility survey or through conversations between clinic staff and study staff when recruiting clinics not in aim 1. To the best of our ability, clinics with transition or disclosure tools already in use will not be included in the RCT. 10 clinics will be randomized to receive the ATP intervention and 10 to receive no intervention. Depending on the heterogeneity of baseline facility factors, restricted randomization may be used to ensure an equal distribution of potentially confounding factors such as urban vs. rural site or clinic size. Dr. Richardson (Biostatistician) will generate the randomization assignment.

All health providers (medical officers, nurses, physicians, counselors and psychologists) who currently work with HIV positive adolescents in intervention facilities will be told about the study by study team personnel and offered the opportunity to participate in the early implementation monitoring activities. This includes the HCW pre-trial survey and twice-monthly planning and feedback meetings and surveys. Specifically, study staff will visit the clinic and meet with all 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 an appendix. Those willing and eligible to participate will be asked to give written consent to be part of the early implementation phase activities that will take place for 6 months. These activities include the pre-trial survey, twice-monthly surveys, and trice-monthly PDSA meetings. HCWs who join the clinic after the trial has started will have the opportunity to consent when they join the clinic. HCWs who join the clinic after the trial has started will not have the opportunity to participate in the pre-trial survey. It will be emphasized that participation is completely voluntary and opting not to participate

will have no repercussions on the provider's employment. 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 the early implementation phase activities of the study. HCWs participating in the early implementation phase activities will receive reimbursement for their time attending twice-monthly meetings and completing surveys. As a token of appreciation for their time, we anticipate paying HCWs 500KES for each feedback session they attend and 300KES for each survey they complete. They will also receive 500KES if they complete the pre-trial survey.

We will conduct transition readiness surveys with adolescents aged 15-24 years who have attained full disclosure. Surveys will be conducted at baseline (clinical trial start) and every 6 months thereafter.

All adolescents 15-24 years who have attained full disclosure and are attending clinic visits will be eligible to participate in the surveys. Adolescents will be recruited during clinic visits by a member of the study team or by phone prior to returning to clinic for their study visit. A recruitment script with guiding information is provided in the appendices. If an adolescent is interested in participating, eligibility will be assessed by clinic or study staff by asking adolescents a series of questions. These questions will confirm that the adolescent knows their HIV status and is within the appropriate age range to participate. Example questions that study staff might ask include: "why do you come to this clinic" and/or "why do you take medications" and "how old are you." Adolescents who meet eligibility criteria and are interested in participating will give written assent or consent to participate in the surveys. We will also request a waiver of parental permission for adolescents ages 15-17 who do not meet emancipated minor criteria. The information collected in the survey is not sensitive and can be classified as minimal risk. In addition, many adolescents ages 15-17 who have already attained full disclosure will be receiving care in the absence of their caregivers. Adolescents will be informed that their data will be linked to their medical record data, but this survey will not contain their name, only their ID. All adolescents who provide consent or assent will be enrolled and participate in this survey. Adolescents who provide assent or consent will take the transition readiness surveys every 6 months. Adolescents will receive 600 KES for completing the survey each time.

Data collection procedures:

The study is not blinded and clinic leadership will be informed of the allocation, either to intervention or no intervention. For both groups, the study team will conduct study specific training. For intervention sites, training will include the use of the disclosure tools, transition tools and other study data collection material. Control sites will undergo training on collection of study related data.

Intervention clinics: The study will aim to optimize implementation of the ATP over the 6-month period at each intervention site and will measure the effect of the well-implemented ATP on transition over a 2-year period.

Enrolled HCWs will be asked to complete a demographic and implementation climate survey one time following enrollment in the early implementation phase activities. This will capture basic demographic information on the cadre of health provider including age, sex and years of experience. The survey will also capture the organizational readiness for change and baseline knowledge of transition services at the clinic. The survey will also assess initial impressions of the ATP. The survey will be administered after obtaining written consent. At each intervention clinic, all enrolled HCWs will meet twice-monthly for the first 6 months of implementation for planning

and feedback meetings. The timing of when these meetings will occur will be determined through conversations between study staff and clinic staff. Planning and feedback discussions will focus on identifying ATP implementation challenges and successes, how challenges were addressed, and identify coordinated ideas for small changes that can improve implementation. Meetings will be audio recorded and transcribed verbatim and used to complete an adaptation-tracking log and PDSA worksheet. The log and worksheet will capture major and minor changes, reasons for changes, date changes were made, and the challenges and successes that were encountered as they used the tools and new innovative ways to address challenges. The log will not include personal identifying information, but will be identified at the clinic level only. We anticipate the meetings will last 1-2 hours in length. Audio files and English transcripts will be uploaded to a password protected secure website for back-up. ATLAS.ti will be used for data management and analysis.

During each planning and feedback meeting, HCWs will also be asked to complete brief surveys that includes questions to assess individual acceptability, feasibility and appropriateness of the adapted intervention. These surveys will also ask questions to probe intervention fidelity. Surveys will be administered immediately before the twice-monthly meetings. During these first 6 months, study coordinators will actively support the clinic in the implementation process. During the adaptation phase, the core elements and key concepts of the tools will be preserved as much as possible. Surveys will be completed on paper and later entered into REDCap or will be directly entered into REDCap using tablets or smart phones. HCWs will be assigned a study ID that will be used throughout the early implementation phase data collection activities. This ID will be used to link changes in acceptability and feasibility over time. HCW names will be stored alongside their study IDs in the link log. The link log will be kept separate from other data collected and stored in a locked cabinet that only trained study staff have access to.

The study will introduce new tools to be used in routine data collection at both intervention and control sites. These are the disclosure checklist and the transition log (attached as appendices). We will also introduce tracking forms and cartoon books to improve disclosure and transition processes at intervention sites. These forms and tools are attached as appendices and include a transition booklet called Taking Charge, a disclosure booklet called "Why I take my Medicines, a transition tracking form, a disclosure readiness assessment, and a transition readiness assessment. During implementation, study coordinators will work with the clinic to determine the best model for data collection in each of the clinics. The data will be collected on paper forms. The new tools will contain a participant identifier, as used in the clinic. At data entry, participant clinic ID numbers will be recorded. This will allow us to link data between study tools and routinely collected patient data. Before analysis, all original patient ID numbers will be replaced with a study ID. We will use a link log to link the participant clinic identifier with the study code. The link log will be stored in a lockable cabinet in the clinic and will only be accessible to study staff. The paper forms will be stored in facilities together with other clinic records. Data will be entered using the Open Data Kit (ODK) platform or mobile REDCap on Android smart phones or study tablets. Data will be uploaded directly to the study's secure server from the smart phone or tablet that is used to collect data, at which point it will be deleted from the phone or tablet. Android phones and tablets will be password protected with a password known only to the study staff using the device. The secure server that warehouses data will be password protected and accessible only to study personnel directly involved in data cleaning and analysis. We will plan to use either wireless internet or 3G to send digital data. To protect the data, the website to which data will be uploaded will use existing well-known SSL/TLS (Secure Socket Layer/Transport Layer Security), as indicated by "HTTPS" in the URL. SSL/TLS is used by sites such as Google to protect data. All digital data will be sent and received using HTTPS.

To track intervention effectiveness for improving adolescent outcomes, we will also abstract data from EMR systems and paper forms in both intervention and control sites (adolescent checklist

and other paper based forms) at baseline (before RCT start), and throughout the duration of the RCT. We will work with data personnel in each of the facilities to develop operating procedures on data abstraction, making use of currently used systems and procedures for reporting data that are already in place at that clinic. All data handled by the study team will be handled and stored as described in aim 1 procedures.

Transition readiness surveys will be collected either on paper CRFs or using REDCap on Tablets. This survey will be administered by a trained clinic staff member or hired study staff. The readiness assessment survey tool is provided as an appendix. Data collected on paper forms will be entered into REDCap by study staff.

List of procedures for the RCT

- a. Meeting with clinic team and leadership to present study and study team
- b. Select 20 clinics for randomization
- c. Conduct baseline pre-trial surveys with adolescents and HCWs
- d. Training of clinic staff on the use of the ATP (intervention sites only)
- e. Training on data collection tools for all sites (disclosure and transition checklists)
- f. Share baseline data with clinic if available
- g. Pre-trial surveys with HCWs on implementation climate
- h. 6 month intensive clinic support and optimization of ATP implementation
- i. Twice-monthly surveys with HCWs and meetings facilitated by the study team aimed at making adaptations and changes to the tool as needed
- j. Completion of study adaptation log and PDSA worksheet
- k. Completion of baseline and 6-monthly surveys with adolescents ages 15-24
- l. Extraction of routine medical records for adolescents ages 10-24
- m. Extraction of data from intervention tracking forms
- n. Continuous support as needed for implementation

7d. Implementation Evaluation

During implementation, we will use quantitative and qualitative tools to measure how well the transition tool is implemented in the intervention sites. Assessment will occur both in the middle and at the end of the intervention period and will include collection of qualitative and/or quantitative information on the acceptability, appropriateness, feasibility of the intervention and intervention fidelity. We will also assess penetration and adoption at each intervention facility. We will gather this information through semi-structured interviews with adolescents and HCWs, FGDs with HCWs at intervention sites, HCW post-trial surveys at intervention sites, data abstraction from study tools and patient charts, and post-trial surveys with adolescents at intervention and non-intervention sites.

Implementation Evaluation FGDs

All HCWs from intervention facilities will be invited to participate in FGDs at 6 months and 24 months post-intervention implementation. All health providers (medical officers, nurses, physicians, counselors and psychologists) who have been implementing the ATP at intervention sites will be offered the opportunity to participate. Specifically, study staff will visit the clinic and meet with all health providers involved in implementing the ATP and will verbally inform them of the study. A script outlining talking points for recruitment is attached as an appendix. Those willing and eligible to participate will be asked to give written consent to be part of the FGD. It will be emphasized that participation is completely voluntary and opting not to participate will have no

repercussions on the HCWs employment. 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 a FGD at either 6 or 24 months post-intervention implementation. HCWs can participate in an FGD at 6 months, at 24 months or both.

FGDs will assess overall perceptions on the ATP, and include questions to measure constructs from the Consolidated Framework for Implementation Research (CFIR). The CFIR is a meta-theoretical framework designed to identify implementation determinants by guiding data collection, analysis, and evidence interpretation. Application of the CFIR in this study will generate key information about the role of context in influencing implementation, thereby informing the future packaging of the intervention and increasing the relevancy of study findings for other settings. We will ask questions to learn from HCW experiences implementing the ATP so that the tool can be revised and adapted for future scale-up. Draft guides for FGDs are attached as appendices. The attached guides provide example open-ended questions. Discussion guides will be validated by piloting practicing the guides with study staff following initial IRB and ERC approval. During the piloting phase, discussion leaders 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 discussion guides will be developed that include optimal phrasing, timing and ordering of discussion questions. While the order and phrasing of guides may change from the guides submitted to the IRB/ERC, the basic content included in the guides will not change between the pilot and final versions of the guides. Guides will be submitted as modifications if the content of the interview questions change during the pilot and final guide development phase.

We will use focus groups because they are useful in fostering rich discussion between group members and participant comments stimulate the thinking and responses of others. Additionally, focus group discussions help to elicit divergent or convergent viewpoints among participants. Focus groups will be used to understand HCW perspectives on implementing the ATP at their facility and how the ATP can be improved. It will be emphasized that participation is completely voluntary and opting not to participate will have no repercussions on the HCW's employment. They will also be reminded that they do not have to participate in the FGDs even if they participated in the early phase implementation activities. HCWs from intervention sites will have the opportunity to participate in the FGDs at 6 months, 24 months, or both. HCWs will provide separate written informed consent to participate in each of the FGDs. During FGDs, participants will meet with trained moderators and note takers in private rooms. FGDs will be conducted by a trained interviewer with previous experience in interviewing different populations, using a semi-structured flexible interview guide and will take approximately 1 ½ to 2 hours to complete. FGDs will be conducted in English or Kiswahili and discussions will be audio-recorded. At the beginning of the focus group discussion, the interviewer will describe the goal of the focus group discussion and information about participation, including the ability not to answer questions and the confidentiality of information shared, and also ask that no names be used during the discussion. The interviewer will also remind participants not to share information about the FGD with other people, including what was discussed and who was present. Before the FGD starts, participants 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. In addition, surveys will quantify the implementation outcomes of fidelity and penetration with questions regarding exposure to training, personal and facility use of the ATP. Their survey information will be recorded in separate forms from the interview data.

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. Despite our best attempts to have participant refrain from using each other's names, the audio file may include the participant's first name (not full name). Neither the transcribed notes from the interviews or transcripts will include any personal identifiers, including the participant's first name. If present in the audio recording, the participant's name will be removed during transcription. Participants will receive KES. 1000 (\$11) as reimbursement for their time. Participants may also receive light refreshments during their time participating in the focus group. 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. The audio recordings of FGDs will be destroyed after study participation and data analysis has been completed and no later than 6 years after the FGD took place. Audio files and English transcripts will be uploaded to a password protected secure website for back-up. ATLAS.ti will be used for data management and analysis.

List of procedures

Listed below are all the required procedures for the FGDs.

- a) Invitation to participate in the FGD
- b) Consent for FGD participation
- c) Schedule FGD date
- d) Complete short demographic and implementation survey
- e) Conduct FGD

Qualitative Interviews

Recruitment and enrollment:

A member of the study team will be stationed at intervention clinics to recruit potential participants and schedule interviews. We will conduct a total of 48 (estimating 8 adolescents total from up to 6 sites) individual interviews with HIV-infected adolescents who have attained full disclosure of their HIV status during the intervention period and 48 (estimating 8 adolescents total from up to 6 sites) individual interviews with adolescents who have transitioned to adult care during the intervention period. We will also conduct 48 individual interviews with 5-10 HCWs at selected intervention clinics. Clinics participating in interviews will be selected based on their performance during intervention implementation. We will select a range of distributions of intervention implementation success, including a mixture of high and low performing clinics.

Adolescents and HCWs will be recruited and enrolled using similar procedures as those described for interviews in Aim 2. Briefly, during clinic visits, adolescents will be invited by study staff to

return to the clinic or stay after their current appointment to participate in individual interviews. Adolescents will be recruited for these in-depth interviews until they reach pre-defined target numbers (8/group/site) or reach data saturation during the interviews (no new information emerges). Before participation in in-depth interviews, each adolescent >18years will give their consent to participate. Adolescents aged less than 18 years will give assent to participate; and their caregivers will give consent for participation. HCWs who meet eligibility criteria will be recruited by study team members to participate in the interviews. It will be emphasized that participation is completely voluntary and opting not to participate will have no repercussions on the provider's employment or clinical care the adolescent receives in the clinic. Prior to conducting consent and beginning each adolescent interview, the interviewer will confirm that the adolescent knows their HIV status by asking "why do you come to this clinic" and/or "why do you take medications" and "how old are you." Before participation in in-depth interviews, participants will give written consent or assent to participate. Interviews will be conducted by study staff and will be audio recorded.

During each IDI, participants will share their experiences with disclosure and transition processes at their clinics and provide feedback on areas that could be improved or strengthened. HCWs will also provide direct feedback on their use of the ATP, drawing again from the CFIR constructs to assess determinants impacting implementation outcomes. Draft guides for all interviews are attached as appendices. The attached guides provide example open-ended questions. Discussion guides will be validated by piloting practicing the guides with study staff following initial IRB and ERC approval. During the piloting phase, interviewers and discussion leaders 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. While the order and phrasing of guides may change from the guides submitted to the IRB/ERC, the basic content included in the guides will not change between the pilot and final versions of the guides. Guides will be submitted as modifications if the content of the interview questions change during the pilot and final guide development phase.

Adolescent interview questions will focus on personal experiences with HIV disclosure and/or transition and seeking and receiving HIV treatment and care services. For HCWs, discussion questions will focus on the services offered to adolescents at their facility and personal experiences with use of the transition and disclosure tools. IDIs will be conducted by a trained interviewer using a semi-structured flexible interview guide and will take approximately 60 minutes to complete. IDIs will be conducted in Kiswahili, Luo, English or other language appropriate for the location where activities are taking place. 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.

Data Collection Procedures:

Prior to conducting the interview, interviewers will help the participant complete a short demographic survey to collect socio-demographic information about the participant. HCW surveys will also assess intervention training, uptake of tools and perception of tools use at the facility they work in. Demographic surveys are attached as appendices. During the interview, the interviewer will guide the flow of discussion and will take notes to document participants' attitudes, non-verbal gestures, body language, and responses.

During each IDI, participants will share their experiences with disclosure and transition processes at their clinics and provide feedback on areas that could be improved or strengthened. Draft guides for all interviews are attached as appendices. The attached guides provide example open-ended questions. Discussion guides will be validated by piloting practicing the guides with study staff, peer educators or other staff at clinics not participating in the IDIs. Piloting will happen following initial IRB and ERC approval. During the piloting phase, interviewers and discussion leaders 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. While the order and phrasing of guides may change from the guides submitted to the IRB/ERC, the basic content included in the guides will not change between the pilot and final versions of the guides. Guides will be submitted as modifications if the content of the interview questions change during the pilot and final guide development phase.

Adolescent interview questions will focus on personal experiences with HIV disclosure and/or transition and seeking and receiving HIV treatment and care services. For HCWs, discussion questions will focus on the services offered to adolescents at their facility and personal experiences with use of the transition and disclosure tools. Similar to the FGD discussion guides, IDI guides for HCWs will include questions to assess implementation context based on the constructs and domains from CFIR. IDIs will be conducted by a trained interviewer using a semi-structured flexible interview guide and will take approximately 60 minutes to complete. IDIs will be conducted in Kiswahili, Luo, English or other language appropriate for the location where activities are taking place. 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.

The interview audio file may include the participant's first name (not full name). Neither the transcribed notes from the interviews or transcripts will include any personal identifiers, including the participant's first name. If present in the audio recording, the participant's name will be removed during transcription. For caregivers (of minor adolescents) and adolescents, reimbursement for transportation costs, up to KES 600 (\$6-7) per participant or accompanying guardian, will be provided. After completing their interviews, HCW participants will receive KES. 1000 (\$11) as reimbursement for their time. Participants may also receive light refreshments during their time participating in the interview. 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. The audio recordings of interview discussions will be destroyed after study participation and data analysis has been completed and no later than 6 years after the interview took place. Audio files and English transcripts will be uploaded to a password protected secure website for back-up. ATLAS.ti will be used for data management and analysis.

List of procedures for individual interviews

- a) Invitation to participate in in-depth interview
- b) Collection of locator information (phone number) and scheduling interview
- c) Written informed consent from participants aged ≥ 18 years or caregiver consent and assent from adolescents if under 18 years
- d) Complete demographic survey with study staff
- e) Conduct in-depth interview

Pre and Post-Trial surveys

Recruitment and Enrollment:

We will conduct 400 pre-trial and 400 post-trial anonymous surveys with adolescents aged 12-24 years at both intervention and control sites and 200 post-trial surveys with HCWs from intervention sites to determine satisfaction with the disclosure and transition processes, and acceptability, feasibility and appropriateness of the intervention. HCW surveys will also assess fidelity, penetration, and adoption of the ATP.

All adolescents attending clinic visits will be eligible to participate in the anonymous surveys. Adolescents will be recruited during clinic visits by a member of the study team. A recruitment script with guiding information is provided in the appendices. If an adolescent is interested in participating, eligibility will be assessed by clinic staff by asking adolescents a series of questions. These questions will confirm that the adolescent knows their HIV status and is within the appropriate age range to participate. Example questions that study staff might ask include: “why do you come to this clinic” and/or “why do you take medications” and “how old are you.” Adolescents who meet eligibility criteria and are interested in participating will give oral assent or consent to participate in the anonymous surveys. A recruitment script with guiding information is provided in the appendices. They will be informed that no identifiable information will be collected in the surveys and that the study teams will not collect any names. All adolescents will provide oral assent or consent to participate in the surveys. Since no identifying information will be collected, we will request waiver of written consent for participation in the surveys. We will also request a waiver of obtaining parental consent for adolescents ages 12-17. We are looking at evaluating transition to adult care, and many adolescents ages 12-17 will have already transitioned to adult care and be receiving care in the absence of their caregivers. All adolescents who provide oral assent or consent will be enrolled and participate in an anonymous survey.

All HCWs working with HIV-infected adolescents at intervention sites are eligible to participate in exit surveys. HCWs who meet eligibility criteria will be recruited by study team members to participate. They will be informed that no identifiable information will be collected. It will be emphasized that participation is completely voluntary and opting not to participate will have no repercussions on the provider’s employment. All HCWs who provide oral consent will be enrolled and participate in an anonymous survey.

Data collection procedures

Pre and post-trial surveys will be collected either on paper CRFs or using mobile REDCap on tablets. These surveys are provided in the appendices. Data collected on paper forms will be entered into REDCap as described earlier.

List of procedures for pre and post-trial surveys

- a. Recruitment to participate in anonymous survey
- b. Oral consent or assent
- c. Complete survey

Post-Trial procedures- Control sites:

At the end of the trial control sites will be offered study tools used in the intervention sites and will be offered training on how to use them. Any material developed including tracking tools will be shared with the control sites to allow them to use tools they find useful. Results of the trial will be presented to all sites in site close-up meetings.

7e. Assessment of participant compliance with study intervention

We will regularly monitor turn-over of trained HCWs, changes in clinic policies and procedures, and other facility-level factors that could affect intervention fidelity.

SECTION 8: STUDY SCHEDULE

An overview of the anticipated overall study schedule for is shown in Table 6a and 6b (by aim). The study will be conducted over five years. AIM 1 will be implemented in year 1. In year 2 we will complete and disseminate results of AIM 1 and complete AIM 2 and select sites for cRCT in AIM 3 as well as finalize adapted transition tool. In Y3 we will initiate the RCT with 2-year follow-up to be completed by mid-Y5. The final 6 months of the study will be used for manuscript preparation and dissemination of results of AIM 3 to community and global stakeholders.

Table 6a: Overall study schedule: 2016-2021

	Y1				Y2				Y3				Y4				Y5			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Study Planning																				
Protocol development																				
IRB Submissions																				
Implementation																				
Site selection																				
EMR data extraction for AIM 1																				
Facility surveys																				
IDIs for adapt																				
HCW workshop																				
HCW FGD to adapt																				
Site randomization																				
Pre-trial surveys																				
Study training																				
RCT																				
Data pull																				
Post-trial surveys																				
Evaluation IDIs																				
Analysis																				
Data Analysis																				
Dissemination																				
Reports to stakeholders																				
Manuscript development																				

Figure 6b: Study timeline by aims

	Year 1		Year 2		Year 3		Year 4		Year 5	
	P1	P2	P1	P2	P1	P2	P1	P2	P1	P2
Develop study material and ethical approval	x	X								
Aim 1: Facility surveys, EMR data abstraction			x	x						
Aim 2: Adaptation and optimization of transition tool			x	x	x					
Aim 3: Cluster RCT						x	x	x	x	
Data analysis				x	x				x	
Dissemination and manuscript preparation					x				x	x

SECTION 9: ASSESSMENT OF SAFETY

There are no medical interventions associated with the study, therefore we anticipate no risk of serious harm to participating HCWs or adolescents. Other study risks include emotional distress associated with the sensitive nature of the disclosure and transition process, breach of patient confidentiality during data extraction or by participation in FGDs and fear of or actual loss of employment associated use of transition tools and checklists.

There is a possibility for social harm (depression, violence after disclosure, abandonment) related to disclosure of HIV status during clinical encounters. However, the possibility of this social harm would exist if this intervention were not conducted.

We will periodically monitor all study sites for unanticipated problems, and record any unanticipated problems. Monitoring will be conducted on-site through observation, follow-up data collection, and feedback from clinic leadership and staff.

9a. Reporting of unanticipated problems and other events

In compliance with federal regulations and UW policy, the Principal Investigator will notify the UW Human Subjects Division (HSD) and/or UW Institutional Review Board (IRB), Kenyan Ethics Committee, and relevant local Kenyan authorities (i.e. Ministry of Health) of any unanticipated problems within 10 business days. Any breach or possible breach of confidentiality of any participants in this study will be reported to UW HSD and/or IRB within 24 hours.

SECTION 10: DATA COLLECTION

Data collection tools submitted with this application can be found in the Appendices.

- *Prospective Data - Facility survey:* This will be administered to a health facility representative and will capture facility characteristics including pediatric clinic model (separate days or integrated), presence and type of transition planning approach, recommended age for transition, and available adolescent and transition services.
- *Prospective Data - In-depth interviews and focus group discussions:* These will be conducted using an interview or discussion guide. Guides for all proposed interviews and focus group discussions are included as appendices. Interviews and focus groups will be audio-recorded and transcribed.

- *Prospective Data - Demographic information:* We will collect demographic information for all participating in the FGD/IDIs. Demographic surveys for each population included in IDIs or FGDs are attached as appendices.
- *Retrospective and Prospective Data - Clinic records:* Adolescent clinic records from the EMR system and routinely collected paper forms will be extracted from all clinics participating in Aim 1 and at baseline, and throughout the RCT, for clinics participating in Aim 3 to assess clinical adolescent outcomes. Data from each pull will capture all records until the previous data pull (Aim 3) or from between January 1, 2016 and December 31, 2017 (Aim 1). Examples of data will be enrollment age, CD4, viral load (where available), WHO stage, hospitalization, caregiver presence, serial visits since enrollment, pediatric or adult clinic day of attendance and reported adherence. This will be collected from the clinic medical records database or paper clinic records, a clinic partner organization, or other location where medical record data for selected clinics is being stored and managed such as the Kenyan National Data Warehouse.
- *Prospective Data - Disclosure readiness assessment and checklist:* This will be completed at every clinic visit to obtain more detailed data on partial and full disclosure in both intervention and control sites. This data will be abstracted from patient files routinely throughout the RCT.
- *Prospective Data - Transition booklet tracking form:* This will be completed at every clinic visit to obtain more detailed data on transition in intervention sites. This data will be abstracted from patient files routinely throughout the RCT.
- *Prospective Data - Transition readiness assessment (HCW tool):* This will be completed by HCWs when adolescents reach age 17 and above in intervention sites. This data will be abstracted from patient files routinely throughout the RCT.
- *Prospective Data - Transition tracking log:* This will be completed at transition to adult clinics and for next 6 months for both intervention and control sites. This data will be abstracted from patient files routinely throughout the RCT. .
- *Prospective Data - Pre-Trial surveys:* Surveys will be conducted with adolescents who have completed disclosure or transitioned to adult care and HCWs from intervention sites. Adolescent surveys will be conducted for both intervention and control sites at the beginning of the study. Information will include basic demographics (age, schooling) and satisfaction with services received. HCW surveys include basic demographic information, initial impressions of the ATP, and implementation climate.
- *Prospective Data - Post-trial surveys:* The surveys will focus on client satisfaction based on the new adapted transition tool and will therefore be refined once the transition tool has been adapted and optimized.
 - *Adolescent post-trial surveys:* Surveys will be conducted with adolescents who have fully completed disclosure or fully transitioned. These surveys will be conducted for both intervention and control sites at the end of the study. Information will include basic demographics (age, schooling) and satisfaction with transition or disclosure services received.
 - *HCW post-trial survey:* Surveys will be conducted with HCWs working at intervention sites. Information will include basic demographics, satisfaction with disclosure and transition tools in the ATP, and acceptability of the ATP. Surveys will also assess training in intervention implementation, use of intervention tools, fidelity to implementation and feasibility of implementing study tools and processes.

- *Prospective Data – Transition readiness surveys:* Surveys will be conducted every 6 months with adolescents ages 15-24 years who have attained full disclosure. The survey will focus on adolescent readiness for transition and will be conducted for both intervention and control sites. Surveys will assess medical knowledge and skills in being independent.

Data Management Responsibilities

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

Data Capture and Storage Methods

Study personnel conducting recruitment procedures will have access to direct identifiers. All study personnel involved in recruitment will be trained in the Protection of Human Subjects. The study staff involved in recruitment team will take every precaution to protect participants' confidentiality.

- During the study, we will collect the following identifiers for participants:
 - Patient IDs for participants providing medical records – we will remove these once all data for a facility has been collected and linked.
 - Names/phone numbers for potential participants identified by clinic staff for interviews, focus groups, the working group, and facility surveys – we will destroy this information for all participants who do not elect to participate once we have finished recruitment at that clinic site. We will retain this information linked to their study ID in a secure link log for people who enroll in the study. Links between participant identifiers and study IDs will be kept for a period of 6 years after the end of the study, at which time the link between participant identifiers and study IDs will be destroyed.
- *Audio-recordings* will be translated and transcribed and will be stored on University of Washington supported One drive for business or other UW IT approved data storage system that becomes available after approval of the study. We will ensure that the storage website uses LMS, has industry standard security, and will be password protected.
- *Facility surveys, pre-trial surveys, post-trial surveys, and transition readiness surveys* will be carried out by trained study staff members using ODK or mobile REDcap on tablets or android phones, and stored on a secure cloud server.
- *Disclosure and transition readiness assessments and transition tracking logs and transition booklet tracking forms* will be entered to ODK or REDCap by study staff

members using ODK or REDCap on tablets or android phones, and stored on a secure cloud server.

- The methods of *EMR data* extraction in the study clinics will follow a data use agreement between the study team and site partners. We will provide a list of variables and records for a site partner designated data administrator to extract. We will receive data in a secure, password protected format (e.g. USB or cloud server). These data will be stored in a password-protected database accessible only to authorized members of the study team.
- Until we finish collecting data and linking patient files together from the multiple data sources (paper forms and electronic medical records), we will retain unique clinic patient IDs alongside their medical record information. We will replace their unique ID with a study unique ID once all data collection from medical records at that clinic has been completed. A document that links the names from the consent forms to the study ID will be maintained for all procedures involving written informed consent. The document will be password protected and accessible only to authorized study staff. The document with the link information will be maintained in a file that does not have study data. Following completion of data collection and cleaning, the data will be in non-identifiable form (coded by study number only). Only de-identified information will be shared. The file containing the link between participant information and study ID will NOT be shared.
- The study PI will oversee and manage data sharing and use of data for future studies. If possible in the future, we will use these data for additional research on issues related to adolescents and/or HIV. Study participants would be able to withdraw their information from any future research up until 6 years after the study has been completed and the link log is destroyed.
- Data Collected: We will obtain names, ages (for adolescents), phone numbers and email addresses for all potential participants who are not participating in the anonymous surveys in order to contact them about the study at appropriate points in time as detailed in the protocol. This information will be provided to study staff by clinic personnel and written down. For participants who decline participation, we will store this information only until we have completed recruitment at their clinic site and will keep the information during recruitment to ensure that we do not contact them again. For participants who decide to enroll in the study and are not part of the anonymous surveys, we will keep a record of the name, age (for adolescents) and phone number (and email address for HCWs) linked to their study ID. This information will be stored separately from any data collected during the study and will be stored for 6 years.

Data Custody and Retrieval Procedures

All data for this study will be under the custody of the Principal Investigator, Site Leader, and authorized study staff. Data retrieval procedures will be similar for all types of data in this study. Authorized study staff members will download the datasets from the secure servers for routine quality checking and analyses. Similarly, EMR data will be retrieved from a secure server or USB, and transferred to a study computer at scheduled intervals. All downloaded data will be maintained on a secured, password-protected study computer. From these data sources, the analysts will create merged datasets for planned analyses.

Study Records Retention

Retention of study records will comply with UW and Federal requirement (<http://f2.washington.edu/fm/recmgt/retentionschedules/gs/general/uwgsResearch#Research>).

All study data and link between HCW, adolescent or caregiver participant identifiers and study ID codes will be retained for 6 years following completion of the study. Audio data will be destroyed after 6 years, unless a waiver has been signed. Participant consents will be retained for 6 years after the end of the study. The link between participant identifiers and study IDs will be kept under lock and key. After this time, links to identifiable data will be destroyed.

SECTION 11: STATISTICAL CONSIDERATIONS

11a. Sample Size Considerations

Aim 1: 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 will stratify clinics to have an equal number of small, medium and large clinics. We propose an evaluation with 102 clinics, 34 clinics per clinic size cluster, and a maximum total sample size of 15,000 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, 2016 will have their medical records pulled.

Based on previous data, we anticipate that we will be able to identify at least 50 adolescents per clinic for a total of at least 5000 adolescents. 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 a 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 $\pm 2.6\%$ to $\pm 1.5\%$ (Table 5). Thus, with 5000 adolescents or more, 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.

Table 7: Precision estimates for prevalence of retention and viral load suppression in HIV-infected adolescents

Indicator	Adolescents evaluated	Observed Prevalence	Events	CI	Precision
Retention or suppressed viral load	5000	50%	2500	47.4-52.6%	$\pm 2.6\%$
	5000	60%	3000	57.5-62.5%	$\pm 2.5\%$
	5000	70%	3500	67.6-72.4%	$\pm 2.4\%$
	5000	80%	4000	77.9-82.1%	$\pm 2.1\%$
	5000	90%	4500	88.5-91.5%	$\pm 1.5\%$

Aim 2: Given that the goal of the interviews conducted in this aim is to gather information on experiences with disclosure and transition and use this information to refine study tools, we believe that conducting 16 focus group discussions with adolescents (N=96), 16 focus group discussions with primary caregivers of adolescents (N=48), 38 interviews with HCWs and 30 interviews with administrators and policy makers, will give us adequate numbers to reach our study goal and enough diversity in experiences to ensure different perspectives are accurately represented in study tool refinement. A working group comprised of approximately 40 HCWs with significant expertise in providing care for HIV-infected children, adolescents and adults will be

sufficient to foster rich discussions around study tools. Including approximately 40 HCWs, will allow participation of all stakeholders.

Aim 3: For the RCT, using a conservative estimate of 20% of clients being between 10-24 years old and each clinic having at least 500 active clients, we anticipate 200 eligible clients per clinic, for a total of 1000 eligible clients per randomization arm.

- We assume that 100 of these eligible clients will be aged 10-15 and that the rate of complete disclosure will be 15% in the control clinics based on our prior studies and the literature with increased prevalence per year of age in this age-window.
- We assume that 100 of these eligible clients will be aged 15-24 years and that 20% (n=20) will be receiving care in a pediatric program and could be eligible to transition (200 per RCT arm). During 2-year follow-up, we anticipate that in the control arm 20% will transition and 10% will transition effectively.

With 10 intervention and 10 control sites, we will have sufficient power to detect an increase in proportion of adolescents with disclosure from 30% to 50%, an increase in proportion who initiate transition from 50% to >80%, and an increase in proportion with effective transition from 10% to 20%. This assumes alpha of 0.05, 80% power, and a conservative estimate of the coefficient of variation of 0.3 (Table 6). Heterogeneity between clusters is expected to decrease with control for baseline testing rates, leading to increased power beyond that which is noted above.

Table 8: Power and sample size ranges

	Outcome Control	Outcome Intervention	Number of clinics per RCT arm to detect difference
Age 10-15	N=1000 (100/clinic)	N=1000 (100/clinic)	
Disclosure process started (proportion)	50% 50% 50%	>80% >90% 100%	9 6 5
Disclosure complete (proportion)	30% 30% 30%	50% 70%	8 4 3
Disclosure age median	14 years old	12 years old	NA
24-month LTFU	20%	10%	7
Age 16-24	N=1000 (100/clinic)	N=1000 (100/clinic)	
Transition discussed (proportion)	20% 20% 50%	40% 60% 100%	6 3 5
Transition complete (proportion)	10%	20%	7
Transition satisfaction	50%	70%	NA
24-month LTFU	25%	15%	10

For the provider and adolescent IDIs, we will select healthcare providers and adolescents from ATP-implementing clinics for individual interviews. Clinics will be purposively selected from among all ATP-implementing clinics. We will purposively select clinics for interviews based on performance, including high and low performing sites as appropriate based on the outcome of the intervention. If the majority of clinics do well, we will purposively select a higher proportion of low performing clinics to understand why they had challenges. If the majority of the clinics do poorly, we will purposively select a higher proportion of high performing clinics to understand how they succeeded.

A total of up to 8 providers per site will be selected from among all providers on site for a total of up to 48 HCWs. HCWs will be purposively selected to represent different cadres of HCWs who provide services for adolescents and are directly involved in implementation of the ATP. We believe that 8 providers per site (48 total) 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.

A total of up to 16 adolescents per site in 6 sites (3 high and 3 low performing sites) will be selected for interviews. We will purposively select an even number of younger adolescents (ages 14-18) and older adolescents (ages 19-24) to capture the impact of elements of the ATP related to both disclosure (younger adolescents) and transition (older adolescents). Clinic providers will assist in identifying and referring adolescents who are aware of their HIV status and have been through disclosure as well as adolescents who have transitioned to adult care. Eligibility of adolescents will be confirmed by reviewing their chart for documentation of disclosure and transition. We believe that 16 adolescents in each of the 6 sites (96 total) will give us adequate numbers to attain saturation during data collection and selecting 8 adolescents from each site from younger and older ages will provide enough diversity in experiences to ensure different perspectives are accurately represented.

11b. Overview of analysis plan

Aim 1

Follow-up at 6-month post-enrollment and annually thereafter will be determined and summarized as proportion retained for given interval (e.g., 6-month retention, 12-month retention, 36-month retention) with anticipated denominator in follow-up based on enrollment date. Cofactors for loss to follow-up will be determined using Cox regression. Potential cofactors of loss to follow-up include age at enrollment, CD4, caregiver type (biologic, mother or father), age at HIV diagnosis, sex, illness or hospitalization, and evidence of transition. Proportion with evidence of transition and mean/median age of transition will be computed. Cofactors of transition will be determined including child/adolescent age, age at HIV diagnosis, evidence of disclosure, caregiver type using logistic regression. Post-transition retention will be determined and cofactors of effective transition (documented 6-month or longer follow-up after transition) will be assessed using logistic regression.

Aim 2

Focus group discussions and interviews will be recorded and transcribed verbatim. Transcripts will be coded and thematic analysis will be conducted on the transcripts using ATLAS.ti. At least 2 researchers will independently code the data, coordinating their findings and analyses to create a comprehensive codebook and concept map. Themes related to how to culturally adapt and improve the described transition intervention, and how to improve clinical care for HIV-infected adolescents, will be identified and used to revise the implementation of the intervention.

Aim 3

The primary analysis will be an intent-to-treat (ITT) analysis.

We will use generalized estimating equations (GEE) clustered on facility level to compare differences in age-appropriate disclosure and change in transition readiness over time between control and intervention communities during baseline and intervention periods. In order to decrease variability between our sites and increase precision of our outcome measures, we will

control for baseline adolescent disclosure and transition proportions in our models. We hypothesize that the increases in disclosure and transition proportions between the baseline and intervention periods will be greater among intervention than control facilities.

The first 6 months of the intervention will be considered a “catch up” period; while outcomes will be compared during the full study period, a sub-group analysis is planned for the first 6 months to see if the effect of the intervention is greater during the “catch-up” period.

Focus group discussions and interviews will be recorded and transcribed verbatim. Transcripts will be coded and thematic analysis will be conducted on the transcripts using ATLAS.ti. At least 2 researchers will independently code the data, coordinating their findings and analyses to create a comprehensive codebook and concept map. Themes related to implementation acceptability, feasibility, appropriateness and challenges and successes will be identified. Proportions satisfied with the transition and disclosure process will be compared between the 2 arms.

SECTION 12: ETHICS/PROTECTION OF STUDY PARTICIPANTS

12a. Informed Consent Process

Clinic participation

This intervention will be at facility level therefore, we will engage with the relevant HIV care partners, county health management and facility administration teams prior to entering health facilities. Because we will be collecting routinely collected program data on adolescent retention and health outcomes, we will request a waiver of individual consent of adolescent patients for abstracting clinic records.

HCW and Policy makers and administrators

HCW participants will provide written informed consent for participation in IDIs, FGDs, implementation evaluation activities, and the working group.

For post-trial surveys among HCWs, we will request waiver of written consent as no identifying information will be collected.

Policy makers and administrators will provide written informed consent for participation in IDIs.

Adolescent patients

The consent and assent process for IDIs and FGDs by age is described below:

- 1) Adolescents ages 14-17 who come with a caregiver: Written informed consent will be sought from the caregiver and written assent will be sought from the minor. We will not enroll any adolescent between ages 14 and 17 who is unaccompanied by a caregiver.
- 2) Adolescents >18: Regardless of whether they are accompanied, adolescents will provide written informed consent.

Pre and post- trial surveys: We will request a waiver of written assent or consent for these participants. We will also request a waiver of parental permission for adolescents ages 12-17. As we will not be collecting any personal information, breach of confidentiality is of higher risk with written documentation rather than verbal agreement. We request waiver of parental consent because many adolescents attend the care clinic independently, without their caregivers. If

caregivers are present with the child participant, we will respect caregivers' wishes if they do not want the child to complete the anonymous survey. Requirement of parental consent would be problematic for adolescents who have transitioned (eg, have assumed autonomy for their own care), and for those whose caregivers would be unavailable to come in and provide consent. Excluding these adolescents would bias the study population.

Transition readiness surveys: Written informed consent or assent will be sought from the adolescent ages 15-24 years. We will request a waiver of parental permission for adolescents ages 15-17 years because many adolescents present to clinic for care unaccompanied and the survey questions are minimal risk and ask about non-sensitive information. Requirement of parental consent would be problematic for adolescents 15-17 years who have attained full disclosure and potentially transitioned (e.g., have assumed autonomy for their own care), and for those whose caregivers would be unavailable to come in and provide consent. Excluding these adolescents would bias the study population.

Caregivers of HIV-infected adolescents

Caregivers will provide written informed consent.

Consent Details:

A consent form describing in detail the study procedures and risks will be provided. Participants will be informed that they are free to decline participation, and that declining to give permission will have no impact on their role in this study. Participants will be informed that they are free to withdraw their permission at any time during the study.

Consent forms and information sheets will be IRB-approved, and the participant is required to read and review the document or have the document read to him or her. The study team member will explain the research study to the participant and answer any questions that may arise. The individual will sign the informed consent document prior to any study-related assessments or procedures. Participants will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. A copy of the informed consent document will be given to participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their clinical care will not be adversely affected if they decline to participate in this study.

Comprehension will be assessed by asking the participant to repeat back what was explained and encourage them to ask questions. Study staff may ask the participant questions like the following to assess comprehension:

- b) "Just so that I'm sure you understand what is expected of you, would you please explain to me what you think we're asking you to do?"
- c) "Describe in your own words the purpose of the study."
- d) "What more would you like to know?"
- e) "What is the possible benefit to you of participating in this study? What are the possible risks?"

If the participant is unable to answer these questions, study staff will go through the consent form with them again. If a participant continues to be unable to understand the study procedures and risks and benefits, the staff person will thank them for their time and let them go without enrolling them into the study.

For all participants that are unable to read, we will ensure that the consent form is read aloud to them and that there is a witness present when they sign the consent form. We will ensure that the witness also signs the form documenting observation of the consent process and the participant's willingness to participate.

Exclusion of Women, Minorities, and Children

There are no exclusions of women or minorities. Eligibility is based on age and occupation. Adolescent patients under age 10 will be excluded from this study because the target population is adolescents and youth ages 10-24.

Translation of Materials:

We anticipate that the majority of study participants will be fluent in either Kiswahili, Luo, or English or other language appropriate for where the research study is taking place. We will generate study materials specific to each of those languages. For interviews and focus group discussions, we will ensure that the interviewer is fluent in the preferred language spoken by patients at the clinic.

We will not provide interpretation services. We will require that our research coordinator(s) and qualitative study staff be fluent in English, Swahili, Luo or another local language spoken in the region where research is taking place. Only participants who understand English, Swahili and/or Luo or another language appropriate for where the study is taking place will be eligible for the study.

At least 1 study staff member will be fluent in every language we will be creating consent and other study related materials for. We will ensure that participants speak with a study staff member fluent in their preferred language when they have questions or concerns about the study.

We will work with translators/interpreters who are fluent in English, Swahili, and other relevant tribal languages to translate consent forms to the appropriate languages. Once consents are translated and transcribed into their appropriate language, they will be back translated to English by another translator/interpreter who has not seen the original English consent form to ensure that the messages and material included in the consent form is accurate. We will correct any information in the translated consents that is not correctly back translated and get approval from the ERC for all translated study materials.

12b. Participant Confidentiality

All key personnel will be trained in the Protection of Human Subjects. The field team will take every precaution to protect participants' confidentiality. To ensure confidentiality, focus group discussions and interviews will take place in rooms where the door to the room can be shut during the discussion. Only designated study staff and the individuals involved in the focus group discussion or interview will be allowed in the room during the focus group discussion or interview.

We only will collect personal identifiers for the purposes of identifying and contacting participants about the study. This information will include the names, telephone numbers and emails for those identified as interested in participating in the study. We will not collect patient identifiers for participants completing pre, during and post-trial anonymous surveys. Personal identifiers will be used to contact participants to remind them of their upcoming study visit and also to contact them if they fail to appear for their scheduled study visit. This information will also be used to contact them again to verify the accuracy of the information collected or to elaborate or clarify certain information provided during study procedures if they select the option to be re-contacted on the consent form.

All participants will be assigned a study identification number (ID). Health information and phone numbers will be recorded and stored under this study ID. Participant identifiers will be linked to their study ID and will be stored in binder in a locked cabinet separately from all other study data. Only necessary study staff will have linkage 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 6 years after the study has ended, 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.

Study staff will take strict measures to maintain confidentiality for participants. Data collected will be kept confidential and access restricted to study staff. All audio-recordings of the IDIs will be kept in a secure database. All other data will be kept in password-protected databases, in a locked study office, accessible only to study personnel. Study identifiers will be linked to coded data; clinical staff will have access to patient identifiers, but the analysts will receive only coded data. Links between patient identifiers and study codes will be kept for a period of 6 years after the end of the study, at which time the link between patient IDs and codes will be destroyed.

12c. Potential Risks and Benefits

Potential Risks

- *Physical:* There are no medical interventions associated with the study, therefore we anticipate no risk of serious harm to participating HCWs, adolescents, caregivers, hospital administrators or policy makers.
- *Other:* Other study risks include emotional distress associated with the sensitive nature of the disclosure process, breach of patient confidentiality during data extraction (adolescent clinic records), and fear of or actual loss of employment associated with implementing the ATP. We are not directly enrolling adolescent clients other than to take part in in-depth interviews, focus group discussions, and anonymous surveys. However, there is a possibility for social harm (depression, violence after disclosure, abandonment) related to disclosure of HIV status during clinical encounters at HIV care. However, the possibility of this social harm would exist if this intervention were not conducted. For the FGDs, it is also possible that a participant may know another member in the discussion and by participating in the discussion the other member might learn of their HIV status. We have outlined this potential risk in the consent form.
- *Other:* There is a possibility that during a clinical encounter with a HCW using the more comprehensive tools that are part of the adolescent transition package that an adolescent patient may be more comfortable disclosing that they are suffering from previously undiagnosed mental health problems such as depression. Any patients with potential mental health problems will be referred for psychosocial support at the facility or nearest referral hospital, according to standard HIV care and treatment guidelines for adolescents at that clinic and within the country.
- *Alternative treatments or procedures:* Not applicable
- *Procedures to minimize psychological risks:* All participants will be assured that their participation is voluntary and that they may withdraw from the study at any time. Study personnel experienced with adolescents will perform the disclosure intervention.

Adolescent participants will be informed that they can skip any question or stop the interview, focus group or surveys at any time. We will ask all the members in focus group discussions to protect each other's privacy, and not to repeat anything that is said or learned once the discussion is over.

- *Procedures to minimize other risks:* Study staff will be trained to take all precautions to ensure confidentiality of participation and data collected, and will have standardized operating procedures to follow to minimize the risks of a participant's loss of confidentiality. Risk of breach of confidentiality of study data is low, as all patient data collected will not include names and will be located on a password protected server, and encrypted prior to upload. Study staff will be trained in the importance of confidentiality during human participants training prior to study implementation.
- The systematic disclosure approach will minimize the possibility of involuntary disclosure of HIV status to an adolescent. Some adolescent patients are receiving HIV care and take ART (which may be called 'medicine' and not HIV medicine), but may not yet know their HIV status, because the caregiver is not ready for the child to learn this information.
- *Additional protection for children:* Additional protections will be afforded to participants in the in-depth interviews or focus group discussions. These protections will depend on adolescents' age and whether they are accompanied by a caregiver. Adolescents accompanied by caregivers will be given the option of having their caregiver present during the interview or focus group. Adolescents will also be given the opportunity to meet with a nurse counselor, or other similar staff member, if they request to see one or if the interviewer believes they should see one following the interview or focus group discussion.

Potential Benefits

- *HCWs and clinics:* HCWs in the intervention sites will receive direct and immediate benefit in receipt of disclosure skills and transition tools that may improve outcomes in their facilities.
- *Adolescent client (clinic attendees):* Adolescent clients of participating health facilities may benefit directly from the improved disclosure services and transition services they receive from trained HCWs.

Unanticipated Problems

In compliance with federal regulations and UW policy, the Principal Investigator will notify the UW Human Subjects Division (HSD) and or UW Institutional Review Board (IRB) of any unanticipated problems within 10 business days and the Kenyan Ethics Committee, and relevant local Kenyan authorities (i.e. Ministry of Health) within 3 business days. Any breach or possible breach of confidentiality of any participants in this study will be reported to UW HSD and/or IRB within 24 hours.

Data Safety and Monitoring

A DSMP is not required for this study. However, we are planning to create an External Advisory Panel (EAP) to act in an advisory capacity to the National Institute of Child Health and Human

Development (NICHD), the University of Washington, School of Medicine, and the University of Nairobi, to monitor recruitment, enrollment, and potential social harms of the intervention.

SECTION 13: USE OF INFORMATION AND PUBLICATIONS

Study results will be presented to all participating sites at the end of the study period. This study will comply with the [NIH Public Access Policy](#), which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive [PubMed Central](#) upon acceptance for publication.

SECTION 14: 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 in Aim 1 regarding current systems in place for adolescent HIV treatment and care.

The generalizability of the intervention in this study may be limited due to the small number of clinics included and inability to have proportional geographical representation. We will rely on clinics to implement the interventions within the regular clinic schedule. Clinics may differ in implementation, we will however collect data to measure how well the intervention is implemented. One strength of this proposal is the ability of qualitative methods to uncover detailed information about questions of interest, including identification of the barriers and facilitators to successful implementation. However, due to the nature of qualitative research methods, there will only be a small number of interviews and focus groups 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 current knowledge about transition and disclosure, development of appropriate tools for assisting with transition, and implementation of the ATP.

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APPENDICES

The following documents are included as appendices in this application.

Study Tools:

1. Adapted Namibia disclosure booklet
2. Taking charge booklet

Data Collection Tools:

Activity	Data collection tool
Aim 1	
Facility Survey	Facility Survey CRF
Retrospective Records Review	Variables to be abstracted
Aim 2	
Adolescents in HIV care (48 not completed transition, 48 transitioned)	General - Adolescent Demographic Survey
	Adolescent Focus Group Discussion Guide – Informational
Caregivers of adolescents who have and have not completed transition (48 total)	Caregiver Demographic Survey
	Caregiver Focus Group Discussion Guide – Informational
HCWs involved in pediatric/adolescent HIV care	General - HCW Demographic Form
	HCW Interview Guide - Informational
Policy makers or administrator heads	Policy-maker/Admin Demographic Form
	Policy-maker/Admin Interview Guide – Informational
Aim 3	
Disclosure outcome	Disclosure Checklist
	Disclosure Readiness assessment
Transition outcome	Transition Tracking Log
	Transition booklet tracking
	Transition readiness assessment (HCW)
	Transition readiness survey (adolescents)
Pre-trial surveys	Pre-trial Adolescent Survey
	Pre-trial HCW Survey
Implementation period	HCW FGD Guide
	HCW implementation survey
	HCW PDSA Worksheet
	HCW FGD Demographic Form
Post-trial IDIs	General - Adolescent Demographic Form
	Post-Trial Adolescent Interview Guide – Disclosure Focus

	Post-Trial Adolescent Interview Guide – Transition Focus
	General - HCW Demographic Form
	Post-Trial HCW Interview Guide
	Adolescent Survey
Post-trial surveys	HCW Survey

Consent Forms:

Study Activity	Consent document
Aim 1	
Facility Survey	Consent for facility survey
Aim 2	
Adolescents in HIV care (48 not completed transition, 48 effectively transitioned)	Adolescent Assent (Age 14-17) for Focus Group Discussion
	Parental consent for Adolescent Informational Focus Group Discussion (Age 14-17)
	Consent for Adolescent Informational Focus Group Discussion (Age 18-24)
Caregivers	Consent for Caregiver Informational Focus Group Discussion
Policy makers	Consent for Policy maker Informational Interview
HCW/Administrator	Consent for HCW/Administrator Informational Interview
Working group	Consent for HCW Working group
Aim 3	
Pre-Trial Surveys	Oral consent for anonymous Adolescent Pre-Trial Survey (age ≥18)
	Oral assent for anonymous Adolescent Pre-Trial Survey (ages 12-17)
Implementation Activities	HCW IS Activities Consent Form
Post-trial IDI	Adolescent Assent (ages 14-17)*
	Consent for Adolescent Post-Intervention IDI (Age 18-24)
	Parental Consent for Adolescent Post-Trial IDI (Age 14-17)
	Consent for HCW Post-Trial IDI
Implementation FGDs	HCW Implementation FGD Consent Form
Transition readiness surveys	Assent and Consent Form for Adolescent Transition Readiness Assessment Survey (15-24 years old)
Post-trial surveys	Oral consent for anonymous Adolescent Post-Trial Survey (age ≥18)
	Oral assent for anonymous Adolescent Post-Trial Survey (ages 12-17)
	Oral consent for anonymous HCW Post-Trial Survey

*Same as aim 2 document

Study Activity	Recruitment Script
Aim 1`	
Facility Survey	Facility Survey Recruitment Script
Aim 2	
Adolescents in HIV care (48 not completed transition, 48 transitioned)	NA
	Caregiver recruitment script for adolescent IDI and FGD
	Adolescent recruitment script
Caregivers	Caregiver recruitment script
Policy makers	Policy maker/Admin/HCW recruitment script
HCW/Administrator	Policy maker/Admin/HCW recruitment script
Working group	HCW recruitment script for Workshop
Aim 3	
Pre-Trial surveys	Adolescent Recruitment Script*
Implementation Activities	HCW IS Activities Recruitment Script
Post-trial IDI	NA
	Adolescent recruitment script*
	Caregiver recruitment script*
	HCW recruitment script*
Implementation FGDs	HCW FGD Recruitment Script
Transition readiness	Adolescent recruitment script*
Post-trial surveys	Adolescent recruitment script*
	HCW recruitment script*

RCT DATA COLLECTION TOOLS

ATTACH Study - Disclosure Tracking Form (All Sites)



SECTION A: Complete at first contact

1. Child ID	May 23, 2019																				
2. Facility MFL code:	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td></tr></table>																				
3. Date of birth of child:	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td colspan="3">Day</td><td colspan="3">Month</td><td colspan="4">Year</td></tr></table>											Day			Month			Year			
Day			Month			Year															
4. Gender of child:	<input type="checkbox"/> Male <input type="checkbox"/> Female																				
5. Who is the child's primary caregiver?	<input type="checkbox"/> Biological mother <input type="checkbox"/> Biological father <input type="checkbox"/> Grandmother <input type="checkbox"/> Aunt/Uncle <input type="checkbox"/> Sibling of child <input type="checkbox"/> Other, sp. _____																				
6. Who brought child to clinic?	<input type="checkbox"/> Parent <input type="checkbox"/> Grandparent <input type="checkbox"/> Came alone <input type="checkbox"/> Aunt/Uncle <input type="checkbox"/> Sibling of child <input type="checkbox"/> Other, sp. _____																				
7. Does the clinic report the child knows they have HIV?	<input type="checkbox"/> Yes (<i>go to section C</i>) <input type="checkbox"/> No																				
8. Does the child know they have HIV?	<input type="checkbox"/> Yes (<i>go to section C</i>) <input type="checkbox"/> No If no, does the child know they have an illness? <input type="checkbox"/> Yes <input type="checkbox"/> No (<i>begin disclosure discussions, go to section B</i>)																				

SECTION C: Complete at full disclosure

1. Place where full disclosure occurred	<input type="checkbox"/> Home <input type="checkbox"/> Clinic <input type="checkbox"/> Hospital												
2. Date of full disclosure:	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td colspan="2">Day</td><td colspan="2">Month</td><td colspan="2">Year</td></tr></table>							Day		Month		Year	
Day		Month		Year									
3. Who conducted full disclosure?	<input type="checkbox"/> Caregiver <input type="checkbox"/> Health provider <input type="checkbox"/> Other, specify _____												
4. Nature of disclosure:	<input type="checkbox"/> Planned <input type="checkbox"/> Unplanned/accidental												
5. Child's reaction to full disclosure	<table border="1"><tr><td> </td></tr><tr><td> </td></tr><tr><td> </td></tr><tr><td> </td></tr><tr><td> </td></tr><tr><td> </td></tr></table>												
6. Go to section D for adolescents who had not attained full disclosure at first contact in the study (those with section B started)													

SECTION B: Complete at every child visit until full disclosure. After full disclosure, complete section C

Date (DD/MMM/YYYY)	Child response to "Why are you taking your medicine?" 1-don't know 2-mentions specific illness not HIV 3-mentions immunity (make body strong, prevent illness) 4-I have HIV 5- other, specify	Who brought child to clinic today?	Disclosure counseling done today (Yes/No)	Content of discussion today (Indicate NONE if no discussion)	If no disclosure discussion, indicate why: 1-child too sick 2-Already disclosed 3- not ready 4-short visit 5-other (specify)
	1 2 3 4 (specify) _____		<input type="checkbox"/> Yes <input type="checkbox"/> No		1 2 3 4 5 (specify) _____

	1 2 3 4 (specify)_____		<input type="checkbox"/> Yes <input type="checkbox"/> No		1 2 3 4 5 (specify)_____
	1 2 3 4 (specify)_____		<input type="checkbox"/> Yes <input type="checkbox"/> No		1 2 3 4 5 (specify)_____
	1 2 3 4 (specify)_____		<input type="checkbox"/> Yes <input type="checkbox"/> No		1 2 3 4 5 (specify)_____

SECTION D: Complete during subsequent follow-up visits after disclosure

Date of follow-up visit	Child reaction since disclosure		Action taken at visit	Action plan	
	Caregiver reflection	Provider reflection		Caregiver	Child
	Behavior:	Mood:			
	Mood:	Adherence:			
	Adherence:	Interaction with caregiver:			
	Interaction with caregiver:	Interaction with provider:			
	Who else has been told the child HIV status				
	Behavior:	Mood:			
	Mood:	Adherence:			
	Adherence:	Interaction with caregiver:			
	Interaction with caregiver:	Interaction with provider:			
	Who else has been told the child HIV status				
	Behavior:	Mood:			
	Mood:	Adherence:			
	Adherence:	Interaction with caregiver:			
	Interaction with caregiver:	Interaction with provider:			

	Who else has been told the child HIV status				
	Behavior:	Mood:			
	Mood:	Adherence:			
	Adherence:	Interaction with caregiver:			
	Interaction with caregiver:	Interaction with provider:			

1-Worse than before disclosure 2-Same as before disclosure 3-Better than before disclosure

Disclosure Readiness Assessment Form



Child ID	May 23, 2019	Facility Name	
Date of birth	<div style="border: 1px solid black; width: 150px; height: 30px; margin: 0 auto; position: relative;"> <div style="position: absolute; left: 5px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 15px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 25px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 35px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 45px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 55px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 65px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 75px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 85px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 95px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 105px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 115px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 125px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 135px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 145px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 155px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 165px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 175px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 185px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 195px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 205px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 215px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 225px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 235px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 245px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 255px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 265px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 275px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 285px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 295px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 305px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 315px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 325px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 335px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 345px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 355px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 365px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 375px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 385px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 395px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 405px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 415px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 425px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 435px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 445px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 455px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 465px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 475px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 485px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 495px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 505px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 515px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 525px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 535px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 545px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 555px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 565px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 575px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 585px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 595px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 605px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 615px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 625px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 635px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 645px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 655px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 665px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 675px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 685px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 695px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 705px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 715px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 725px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 735px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 745px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 755px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 765px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 775px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 785px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 795px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 805px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 815px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 825px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 835px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 845px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 855px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 865px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 875px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 885px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 895px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 905px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 915px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 925px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 935px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 945px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 955px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 965px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 975px; top: 5px; width: 10px; height: 10px;"></div> <div style="position: absolute; left: 985px; top: 5px; width: 10px; height: 10px;"></div> </div>	Gender	<input type="checkbox"/> Male <input type="checkbox"/> Female
	Age (if date of birth unknown)	Who brought child to the clinic?	<input type="checkbox"/> Mother <input type="checkbox"/> Father <input type="checkbox"/> Aunt/Uncle <input type="checkbox"/> Sibling <input type="checkbox"/> Grandparent <input type="checkbox"/> Other relative specify _____ <input type="checkbox"/> other non-relative specify _____

This form will be completed with the caregiver during regular scheduled visits for adolescents who have not reached full disclosure. **Adolescents who have not reached full disclosure should not be present during interview.**

		Visit Dates		
		__/__/__	__/__/__	__/__/__
1.	Who else lives in the child's household	<input type="checkbox"/> Mother <input type="checkbox"/> Father <input type="checkbox"/> Aunt/Uncle <input type="checkbox"/> Sibling <input type="checkbox"/> Grandparent <input type="checkbox"/> Other relative <input type="checkbox"/> other non-relative	<input type="checkbox"/> Mother <input type="checkbox"/> Father <input type="checkbox"/> Aunt/Uncle <input type="checkbox"/> Sibling <input type="checkbox"/> Grandparent <input type="checkbox"/> Other relative <input type="checkbox"/> other non-relative	<input type="checkbox"/> Mother <input type="checkbox"/> Father <input type="checkbox"/> Aunt/Uncle <input type="checkbox"/> Sibling <input type="checkbox"/> Grandparent <input type="checkbox"/> Other relative <input type="checkbox"/> other non-relative
2.	Who gives the child medicine	<input type="checkbox"/> Mother <input type="checkbox"/> Father <input type="checkbox"/> Aunt/Uncle <input type="checkbox"/> Sibling <input type="checkbox"/> Grandparent <input type="checkbox"/> Self <input type="checkbox"/> Other relative <input type="checkbox"/> other non-relative	<input type="checkbox"/> Mother <input type="checkbox"/> Father <input type="checkbox"/> Aunt/Uncle <input type="checkbox"/> Sibling <input type="checkbox"/> Grandparent <input type="checkbox"/> Self <input type="checkbox"/> Other relative <input type="checkbox"/> other non-relative	<input type="checkbox"/> Mother <input type="checkbox"/> Father <input type="checkbox"/> Aunt/Uncle <input type="checkbox"/> Sibling <input type="checkbox"/> Grandparent <input type="checkbox"/> Self <input type="checkbox"/> Other relative <input type="checkbox"/> other non-relative
3.	Who brings the child to the clinic	<input type="checkbox"/> Mother <input type="checkbox"/> Father <input type="checkbox"/> Aunt/Uncle <input type="checkbox"/> Sibling <input type="checkbox"/> Grandparent <input type="checkbox"/> Self <input type="checkbox"/> Other relative <input type="checkbox"/> other non-relative	<input type="checkbox"/> Mother <input type="checkbox"/> Father <input type="checkbox"/> Aunt/Uncle <input type="checkbox"/> Sibling <input type="checkbox"/> Grandparent <input type="checkbox"/> Self <input type="checkbox"/> Other relative <input type="checkbox"/> other non-relative	<input type="checkbox"/> Mother <input type="checkbox"/> Father <input type="checkbox"/> Aunt/Uncle <input type="checkbox"/> Sibling <input type="checkbox"/> Grandparent <input type="checkbox"/> Self <input type="checkbox"/> Other relative <input type="checkbox"/> other non-relative
4.	Who knows the child's HIV status?	<input type="checkbox"/> Mother <input type="checkbox"/> Father <input type="checkbox"/> Aunt/Uncle <input type="checkbox"/> Sibling <input type="checkbox"/> Grandparent <input type="checkbox"/> Self <input type="checkbox"/> Other relative <input type="checkbox"/> other non-relative	<input type="checkbox"/> Mother <input type="checkbox"/> Father <input type="checkbox"/> Aunt/Uncle <input type="checkbox"/> Sibling <input type="checkbox"/> Grandparent <input type="checkbox"/> Self <input type="checkbox"/> Other relative <input type="checkbox"/> other non-relative	<input type="checkbox"/> Mother <input type="checkbox"/> Father <input type="checkbox"/> Aunt/Uncle <input type="checkbox"/> Sibling <input type="checkbox"/> Grandparent <input type="checkbox"/> Self <input type="checkbox"/> Other relative <input type="checkbox"/> other non-relative

5	Do any other household members also have HIV	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
6	Are any family members taking ARVs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
7a	Has the caregiver ever discussed with other household members what they think about informing the child about his/her HIV status?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
7b	What was the outcome?	<input type="checkbox"/> Child should be told now <input type="checkbox"/> Child should be told later	<input type="checkbox"/> Child should be told now <input type="checkbox"/> Child should be told later	<input type="checkbox"/> Child should be told now <input type="checkbox"/> Child should be told later
8	What has the child been told about why he/she comes to clinic or takes medication?	<input type="checkbox"/> They have illness <input type="checkbox"/> To remain strong <input type="checkbox"/> To prevent illness <input type="checkbox"/> other specify _____	<input type="checkbox"/> They have illness <input type="checkbox"/> To remain strong <input type="checkbox"/> To prevent illness <input type="checkbox"/> other specify _____	<input type="checkbox"/> They have illness <input type="checkbox"/> To remain strong <input type="checkbox"/> To prevent illness <input type="checkbox"/> other specify _____
9	What does the caregiver think the child believes is the reason that he/she comes to clinic and takes medication?	<input type="checkbox"/> They have illness <input type="checkbox"/> To remain strong <input type="checkbox"/> To prevent illness <input type="checkbox"/> other specify _____	<input type="checkbox"/> They have illness <input type="checkbox"/> To remain strong <input type="checkbox"/> To prevent illness <input type="checkbox"/> other specify _____	<input type="checkbox"/> They have illness <input type="checkbox"/> To remain strong <input type="checkbox"/> To prevent illness <input type="checkbox"/> other specify _____
10a	What questions has the child been asking, if any?	<input type="checkbox"/> Why they take medicine <input type="checkbox"/> When they will stop medicine <input type="checkbox"/> Why others not taking medicine <input type="checkbox"/> other specify _____	<input type="checkbox"/> Why they take medicine <input type="checkbox"/> When they will stop medicine <input type="checkbox"/> Why others not taking medicine <input type="checkbox"/> other specify _____	<input type="checkbox"/> Why they take medicine <input type="checkbox"/> When they will stop medicine <input type="checkbox"/> Why others not taking medicine <input type="checkbox"/> other specify _____
10b	How did the caregiver answer?	<input type="checkbox"/> They have illness <input type="checkbox"/> To remain strong <input type="checkbox"/> To prevent illness <input type="checkbox"/> other specify _____	<input type="checkbox"/> They have illness <input type="checkbox"/> To remain strong <input type="checkbox"/> To prevent illness <input type="checkbox"/> other specify _____	<input type="checkbox"/> They have illness <input type="checkbox"/> To remain strong <input type="checkbox"/> To prevent illness <input type="checkbox"/> other specify _____
11a	Does the child ever talk about HIV?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

11b	What does the child say?	<input type="checkbox"/> HIV can be treated <input type="checkbox"/> People with HIV can live normal lives <input type="checkbox"/> HIV kills <input type="checkbox"/> other specify _____	<input type="checkbox"/> HIV can be treated <input type="checkbox"/> People with HIV can live normal lives <input type="checkbox"/> HIV kills <input type="checkbox"/> other specify _____	<input type="checkbox"/> HIV can be treated <input type="checkbox"/> People with HIV can live normal lives <input type="checkbox"/> HIV kills <input type="checkbox"/> other specify _____
12a	How is the child doing in school?	<input type="checkbox"/> Coping well <input type="checkbox"/> Not coping well	<input type="checkbox"/> Coping well <input type="checkbox"/> Not coping well	<input type="checkbox"/> Coping well <input type="checkbox"/> Not coping well
12b	How is the child's school performance?	<input type="checkbox"/> Above average <input type="checkbox"/> Average <input type="checkbox"/> Below average	<input type="checkbox"/> Above average <input type="checkbox"/> Average <input type="checkbox"/> Below average	<input type="checkbox"/> Above average <input type="checkbox"/> Average <input type="checkbox"/> Below average
12c	Does the child like school?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
13	Does he/she have friends?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
14	How is the child's behaviour at home?			
15	What worries does the caregiver have with regard to the child learning of his/her HIV status?	<input type="checkbox"/> Child will not cope well <input type="checkbox"/> Child will blame parent <input type="checkbox"/> other, specify _____	<input type="checkbox"/> Child will not cope well <input type="checkbox"/> Child will blame parent <input type="checkbox"/> other, specify _____	<input type="checkbox"/> Child will not cope well <input type="checkbox"/> Child will blame parent <input type="checkbox"/> other, specify _____
16	How does the caregiver prefer that child be disclosed to:	<input type="checkbox"/> By the caregiver <input type="checkbox"/> By the caregiver with another family member <input type="checkbox"/> By the caregiver with the HCW <input type="checkbox"/> By HCW with caregiver	<input type="checkbox"/> By the caregiver <input type="checkbox"/> By the caregiver with another family member <input type="checkbox"/> By the caregiver with the HCW <input type="checkbox"/> By HCW with caregiver	<input type="checkbox"/> By the caregiver <input type="checkbox"/> By the caregiver with another family member <input type="checkbox"/> By the caregiver with the HCW <input type="checkbox"/> By HCW with caregiver
17	When does the caregiver think the child should be told?	<input type="checkbox"/> Today <input type="checkbox"/> In 3 mo <input type="checkbox"/> In 6 mo <input type="checkbox"/> In 12 mo	<input type="checkbox"/> Today <input type="checkbox"/> In 3 mo <input type="checkbox"/> In 6 mo <input type="checkbox"/> In 12 mo	<input type="checkbox"/> Today <input type="checkbox"/> In 3 mo <input type="checkbox"/> In 6 mo <input type="checkbox"/> In 12 mo

		<input type="checkbox"/> other, specify_____	<input type="checkbox"/> other, specify_____	<input type="checkbox"/> other, specify_____
18	What does the caregiver think the child's reaction will be when he/she is informed about his/her HIV status?			
19	What questions does the caregiver have about HIV?			

ATTACH Study – Adolescent Transition To Adult Care for HIV-infected Adolescents in Kenya

Healthcare Worker Focus Group Discussion Guide IS Determinants



Facilitator Instructions: Copies of the informed consent form should be provided to participants and read aloud for the benefit of those who cannot read. Participants should be provided an opportunity to ask any questions. Verbal agreement to participate should be taped.

Before beginning the discussion, make sure each participant has completed the short demographic survey. *Make sure that the study ID on the Demographic Survey matches the ID that will be used to identify the participant during the focus group discussion.

The following set of questions is a guide. Try to ask all the questions below in the order given, but it is more important to maintain the flow of discussion. Suggested probes have been included.

1. Section topics are in **bold text**.
 2. Scripts to introduce the discussion, sections and questions appear in normal font prior to the section/questions.
 3. There are two levels of questions:
 - a. Primary interview questions: are numbered, and cover topics that interviewers are required to raise in each interview. You may adapt the questions and/or ask them in a different order, depending on how the discussion develops. However, you will have to ensure that by the end of the discussion, all the topics and answers to the primary questions have been covered.
 - b. Probes: are lettered (a, b, c...) or use small roman numerals (i, ii, iii...). If you find that the participants provide little information in response to the primary question, these probes may be used to encourage further discussion. You are not required to use or get information about each probe. So, depending on what has already been discussed, and the IDI context, you may use these probes or not.
 4. *Instructions to facilitator are in **bold italics and [brackets]**. It is important to read these to know the correct questions to pose to each participant group.*
 5. Words found in (parentheses) are meant to provide examples that the interviewer can use to clarify the question if necessary.
-

Welcome and Introductions

Before turning on the recorder, start with the following introductory script:

“My name is _____ and this is (introduce note-taker). Thank you for agreeing to talk to me today. This project is being funded by the US National Institutes of Health. As mentioned earlier, I am a researcher and I am trying to learn more about how health providers take care of HIV-infected adolescents. Your facility was recently selected to participate in pilot study looking at a new intervention to help improve the transitions process for HIV-infected adolescents moving from pediatric to adult HIV care. This intervention package is called the Adolescent Transition Package, or ATP. We are interested in hearing your thoughts and experiences using the adolescent transition package to guide disclosure of HIV status to adolescents and help improve the documentation and facilitation of the transition process from pediatric to adult HIV clinical care. We look forward to hearing your recommendations on ways to improve this package of services for healthcare workers who will use it during the larger clinical trial. Thank you for allowing us to spend time with you getting your feedback. We will use the information you provide today to improve the ATP and recommend solutions for better care for HIV infected adolescents.

How many of you have participated in a focus group discussion before? [show of hands]

Before we get started today, here are a few important things to know:

- We are here to learn from you. There are no right or wrong answers to anything we will be asking. We are interested in your opinions; we are not testing your knowledge in any way.*
- If there is any question you would rather not answer, for any reason, please just say “Pass,” and we will move on to the next question. You can stop participating at any time.*
- Also, the purpose of our discussion today is not for everyone to agree. We are interested in hearing all of your opinions, even if you are unsure about something or if you disagree with something someone said. If you have a different idea from what others have said, please feel free to share your point of view.*
- Please stop me from moving on to a new subject if you still have something you would like to say, and feel free to come back to a topic if you think of additional thoughts as we go on.*
- We also ask that everyone please keep confidential what others share in this discussion. We, as researchers on the study, will also keep your information confidential.*
- The research team may take short sections of what you say and share them with non-study members. The research team will take information about your age, education, and HIV treatment experience and combine this information with all of the other healthcare workers doing these discussions.*
- To make sure we have heard what you say correctly, I will be using this audio recorder. This will also make it easier for me to listen to what you have to say in today’s discussion. When we start the discussion, we will turn on a recorder and*

record the rest of the discussion. This recording will be transformed into a written document but the transcript will not have your names on it.

- *The information you share with us today will not affect your employment in any way.*
- *Each of you have been assigned to a study number. This will help us keep information about who you are private from others. If you want to respond to something someone else in the group said, please refer to them by their study number, and not their names, even if you know them personally.*

[Logistics: please turn off cell phone or put on silent mode and keep away from sight; location of restrooms; food and beverages, etc.]

We'll talk for about one and a half hours.

Does anyone have any questions before we get started?

Everyone has previously agreed to have our conversation recorded. Can everyone confirm again that it is okay if I tape our discussion? [Wait for the participants to give verbal consent to taping; those who decline at this stage will be asked to leave the group and not participate]

I am turning on the recorder now.

Before beginning interview questions, please read the following script for the recording:

Today is [day of week], [month, day, year] and it is now [time of day]. This is focus group [group ID number] conducted at [discussion location].

You are now ready to begin asking the questions outlined below.

.....

Semi-Structured Focus Group Discussion Questions

The following questions will ask you about your experiences providing clinical care for HIV-infected adolescents using the ATP. When answering these questions, think about your own, as well as other health provider's experiences.

1. Overall, what do you think of the adolescent transition package or ATP?
 - a. What did you think about the ATP when you first started using it?
 - b. What do you think about it now that you've been using it for longer?
 - i. Is it easy/hard to use? What about before?
 - ii. What do you like/dislike about using it now? What about before?
 - iii. What kinds of adaptations or changes have you made to the intervention during the time you've been using it in your clinic?
 - iv. If you think about continuing to use the ATP, what additional changes would you like to make to how you use the ATP?
 - v. Are there any tools or processes that are part of the ATP that you think shouldn't be changed?

- vi. Are there any other general recommendations you have for improving the ATP?
2. How do you think the tools in the ATP compare to other similar existing toolsets for adolescents living with HIV? (*think specifically about tools you know of for helping with transition to adult care or disclosure of HIV diagnosis*).
- i. What other tools are you aware of that help with disclosure of HIV diagnosis or transition to adult care?
 - ii. What are the advantages of the ATP compared to other tools?
 - iii. What are the disadvantages of the ATP compared to other tools?
3. How often do you use the tools and processes of the ATP when providing clinical care to adolescents?
- i. Do you use the intervention tools with every adolescent? If no, how do you decide who you will use the tools with?
 - ii. What components of ATP do you use most frequently? Why? Why not the others?
 - b. Overall, do you think the package helped you or made it harder for you to provide HIV care to adolescents? Why do you think that?
4. Tell me about your experiences using the transition tools in the adolescent transition package
- a. How comfortable are you guiding adolescents through the transition process?
 - i. Has this changed since you were exposed to the adolescent transition package transition tools?
 - b. Did you use all of the tools equally? Why?
 - c. What part of the transition intervention tools did you like the best? What about the transition intervention tools was challenging?
 - d. If you were telling other healthcare workers about the transition tools from the adolescent transition package, what would you tell them?
 - e. What recommendations do you have for us that could help improve the transition tools from the adolescent transition package?
5. Tell me about your experiences using the disclosure tools (disclosure tracking form and comic book) in the adolescent transition package
- a. How comfortable are you doing HIV disclosure to adolescents?
 - i. Has this changed since you were exposed to the adolescent transition package disclosure tools?
 - b. Did you use all of the disclosure tools equally? Why?
 - c. What part of the disclosure intervention tools did you like the best? What about the disclosure intervention tools was challenging?
 - d. Did you ever use the disclosure tools with adolescents who already know their status? Why? Can you tell me about an experience you had when you used the tools with an adolescent who already knew their status?
 - e. If you were telling other healthcare workers about the disclosure tools from the adolescent transition package, what would you tell them?

- f. What recommendations do you have for us that could help improve the disclosure intervention tools in the adolescent transition package?
6. In what way do you think ATP impacted the provision of adolescent HIV services in this clinic?
- a. In what way, if at all, did the ATP impact adolescent health in this clinic?
 - b. In what ways, if at all, do you think that this package affected the quality of care that HIV-infected adolescents receive at this clinic? Please give specific examples.
7. Think about a new clinic that is about to start using the ATP. Based on your experiences using the ATP, what are the most important things for them to know about using the ATP?
- a. What kinds of costs do you think they will have when they first start to implement the ATP?
 - b. What kinds of support materials (training, tools, clinic infrastructure) will be most important for them?
 - c. Who at their clinic would need to be supportive of the intervention for it to get implemented?
 - i. Was there anyone here at your clinic who was really important in influencing how the ATP was used?
 - d. What did you think of the training you received to use the ATP?
 - i. What did you like about the training?
 - ii. What could be done differently in the future to make you feel more prepared to use the ATP?

Today, we talked about the Adolescent Transition Package that you have been using at your clinic.

Before we end, is there anything else you would like to add?

Do you have any questions for me before we end our conversation today?

Thank you very much for your time and for all the helpful information you have provided!

ATTACH Study – Adolescent Transition To Adult Care for HIV-Infected Adolescents in Kenya

Date :
Day Month Year

Clinic:

Survey: ☐1 ☐2 ☐3 ☐4 ☐5 ☐6
☐7 ☐8 ☐9 ☐10 ☐11 ☐12

HCW Implementation Survey



HCW ID:

Section 1: Overview

1. During the past 2 weeks, what tools from the Adolescent Transition Package did you use?

☐ None

- Or -

Disclosure Tools	Transition Tools
<input type="checkbox"/> Disclosure Booklet (Why I take my Medicines)	<input type="checkbox"/> Transition Booklet (Taking Charge)
<input type="checkbox"/> Disclosure Tracking Form	<input type="checkbox"/> Transition Progress Tracking Form
<input type="checkbox"/> Disclosure Readiness Assessment	<input type="checkbox"/> Transition Readiness Assessment
2. During the last 2 weeks, how often did you use any of the tools from the Adolescent Transition Package:

☐ With every adolescent ☐ With many adolescents ☐ With some adolescents

☐ Not at all

Section 2: Think about the change(s) you made to how you were using the ATP. Respond to the following questions related to that specific change.

3	<p>The change(s) your clinic made to the Adolescent Transition Package 2 weeks ago were targeting the following:</p> <p>Overall ATP Implementation <input type="checkbox"/> - and/or - Implementation of specific tools <input type="checkbox"/></p> <p>If specific tools were targeted by the change(s), please note which tools:</p> <table border="0"> <tr> <td>Disclosure Tools</td> <td>Transition Tools</td> </tr> <tr> <td><input type="checkbox"/> Disclosure Booklet (Why I take my Medicines)</td> <td><input type="checkbox"/> Transition Booklet (Taking Charge)</td> </tr> <tr> <td><input type="checkbox"/> Disclosure Tracking Form</td> <td><input type="checkbox"/> Transition Progress Tracking Form</td> </tr> <tr> <td><input type="checkbox"/> Disclosure Readiness Assessment</td> <td><input type="checkbox"/> Transition Readiness Assessment</td> </tr> </table> <p>In your own words, please describe the change(s) that was made:</p> <hr/> <hr/> <hr/>	Disclosure Tools	Transition Tools	<input type="checkbox"/> Disclosure Booklet (Why I take my Medicines)	<input type="checkbox"/> Transition Booklet (Taking Charge)	<input type="checkbox"/> Disclosure Tracking Form	<input type="checkbox"/> Transition Progress Tracking Form	<input type="checkbox"/> Disclosure Readiness Assessment	<input type="checkbox"/> Transition Readiness Assessment
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<input type="checkbox"/> Disclosure Booklet (Why I take my Medicines)	<input type="checkbox"/> Transition Booklet (Taking Charge)								
<input type="checkbox"/> Disclosure Tracking Form	<input type="checkbox"/> Transition Progress Tracking Form								
<input type="checkbox"/> Disclosure Readiness Assessment	<input type="checkbox"/> Transition Readiness Assessment								
4	<p>Overall, I like the change that we made to how the ATP is being used in my clinic:</p> <p><input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree</p>								
5	<p>I believed that this change was the right change to make to improve how the Adolescent Transition Package is used:</p> <p><input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree</p>								
6	<p>During the past 2 weeks, I was able to make the agreed upon change(s) to how the Adolescent Transition Package is used:</p>								

	<p> <input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree </p> <p>Please describe what enabled you to stick to making the changes as planned:</p> <hr/> <hr/> <p>Please describe what challenges made it hard to make the changes as planned:</p> <hr/> <hr/>
7	<p>The change(s) you made to using the ATP made the ATP easier to use:</p> <p> <input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree </p> <p>In your own words, please tell us why you felt that way:</p> <hr/> <hr/>
8	<p>The change(s) you made to the ATP made it easier to integrate the ATP into my daily practice or daily routine at the clinic when I'm taking care of adolescents:</p> <p> <input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree </p> <p>In your own words, please tell us why you felt that way:</p> <hr/> <hr/>

9	<p>The change(s) you made to using the ATP made it take more time to use the ATP:</p> <p><input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree</p> <p>In your own words, please tell us why you felt that way:</p> <hr/> <hr/>
10	<p>The change(s) you made to using the ATP will make the transition process better for adolescents:</p> <p><input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree</p>
11	<p>The change(s) you made to using the ATP will make the transition process easier for healthcare workers.</p> <p><input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree</p>
12	<p>The change(s) you made to using the ATP will make the transition process easier for parents/caregivers.</p> <p><input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree</p>
13	<p>The change(s) you made to using the ATP will make the disclosure process easier for adolescents:</p> <p><input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree</p>
14	<p>The change(s) you made to using the ATP will make the disclosure process easier for healthcare workers.</p> <p><input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree</p>
15	<p>The change(s) you made to using the ATP will make the disclosure process easier for parents/caregivers.</p>

	<input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree
16	<p>Based on my experience using the Adolescent Transition Package tools, I would recommend that we take the following action for the change(s) we have been testing:</p> <p><input type="checkbox"/> Adapt: Improve the change and continue testing this change again</p> <p>Please describe what you might adapt to improve this change:</p> <hr/> <hr/> <p><input type="checkbox"/> Adopt: Make this change a permanent part of using the Adolescent Transition Package tools</p> <p><input type="checkbox"/> Abandon: Discard this change and try a different idea</p> <p>Please describe what other changes you might make to improve using the ATP:</p> <hr/> <hr/>
Section 3: Summary Please think about the ATP overall, and not the specific changes you made over the past few weeks, when responding to the following questions.	
17	<p>Overall, I like using the Adolescent Transition Package tools.</p> <input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree
18	<p>I would like to continue using the Adolescent Transition Package Tools</p> <input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree


Thank you for taking the time to fill out this survey!

ANY ADDITIONAL COMMENTS

Form entered into database by _____

Date __/__/____
Day Month

ATTACH Study – Adolescent Transition To Adult Care for HIV-Infected Adolescents in Kenya

<p>Date of Interview: </p> <p style="text-align: center; margin-left: 100px;">Day Month Year</p> <p>FGD start time: ____:____ <input type="checkbox"/> am <input type="checkbox"/> pm</p> <p>FGD site: _____</p> <p>Name of Interviewer: _____</p> <p>Name(s) of other study staff present: _____</p>	 HCW Demographic Survey IS FGD
<p>Health Provider ID (label)</p>	

Instructions: *This is a brief survey that will ask demographic questions about health provider participants to pair with FGD transcripts. This form will also collect individual ATP implementation information.*

Section 1: Participant Characteristics	
1	Primary location of your work: <input type="checkbox"/> CCC <input type="checkbox"/> Other _____
2	Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female
3	Age of HCW: ____ ____ years
4	<p>4a. What is your highest level of education? (<i>highest level of education completed</i>)</p> <p><input type="checkbox"/> none <input type="checkbox"/> primary: class ____ (1-8) <input type="checkbox"/> secondary: form ____ (1-4)</p> <p><input type="checkbox"/> polytechnic: year ____ (1-4) <input type="checkbox"/> university/college year ____ (1-6)</p> <p>4b. How many years of education have you completed: ____ years</p>
5	<p>What is your current employment classification? (<i>tick all that apply</i>)</p> <p><input type="checkbox"/> Peer Counselor <input type="checkbox"/> Clinical Officer <input type="checkbox"/> Psychologist</p>

	<input type="checkbox"/> Nurse Counselor <input type="checkbox"/> Doctor <input type="checkbox"/> Social worker <input type="checkbox"/> Nurse <input type="checkbox"/> Counselor <input type="checkbox"/> Other, specify: _____
6	Number of years at current clinic: <input type="text"/> <input type="text"/> years and <input type="text"/> <input type="text"/> months
7	Number of years of experience providing HIV care: <input type="text"/> <input type="text"/> years and <input type="text"/> <input type="text"/> months
8	Number of years caring for HIV positive individuals (any age): <input type="text"/> <input type="text"/> years and <input type="text"/> <input type="text"/> months
9	Number of years caring for HIV positive adolescents and youth (ages 10-24): <input type="text"/> <input type="text"/> years and <input type="text"/> <input type="text"/> months
10	Based on your role in the clinic, how often are you involved in assisting with HIV disclosure to children and adolescents? <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Never Rarely Occasionally Often Always Not Applicable
11	Based on your role in the clinic, how often are you involved in helping adolescents transition from adolescent to adult care? <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Never Rarely Occasionally Often Always Not Applicable
Section 2: Training	
12	Did you receive training on the ATP? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please answer the following: Who led the training: <input type="checkbox"/> Staff from your clinic <input type="checkbox"/> Staff from the ATTACH study When was the training: <input type="checkbox"/> <1 month ago <input type="checkbox"/> 1-3 months ago <input type="checkbox"/> 3-6 months ago <input type="checkbox"/> 6-12 months ago <input type="checkbox"/> >12 months ago What tools did the training cover: Overall ATP Implementation <input type="checkbox"/> - and/or - Specific ATP tools <input type="checkbox"/>

	<p>If only specific tools were included, please note which tools:</p> <table border="0"> <tr> <td data-bbox="142 310 829 590"> <p>Disclosure Tools</p> <p><input type="checkbox"/> Disclosure Booklet (Why I take my Medicines)</p> <p><input type="checkbox"/> Disclosure Tracking Form</p> <p><input type="checkbox"/> Disclosure Readiness Assessment</p> </td><td data-bbox="829 310 1502 590"> <p>Transition Tools</p> <p><input type="checkbox"/> Transition Booklet (Taking Charge)</p> <p><input type="checkbox"/> Transition Progress Tracking Form</p> <p><input type="checkbox"/> Transition Readiness Assessment</p> </td></tr> </table> <p>In your own words, please describe the training you received:</p> <hr/> <hr/> <hr/>	<p>Disclosure Tools</p> <p><input type="checkbox"/> Disclosure Booklet (Why I take my Medicines)</p> <p><input type="checkbox"/> Disclosure Tracking Form</p> <p><input type="checkbox"/> Disclosure Readiness Assessment</p>	<p>Transition Tools</p> <p><input type="checkbox"/> Transition Booklet (Taking Charge)</p> <p><input type="checkbox"/> Transition Progress Tracking Form</p> <p><input type="checkbox"/> Transition Readiness Assessment</p>
<p>Disclosure Tools</p> <p><input type="checkbox"/> Disclosure Booklet (Why I take my Medicines)</p> <p><input type="checkbox"/> Disclosure Tracking Form</p> <p><input type="checkbox"/> Disclosure Readiness Assessment</p>	<p>Transition Tools</p> <p><input type="checkbox"/> Transition Booklet (Taking Charge)</p> <p><input type="checkbox"/> Transition Progress Tracking Form</p> <p><input type="checkbox"/> Transition Readiness Assessment</p>		
13	<p>What is your current level of confidence in assessing whether caregivers are ready to tell their children that they have HIV?</p> <p><input type="checkbox"/> Not confident <input type="checkbox"/> somewhat confident <input type="checkbox"/> very confident <input type="checkbox"/> fully confident</p>		
14	<p>What is your current level of confidence in addressing caregivers' fears about disclosing HIV status to children?</p> <p><input type="checkbox"/> Not confident <input type="checkbox"/> somewhat confident <input type="checkbox"/> very confident <input type="checkbox"/> fully confident</p>		
15	<p>What is your current level of confidence in assisting with HIV disclosure to children?</p> <p><input type="checkbox"/> Not confident <input type="checkbox"/> somewhat confident <input type="checkbox"/> very confident <input type="checkbox"/> fully confident</p>		
16	<p>What is your current level of confidence in doing post HIV disclosure counseling to children and addressing any emotional reactions?</p> <p><input type="checkbox"/> Not confident <input type="checkbox"/> somewhat confident <input type="checkbox"/> very confident <input type="checkbox"/> fully confident</p>		
17	<p>Do the ATP tools improve your ability to assist with the HIV disclosure process for adolescents who do not know their HIV status?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>		
18	<p>What is your current level of confidence in assessing adolescents are ready to transition to adult care?</p>		

	<input type="checkbox"/> Not confident <input type="checkbox"/> somewhat confident <input type="checkbox"/> very confident <input type="checkbox"/> fully confident
19	What is your current level of confidence in preparing adolescents to transition to adult care? <input type="checkbox"/> Not confident <input type="checkbox"/> somewhat confident <input type="checkbox"/> very confident <input type="checkbox"/> fully confident
20	How often do you follow-up with adolescents after they transition to adult care? <input type="checkbox"/> never <input type="checkbox"/> sometimes <input type="checkbox"/> often <input type="checkbox"/> always
21	Do the ATP tools improve your ability to assist with transition to adult care for adolescents with HIV attending your clinic? <input type="checkbox"/> Yes <input type="checkbox"/> No
Section 3: Acceptability	
22	The Adolescent Transition Package helped me provide better care for adolescents. <input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree
23	I found the Adolescent Transition Package useful in my practice. <input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree
24	I liked using the Adolescent Transition Package. <input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree
25	I would like to continue using the Adolescent Transition Package. <input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree
Section 4: Appropriateness	
26	I think the Adolescent Transition Package helps keep adolescents retained in care. <input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree
27	I think the Adolescent Transition Package helps adolescents reach or maintain suppressed viral loads. <input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree
28	I think the Adolescent Transition Package makes the disclosure process easier for healthcare workers . <input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree

29	<p>I think the Adolescent Transition Package improves the disclosure process for adolescents.</p> <p><input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree</p>
30	<p>I think the Adolescent Transition Package improves the disclosure process for parents/caregivers.</p> <p><input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree</p>
31	<p>I think the Adolescent Transition Package makes the transition process easier for healthcare workers.</p> <p><input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree</p>
32	<p>I think the Adolescent Transition Package improves the transition process for adolescents.</p> <p><input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree</p>
33	<p>I think the Adolescent Transition Package improves the transition process for parents/caregivers.</p> <p><input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree</p>
Section 5: Feasibility	
34	<p>I think the Adolescent Transition Package is easy for healthcare workers to use.</p> <p><input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree</p> <p>Please describe why you think that:</p> <p>_____</p> <p>_____</p>
35	<p>I think the Adolescent Transition Package can be further improved.</p> <p><input type="checkbox"/> Strongly agree <input type="checkbox"/> Somewhat agree <input type="checkbox"/> Neutral <input type="checkbox"/> Somewhat disagree <input type="checkbox"/> Strongly disagree</p> <p>Please describe why you think that and/or how you would improve it:</p> <p>_____</p> <p>_____</p>

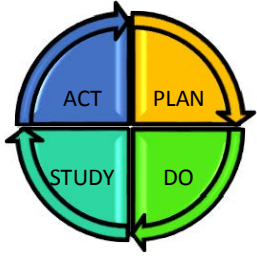
Section 6: Fidelity									
36	<p>During the past 2 weeks, what tools from the Adolescent Transition Package did you use?</p> <p><input type="checkbox"/> None</p> <p>- Or -</p> <table border="0"> <tr> <td>Disclosure Tools</td> <td>Transition Tools</td> </tr> <tr> <td><input type="checkbox"/> Disclosure Booklet (Why I take my Medicines)</td> <td><input type="checkbox"/> Transition Booklet (Taking Charge)</td> </tr> <tr> <td><input type="checkbox"/> Disclosure Tracking Form</td> <td><input type="checkbox"/> Transition Progress Tracking Form</td> </tr> <tr> <td><input type="checkbox"/> Disclosure Readiness Assessment</td> <td><input type="checkbox"/> Transition Readiness Assessment</td> </tr> </table>	Disclosure Tools	Transition Tools	<input type="checkbox"/> Disclosure Booklet (Why I take my Medicines)	<input type="checkbox"/> Transition Booklet (Taking Charge)	<input type="checkbox"/> Disclosure Tracking Form	<input type="checkbox"/> Transition Progress Tracking Form	<input type="checkbox"/> Disclosure Readiness Assessment	<input type="checkbox"/> Transition Readiness Assessment
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<input type="checkbox"/> Disclosure Readiness Assessment	<input type="checkbox"/> Transition Readiness Assessment								
37	<p>During the last 2 weeks, how often did you use any of the tools from the Adolescent Transition Package:</p> <p><input type="checkbox"/> With every adolescent <input type="checkbox"/> With many adolescents <input type="checkbox"/> With some adolescents</p> <p><input type="checkbox"/> Not at all</p>								
38	<p>How often did you use the disclosure tracking tool to track disclosure progress with adolescents who don't know their HIV status?</p> <p><input type="checkbox"/> With every adolescent <input type="checkbox"/> With many adolescents <input type="checkbox"/> With some adolescents</p> <p><input type="checkbox"/> Not at all</p>								
39	<p>How often did you use the disclosure readiness assessment with adolescents who don't know their HIV status?</p> <p><input type="checkbox"/> With every adolescent <input type="checkbox"/> With many adolescents <input type="checkbox"/> With some adolescents</p> <p><input type="checkbox"/> Not at all</p>								
40	<p>How often did you use the disclosure booklet "Why I take my medicines" with adolescents who don't know their HIV status?</p> <p><input type="checkbox"/> With every adolescent <input type="checkbox"/> With many adolescents <input type="checkbox"/> With some adolescents</p> <p><input type="checkbox"/> Not at all</p>								

41	<p>How often did you use the disclosure booklet “Why I take my medicines” with adolescents who already know their HIV status?</p> <p> <input type="checkbox"/> With every adolescent <input type="checkbox"/> With many adolescents <input type="checkbox"/> With some adolescents <input type="checkbox"/> Not at all </p>
42	<p>How often did you use the transition booklet tracking tool with adolescents who you read the Taking Charge booklet with?</p> <p> <input type="checkbox"/> With every adolescent <input type="checkbox"/> With many adolescents <input type="checkbox"/> With some adolescents <input type="checkbox"/> Not at all </p>
43	<p>How often do you use the transition booklet “Taking Charge”?</p> <p> <input type="checkbox"/> With every adolescent <input type="checkbox"/> With many adolescents <input type="checkbox"/> With some adolescents <input type="checkbox"/> Not at all </p>
44	<p>How often did you use the transition readiness assessment with adolescents who had completed reading the “Taking Charge” booklet?</p> <p> <input type="checkbox"/> With every adolescent <input type="checkbox"/> With many adolescents <input type="checkbox"/> With some adolescents <input type="checkbox"/> Not at all </p>
45	<p>How often did you use the transition readiness assessment with adolescents who had NOT completed reading the “Taking Charge” booklet?</p> <p> <input type="checkbox"/> With every adolescent <input type="checkbox"/> With many adolescents <input type="checkbox"/> With some adolescents <input type="checkbox"/> Not at all </p>

COMMENTS

Form entered into database by _____

Date __/__/____
Day Month



ATTACH Study – Adolescent Transition To Adult Care for HIV-Infected Adolescents in Kenya

Date :

Day



PDSA

Worksheet] 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12

PLAN

1. Describe all the challenges in using the ATP discussed during the meeting today:

2. Describe the specific problem that the group decided to try and fix:

3. Describe the small change (adaptation) that will be tested during the next 2 weeks.
 - a) WHAT? Specific tasks:
 - b) WHO? Staff member responsible for making the change:
 - c) WHEN? Start date for the change:

4. Describe why the team selected this small change to test:

Return Date: _____

Day Month Year

DO

1. Was the change (adaptation) carried out as planned ☐ Yes ☐ No

STUDY

2. Compare your experience implementing the ATP with the change to how implementing the ATP was before you made the change.

A. Briefly describe what went well with making the change?

B. Briefly describe what didn't go well with making the change?

C. Was implementing the ATP easier with the change? ☐ Yes ☐ No

ACT

3. What was the final decision related to this change (adaptation)? ☐ Adapt ☐ Adopt ☐ Abandon

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Version 1.0



Transition Readiness Assessment Form

Complete at first contact and every 6 months for all adolescents and young adults age 15-24

Child ID	May 23, 2019	Facility Code	Support person
Date	<div> <div></div> <div></div> <div></div> </div> <div>Day Month Year</div>	Gender <input type="checkbox"/> Male <input type="checkbox"/> Female	<input type="checkbox"/> Parent <input type="checkbox"/> Sibling
Date of full disclosure	<div> <div></div> <div></div> <div></div> </div> <div>Day Month Year</div>	Date of birth <div> <div></div> <div></div> <div></div> </div> <div>Day Month Year</div>	<input type="checkbox"/> Grandparent <input type="checkbox"/> Spouse
			<input type="checkbox"/> Other relative _____
			<input type="checkbox"/> Other non-relative _____
Point of entry at enrollment	<input type="checkbox"/> CCC <input type="checkbox"/> Adolescent clinic <input type="checkbox"/> Pediatric clinic <input type="checkbox"/> PMTCT <input type="checkbox"/> Other:specify _____		

Assessment Areas		Response Options		
		No (Unable to complete task)	Partially (Gaps in knowledge)	Yes (Can fully complete task)
1.	Can explain what HIV is			
2.	Can explain how ARVs work			
3.	Knows the names of their ARVs			
4.	Can explain what it means to have a suppressed viral load			
5.	Can define the cut-offs for viral suppression			
6.	Knew the day and date of <u>current</u> clinic visit			
7.	Came to clinic on the scheduled day for <u>current</u> visit			
8.	What financial arrangements did the adolescent have to come to clinic? <input type="checkbox"/> Transportation costs <input type="checkbox"/> Food costs <input type="checkbox"/> Medicine costs <input type="checkbox"/> Other, specify _____			
9.	Knew where financial support to attend clinic would come from			
10.	Can explain what to do if they miss a medication dose			
11.	Can explain when they need to go to a clinic for review			
12.	Can describe what to do when they get to the clinic			
13.	Will collect medicine from pharmacy on their own			
14.	Came to clinic alone			
12a.	If yes to 12, why? <input type="checkbox"/> Caregiver not available <input type="checkbox"/> Caregiver felt child is old enough <input type="checkbox"/> No transport money available for caregiver <input type="checkbox"/> Wants to come alone <input type="checkbox"/> Other specify _____			
15.	Can name different contraception options			
16.	Can explain medical problems and report symptoms			
17.	Feels free to ask the health care worker questions about their health			

18.	Feels free to ask the health care workers for reproductive health services like condoms and birth control			
19.	Can identify at least one person in the clinic that they feel safe to seek help from			
20.	Attends a peer support group			
21.	Can explain when and how they would disclose HIV status to someone else (if necessary)			
22.	Has disclosed their HIV status to someone else (by themselves)			
23.	Able to verbalize long-term life goals			
24.	Agrees that he/she is ready to transition			
24a.	If not ready to transition, describe why			

Growing Up and Taking Charge Tracking Form

SECTION A: Complete at first contact

Child ID		Facility Name	<input type="checkbox"/> CCC <input type="checkbox"/> Adolescent clinic <input type="checkbox"/> PMTCT
Date of birth	<div style="border: 1px solid black; padding: 2px; display: flex; justify-content: space-between;"> Day Month Year </div>	Point of entry at enrollment	<input type="checkbox"/> Male <input type="checkbox"/> Female
Date of full disclosure	<div style="border: 1px solid black; padding: 2px; display: flex; justify-content: space-between;"> Day Month Year </div>	Age	

Please complete this form at every visit. At age _____ begin readiness assessment evaluation using the readiness assessment tool.

	___/___/___			___/___/___			___/___/___			___/___/___		
	D	M	ND	D	M	ND	D	M	ND	D	M	ND
<input type="checkbox"/> Treatment literacy												
<input type="checkbox"/> Self-management												
<input type="checkbox"/> Communication												
<input type="checkbox"/> Support												

*D: Discussed – Put an X if the topic was discussed with the adolescent during the visit; M: Mastered – Put an X if the adolescent fully understands the concept. ND: Not discussed

RCT CONSENT FORMS

University of Washington (UW) & University of Nairobi (UoN) Collaborative Study Group
Adolescent Transition To Adult Care for HIV-infected adolescents in Kenya (ATTACH)

Parental Consent for Disclosure readiness assessment

Investigators

NAME	POSITION	DEPARTMENT	TELEPHONE NUMBERS
Grace John-Stewart	Co-Principal Investigator	Global Health, UW	+1-206-543-4278
Dalton Wamalwa	Co-Principal Investigator	University of Nairobi	0733-558943
Kristin Beima-Sofie	Co-Investigator	Global Health, UW	+1-206-685-8332
Gabrielle O'Malley	Co-Investigator	Global Health, UW	+1-206-685-0775
Bartilol Kigen	Co-Investigator	NASCOP	0775-597297
Laura Oyiengo	Co-Investigator	NASCOP	0719-441332
Cyrus Mugo	Co-Investigator	University of Nairobi	0721-599626
Irene Njuguna	Co-Investigator	Kenyatta National Hospital	0721-871009

Emergency telephone number: Dr. Cyrus Mugo, 0721599626

Ethics and Research Committee Chairperson: Professor AN Guantai, Telephone 020-272-6300 Extension 44102

University of Washington Human Subjects Division: Telephone +1-206-543-0098.

A. Researchers' statement

1. Introduction

We are asking for your consent, as a caregiver/parent for your child, to participate in a research study. The study is being done by the University of Nairobi and the University of Washington. The purpose of this consent process is to give you the information you will need to help you decide whether or not you want to participate. You may ask questions about the purpose of the research study, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research study or this form that is not clear. When we have answered all of your questions, you can decide if you want to be in the study. This process is called "informed consent." We will give you a copy of this form for your records.

2. Purpose and Benefits

We are asking for your permission to participate in this study because your child receives care in this clinic. As you may know, as children or adolescents get older, they need to be told they have HIV. We are asking you to participate because your child does not know they have HIV. We would like to know what you think about whether your child is ready to know their HIV status. We want to know what parent/caregivers think about the time children should know that they have HIV. This information may help make the experience better for other children and parents/caregivers.

3. Procedures

If you agree to take part in the study, this is what will happen. We will ask you to talk with a member of the study team and they will help you answer a short survey. This survey will be done in a private room with the door shut. We will ask that your child waits outside the room or in a different room. Your child will not be told what we are discussing.

First, we will ask you questions about your home, who takes care of your child and what they know about HIV. We will ask you what your child thinks about why they take their medicine. We will ask you who else knows your child's HIV status. We will also ask how your child is doing in school and if they have any problems.

We will ask you these questions every 6 months or until your child knows they have HIV.

Today, if you agree to participate, you will sign or make your mark on this consent form. You will be given a copy of this consent form for your records. We will then arrange a time for you to talk to our study team. The survey will take about 20 minutes.

4. Risks, Stress, and Discomfort

The questions will not harm you but you may become embarrassed, worried or anxious when talking about your child's HIV.

You may be worried that your child may accidentally find out they have HIV. However, we will not involve your child in this discussion.

There is a risk that by being in a study someone could learn your child's HIV status, for example, someone could see you coming to the HIV clinic or talking to study staff. However, we have measures in place to protect your privacy. We will only ask you questions in a room without anyone else.

5. Alternatives to participation

There may be other studies going on here or in the community that you may be eligible for. If you wish, we will tell you about other studies that we know about.

6. Benefits

You will not directly benefit from the study. These questions may prepare you for the disclosure process. Your answers to questions may help us to improve services for children and adolescents with HIV.

7. Other information

Your Participation is Voluntary

This consent form gives information about the study. We will discuss the study with you and answer any questions you may have. If you agree to take part, we will ask you to sign your name or make your mark on this form. We will offer you a copy to keep.

It is important that you know the following:

- You do not have to be in this study if you do not want to,
- You may decide to stop the study at any time, without losing your access to care at this facility.

Costs to You

There is no cost to you for participation.

Reimbursement

You will receive KSH. 600 for your transportation costs and your time and effort after completing each survey.

8. Source of funding

The study team and/or the University of Washington are receiving financial support from the National Institutes of Health in the United States.

9. Confidentiality of Research Information

Confidentiality

The information you provide during your interview will be kept secret by the study staff. We will not write down or tell your name to anyone who is not part of the study without your permission in writing. We will not publish or discuss in public anything that could identify you or your child. We will use a number code to identify your responses and will only link the number code to your child's name in a special book called a link log. This link log will only be available to the study team. We will destroy the link log 6 years after we complete the surveys.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

The records of this discussion may be reviewed by assessment staff and representatives of:

- the University of Washington, including the Institutional Review Board
- the Kenyatta National Hospital and University of Nairobi Ethics and Research Committee

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the US federal government who needs it in order to audit or evaluate the research;
- people at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;

We are required to describe the additional confidentiality protections that we have from our funding agency:

We have a Certificate of Confidentiality from the United States National Institute Health (NIH). These protections only apply to data held in the United States.

This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law in the United States. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- A member of the United States government who needs it in order to audit or evaluate the research;
- Individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- Relevant authorities as required by other Federal, State, or local laws.

Research-Related Injury

It is unlikely that you will be injured as a result of participating in this survey. There is no program for monetary compensation or other forms of compensation for injuries. You do not give up any legal rights by signing this consent form.

Problems or Questions:

If you ever have any questions about the study you should contact Dr. Cyrus Mugo, 0721599626. If you have questions about your rights as a research participant, or feel you have been harmed by the study, you should contact Professor Guantai, the Chair of the KNH/UoN ERC, at 2726300-Extension 44102. You can also contact the UW HSD at +1-206-543-0098.

B. Study Participant's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have more questions later, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the KNH/UoN Ethics and Research Committee at 2726300 Extension 44102. I will receive a copy of the consent form.

_____ Participant's Name	_____ Signature/Thumbprint	_____ Date
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_____ Witness name (if unable to sign)	_____ Signature/Thumbprint	_____ Date
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(Note: a witness is an individual who must be independent of the study, literate and selected by the participant)

_____	_____	_____
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ATTACH Protocol, Version 2.2
May 23, 2019

Study Staff Conducting
Consent Discussion

Signature

Date

Copies to: Researcher, Participant

University of Washington (UW) & University of Nairobi (UoN) Collaborative Study Group

Adolescent Transition To Adult Care for HIV-infected adolescents in Kenya (ATTACH)

**Assent Form for Adolescent Transition Readiness Assessment Survey
(10-14 years old)**

Investigators

NAME	POSITION	DEPARTMENT	TELEPHONE NUMBERS
Grace John-Stewart	Co-Principal Investigator	Global Health, UW	+1-206-543-4278
Dalton Wamalwa	Co-Principal Investigator	University of Nairobi	0733-558943
Kristin Beima-Sofie	Co-Investigator	Global Health, UW	+1-206-685-8332
Gabrielle O'Malley	Co-Investigator	Global Health, UW	+1-206-685-0775
Martin Sirengo	Co-Investigator	NASCOP	0719-441332
Bartilol Kigen	Co-Investigator	NASCOP	0722774991
Laura Oyiengo	Co-Investigator	NASCOP	0719-441332
Cyrus Mugo	Co-Investigator	University of Nairobi	0721-599626
Irene Njuguna	Co-Investigator	Kenyatta National Hospital	0721-871009

Emergency telephone number: Dr. Cyrus Mugo, 0721599626

Ethics and Research Committee Chairperson: Professor AN Guantai, Telephone 020-272-6300 Extension 44102

University of Washington Human Subjects Division: Telephone +1-206-543-0098.

Researchers' statement

We are asking you to volunteer for a research study. The study is being done by the University of Nairobi and the University of Washington. Before you decide to take part in this study, we would like to explain the purpose, procedures, risks, and benefits of the study. It is important that you understand that it is your choice to take part in this study. If you join the study, you can withdraw from the study at any time. If you decide not to take part in the study, it will not affect any care or services that you receive from this clinic. We will ask you to review this form and we will answer any questions you have about the study. When we have answered all of your questions, you can decide if you want to be in the study. We will retain a copy of this consent form and give you a copy to take with you.

Purpose of Study

We are asking you to participate in this study because you receive care in this clinic. As young people get older, they need to be able to take care of their own health. They need to know what to do to improve their health and how to do it on their own. Sometimes caregivers may help, but sometimes they may not be available. Young people need to know what to do to take care of themselves when they have and do not have a caregiver there to help. The process of learning how to take care of yourself and your own health, without your caregiver, is called transition.

We want to know how we can best support you, and other young people like you, to take care of your own health. We want to know what you have learned and how we can help make it better. We will use your experience to think about how we can make the process of learning to take care of your own health better. Improving this process may help young people like you keep their clinic appointments and take medicine better.

Study Procedures

This is what will happen if you agree to take part in this study. We will ask you to read, discuss, and sign or make your mark on this form. After this form is signed or marked, we will ask you to complete a survey. You can take this survey during your normal clinic visits or at another time convenient to you. One of our research staff will help you complete the survey. These questions will take about 10 minutes to complete. The questions will be about what you did to get ready to come to the clinic and what happened at the clinic. We will also ask what you know about HIV and HIV medicine.

We will ask you to take the surveys every 6 months to see what you are learning and how that has changed. All surveys will ask similar questions. Once you have taken the surveys, your participation in this study will end.

Risks, Stress, and Discomfort

The questions will not harm you but you may become embarrassed, worried or anxious when talking about HIV or what you know about HIV. You may be afraid of having to take care of yourself as you grow.

Others may learn that you are part of the study. We have steps in place to protect your confidentiality and will do everything possible to reduce this risk. You will take the surveys with only the research study staff and away from other people. We will not share any information from the surveys with anyone outside the study team, including a caregiver or partner.

Alternatives to participation

There may be other studies going on here or in the community that you may be eligible for. If you wish, we will tell you about other studies that we know about.

Benefits

You will not directly benefit from the study. However, your answers to questions may help us improve how we help young people learn to take care of their own health.

Other information

Your Participation is Voluntary

This consent form gives information about the study. We will discuss the study with you and answer any questions you may have. If you agree to take part, we will ask you to sign your name or make your mark on this form. We will offer you a copy to keep.

It is important that you know the following:

- You do not have to be in this study if you do not want to,
- You may decide not to join the study, or to stop the study at any time, without losing your access to care at this facility.
- If you participate in the study, all the information you provide will be confidential.

Costs to You

There is no cost to you for participation.

Reimbursement

You will receive KSH. 600 for your transportation costs and for your time and effort if you take part in the study.

8. Source of funding

The study team and/or the University of Washington are receiving financial support from the National Institutes of Health in the United States.

Confidentiality of Research Information

Confidentiality

The information you provide will be kept secret by the healthcare workers and study staff. We will not write down or tell anyone your name that is not working on this study without your permission in writing. We will not publish or discuss in public anything that could identify you. We will use a number code to identify you and will only link the number code to your name in a special book called a link log. This link log will be stored in a room under lock and key and the link log will only be available to the study team. We will destroy the link log 6 years after the study ends. De-identified data may be used for future research studies or distributed to other investigators for future research studies.

If you are being abused, we will refer you for additional support services.

Government or representatives from the funding agency sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your data may be reviewed. Reviewers will protect your privacy. Study data will not be used to put you at legal risk of harm.

Study data may also be reviewed by ethics committees that protect the rights of study participants. This study may be reviewed by:

- the University of Washington, including the Institutional Review Board
- the Kenyatta National Hospital and University of Nairobi Ethics and Research Committee
- National Institutes of Health

We have a Certificate of Confidentiality from the United States National Institute Health (NIH). These protections only apply to data held in the United States.

This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law in the United States. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- A member of the United States government who needs it in order to audit or evaluate the research;

- Individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- Relevant authorities as required by other Federal, State, or local laws.

Research-Related Injury

It is unlikely that you will be injured as a result of participating in this study. There is no program for monetary compensation or other forms of compensation for injuries. You do not give up any legal rights by signing this consent form.

Problems or Questions:

If you ever have any questions about the study you should contact Dr. Cyrus Mugo, at 0721599626. If you have questions about your rights as a research participant, or feel you have been harmed by the study, you should contact Professor Guantai, the Chair of the KNH/UoN ERC, at 2726300-Extension 44102. You can also contact the UW HSD at +1-206-543-0098.

B. Study Participant's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have more questions later, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the KNH/UoN Ethics and Research Committee at 2726300-Extension 44102. I will receive a copy of the consent form.

_____ Participant's Name	_____ Signature/Thumbprint	_____ Date
_____ Witness name (if unable to sign) <i>(Note: a witness is an individual who must be independent of the study, literate and selected by the participant)</i>	_____ Signature/Thumbprint	_____ Date
_____ Study Staff Conducting Consent Discussion	_____ Signature	_____ Date

Copies to: Researcher, Participant

University of Washington (UW) & University of Nairobi (UoN) Collaborative Study Group

Adolescent Transition To Adult Care for HIV-infected adolescents in Kenya (ATTACH)

**Caregiver Consent Form for Adolescent Transition Readiness Assessment Survey
(10-14 years old)**

Investigators

NAME	POSITION	DEPARTMENT	TELEPHONE NUMBERS
Grace John-Stewart	Co-Principal Investigator	Global Health, UW	+1-206-543-4278
Dalton Wamalwa	Co-Principal Investigator	University of Nairobi	0733-558943
Kristin Beima-Sofie	Co-Investigator	Global Health, UW	+1-206-685-8332
Gabrielle O'Malley	Co-Investigator	Global Health, UW	+1-206-685-0775
Martin Sirengo	Co-Investigator	NASCOP	0719-441332
Bartilol Kigen	Co-Investigator	NASCOP	0722774991
Laura Oyiengo	Co-Investigator	NASCOP	0719-441332
Cyrus Mugo	Co-Investigator	University of Nairobi	0721-599626
Irene Njuguna	Co-Investigator	Kenyatta National Hospital	0721-871009

Emergency telephone number: Dr. Cyrus Mugo, 0721599626

Ethics and Research Committee Chairperson: Professor AN Guantai, Telephone 020-272-6300 Extension 44102

University of Washington Human Subjects Division: Telephone +1-206-543-0098.

Researchers' statement

We are requesting you to allow your child to volunteer for a research study. The study is being done by the University of Nairobi and the University of Washington. Before you decide to take part in this study, we would like to explain the purpose, procedures, risks, and benefits of the study. It is important that you understand that it is your choice to have your child take part in this study. If your child joins the study, he/she can withdraw from the study at any time. If you decide not allow your child to take part in the study, it will not affect any care or services that your child will receive from this clinic. We will ask you to review this form and we will answer any questions you have about the study. When we have answered all of your questions, you can decide if you want your child to be in the study. We will retain a copy of this consent form and give you a copy to take with you.

Purpose of Study

We are requesting your permission for your child to participate in this study because you receive care in this clinic. As young people get older, they need to be able to take care of their own health. They need to know what to do to improve their health and how to do it on their own. Sometimes caregivers may help, but sometimes they may not be available. Young people need to know what to do to take care of themselves when they have and do not have a caregiver there to help. The process of learning how to take care of their own health, without their caregiver, is called transition.

We want to know how we can best support your child, and other young people like them, to take care of their own health. We want to know what your child has learned and how we can help make it better. We will use your child's experience to think about how we can make the process of learning to take care of his/her own health better. Improving this process may help young people like your child keep their clinic appointments and take medicine better.

Study Procedures

This is what will happen if you allow your child to take part in this study. We will ask you to read, discuss, and sign or make your mark on this form. After this form is signed or marked, we will ask your child to complete a survey. Your child can take this survey during his/her normal clinic visits or at another time convenient to them. One of our research staff will help your child complete the survey. These questions will take about 10 minutes to complete. The questions will be about what your child did to get ready to come to the clinic and what happened at the clinic. We will also ask what he/she knows about HIV and HIV medicine.

We will ask your child to take the surveys every 6 months to see what they are learning and how that has changed. All surveys will ask similar questions. Once your child has taken the surveys, their participation in this study will end.

Risks, Stress, and Discomfort

The questions on the survey will not harm your child but he/she may become embarrassed, worried or anxious when talking about HIV or what they know about HIV. Your child may also be afraid of having to take care of themselves as they grow.

Others may learn that your child is part of the study. We have steps in place to protect your child's confidentiality and will do everything possible to reduce this risk. Your child will take the surveys with only the research study staff and away from other people. We will not share any information from the surveys with anyone outside the study team, including a caregiver or partner.

Alternatives to participation

There may be other studies going on here or in the community that your child may be eligible for. If you wish, we will tell you about other studies that we know about.

Benefits

Your child will not directly benefit from the study. However, his/her answers to questions may help us improve how we help young people learn to take care of their own health.

Other information

Your Participation is Voluntary

This consent form gives information about the study. We will discuss the study with you and answer any questions you may have. If you give permission for your child to take part, we will ask you to sign your name or make your mark on this form. We will offer you a copy to keep.

It is important that you know the following:

- You do not have to let your child participate in this study if you do not want to,
- You may decide not to have your child join the study, or to stop participating in the study at any time, without losing your access to care at this facility.
- If your child participates in the study, all the information he/she provides will be confidential.

Costs to You

There is no cost to your child for participation.

Reimbursement

Your child will receive KSH. 600 for their transportation costs and for their time and effort if they take part in the study.

8. Source of funding

The study team and/or the University of Washington are receiving financial support from the National Institutes of Health in the United States.

Confidentiality of Research Information

Confidentiality

The information your child provides will be kept secret by the healthcare workers and study staff. We will not write down or tell anyone your child's name that is not working on this study without your permission in writing. We will not publish or discuss in public anything that could identify your child. We will use a number code to identify your child and will only link the number code to your child's name in a special book called a link log. This link log will be stored in a room under lock and key and the link log will only be available to the study team. We will destroy the link log 6 years after the study ends. De-identified data may be used for future research studies or distributed to other investigators for future research studies.

If your child is being abused, we will refer him/her for additional support services.

Government or representatives from the funding agency sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your child's data may be reviewed. Reviewers will protect your child's privacy. Study data will not be used to put your child at legal risk of harm.

Study data may also be reviewed by ethics committees that protect the rights of study participants. This study may be reviewed by:

- the University of Washington, including the Institutional Review Board
- the Kenyatta National Hospital and University of Nairobi Ethics and Research Committee
- National Institutes of Health

We have a Certificate of Confidentiality from the United States National Institute Health (NIH). These protections only apply to data held in the United States.

This helps us protect your child's privacy. The Certificate means that we do not have to give out identifying information about your child even if we are asked to by a court of law in the United States. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your child's research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- A member of the United States government who needs it in order to audit or evaluate the research;
- Individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;

- Relevant authorities as required by other Federal, State, or local laws.

Research-Related Injury

It is unlikely that your child will be injured as a result of participating in this study. There is no program for monetary compensation or other forms of compensation for injuries. You do not give up any legal rights by signing this consent form.

Problems or Questions:

If you ever have any questions about the study you should contact Dr. Cyrus Mugo, at 0721599626. If you have questions about your rights as a research participant, or feel you have been harmed by the study, you should contact Professor Guantai, the Chair of the KNH/UoN ERC, at 2726300-Extension 44102. You can also contact the UW HSD at +1-206-543-0098.

B. Study Participant's statement

This study has been explained to me. I allow my child to volunteer to take part in this research. I have had a chance to ask questions. If I have more questions later, I can ask one of the researchers listed above. If I have questions about my child's rights as a research subject, I can call the KNH/UoN Ethics and Research Committee at 2726300-Extension 44102. I will receive a copy of the consent form.

Participant's Name

Caregiver's Name Signature/Thumbprint Date

Witness name
(if unable to sign)
(Note: a witness is an individual who must be independent of the study, literate and selected by the participant)

Signature/Thumbprint Date

Study Staff Conducting
Consent Discussion Signature Date

Copies to: Researcher, Participant

University of Washington (UW) & University of Nairobi (UoN) Collaborative Study Group

Adolescent Transition To Adult Care for HIV-infected adolescents in Kenya (ATTACH)

**Assent and Consent Form for Adolescent Transition Readiness Assessment Survey
(15-24 years old)**

Investigators

NAME	POSITION	DEPARTMENT	TELEPHONE NUMBERS
Grace John-Stewart	Co-Principal Investigator	Global Health, UW	+1-206-543-4278
Dalton Wamalwa	Co-Principal Investigator	University of Nairobi	0733-558943
Kristin Beima-Sofie	Co-Investigator	Global Health, UW	+1-206-685-8332
Gabrielle O'Malley	Co-Investigator	Global Health, UW	+1-206-685-0775
Martin Sirengo	Co-Investigator	NASCOP	0719-441332
Bartilol Kigen	Co-Investigator	NASCOP	0722774991
Laura Oyiengo	Co-Investigator	NASCOP	0719-441332
Cyrus Mugo	Co-Investigator	University of Nairobi	0721-599626
Irene Njuguna	Co-Investigator	Kenyatta National Hospital	0721-871009

Emergency telephone number: Dr. Cyrus Mugo, 0721599626

Ethics and Research Committee Chairperson: Professor AN Guantai, Telephone 020-272-6300 Extension 44102

University of Washington Human Subjects Division: Telephone +1-206-543-0098.

Researchers' statement

We are asking you to volunteer for a research study. The study is being done by the University of Nairobi and the University of Washington. Before you decide to take part in this study, we would like to explain the purpose, procedures, risks, and benefits of the study. It is important that you understand that it is your choice to take part in this study. If you join the study, you can withdraw from the study at any time. If you decide not to take part in the study, it will not affect any care or services that you receive from this clinic. We will ask you to review this form and we will answer any questions you have about the study. When we have answered all of your questions, you can decide if you want to be in the study. We will retain a copy of this consent form and give you a copy to take with you.

Purpose of Study

We are asking you to participate in this study because you receive care in this clinic. As young people get older, they need to be able to take care of their own health. They need to know what to do to improve their health and how to do it on their own. Sometimes caregivers may help, but sometimes they may not be available. Young people need to know what to do to take care of themselves when they have and do not have a caregiver there to help. The process of learning how to take care of yourself and your own health, without your caregiver, is called transition.

We want to know how we can best support you, and other young people like you, to take care of your own health. We want to know what you have learned and how we can help make it better. We will use your experience to think about how we can make the process of learning to take care of your own health better. Improving this process may help young people like you keep their clinic appointments and take medicine better.

Study Procedures

This is what will happen if you agree to take part in this study. We will ask you to read, discuss, and sign or make your mark on this form. After this form is signed or marked, we will ask you to complete a survey. You can take this survey during your normal clinic visits or at another time convenient to you. One of our research staff will help you complete the survey. These questions will take about 10 minutes to complete. The questions will be about what you did to get ready to come to the clinic and what happened at the clinic. We will also ask what you know about HIV and HIV medicine.

We will ask you to take the surveys every 6 months to see what you are learning and how that has changed. All surveys will ask similar questions. Once you have taken the surveys, your participation in this study will end.

Risks, Stress, and Discomfort

The questions will not harm you but you may become embarrassed, worried or anxious when talking about HIV or what you know about HIV. You may be afraid of having to take care of yourself as you grow.

Others may learn that you are part of the study. We have steps in place to protect your confidentiality and will do everything possible to reduce this risk. You will take the surveys with only the research study staff and away from other people. We will not share any information from the surveys with anyone outside the study team, including a caregiver or partner.

Alternatives to participation

There may be other studies going on here or in the community that you may be eligible for. If you wish, we will tell you about other studies that we know about.

Benefits

You will not directly benefit from the study. However, your answers to questions may help us improve how we help young people learn to take care of their own health.

Other information

Your Participation is Voluntary

This consent form gives information about the study. We will discuss the study with you and answer any questions you may have. If you agree to take part, we will ask you to sign your name or make your mark on this form. We will offer you a copy to keep.

It is important that you know the following:

- You do not have to be in this study if you do not want to,
- You may decide not to join the study, or to stop the study at any time, without losing your access to care at this facility.
- If you participate in the study, all the information you provide will be confidential.

Costs to You

There is no cost to you for participation.

Reimbursement

You will receive KSH. 600 for your transportation costs and for your time and effort if you take part in the study.

8. Source of funding

The study team and/or the University of Washington are receiving financial support from the National Institutes of Health in the United States.

Confidentiality of Research Information

Confidentiality

The information you provide will be kept secret by the healthcare workers and study staff. We will not write down or tell anyone your name that is not working on this study without your permission in writing. We will not publish or discuss in public anything that could identify you. We will use a number code to identify you and will only link the number code to your name in a special book called a link log. This link log will be stored in a room under lock and key and the link log will only be available to the study team. We will destroy the link log 6 years after the study ends. De-identified data may be used for future research studies or distributed to other investigators for future research studies.

If you are being abused, we will refer you for additional support services.

Government or representatives from the funding agency sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your data may be reviewed. Reviewers will protect your privacy. Study data will not be used to put you at legal risk of harm.

Study data may also be reviewed by ethics committees that protect the rights of study participants. This study may be reviewed by:

- the University of Washington, including the Institutional Review Board
- the Kenyatta National Hospital and University of Nairobi Ethics and Research Committee
- National Institutes of Health

We have a Certificate of Confidentiality from the United States National Institute Health (NIH). These protections only apply to data held in the United States.

This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law in the United States. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- A member of the United States government who needs it in order to audit or evaluate the research;
- Individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- Relevant authorities as required by other Federal, State, or local laws.

Research-Related Injury

It is unlikely that you will be injured as a result of participating in this study. There is no program for monetary compensation or other forms of compensation for injuries. You do not give up any legal rights by signing this consent form.

Problems or Questions:

If you ever have any questions about the study you should contact Dr. Cyrus Mugo, at 0721599626. If you have questions about your rights as a research participant, or feel you have been harmed by the study, you should contact Professor Guantai, the Chair of the KNH/UoN ERC, at 2726300-Extension 44102. You can also contact the UW HSD at +1-206-543-0098.

B. Study Participant's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have more questions later, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the KNH/UoN Ethics and Research Committee at 2726300-Extension 44102. I will receive a copy of the consent form.

_____ Participant's Name	_____ Signature/Thumbprint	_____ Date
_____ Witness name (if unable to sign) <i>(Note: a witness is an individual who must be independent of the study, literate and selected by the participant)</i>	_____ Signature/Thumbprint	_____ Date
_____ Study Staff Conducting Consent Discussion	_____ Signature	_____ Date

Copies to: Researcher, Participant

University of Washington (UW) & University of Nairobi (UoN) Collaborative Study Group

Adolescent Transition To Adult Care for HIV-infected adolescents in Kenya (ATTACH)

Consent for participation in implementation activities

Investigators

NAME	POSITION	DEPARTMENT	TELEPHONE NUMBERS
Grace John-Stewart	Co-Principal Investigator	Global Health, UW	+1-206-543-4278
Dalton Wamalwa	Co-Principal Investigator	University of Nairobi	0733-558943
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Irene Njuguna	Co-Investigator	Kenyatta National Hospital	0721-871009

Emergency telephone number: Dr. Cyrus Mugo, 0721599626

Ethics and Research Committee Chairperson: Professor AN Guantai, Telephone 020-272-6300 Extension 44102

University of Washington Human Subjects Division: Telephone +1-206-543-0098.

A. Researchers' statement

1. Introduction

We are asking your consent to volunteer for a research study. The study is being done by the University of Nairobi and the University of Washington. The purpose of this consent process is to give you the information you will need to help you decide whether or not you want to participate. You may ask questions about the purpose of the research study, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research study or this form that is not clear. When we have answered all of your questions, you can decide if you want to be in the study. This process is called "informed consent." We will give you a copy of this form for your records.

2. Purpose and Benefits

We are asking you to participate in this study because you work with adolescents in the HIV clinic at your facility. Your facility has been selected to participate in a clinical trial that will introduce an intervention package, the Adolescent Transition Package, for use in the transition process from pediatric to adult HIV care at your clinic. The tool includes a transition flipchart, disclosure booklet, and tracking tools that provide a structured process to guide HIV disclosure and transition to adult care for adolescents living with HIV. This tool was developed with input from policy makers, caregivers, adolescents and other health care workers in Kenya.

Since you are one of the first clinics to use this tool, we would like to get your feedback on the tool during the time when your clinic is first using it. We want to find out what you think about the tool, how practical it is to use and what areas of the tool can be modified to improve it.

The information from this study may benefit adolescents by improving transition procedures in clinic resulting to less loss to follow-up and better adherence to ART.

3. Procedures

If you agree to be a part of this study, first, we will ask you some questions about yourself, such as your age, education, and experience in adolescent care. We will then ask you to participate in the following activities:

Pre-Implementation survey:

We will share the Adolescent Transition Package tools with you and walk you through the basics of using the tools during a training with providers from your clinic. We will then ask you to complete a brief survey. The survey will ask information about you such as your age, clinical training, and experience taking care of adolescents. It will also ask you to describe the current processes in place at your clinic related to HIV disclosure and transition from child/adolescent to adult care. The survey will also ask questions about your opinion on the environment at your clinic, and how new policies and programs get implemented. We will ask questions to determine how the environment at your clinic might influence how the Adolescent Transition Package gets used at your clinic. We want to know how easy and practical you think the tool will be to use. The survey will be done on paper or tablets and will take about 1 hour to complete. You will complete the survey on your own or with a study team member.

Adaptation meetings with the study team

We will ask you to take part in meetings happening every 2 weeks. Meetings will include other healthcare providers at your clinic. During meetings, we will talk with you about using the Adolescent Transition package tools. This meeting will last about 1-2 hours. We will ask you to talk about what you find easy and hard about using the tools. As a group, we will ask you to come up with specific changes on how the tool is used that will improve experiences and processes using the tools. At the end of the meeting, we will agree as a group on which changes to make to the tools, and try out those changes during the next 2 weeks. A study team member will be present to guide these meetings. The meetings will serve as a space to generate ideas to improve your experiences using the tools.

We will audio record the discussion at each meeting so that we may later write down what you have told us and track the suggestions and changes you are making over time. A member of the study staff will write notes on what is said during each discussion. We will continue to monitor changes to tools and have meetings for the first 6 months that the Adolescent Transition Package is used at your clinic. There will be no more than 12 meetings total.

Short evaluation surveys

Prior to the start of each meeting, we will ask you to participate in a brief survey. The survey will ask about the acceptability and feasibility of the changes you made to the tool over the past few weeks. We will ask you about your experiences using the tool during those weeks, and what additional challenges you had. We will also ask you what helped make using the tool easier. Surveys will be done on paper or tablets and will take 15-30 minutes to complete. You will complete the survey on your own or with a study team member.

4. Risks, Stress, and Discomfort

There are no physical risks for this pilot study.

During the weekly meetings you may become embarrassed, worried or anxious when talking about your opinions in the presence of other providers or sharing your experiences. You can leave the group at any time if you do not want to participate anymore. It is possible that others in the weekly meetings may have different opinions from yours and, because of this, may treat you differently or discuss your opinions outside the meeting. If you are not comfortable with this, you should not take part in this study.

We may ask things on the surveys that make you feel uncomfortable. You can end the survey at any time if you do not want to answer more questions. You do not have to take all the surveys if you do not want to. Your answers will be confidential. You will take the surveys by yourself, and away from other people.

The study team members will make every effort to uphold individual opinions, privacy and confidentiality while you are participating.

5. Alternatives to participation

There may be other studies going on here or in the community that you may be eligible for. If you wish, we will tell you about other studies that we know about.

6. Benefits

You may not directly benefit from this study. However, your contributions to understanding how implementing the tool went for you will help us optimize the tool for you clinic and other clinics who might use it in the future. This information will be used to improve transition practices in clinics and transition experiences for adolescents.

7. Other information

Your Participation is Voluntary

This consent form gives information about the implementation evaluation activities. We will discuss it with you and answer any questions you may have. If you agree to take part, we will ask you to sign your name on this form. We will offer you a copy to keep.

It is important that you know the following:

- You do not have to be in this study if you do not want to,
- You may decide not to join the study, or to stop the study at any time, without any impact on your employment at this clinic.

Costs to You

There is no cost to you for participation.

Reimbursement

We will reimburse you for your time and effort completing surveys and attending twice-monthly meetings. You will receive 500 KSH for each feedback meeting you attend and 300 KSH for each short evaluation survey you complete. You will receive 500 KSH for completing the pre-implementation survey.

Permission for future contact

We would like to be able to contact you again in case we have questions about information you shared with us during the discussions. You can indicate your choice about future contact at the end of this form. Agreeing to future contact does not obligate you to participate in any future study activities.

8. Source of funding

The study team and/or the University of Washington are receiving financial support from the National Institutes of Health in the United States.

9. Confidentiality of Research Information

Confidentiality

The information you provide during the meetings and through surveys will be held in strict confidence by the study team and no identifying information of any kind will be released to any other person or agency without your permission in writing. All of your information will be kept in a secure location at the clinic only. The recordings of the discussion that we collect will not be directly linked to your name and contact information. We will use a number code to identify your responses and will only link the number code to your name in a special book called a link log. This link log will be stored in a room under lock and key. This link log will only be available to the study team. We will destroy the link log and the audio recordings 6 years after we complete the interviews.

Any publication of this process will not use your name or identify you personally. The research team may take short sections of what you say and share them with non-study members. De-identified transcripts of meetings, adaptation tracking forms and survey results may be used for future research studies or distributed to other investigators for future research studies. We will not publish or discuss in public anything that could identify you.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this assessment takes place, your records may be examined. The reviewers will protect your privacy. The assessment records will not be used to put you at legal risk of harm.

The records of this discussion may be reviewed by assessment staff and representatives of:

- the University of Washington, including the Institutional Review Board
- the Kenyatta National Hospital and University of Nairobi Ethics and Research Committee
- National Institutes of Health (NIH), United States

We have a Certificate of Confidentiality from the United States National Institute Health (NIH). These protections only apply to data held in the United States.

This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law in the United States. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- A member of the United States government who needs it in order to audit or evaluate the research;
- Individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- Relevant authorities as required by other Federal, State, or local laws.

Research-Related Injury

It is unlikely that you will be injured as a result of participating in this pilot study. There is no program for monetary compensation or other forms of compensation for injuries. You do not give up any legal rights by signing this consent form.

Problems or Questions:

If you ever have any questions about the study you should contact Dr. Cyrus Mugo, at 0721599626. If you have questions about your rights as a research participant, or feel you have been harmed by the study, you should contact Professor Guantai, the Chair of the KNH/UoN ERC, at 2726300 Extension 44102. You can also contact the UW HSD at +1-206-543-0098.

B. Study Participant's statement

The pilot study has been explained to me. I have had a chance to ask questions. If I have more questions later, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the KNH/UoN Ethics and Research Committee at 2726300 Extension 44102. I will receive a copy of the consent form.

I agree _____ I do not agree _____
to participate in the implementation evaluation activities described in this form

I agree _____ I do not agree _____
to have my voice recorded during the twice-monthly meetings
(*Participant is not eligible to participate if this box is not checked)

I agree _____ I do not agree _____
to have study staff contact me again about information I shared during the twice-monthly meetings.

_____	_____	_____
Participant's Name	Signature/Thumbprint	Date

_____	_____	_____
Study Staff Conducting Consent Discussion	Signature	Date

Copies to: Researcher
 Participant

University of Washington (UW) & University of Nairobi (UoN) Collaborative Study Group
Adolescent Transition To Adult Care for HIV-infected adolescents in Kenya (ATTACH)
Consent for participation in implementation evaluation HCW focus group discussion

Investigators

NAME	POSITION	DEPARTMENT	TELEPHONE NUMBERS
Grace John-Stewart	Co-Principal Investigator	Global Health, UW	+1-206-543-4278
Dalton Wamalwa	Co-Principal Investigator	University of Nairobi	0733-558943
Kristin Beima-Sofie	Co-Investigator	Global Health, UW	+1-206-685-8332
Gabrielle O'Malley	Co-Investigator	Global Health, UW	+1-206-685-0775
Bartilol Kigen	Co-Investigator	NASCOP	0775-597297
Laura Oyiengo	Co-Investigator	NASCOP	0719-441332
Cyrus Mugo	Co-Investigator	University of Nairobi	0721-599626
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Emergency telephone number: Dr. Cyrus Mugo, 0721599626

Ethics and Research Committee Chairperson: Professor AN Guantai, Telephone 020-272-6300 Extension 44102

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A. Researchers' statement

1. Introduction

We are asking your consent to volunteer for a research study. The study is being done by the University of Nairobi and the University of Washington. The purpose of this consent process is to give you the information you will need to help you decide whether or not you want to participate. You may ask questions about the purpose of the research study, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research study or this form that is not clear. When we have answered all of your questions, you can decide if you want to be in the study. This process is called "informed consent." We will give you a copy of this form for your records.

2. Purpose and Benefits

We are asking you to participate in this study because you participated in implementing a new intervention package, the Adolescent Transition Package, for use in the transition process from pediatric to adult HIV care at your clinic. The tool includes a transition flipchart, disclosure booklet, and tracking tools that provide a structured process to guide HIV disclosure and transition to adult care for adolescents living with HIV. This tool was developed with input from policy makers, caregivers, adolescents and other health care workers in Kenya.

We want to find out what you thought about using the tool, how practical it is to use and what areas of the tool can be modified to improve use.

The information from this study may benefit adolescents by improving transition procedures in the clinic, resulting to less loss to follow-up and better adherence to ART.

3. Procedures

If you agree to be a part of this study, we will ask you to talk in a group of other health care workers who have used the tool. This kind of group discussion is called a focus group discussion. Two members of the study team will lead the discussion. We will audio record the discussion so that we may later write down what you have told us. A member of the study staff will write notes on what is said during the discussion.

If you decide to participate, we will schedule a time for you to participate in the discussion.

At the beginning of the focus group discussion, we will ask you to first complete a short demographic survey to know information about you such as your age, clinical training, and experience taking care of adolescents. We will specifically ask you about training in using the Adolescent Transition Package and your use of the study tools.

During the focus group discussion, we will ask you to share your experiences with helping adolescents through disclosure or transition processes. We will also ask you about using the transition tools included in the Adolescent Transition Package, including the transition flip chart, disclosure booklet, and tracking tools. We will ask your views on what you think about its use in your clinic. We will ask you how easy or how difficult it is to use the tool and your opinion on what changes make it easier to implement. We will also ask you about your perceptions on how the tool may or may not be influencing adolescent disclosure and transition experiences.

The discussion will take about 2 hours. We will not use your names when we talk. We will not share any information you provide us with your co-workers, supervisors or anyone else outside the study team.

4. Risks, Stress, and Discomfort

There are no physical risks for this study.

During the focus group discussion, you may become embarrassed, worried or anxious when talking about your opinions in the presence of other providers or sharing your experiences. You can leave the group at any time if you do not want to participate anymore.

It is possible that others in the focus group discussion may have different opinions from yours and, because of this, may treat you differently or discuss your opinions outside the meeting. If you are not comfortable with this, you should not take part in this study.

The assessment staff will make every effort to uphold individual opinions, privacy and confidentiality while you are participating. We will ask all the healthcare workers participating in this discussion to protect each other's privacy, and not to repeat anything that is said once the

discussion is over. But it is possible that another member of the group could tell someone outside the discussion about something you say.

We will make audio recordings of the discussion. Although we will store the recordings in a safe place, it is possible that someone not associated with the research could recognize your voice from the recordings.

5. Alternatives to participation

There may be other studies going on here or in the community that you may be eligible for. If you wish, we will tell you about other studies that we know about.

6. Benefits

You will not directly benefit from this focus group discussion. However, your contributions to this will help us optimize implementation of the tool in your clinic and other clinics in the future. This information will be used to improve transition practices in clinics and transition experiences for adolescents.

7. Other information

Your Participation is Voluntary

This consent form gives information about the focus group discussion. We will discuss it with you and answer any questions you may have. If you agree to take part, we will ask you to sign your name on this form. We will offer you a copy to keep.

It is important that you know the following:

- You do not have to be in this study if you do not want to,
- You may decide not to join the study, or to stop the study at any time, without any impact on your employment at this clinic.

Costs to You

There is no cost to you for participation.

Reimbursement

We will reimburse KSH 1000 for your time and effort.

Permission for future contact

We would like to be able to contact you again in case we have questions about information you shared with us during the discussion. You can indicate your choice about future contact at the end of this form. Agreeing to future contact does not obligate you to participate in any future study activities.

8. Source of funding

The study team and/or the University of Washington are receiving financial support from the National Institutes of Health in the United States.

9. Confidentiality of Research Information

Confidentiality

The information you provide during the meetings will be held in strict confidence by the study team and no identifying information of any kind will be released to any other person or agency without your permission in writing. All of your information will be kept in a secure location at the clinic only. The recordings of the discussion that we collect will not be directly linked to your name and contact information. We will use a number code to identify your responses and will only link the number code to your name in a special book called a link log. This link log will be stored in a room under lock and key. This link log will only be available to the study team. We will destroy the link log and the audio recordings 6 years after we complete the interviews.

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- the Kenyatta National Hospital and University of Nairobi Ethics and Research Committee
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Problems or Questions:

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B. Study Participant's statement

The focus group discussion has been explained to me. I have had a chance to ask questions. If I have more questions later, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the KNH/UoN Ethics and Research Committee at 2726300 Extension 44102. I will receive a copy of the consent form.

I agree _____ I do not agree _____
to have my voice recorded during the focus group discussion.
(*Participant is not eligible to participate if this box is not checked)

I agree _____ I do not agree _____
to have study staff contact me again about information I shared during the focus group discussion.

Participant's Name	Signature/Thumbprint	Date
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Study Staff Conducting Consent Discussion	Signature	Date
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Copies to: Researcher
 Participant