

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



Study sponsor: National Institutes of Health, Grant Number
1R01HD089850-01
Principal Investigator: Grace John-Stewart, MD, MPH, PhD

Version Number: 2.6

December 29, 2020

Table of Contents

LIST OF ABBREVIATIONS AND ACRONYMS	III
INVESTIGATORS	IV
SIGNATURE PAGE.....	VI
PROTOCOL SUMMARY	VII
SECTION 1: BACKGROUND INFORMATION AND LITERATURE REVIEW	1
1a. Background Information	1
1b. Literature Review	2
1c. Rationale	4
SECTION 2: OBJECTIVES	5
2a. Study Objective	5
2b. Specific Objectives	5
SECTION 3: STUDY OUTCOMES.....	6
Table 1: Outcome, metric and data source	7
SECTION 4: STUDY DESIGN	8
SECTION 5: STUDY SITES AND POPULATIONS.....	10
5a. Study sites.....	10
5b. Study population.....	11
Table 2: Purposive sampling scheme and data collection details for Aim 2.....	12
Table 3: Details of cluster RCT design, enrollment and data collection	13
5c. Participant inclusion criteria	14
5d. Site/participant exclusion criteria	15
Table 4. Inclusion Criteria for all participants/clinics	16
5e. Randomization procedures.....	18
5f. Masking procedures	19
5g. Participant Withdrawal.....	19
SECTION 6: STUDY INTERVENTION.....	20
Table 5: Core elements of the Got Transition Program	20
SECTION 7: STUDY PROCEDURES	21
7a. Programmatic data analysis and facility surveys.....	22
7b. Adapt and Optimize phase.....	24
7c. Cluster Randomized Controlled Trial (RCT).....	30
7d. Implementation Evaluation	34
7e. Assessment of participant compliance with study intervention	40
SECTION 8: STUDY SCHEDULE.....	41
Table 6a: Overall study schedule: 2016-2021	41
SECTION 9: ASSESSMENT OF SAFETY	42
9a. Reporting of unanticipated problems and other events	42
SECTION 10: DATA COLLECTION.....	42
SECTION 11: STATISTICAL CONSIDERATIONS	47
11a. Sample Size Considerations.....	47

Table 7: Precision estimates for prevalence of retention and viral load suppression in HIV-infected adolescents	47
Table 8: Power and sample size ranges	48
11b. Overview of analysis plan	49
SECTION 12: ETHICS/PROTECTION OF STUDY PARTICIPANTS	50
12a. Informed Consent Process	50
12b. Participant Confidentiality	52
12c. Potential Risks and Benefits	53
SECTION 13: USE OF INFORMATION AND PUBLICATIONS.....	55
SECTION 14: LIMITATIONS	55
REFERENCES	57
APPENDICES.....	60

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

INVESTIGATORS

Principal Investigator Grace John-Stewart
Professor, Medicine, Epidemiology, Pediatrics, Global Health
University of Washington
Harborview Medical Center
325 9th Avenue, Box 359932
Seattle WA 98104 USA
Tel: +1-206-543-4278
Email: gjohn@uw.edu

Co-Principal Investigator Dalton Wamalwa MBChB, MMed, MPH
Associate Professor, Paediatrics & Child Health
University of Nairobi / Kenyatta National Hospital
Tel: +254721239493
Email: dalton@africaonline.co.ke

Co-Investigators Kristin Beima-Sofie, PhD, MPH
Acting Assistant Professor, Global Health
University of Washington
beimak@uw.edu

Gabrielle O'Malley, PhD
Associate Professor, Global Health
University of Washington
gomalley@uw.edu

Bartilol Kigen, MBChB, MMed
Head, National AIDS and STI Control Program,
Ministry of Health, Kenya
head@nascop.or.ke

Martin Sirengo, MBChB, MMed
Head, National AIDS and STI Control Program,
Ministry of Health, Kenya
msirengo@nascop.or.ke

Laura Oyiengo, MBChB, MMed
Program Manager, Pediatrics
National AIDS and STI Control Program,
Ministry of Health, Kenya
bonarerimk@gmail.com

Cyrus Mugo Wachira, MBChB, MPHc
Study Coordinator
University of Nairobi / Kenyatta National Hospital
cyrusmugodr@gmail.com

Irene Njuguna, MBChB, Msc., MPHc
Research Scientist
Kenyatta National Hospital / University of Washington
irenen@uw.edu

**Collaborating
Institutions**

University of Washington
4333 Brooklyn Avenue NE
Box 359472
Seattle WA 98195 USA

University of Nairobi / Kenyatta National Hospital
Off Ngong Road
PO Box 19676-00202
Nairobi, Kenya

National AIDS and STI Control Program (NASCOPI),
Ministry of Health
P.O. Box 19361-00202
Nairobi, Kenya

**Funding
Agencies**

National Institutes of Health (NIH)
Grant: 1R01HD089850-01 (John-Stewart, PI) – “Transitioning from Pediatric
to Adult HIV care in Kenya”

SIGNATURE PAGE

Grace John-Stewart, MD, PhD gjohn@uw.edu	 Principal Investigator signature	April, 20, 2018 Date
Dalton Wamalwa MBChB, MMed, MPH dalton@africaonline.co.ke	_____ Co-Investigator signature	April, 20, 2018 Date
Kristin Beima-Sofie, PhD, MPH beimak@uw.edu	 Co-Investigator signature	April, 20, 2018 Date
Gabrielle O'Malley, PhD gomalley@uw.edu	 Co-Investigator signature	April, 20, 2018 Date
Bartilol Kigen, MBChB, MMed head@nascop.or.ke	_____ Co-Investigator signature	April, 20, 2018 Date
Martin Sirengo, MBChB, MMed msirengo@nascop.or.ke	_____ Co-Investigator signature	April, 20, 2018 Date
Laura Oyiengo, MBChB, MMed bonarerimk@gmail.com	_____ Co-Investigator signature	April, 20, 2018 Date
Cyrus Mugo Wachira, MBChB cyrusmugodr@gmail.com	 Co-Investigator signature	April, 20, 2018 Date
Irene Njuguna, MBChB, Msc. irenen@uw.edu	 Co-Investigator signature	April, 20, 2018 Date

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 children, adolescents and youth ages 6-24 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 60 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 IeDEA 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, 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: The ATP will increase proportion of children and 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 children and 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	Disclosure readiness	Disclosure readiness assessment

			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):

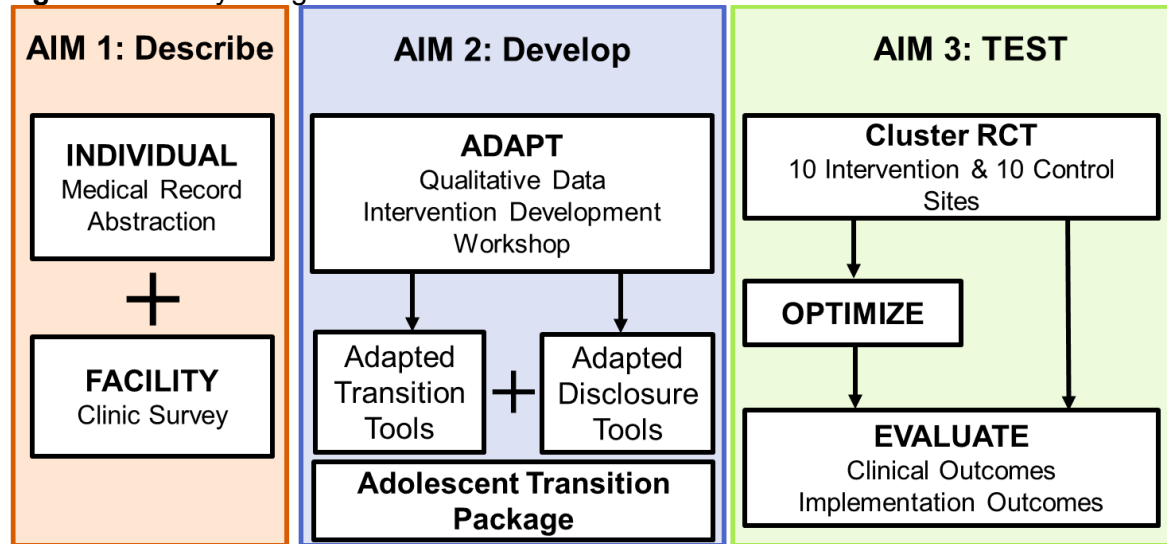
Formative phase:

- 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, including 10 study nurses implementing trial procedures, 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 caregivers of children and young adolescents preparing for disclosure, and adolescents and young adults ages 10-24 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. Caregivers of children and young adults who have not yet reached disclosure, as well as fully disclosed 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/REVISE	
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 children, adolescents and young adults aged 6-24 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 60 HCWs from all 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 caregivers of children and adolescents who have not yet reached full disclosure, and adolescents and young adults ages 10-24 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 6-24 per clinic	50-500	50-500
Minimum number of clients aged 6-24 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 transition readiness assessment form	2000	2000
Maximum number of children completing disclosure readiness assessment form		1000
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	-	60
HCWs completing post-trial FGDs		200

Maximum number of HCWs completing IDIs for cost estimation and time and motion observation		60
--	--	----

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. Child and adolescent records will be abstracted for all 6-24 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 up to the age of 24 years who have attained full disclosure and caregivers of children and adolescents who have not yet reached full disclosure. Adolescents and/or caregivers will give consent and/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 or by the ATTACH study during the intervention period and providing clinical services or performing study activities with 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)	<ul style="list-style-type: none"> ≥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	<ul style="list-style-type: none"> ≥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	<ul style="list-style-type: none"> ≥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
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	20 clinics; surveys completed at baseline and study end	<ul style="list-style-type: none"> ≥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
Pre-trial surveys	Adolescent	Selected from intervention and control sites	400 surveys	<ul style="list-style-type: none"> - Between 12 and 24 years of age -Willing to complete anonymous survey - Knows HIV status
	HCW	Selected from intervention sites	200 surveys	<ul style="list-style-type: none"> ≥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	<ul style="list-style-type: none"> ≥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	<ul style="list-style-type: none"> ≥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)	<ul style="list-style-type: none"> ≥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	Up to 16 selected from intervention sites	16 (from a subset of clinics reporting use of disclosure tools)	-Attained full HIV disclosure during the intervention period or recently (<24 months) disclosed to -Between 14 and 24 years of age
	Adolescents who were exposed to the intervention	6-10 selected from each intervention site	80 (from all intervention clinics)	-Exposed to the intervention during the intervention period -Between 14 and 24 years of age
	HCW	5-10 HCW selected from each selected intervention site	60 IDI (from all intervention clinics)	-≥18 years of age -Working in intervention clinics or on the ATTACH study 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
Transition Readiness assessment surveys	Adolescents ages 10-24 years	Selected from all 20 selected facilities	Up to 4000 (2000 per arm)	-Aged 10-24 years of age -Willing to complete survey - Knows HIV status
Disclosure Readiness assessment surveys	Caregivers of children or adolescents ages 6-17 who do not know their HIV status	Selected from intervention facilities	Up to 1000	-≥18 years of age -Caregiver of adolescent aged 6-18 who does not yet know their HIV status -Willing to complete survey
Retrospective Records Review	Adolescents ages 10-24	All adolescents from the 20 selected facilities	Up to 4000 (2000 per arm)	-Aged 6-24 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 6 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

COVID-19 ADAPTED STUDY PROCEDURES

As a result of the COVID-19 pandemic and resultant changes to visit schedules and client contact time, we propose the following changes to study procedures during the pandemic period:

The transition intervention will be delivered either in person or on phone by clinic based health care workers where possible, or by phone by hired study staff. Delivery will be guided by current recommendations and guidelines from the Kenyan MOH regarding care for adolescents living with HIV and country mandates.

Transition readiness assessments will be conducted through phone interview rather than in person. These were already conducted by study staff, and will continue to be conducted by the same hired study staff.

Enrolled participants will give oral consent by phone (using the phone interview guide) to continue with transition readiness assessments by phone. This will be obtained and documented by study staff. Study link logs will be converted to electronic logs with password protection and accessible only to study staff to limit visits to the clinic by study staff.

Enrolled participants in intervention and control sites will receive phone calls from study staff to see how they are coping, adhering to treatment and receive COVID-19 related information.

Participants will be reimbursed via mobile money transfer for the 6 monthly transition readiness assessments.

All new enrollment is suspended, but may be reopened when identified as safe and clinical procedures for adolescents living with HIV are returned to normal in the country.

In-person disclosure related study activities are suspended; however, HCWs in facilities can use disclosure tools as needed to assist them with providing routine care for adolescents living with HIV and their primary caregivers.

In-person continuous quality improvements (CQI) activities are suspended, phone based or other virtual CQI activities may resume if possible and may include multiple shorter check-in phone visits with individual, rather than groups, of healthcare providers, and will check in on healthcare providers well-being including how they are coping with COVID-19.

FGDs scheduled to be held with HCWs after 6 months of intervention implementation will be postponed until it is deemed safe to meet in person or virtual delivery/hosting platforms have been identified and organized.

When determined to be safe, and in accordance with MOH and country-specific guidelines, study procedures will return to those detailed below that involve in-person interactions.

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. We will conduct facility surveys with all 20 facilities prior to implementation of aim 3 activities. The facility survey will be repeated at the end of the trial, to capture new information on clinic practices and changes in staffing. Procedures for the survey are similar to those described in aim 1. The same facility survey tool used in aim 1 will be used to capture this data. 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, as well as updated information on routine clinic procedures and staffing numbers throughout the entire 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. Because of clinic staff turnover, a new facility designee can complete the survey at each time point.

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

joint 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.

We will conduct disclosure readiness surveys at intervention sites with caregivers of children and adolescents aged 6-19 years who have not yet attained full disclosure. Surveys will be conducted at baseline (clinical trial start) and every 6 months thereafter until the study ends or the child/adolescent has reached full disclosure.

All caregivers of children and adolescents ages 6-19 years who have not yet attained full disclosure and are attending clinic visits at intervention sites will be eligible to participate in the surveys. Caregivers will be recruited during clinic visits by a member of the study team or by phone prior to returning to clinic for their child's study visit. A recruitment script with guiding information is provided in the appendices. If a caregiver is interested in participating, eligibility will be assessed by clinic or study staff by asking a series of questions. These questions will confirm that the caregiver is someone responsible for caring for the child and that the child or adolescent does not know their HIV status. Example questions that study staff might ask include: "how old is the child you bring to this clinic," "does the child know that they have HIV" and "are you this child's primary guardian."

Caregivers who meet eligibility criteria and are interested in participating will give written consent to participate in the surveys. Caregivers will be informed that their data will be linked to their child's medical record data, but this survey will not contain their name, only their ID. All caregivers who provide consent will be enrolled and participate in this survey. Caregivers who provide consent will take the disclosure readiness surveys every 6 months and 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 and disclosure 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 tools are 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 transition readiness surveys with adolescents ages 15-24
- l. Completion of baseline and 6-monthly disclosure readiness surveys with caregivers of adolescents ages 6-17 who do not know their HIV status
- m. Extraction of routine medical records for adolescents ages 6-24
- n. Extraction of data from intervention tracking forms
- o. 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 at the end of the trial. 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 months or post-intervention implementation. HCWs can participate in an FGD at 6 months, at the end of the trial, 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. We will also ask questions about delivery of the intervention by phone, as it was adapted in response to COVID-19. 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, at trial end, 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 16 (estimating limited intervention exposure due to COVID-19) individual interviews with HIV-infected adolescents who have attained full disclosure of their HIV status during the intervention period or recently (defined within the previous 24 month) and 80 (estimating 6-10 adolescents total from all intervention sites) individual interviews with adolescents who were exposed to the transition intervention during the intervention period. We will also conduct 60 individual interviews with 5-10 HCWs at selected intervention clinics, including 10 IDIs with ATTACH study nurses. All clinics will participate in end of trial data collection.

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, exposure to intervention materials, 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, as well as delivery of the intervention by phone. 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. ATTACH study nurse IDIs will include questions to evaluate delivery of the transition readiness assessment, a tool only administered by study staff. 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 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 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 10-24 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.

- *Prospective Data – Disclosure readiness surveys:* Surveys will be conducted every 6 months with caregivers of children and adolescents ages 6-17 who have not reached full disclosure from intervention sites. Surveys will assess caregiver readiness for disclosure.

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%	+/-2.6%
	5000	60%	3000	57.5-62.5%	+/-2.5%
	5000	70%	3500	67.6-72.4%	+/-2.4%
	5000	80%	4000	77.9-82.1%	+/-2.1%
	5000	90%	4500	88.5-91.5%	+/-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 6-15 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 60 providers will be selected from among all providers at intervention facilities, including 10 IDIs with ATTACH study staff. 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 5 providers per site (50 total), and 10 ATTACH study nurses, 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 96 adolescents will be selected for interviews. We will purposively select adolescents with a range of ages and intervention exposure. 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 been exposed to the ATP. Eligibility of adolescents will be confirmed by reviewing their chart for documentation of disclosure and transition intervention exposure. We believe that 6-10 adolescents from each site (96 total) will give us adequate numbers to attain saturation during data collection and 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

COVID-19 ADAPTED STUDY PROCEDURES

As a result of the COVID-19 pandemic, some activities will be move to being offered by phone. For adolescents, study activities conducted by phone pose potential additional risks of inadvertent disclosure of adolescent HIV status for participating adolescents. However, healthcare providers already routinely call adolescents to remind them of clinic visits and support groups, and may be moving to provide more services by phone to minimize exposure at clinics during the COVID-19 pandemic. To minimize potential disclosure risks, we will first confirm that the person on the phone is the enrolled study participant. We will also ask the participant to confirm willingness to participate in phone-based activities. We are also only offering services to adolescents who know their status, as part of the inclusion criteria for enrolling in the transition intervention activities.

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 10-24 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 6 will be excluded from this study because the target population is children, adolescents and youth ages 6-24.

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.

REFERENCES

1. UNAIDS. Core Epidemiology Slides, July 2015. http://www.unaids.org/sites/default/files/media_asset/20150714_epi_core_en.pdf 2015.
2. WHO. HIV/AIDS Data and Statistics. <http://www.who.int/hiv/data/en/> 2015.
3. PEPFAR. The U.S. President's Emergency Plan for AIDS Relief and Children's Investment Fund Foundation Launch \$200 million Accelerating Children's HIV/AIDS Treatment Initiative (ACT) to Save Lives. <http://www.pepfar.gov/press/releases/2014/230334.htm> 2014.
4. Kabue MM, Buck WC, Wanless SR, Cox CM, McCollum ED, Caviness AC, *et al*. Mortality and clinical outcomes in HIV-infected children on antiretroviral therapy in Malawi, Lesotho, and Swaziland. *Pediatrics* 2012,**130**:e591-599.
5. Wamalwa D, Benki-Nugent S, Langat A, Tapia K, Ngugi E, Slyker JA, *et al*. Survival benefit of early infant antiretroviral therapy is compromised when diagnosis is delayed. *Pediatr Infect Dis J* 2012,**31**:729-731.
6. Violari A, Cotton MF, Gibb DM, Babiker AG, Steyn J, Madhi SA, *et al*. Early antiretroviral therapy and mortality among HIV-infected infants. *N Engl J Med* 2008,**359**:2233-2244.
7. Brady MT, Oleske JM, Williams PL, Elgie C, Mofenson LM, Dankner WM, *et al*. Declines in mortality rates and changes in causes of death in HIV-1-infected children during the HAART era. *J Acquir Immune Defic Syndr* 2010,**53**:86-94.
8. IATT. All In to End Adolescent AIDS. <http://allintoendadolescentaids.org> 2015.
9. Koech E, Teasdale CA, Wang C, Fayorsey R, Alwar T, Mukui IN, *et al*. Characteristics and outcomes of HIV-infected youth and young adolescents enrolled in HIV care in Kenya. *AIDS* 2014,**28**:2729-2738.
10. Porth ea. Disparities and trends in AIDS mortality among adolescents living with HIV in low- and middle-income countries. . *20th International AIDS Conference, Melbourne, July 2014*. 2014:abstract MOAC0101.
11. Bibace R, Walsh ME. Development of children's concepts of illness. *Pediatrics* 1980,**66**:912-917.
12. Wiener L, Mellins CA, Marhefka S, Battles HB. Disclosure of an HIV diagnosis to children: history, current research, and future directions. *J Dev Behav Pediatr* 2007,**28**:155-166.
13. DeMatteo D, Wells LM, Salter Goldie R, King SM. The 'family' context of HIV: a need for comprehensive health and social policies. *AIDS Care* 2002,**14**:261-278.
14. Klitzman R, Marhefka S, Mellins C, Wiener L. Ethical issues concerning disclosures of HIV diagnoses to perinatally infected children and adolescents. *J Clin Ethics* 2008,**19**:31-42.
15. Vaz LM, Maman S, Eng E, Barbarin OA, Tshikandu T, Behets F. Patterns of Disclosure of HIV Status to Infected Children in a Sub-Saharan African Setting. *J Dev Behav Pediatr* 2011.
16. Menon A, Glazebrook C, Campain N, Ngoma M. Mental health and disclosure of HIV status in Zambian adolescents with HIV infection: implications for peer-support programs. *J Acquir Immune Defic Syndr* 2007,**46**:349-354.
17. Biadgilign S, Deribew A, Amberbir A, Escudero HR, Deribe K. Factors Associated with HIV/AIDS Diagnostic Disclosure to HIV-infected Children Receiving HAART: A Multi-Center Study in Addis Ababa, Ethiopia. *PLoS ONE* 2011,**6**:e17572.
18. Wariua G, Farquhar C, Melvin A, John-Stewart G. Prevalence and Correlates of Pediatric HIV Disclosure in a Kenyan Clinic. In: *International Aids Society Conference*. Mexico; 2008.

19. Moodley K, Myer L, Michaels D, Cotton M. Paediatric HIV disclosure in South Africa -- caregivers' perspectives on discussing HIV with infected children. *S Afr Med J* 2006,**96**:201-204.
20. Bikaako-Kajura W, Luyirika E, Purcell DW, Downing J, Kaharuza F, Mermin J, *et al.* Disclosure of HIV status and adherence to daily drug regimens among HIV-infected children in Uganda. *AIDS Behav* 2006,**10**:S85-93.
21. Kallem S, Renner L, Ghebremichael M, Paintsil E. Prevalence and Pattern of Disclosure of HIV Status in HIV-Infected Children in Ghana. *AIDS Behav* 2010.
22. Vreeman RC, Nyandiko WM, Ayaya SO, Walumbe EG, Marrero DG, Inui TS. The perceived impact of disclosure of pediatric HIV status on pediatric antiretroviral therapy adherence, child well-being, and social relationships in a resource-limited setting. *AIDS Patient Care STDS* 2010,**24**:639-649.
23. Funck-Brentano I, Costagliola D, Seibel N, Straub E, Tardieu M, Blanche S. Patterns of disclosure and perceptions of the human immunodeficiency virus in infected elementary school-age children. *Arch Pediatr Adolesc Med* 1997,**151**:978-985.
24. Grubman S, Gross E, Lerner-Weiss N, Hernandez M, McSherry GD, Hoyt LG, *et al.* Older children and adolescents living with perinatally acquired human immunodeficiency virus infection. *Pediatrics* 1995,**95**:657-663.
25. Instone SL. Perceptions of children with HIV infection when not told for so long: implications for diagnosis disclosure. *J Pediatr Health Care* 2000,**14**:235-243.
26. Lester P, Chesney M, Cooke M, Weiss R, Whalley P, Perez B, *et al.* When the time comes to talk about HIV: factors associated with diagnostic disclosure and emotional distress in HIV-infected children. *J Acquir Immune Defic Syndr* 2002,**31**:309-317.
27. Thorne C, Newell ML, Peckham CS. Disclosure of diagnosis and planning for the future in HIV-affected families in Europe. *Child Care Health Dev* 2000,**26**:29-40.
28. Wiener LS, Battles HB, Heilman N, Sigelman CK, Pizzo PA. Factors associated with disclosure of diagnosis to children with HIV/AIDS. *Pediatr AIDS HIV Infect* 1996,**7**:310-324.
29. Mialky E, Vagnoni J, Rutstein R. School-age children with perinatally acquired HIV infection: medical and psychosocial issues in a Philadelphia cohort. *AIDS Patient Care STDS* 2001,**15**:575-579.
30. Cohen J, Reddington C, Jacobs D, Meade R, Picard D, Singleton K, *et al.* School-related issues among HIV-infected children. *Pediatrics* 1997,**100**:E8.
31. Wiener LS, Battles HB. Untangling the web: a close look at diagnosis disclosure among HIV-infected adolescents. *J Adolesc Health* 2006,**38**:307-309.
32. Brown BJ, Oladokun RE, Osinusi K, Ochigbo S, Adewole IF, Kanki P. Disclosure of HIV status to infected children in a Nigerian HIV Care Programme. *AIDS Care* 2011:1-6.
33. Vaz L, Corneli A, Dulyx J, Rennie S, Omba S, Kitetele F, *et al.* The process of HIV status disclosure to HIV-positive youth in Kinshasa, Democratic Republic of the Congo. *AIDS Care* 2008,**20**:842-852.
34. Mellins CA, Brackis-Cott E, Dolezal C, Richards A, Nicholas SW, Abrams EJ. Patterns of HIV Status Disclosure to Perinatally HIV-Infected Children and Subsequent Mental Health Outcomes. *Clin Child Psychol Psychiatry* 2002,**7**:101-114.
35. Slavin LA, O'Malley JE, Koocher GP, Foster DJ. Communication of the cancer diagnosis to pediatric patients: impact on long-term adjustment. *Am J Psychiatry* 1982,**139**:179-183.
36. Blasini I, Chantry C, Cruz C, Ortiz L, Salabarría I, Scalley N, *et al.* Disclosure model for pediatric patients living with HIV in Puerto Rico: design, implementation, and evaluation. *J Dev Behav Pediatr* 2004,**25**:181-189.

37. Gerson AC, Joyner M, Fosarelli P, Butz A, Wissow L, Lee S, *et al.* Disclosure of HIV diagnosis to children: When, where, why, and how. *Journal of Pediatric Health Care* 2001,**15**:161.
38. Cohen FL. Research on families and pediatric human immunodeficiency virus disease: a review and needed directions. *J Dev Behav Pediatr* 1994,**15**:S34-42.
39. Lee CL, Johann-Liang R. Disclosure of the diagnosis of HIV/AIDS to children born of HIV-infected mothers. *AIDS Patient Care STDS* 1999,**13**:41-45.
40. Kouyoumdjian FG, Meyers T, Mtshizana S. Barriers to disclosure to children with HIV. *J Trop Pediatr* 2005,**51**:285-287.
41. Ostrom RA, Serovich JM, Lim JY, Mason TL. The role of stigma in reasons for HIV disclosure and non-disclosure to children. *AIDS Care* 2006,**18**:60-65.
42. Corneli A, Vaz L, Dulyx J, Omba S, Rennie S, Behets F. The role of disclosure in relation to assent to participate in HIV-related research among HIV-infected youth: a formative study. *J Int AIDS Soc* 2009,**12**:17.
43. Hammami N, Nostlinger C, Hoeree T, Lefevre P, Jonckheer T, Kolsteren P. Integrating adherence to highly active antiretroviral therapy into children's daily lives: a qualitative study. *Pediatrics* 2004,**114**:e591-597.
44. Xu T, Wu Z, Rou K, Duan S, Wang H. Quality of life of children living in HIV/AIDS-affected families in rural areas in Yunnan, China. *AIDS Care* 2010,**22**:390-396.
45. Santamaria EK, Dolezal C, Marhefka SL, Hoffman S, Ahmed Y, Elkington K, *et al.* Psychosocial Implications of HIV Serostatus Disclosure to Youth with Perinatally Acquired HIV. *AIDS Patient Care STDS* 2011,**25**:257-264.
46. Vreeman RC, Gramelspacher AM, Gisore PO, Scanlon ML, Nyandiko WM. Disclosure of HIV status to children in resource-limited settings: a systematic review. *J Int AIDS Soc* 2013,**16**:18466.
47. Ngugi ENB, Katana A, Nganga L, Waruru A, Gichangi A, Mukui I, Inwani I. HIV disclosure and clinical outcomes among HIV-infected adolescents enrolled in HIV care in Kenya 2004-2011: results from a national retrospective cohort study. *7th IAS Conference on HIV Pathogenesis and Treatment, Melbourne, AU* 2014:Abstract 200748201; TUPE200748432.
48. Krauss B, Letteney S, De Baets A, Murugi J, Okero FA. Guideline on HIV disclosure counselling for children up to 12 years of age. In. Geneva Switzerland: World Health Organization; 2011.
49. National Aids and STI Control Program; Ministry of Public Health and Sanitation K. Guidelines for Antiretroviral Therapy in Kenya: 4th Edition 2011. In. 4th Edition ed. Nairobi, Kenya: NASCOP; 2011.
50. National Aids and STI Control Program; Ministry of Public Health and Sanitation K. National Guidelines for HIV Testing and Counseling in Kenya. In. Nairobi, Kenya: NASCOP; 2008.
51. Brandt L, Beima-Sofie K, Hamunime N, Shepard M, Ferris L, Ingo P, *et al.* Growing-up just like everyone else: key components of a successful pediatric HIV disclosure intervention in Namibia. *AIDS* 2015,**29 Suppl 1**:S81-89.
52. AAP A, ACP. Clinical Report: Supporting the Health Care Transition from Adolescence to Adulthood in the Medical Home. *Pediatrics* 2011,**128**:182-200.
53. Zhang LF, Ho JS, Kennedy SE. A systematic review of the psychometric properties of transition readiness assessment tools in adolescents with chronic disease. *BMC Pediatr* 2014,**14**:4.
54. CIPHER. CIPHER Adolescent Transition Report. <http://www.iasociety.org/What-we-do/Paediatrics-CIPHER/2nd-Adolescent-Transition-Workshop> 2015.

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
	Post-Trial ATTACH Staff Interview Guide
Post-trial surveys	Adolescent Survey
	HCW Survey
COVID-19 Adapted Forms	CQI Phone Delivery Script
	Transition Readiness Assessment Delivery Script
	Transition Intervention Delivery Script

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 (10-24 years old)
Disclosure readiness surveys	Caregiver consent for disclosure readiness survey
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

Recruitment Scripts:

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*
Disclosure readiness	Caregiver recruitment script
Post-trial surveys	Adolescent recruitment script*
	HCW recruitment script*

*Same as aim 2 document

ATTACH STUDY ANALYSIS PLAN (Finalized 2.13.2020)

SUMMARY

Study Purpose: To determine whether an adolescent transition package (with transition and disclosure tools) improves **mean transition readiness** among HIV positive adolescents in care in Kenya.

Study Design: Cluster randomized trial

Study Population and Sites:

Population:

- HIV-positive adolescents and youth between the ages of 10 and 24

Sites:

- 20 HIV clinics in Nairobi, Nakuru, Homabay and Kajiado, Kenya

Study Duration: Estimated 18 months total (enrollment and 1-year follow-up)

Randomization: 10 clinics randomized to intervention sites and 10 to control.

Intervention:

Adolescent Transition Package (ATP): The ATP will consist of a validated disclosure booklet and disclosure tracking tool, and a HCW administered transition booklet and transition tracking logs, implemented in intervention sites. HCW in intervention sites will be trained on implementation of the ATP with continued support for the clinic in the first 3 months of the intervention. In control sites, parallel data collection for primary outcomes will be conducted.

Primary endpoints: Transition readiness

Secondary endpoints: Overall clinic retention and overall viral suppression

Exploratory outcome: % with full disclosure, Time to full disclosure, Post transition retention

DATA ANALYSIS

Primary outcome: transition readiness among HIV positive adolescents age 15-24

- a. Transition readiness score overall (all domains)
- b. Treatment literacy readiness score
- c. Self-management readiness score
- d. Communication readiness score
- e. Support readiness score

Analysis

Primary analysis ITT: Mixed effects linear regression to compare transition readiness scores (overall and by domain) over time in control and intervention sites with adjustment for multiple testing (Benjamin-Hochberg method).

Time points: Enrollment, month 6, month 12

Sample size and power table

Assumptions: 80% power, alpha 0.05, ICC 0.2, average cluster size of 50

Mean difference	SD	Number of Clusters per Arm
0.5	1	4
0.5	2	15
1.0	2	4
1.0	3	9
1.5	3	4
1.5	4	7
2.0	5	6
2.0	6	9

Secondary outcomes

- a. Overall retention in 10-24 year olds: defined as proportion of 10-24 year olds completing visits within 6 months of last visit
- b. Overall viral suppression: defined as proportion of 10-24 year olds with viral load of less than 1000 copies per ml after at least 6 months of ART

Analysis

Overall retention/suppression: Generalized estimating equations (GEE) to compare retention and viral suppression in intervention and control sites

Time-points: Baseline, month 6, month 12

Minimum detectable differences in proportions with outcomes

Assumption: 80% power, alpha 0.05, ICC 0.2, 10 clusters per arm, average cluster size of 50

Proportion with outcome in arm 1	Proportion with outcome in arm 2
0.2	0.31
0.3	0.44
0.4	0.56

0.5	0.69
0.6	0.81
0.7	0.93

Exploratory analyses

1. Post-transition retention defined as completing and adult clinic visit day after transfer to adult services and at least 1 other visit within 6 months of the adult visit (total of 2 visits):
Analysis: GEE to compare post-transition retention in intervention and control sites
2. Principal components analysis to identify the most representative components of data in the 4 domains of the readiness assessment checklist (HIV treatment literacy (Q 1-5), self-management (Q6, 7, 9-14, communication Q16-19, support 20-22) and then factor analysis to determine the most important components.
3. Proportion of children with full disclosure and time to full disclosure. Children who do not know their HIV status from HCW assessment. Child will be asked why they are taking medicine; if they report they have HIV they have reached full disclosure. If they mention any other illness or other responses they will not have reached full disclosure.
End point: Child says they have HIV in response to the question “why are you taking your medicine”
Analysis: Descriptive %, time to full disclosure

Appendix 1: Schedule for data collection

	Tools	Mo 0	Mo 3	Mo 6	Mo 9	Mo 12
Primary outcome						
Transition readiness	Transition readiness assessment	X		X		X
Secondary outcome						
% with full disclosure	Disclosure checklist	X	X	X	X	X
Time to full disclosure	Disclosure checklist	X	X	X	X	X
Age at full disclosure	Disclosure checklist	X	X	X	X	X
Post transition retention*	Transition log	X	X	X	X	X
Overall retention	EMR	X		X		X
Overall viral suppression	EMR	X		X		X

*only in adolescent models of care