# Simulated Patient Encounters to Promote Early Detection and Engagement in Care for Adolescents (SPEED)

Grant Number: R01HD08507-01

Principal Investigator: Pamela Kohler, PhD, MPH, RN

Version Number: 7.0

May 11, 2020

## LIST OF ABBREVIATIONS

| | |
|---|---|
| APS | Adolescent package of services |
| ART | Antiretroviral therapy |
| CAB | Community advisory board |
| CCC | Comprehensive care clinic |
| CATCH | Counseling and testing for children at home |
| CEA | Cost-effectiveness analysis |
| CQI | Continuous quality improvement |
| DALY | Disability-adjusted life year |
| DASH | Developing adolescent strategies for HIV testing |
| FGD | Focus group discussion |
| FP | Family planning |
| GBV | Gender-based violence |
| HCW | Health care worker |
| HIV | Human Immunodeficiency Virus |
| IDI | In-depth interview |
| KNH | Kenyatta National Hospital |
| NASCOP | National AIDS and STI Control Programme |
| PMTCT | Prevention of mother-to-child transmission |
| PUSH | Pediatric urgent start of HAART |
| STI | Sexually transmitted infection |
| VCT | Voluntary counseling and testing |
| WHO | World Health Organization |
| SP | Standardized Patient Actor |
| YFS | Youth-friendly services |

## PROTOCOL SUMMARY

**Title:** Simulated Patient Encounters to Promote Early Detection and Engagement in Care for Adolescents (SPEED)

**Objective:** This study aims to develop and evaluate a clinical training intervention utilizing standardized patient actors to improve communication and interpersonal skills of health care workers in working with adolescents, resulting in increased engagement in HIV care.

**Aims:**

Aim 1: To develop case scripts specific to adolescent HIV care for use in SP encounters

Aim 2: To assess the impact of SP encounters on the likelihood of adolescent patients retained in care, and adherent to ART at public HIV treatment facilities in Kenya

Aim 3: To estimate the cost-effectiveness of SP training per adolescent retained in care

**Methods**

Aim 1: Pilot testing and standardization of SP training tools and scoring with 10 health care workers (HCW) in HIV care

Aim 2: Stepped-wedge randomized controlled trial

Aim 3: Cost-effectiveness and cost-utility analysis

**Population:**

Health care workers: Currently employed in HIV care services

Adolescents: HIV-infected boys and girls ages 10-24 years

**Number of Sites:** 24 sites in Nairobi, Kiambu, Homa Bay, and Kisumu Counties in Kenya

**Study Duration:** 4 years

**Outcomes**

Aim 1: Final scripts/ tools and scoring rubric for use in SP encounters

Aim 2: Trial

- Primary Outcome: Retention in HIV care
  - Return for 1st follow-up visit among newly enrolled clients OR follow-up visit after 're-engagement visit' (after LTFU for >3 months)
  - Return for ANY follow-up visit within 3 months among currently enrolled HV-positive adolescent patients
- Secondary Outcomes:
  - Satisfaction (adolescents and HCWs)
  - HCW competency in adolescent friendly counseling

- Medication adherence
- Viral suppression
- Assessment, referral, and linkage to affiliated services
- AIDS defining illness
- Outpatient visits and hospitalizations
- Mortality

Aim 3: Cost Effectiveness and Cost Utility analyses

- Cost per additional HIV-infected adolescent retained in care
- Cost per additional life year saved and disability-adjusted life (DALY) averted

## KEY ROLES AND CONTACT INFORMATION

**Principal Investigator**
Pamela Kohler PhD, MPH, RN
Assistant Professor, Global Health, Psychosocial & Community Health
University of Washington
325 9th Avenue, Box 359932
Seattle WA 98104 USA
Tel: 206.616.7962 / Fax: 206.221.4945
Email: pkohler2@uw.edu

**Site Director**
Dalton Wamalwa MBChB, MMed, MPH
Senior Lecturer, Paediatrics & Child Health
University of Nairobi / Kenyatta National Hospital
Email: dalton@africaonline.co.ke

**Co-Investigators**
Grace John-Stewart, PhD, MPH, MD
Professor, Medicine, Epidemiology, Pediatrics, Global Health
University of Washington
gjohn@uw.edu

Barbra Richardson, PhD, MS
Research Professor, Global Health, Biostatistics
University of Washington
barbrar@uw.edu

Joseph Babigumira, PhD, MS, MBChB
Assistant Professor, Global Health, Pharmacy
University of Washington
babijo@uw.edu

Brandon Guthrie, PhD, MPH
Assistant Professor, Global Health, Epidemiology
University of Washington
brguth@uw.edu

Irene Inwani, MBChB, MMed
Consultant Pediatrician
Kenyatta National Hospital
iinwani@yahoo.com

David E. Bukusi, MBChB, MMed
Head, KNH VCT and HIV Prevention Unit/Youth Centre
Kenyatta National Hospital
davidbukusi@gmail.com

Jennifer Slyker, PhD, MSc
Assistant Professor, Global Health
University of Washington
jslyker@uw.edu

Kate Wilson, PhD, MPH
Postdoctoral Research Fellow, Global Health
University of Washington
ksw@uw.edu

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

Anjuli Wagner, PhD, MPH
Postdoctoral Research Fellow, Global Health
University of Washington
anjuliw@uw.edu

**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
Nairobi, Kenya 00202

**Funding**

National Institutes of Health (NIH)
Grant: 1R01HD085807-01 (Kohler, PI) – "Simulated Patient Encounters to Promote Early Detection and Engagement in HIV Care for Adolescents"

# 1. BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

## 1a. Background Information

Sub-Saharan Africa has disproportionately high burden of adolescent HIV infection

Despite enormous expansion of HIV testing and treatment services in resource-limited settings, adolescents (ages 10-19) and youth (ages 20-24) continue to be substantially and disproportionately affected by HIV [1]. In 2012, an estimated 2.1 million adolescents were living with HIV , and 300,000 adolescents were newly infected [2]. And while mortality has decreased in adult and pediatric populations, there has been a 50% *increase* in adolescent HIV-related deaths over the last 7 years. Sub-Saharan Africa is home to 80% of adolescents and youth living with HIV globally [3]. Kenya alone accounts for 7% of all new adolescent HIV infections [2].

Substantial barriers for adolescent linkage to and retention in the HIV care cascade

Although HIV services have expanded throughout Africa, there has been less programmatic focus on adolescent HIV care than on adult care [1, 4, 5]. Inadequate provision of accessible and acceptable HIV testing, counseling, and treatment services is cited as a barrier to uptake of and retention in HIV care among adolescents [6]. For example, a recent Kenyan HIV treatment cohort study reported that 25% of youth and adolescents did not return after their first visit, 41% were lost in the first 12-months of the pre-ART period, and 21% of those initiating ART were lost within one year; rates higher than reported in adult programs [7]. Optimizing impact of HIV treatment programs requires early identification of HIV status, prompt linkage to care, and sustained adherence to antiretroviral therapy (ART). Loss throughout the care cascade translates to poor health outcomes and increased mortality, and subsequent HIV transmission due to uncontrolled viral load in all age groups. There is an urgent need for evidence-based interventions that promote adolescent uptake of and retention in HIV care [5].

HCWs lack confidence in their ability to provide HIV care for adolescents

A study of reproductive health HCWs in Kenya documented a disconnect between advertised “youth friendly services” and HCWs’ lack of competency and training to carry out adolescent friendly care [8]. For example, while guidelines call for “adolescent friendly HIV testing”, few details are provided to define what an “adolescent friendly” approach actually entails. Health HCWs expressed feeling a lack of competency in providing services to young people, especially related to counselling and interpersonal communication [8]. HCWs reported feeling conflicted between their own personal feelings, cultural and religious values and beliefs, and their wish to support young people's rights to accessing services.

In our preliminary studies, health care workers tasked with providing adolescent HIV testing services also reported feeling inadequately prepared to cope with the needs of this age group Themes included concern over adolescent depression and mental health, provider lack of confidence in counseling skills or fear of doing the wrong thing, concern over how to handle/advise adolescent disclosure and parental issues, and questions of adolescent autonomy and consent.

Adolescents have unique needs in HIV care and treatment

Few studies describe experiences of adolescents in accessing and engaging in HIV services. Adolescents experience unique physiological, developmental, and psychosocial changes that could potentially aggravate preexisting stressors associated with HIV infection [9-11]. Young people with HIV are particularly vulnerable to issues of mental health and depression, which can exacerbate poor adherence and retention in care [12]. Reported programmatic barriers include fear of harsh treatment by health care providers and lack of confidentiality or privacy in the health clinic [8].

Although adolescent-friendly policies exist, evidence-based interventions to improve health care workers competencies to provide high quality adolescent care are lacking

Globally, initiatives are underway to promote "adolescent friendly" health services. The WHO recommendations for adolescent friendly services include development of adolescent-specific skills and behaviors of health providers, assuring health facilities are appropriately equipped and appealing for adolescents, adolescents are aware of where they can obtain health services, and communities are aware and supportive of the health-services needs of adolescents. Adolescent friendly care aims to ensure that health providers are "*non-judgmental* and *considerate* in their dealings with adolescents" and that they have the "*competencies to deliver the right health services* in the right way" [13].

Patient-centered care is the missing link in the implementation 'know-do' gap to enhance adolescent HIV care

The impact and effectiveness of antiretroviral treatment (ART) is diminished by failure to adequately cover the adolescent population and to deliver services in an approachable and accessible manner. This type of "know-do" gap has been suggested to be rooted in lack of attention to ***quality*** in implementation of proven interventions like ART [14]. Quality of care is defined by the Institute of Medicine as safe, effective, **patient-centered**, efficient, timely and equitable [15]. Patient-centered communication, as defined by the Kalamazoo Consensus, includes building a relationship, opening discussion, gathering information, understanding the patient perspective, sharing information, reaching an agreement and providing closure [16]. These key components of care are often under-trained and under-implemented in resource-limited settings. A recent health facility assessment of HIV linkage and retention in care in Kenya noted that reported barriers (stigma associated with health facilities, poor provider-patient interactions) reflected a need for a new **patient-centered approach to HIV care** [17].

There is evidence that standardized patient actors improve quality of clinical care

Standardized patients (SPs) are trained actors that work with health care providers in mock clinical encounters for the purposes of training and evaluation [18]. Used since the 1960s in clinical and medical education and for licensing exams,[19] SPs are increasingly used as a mechanism to develop and improve skills related to patient-centered communication: empathy, communication skills, and counseling. As an evaluation tool, SPs are considered the gold-standard in measuring quality of care [19] and have been shown to accurately assess provider

performance in a variety of settings.[20-23] Not only are SPs an accurate measurement of care, reliably predicting provider behavior and clinical performance, but they can be used as a teaching mechanism. For example, in Mexico, training of delivery-room staff with low-tech simulations of obstetric emergencies resulted in improved process outcomes of health care provider knowledge and self-efficacy, but also significantly improved client health outcomes including perinatal mortality, eclampsia, and cesarean deliveries [24-26]. Other uses of actors include breaking bad news for oncology fellows [27], motivational interviewing training for community substance abuse providers [28], and end of life difficult conversations for surgical intensive care unit personnel.[29]

Improving clinical care and adolescent-friendly services may result in increased engagement in care

Despite clear guidelines for the type of behaviors and messaging to be practiced by health care providers, we are unaware of any scalable, evidence-based interventions that build adolescent friendly capacities in health care providers and that have been linked to improved adolescent care outcomes. A systematic review of adolescent friendly interventions found few rigorous studies of adolescent provider training programs [30]. Given the success of standardized patient and simulation programs in other settings, it is plausible that high-quality, patient-centered approaches could increase linkage to care, retention, and ART adherence among HIV-infected adolescents in sub-Saharan Africa.

## 1b. Rationale

An SP intervention for health providers has the potential to promote high-quality patient centered HIV services for adolescents by providing health workers with technical skills and pragmatic experiences. This improvement in delivery of care can, in turn, address barriers cited by adolescents and improve linkage to, and retention in, vital HIV services. By increasing engagement in care, the program can ultimately improve survival and decrease subsequent HIV transmission among adolescents in Kenya.

# 2. OBJECTIVES

## 2a. Study Objective

This study aims to develop and evaluate a clinical training intervention utilizing standardized patient actors to improve communication and interpersonal skills of health care workers in caring for HIV infected adolescents (ages 10-24 years), resulting in increased engagement in HIV care.

## 2b. Specific Aims

**Aim 1: To develop patient case scripts specific to adolescent HIV-related care and counseling needs in Kenya, and to establish the number of training interactions necessary to reach competency**

Hypothesis: Utilization of real-world adolescent experiences in a simulated patient actor training

program will improve health care provider communication and counseling skills with adolescents in Kenyan HIV care programs

*Approach: Case scripts will be developed for male and female SP actors, derived from in-depth interviews with HIV-infected adolescents. We will establish competency scores and pass/fail cut-offs with a pilot sample of 10 health care workers (HCWs).*

**Aim 2: To assess the impact of SP encounters on the likelihood of adolescent patients retained in HIV care, and adherent to ART at public HIV treatment facilities in Kenya**

Hypothesis: SP encounters will increase provider confidence and capacity to facilitate HIV status disclosure and provide supportive interactions with HIV-infected youth, which will significantly increase retention in HIV care and improve ART adherence among adolescents.

*Approach: We will utilize a stepped wedge study design to assess retention in HIV services among HIV-infected adolescents. We will compare periods when clinics have received the SP training ('exposed periods') to 'control periods' prior to this training, when clinics are providing standard care. Data will be extracted via electronic medical records.*

**Aim 3: To estimate the cost-effectiveness of SP training per additional adolescent retained in care and cost-utility per life-year saved and per disability-adjusted life-year (DALY) averted for each adolescent**

Hypothesis: An interactive SP training program will be cost-effective

*Approach: We will measure detailed healthcare and program costs. We will use these costs to (1) estimate the short-term cost-effectiveness (measured as cost per additional adolescent retained in care) and (2), use modeling methods to estimate the long-term cost utility (measured as cost per disability-adjusted life-year averted).*

## 3. STUDY OUTCOMES

### 3a. Primary outcomes

Aim 2: Stepped-wedge randomized controlled trial (RCT)

The primary outcome for this study is **adolescent retention in HIV care**, defined as:

- Return for 1st follow-up visit after first enrollment visit OR return for follow-up visit after a 're-engagement visit' among adolescents who had previously been lost to follow-up (LTFU)

- Retention in care for ANY follow-up visit within 3 months among adolescents currently enrolled in HIV care (which can be referred to as “actively enrolled”)

*Description:*

*First follow-up visit after enrollment visit*: The number and proportion of adolescents who return to clinic within 3 months of an enrollment visit

*Follow-up visit after re-engagement in care among LTFU adolescents*: Lost to follow-up is defined as no clinic record for at least 3 months, and no record of death or transfer to another facility. Among adolescents who return to clinic after LTFU, we will collect the number and proportion of adolescents who return for a subsequent visit within 3 months.

*Return for follow-up among those currently enrolled in care:* To evaluate whether the SPEED intervention may result in better adherence to visit schedule among adolescents currently enrolled in HIV care (i.e. not newly enrolled or previously LTFU), we will also measure return for any follow-up visit within 3 and 6 months.

## 3b. Secondary outcomes:

Aim 1: Pilot testing of case scripts and establishment of competency

- Final case scripts
- Numeric scores on HCW checklist
- Proportion of HCWs with pass/fail scores
- Numeric scores on actor feedback checklists
- Numeric scores on HCW satisfaction survey
- Numeric scores on HCW self-rated competency survey

Aim 2: Stepped-wedge randomized controlled trial

In addition to the primary outcomes, the RCT will have several secondary outcomes, summarized in in Table 1:

Analyses of *process outcomes* to understand intervention mechanism will include:

- Pre/post-measures of HCW and patient satisfaction
- Pre/post-measures of HCW competency scores
- Associations between HCW competency scores and care outcomes
- Associations between HCW competency scores and adolescent satisfaction outcomes

- Exit interviews in a purposeful sample of HCW participants at the end of the trial

**Table 1. Summary of process outcomes, exploratory outcomes, and indicators in Aim 2 RCT**

| Process Outcomes | Indicator | Source |
|---|---|---|
| HCW competency | Mean HCW scores per clinic | Faculty graded scores<br>Exit interviews |
| HCW satisfaction | Mean HCW score per clinic | HCW survey |
| Adolescent patient satisfaction | Mean adolescent score per clinic | Tablet-based questionnaire |
| **Clinical/Exploratory Outcomes** | | |
| Adherence | Refills within 1 week of scheduled return visit | Clinic/pharmacy records |
| Viral suppression | Viral load (VL) <1000 copies per ml and a second analysis using VL <400 copies/ml | Clinic records |
| Linkage to APS services | STI/TB screening, Contraception uptake, mental health referral | Clinic records |
| AIDS defining illness | Diagnosis of at least one AIDS defining illness per national guidelines | Clinic record |
| Mortality | Death during follow up | Clinic records |

Aim 3: Cost Effectiveness Analysis (CEA) and Cost Utility Analysis (CUA)

This aim will assess the following measures:

- SPEED intervention costs
- Cost per additional HIV-infected adolescent retained in care
- Cost per additional life year saved and disability-adjusted life year (DALY) averted. This estimate is the gold standard in health economics. This analysis will be performed once an adequate mathematical model of adolescent DALYs is developed.

*Additional exploratory outcomes*

- Cost per additional HIV-infected adolescent with ≥80% adherence
- Cost per additional HIV-infected adolescent virally suppressed
- Cost per additional HIV-infected adolescent linked to APS services

## 4. STUDY DESIGN

This study uses a stepped wedge approach to evaluate a **clinical training intervention** which utilizes standardized patient actors to improve communication and interpersonal skills of health care workers in working with adolescents, resulting in increased engagement in HIV care.

The pilot phase will inform the creation of case scripts and test them in a sample of health care workers. The trial phase will evaluate effectiveness of the SP training intervention through a stepped-wedge trial design. This study design is well-suited to interventions that occur at the clinic, rather than individual, level and to interventions that are not feasible to implement simultaneously at a large number of clinics. The randomization at a clinic level to *when the intervention is introduced* allows for the traditional benefits of randomization. Additional analyses will measure the cost-effectiveness and cost-utility of the intervention.

# 5. STUDY ENROLLMENT AND WITHDRAWAL

## 5a. Study sites

The pilot phase will recruit health workers from Kenyatta National Hospital (KNH) in Nairobi, Kenya. The randomized controlled trial (RCT) will enroll health workers from up to 24 clinics that provide adolescent HIV care services in Nairobi and Western Kenya.

## 5b. Study population

The SP intervention involves a training program for HCWs who provide clinical services to adolescents living with HIV. Enrolled HCWs include clinical officers, psychologists (where available), doctors, and nurses. Additional cadres may be included, depending on their roles at the site, if they provide direct clinical services to adolescents. The study will enroll adolescent clients at each study site to assess outcomes of patient satisfaction, however adolescent retention and clinical outcomes will be assed via a de-identified audit of clinic electronic medical records (EMR).

**Justification for involvement of adolescents:** In sub-Saharan Africa, adolescents are at high risk for acquiring HIV, have poor HIV testing coverage, and are at high risk for poor treatment adherence. The purpose of this research is to improve adolescent HIV care. Collection of data about adolescents is necessary to determine the effectiveness and cost-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 2 below. Eligible clinics must have at least 40 adolescents enrolled in care, a current EMR system, and no other special adolescent interventions. The eligibility criteria for the pilot phase is the same as for HCWs in the RCT. Health care worker participants must be 18 years of age or older, employed at trial sites and provide clinical services to adolescents. Adolescent records will be abstracted among 10-24 year olds enrolled in HIV care. Adolescent clients between the ages of 10-24 presenting for HIV care at enrolled sites will be eligible to complete patient satisfaction surveys.

## 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 training intervention at that site and/or the collection of outcome measures.

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. This applies both to the pilot phase and the RCT.

**Table 2. Inclusion Criteria for all Participants**

| Population | Sampling | N | Inclusion Criteria |
|---|---|---|---|
| Clinic clusters | Selected from clinics with ≥40 adolescent clients | 24 | ≥40 adolescents currently in HIV care<br><br>EMR data system<br><br>No concurrent adolescent interventions |
| Health Care Workers (e.g. doctors, nurses, clinical officers, nurse counselors) | Up to 10 per clinic | 240 | >18 years of age<br><br>Employed at trial site in clinical care for at least three months and/or have a 1 year contract (i.e. not temporary staff)<br><br>Provides clinical services to adolescents |
| Adolescent client records | Complete record audit | Up to 50,000 | Records of clients age 10-24 in trial sites |
| Adolescent clients | Up to 20 per clinic per time point | Up to 2,400 | Ages 10-24<br><br>Seeking counseling or treatment services at trial site<br><br>HIV-infected |

## 5e. Strategies for recruitment and retention

Pilot phase

Up to 10 HCWs who are >18 years of age, and employed in HIV care at Comprehensive Care Centers (CCCs) and adolescent clinics at KNH will be recruited to participate in the pilot testing of study tools and scoring rubric. We will obtain permission from the clinic directors before recruitment. We will receive a list of potential participants. A member of the study team will be stationed at the clinics and approach potential participants to learn more about the pilot testing phase of the study. In this phase, HCW participants will take part in a pilot 2-3 day training that includes a didactic component, 6-7 SP encounters, group debriefing and discussion. Participants will provide their contact information to ensure completion of the training.

Stepped-wedge randomized controlled trial

- *Clinics/individual HCW participants:* For the stepped-wedge trial, the SPEED study team will identify up to 24 clinics that meet study eligibility criteria. We will receive permission from NASCOP and local administrative teams 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 SP intervention 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 first to gain access to providers. A study staff member will then approach those providers to invite them to learn more about the study.

  Within participating clinics, all clinical providers who have contact with adolescent clients will be approached for participation. Eligible providers at that facility will give informed consent (see Section 13). Eligible providers at that facility will give informed consent. We anticipate an average of 10 HCWs per site, depending on clinic size.

- *Adolescents attending clinics:* A clinical staff member will be instructed by our Study Team to refer consecutively, all adolescents seeking HIV care on a given day, to the Study Team member. This Team member will be at each clinic to invite adolescents to complete an anonymous, tablet-based survey to assess satisfaction with their counseling or treatment encounter. We will track numbers of adolescents referred compared to total adolescent patients, and reasons for not referring to identify any differences in referrals by time of day or day of week.

  We expect to enroll at least 5 adolescents per clinic per time period and up to 20, depending on clinic volume (20 adolescents X 5 time periods X 24 clinics = up to 2,400). A Study Team member will be at each clinic for 1-3 days for recruitment.

- *Retention strategies for HCWs and adolescents:* While the intervention targets health facilities, we will track individual providers to assess retention in service provision at clinical intervention sites, using a facility survey to monitor staff turnover. In addition, provider names and phone numbers will be recorded, and we will assess the provider's continued employment at the sites, as well as any cross-over to other study sites, at each measurement time point. Adolescent surveys will be cross-sectional at each time point. Accordingly, there is no need for a retention strategy for this group.

Cost Effectiveness Analysis and Cost Utility Analysis (CUA)

No participants will be recruited specifically for this analysis. Questions on direct and indirect costs, as well as clinic and hospital visits, to the adolescents will be included in the adolescent satisfaction survey (Appendices). Other cost data will be drawn from program data, the literature, and our prior studies.

## 5f. Randomization procedures

For the stepped-wedge randomized controlled trial, the 24 clinics will be randomized to ***the time*** when they receive the SPEED intervention. In this one-way cross-over design, all 24 sites will eventually receive the intervention. Groups of 6 clinics will be randomized to receive the intervention in one of four waves. We will use stratified randomization where facilities are also allocated to waves according to region and by facility size, defined as 'high volume', more than 73 AYA enrolled and medium volume, 73 or fewer AYA enrolled, based on the median, to ensure balance of characteristics in each wave [31]. A UW Biostatistician will generate the randomization assignment for each clinic in R Statistical Software (R Core Team, Vienna, Austria).

## 5g. Masking procedures

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

## 5h. Participant Withdrawal

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

Reasons for Withdrawal

Reasons for a study clinic to withdraw may include: clinic closure or major changes in HIV testing and treatment policies, procedures, or organization structural that would prevent or substantially limit our ability to conduct this study.

Reasons for HCW participant withdrawal may include: discomfort or distress as a result of the training, lack of time to complete the follow-up surveys, or job termination or relocation.

Reasons for an adolescent participant to not complete the satisfaction survey may include, lack of time, comfort, or interest in answering the questions.

An investigator may terminate a study participant's 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 if*** a HCW participant behaves in a way that disrupts or prevents the successful conduct of the SP encounter training.

Handling of participant withdrawals

The study team will track the withdrawal of any clinic during the trial. The timing and reasons for withdrawal will be recorded, and reported to the PI. HCW participants in the clinical intervention may withdraw at any time without affecting their regular job. The study team will record the timing and reasons for withdrawal of individual HCW participants. The participant will be thanked for their time in the study and not contacted further by the study team. No replacement of study clinics or HCW participants will be conducted because of design and logistical challenges.

## 6. SPEED STUDY INTERVENTION

This study is evaluating a clinical training intervention utilizing standardized patients (SPs) that is anchored in social learning and behavioral theories [31, 32]. Standardized patients (SPs) are trained actors that work with health care providers in mock clinical training encounters, with a focus on improving communication skills and empathy. Through SP encounters, HCWs learn through cycles of concrete experiences, reflection, conceptualization, and active experimentation in a safe and controlled setting. We hypothesize that improved communication skills, competency, and empathy that HCWs will gain through this training will motivate adolescent patients to stay engaged in HIV care, including initiating and adhering to ART.

The clinical training intervention will consist of a combination of didactic sessions and SP encounters. Provider participants will receive orientation to the SP actor methodology as well as content related to communication skills and adolescent care. The intervention training schedule will be planned to minimize disruption to clinic operations.

For each wave of six clinics in the RCT, we estimate that it will take about 2 weeks (not more than 4 weeks) to train all HCWs in the Nairobi/Kiambu and Western Kenya sites. This timeframe will vary based on HCW availability and travel.

## 7. STUDY PROCEDURES

Study procedures for the SPEED study consist of a pilot phase, which aims to test training materials and establish competency scores for participating providers; and a randomized trial phase, which will implement and evaluate the SP training intervention.

Note on recruitment, hiring, and training of SP actors

We will contract with a professional Kenyan casting agency to identify and train 6-7 actors over 18 who are able to portray adolescent cases ages 14 – 19. *These actors will be part of the study staff and are not participants.*

The actors will be trained on each adolescent patient case by a behavioral expert before the pilot phase. They will also be trained in human participants protections because of their contact with study participants (HCW participants). Actors will sign confidentiality agreements to ensure that they do not discuss the SP encounters, and other identifying information, to people outside of the study.

Actors will receive annual refresher training in the case scripts. The Study Team will monitor the actors' attendance at all HCW trainings, and report any problems to the casting agency.

### 7a. Pilot Phase

Development of adolescent case scripts

We have analyzed in-depth interviews of HIV-positive adolescents enrolled in an ongoing study on HIV testing and counseling at KNH to develop the case scripts which the actors will portray. Each case describes medical and social history of the adolescent, and the primary concern at that visit which the HCW must identify. The cases were developed to reflect a range of issues that may affect adolescent patients seeking HIV care, including around disclosure, depression, fertility desire, sexual behavior and sexuality, and gender-based violence. There are male and female cases, ranging in ages between 14 and 19.

Materials piloting and competency assessment

In the pilot phase, we will determine the logistics of the training timing and schedule and establish pass/fail cut-off scores for acceptable competency. HCWs will sign standard written informed consent. The pilot phase will consist of the intervention training for 10 HCWs in HIV care at Kenyatta National Hospital. The training will take place over approximately 2-3 days and include didactic and role-playing experiences with the SPs. During the training, provider participants will rotate through up to 7 video-taped SP encounters. Each encounter will last approximately 10-15 minutes. During the encounter, the HCW will counsel the SP as if they were a real client. Encounters will be followed by facilitated group debriefing sessions. The trainer will facilitate discussion and each provider will have the opportunity to discuss their experience and receive feedback from peers and actors. Faculty experts will review and grade the videotapes via an online learning management system. A study team of faculty and experts from Kenya and the US with expertise in adolescent health will provide structured feedback on participants' technical competency according to a faculty checklist.

Training evaluation

At completion of the training session, all HCW participants will complete a training satisfaction survey and a competency survey. Due to COVID-19 pandemic starting March 2020, HCW surveys for Wave 4 will be conducted by phone instead of in-person at a healthcare facility. After the implementation period, about 5 HCWs will be invited to participate in brief exit interviews on relevance of the training to their work, and barriers and facilitators to implementing skills they learned. Exit interviews will be conducted by a study staff member in a private room and last up to 30 minutes.

## 7b. Stepped Wedge Randomized Controlled Trial (RCT)

We will conduct a stepped wedge randomized controlled trial (RCT) to test the impact of the finalized clinical training intervention on health seeking behaviors of HIV-infected adolescents.

Baseline assessment

At each of the enrolled clinics, we will conduct a baseline assessment of all clinical and satisfaction endpoints, including audits of adolescent client clinical records, and adolescent satisfaction surveys. Facility surveys will be conducted with a clinic representative to assess staffing, training experience, and current services for adolescent HIV care.

Intervention waves

Each intervention wave will train HCWs from 6 clinics. At the beginning of training, participant HCWs will fill out social demographic forms. They will then complete the training sessions, including didactic lessons, videotaped encounters, and debriefing sessions. Feedback and scoring will be provided using SP checklists for emotional responses, faculty checklist for technical skill, and group discussion for peer support. Intervention waves will be repeated until all sites have received the training (see timeline).

## 7c. Procedures for training interventionists and monitoring intervention fidelity

A consultant expert will train the SP actors on procedures for conducting the encounters and giving feedback. Intervention fidelity (fidelity of the actors to their assigned cases) will be monitored during the trial through period assessments of actor fidelity. Study team members will review a random sample of video-taped encounters in each intervention wave, and rate actor fidelity according to a standard actor fidelity checklist (see Appendices). In addition, the trainer will provide periodic refresher trainings for the actors during the trial.

## 7d. Assessment of participant compliance with study intervention

Once the training is completed, we will regularly conduct facility surveys to monitor turn-over of SPEED trained HCWs, changes in clinic policies and procedures, and other facility-level factors that could affect intervention fidelity.

## 8. STUDY SCHEDULE

In this trial, there will be 4 waves of 6 clinics per wave, and 5 measurement periods, including baseline (Table 3). Total duration of the trial is approximately 3 years. Each wave will be rolled out approximately every nine months. Data pulls will occur 15 months after the HCW training, to ensure that all clients who present within the exposure time period have a full 6 months to return for care.

**Table 3. Overview of stepped-wedge trial timing, by cluster wave**

| | **Introduction of Intervention** | | | | |
|---|---|---|---|---|---|
| **Clinic clusters** | Baseline | Month 1 | Month 10 | Month 19 | Month 28 |
| Wave 1: Sites 1-6 | 0 | X | X | X | X |
| Wave 2: Sites 7-12 | 0 | 0 | X | X | X |
| Wave 3: Sites 13-18 | 0 | 0 | 0 | X | X |
| Wave 4: Sites 19-24 | 0 | 0 | 0 | 0 | X |

An overview of the anticipated overall study schedule for one wave is shown in Table 4, following page. The study will be conducted over five years. During year one, we anticipate script development, recruiting and training SPs, developing measurement checklists, and piloting initial encounters at Kenyatta National Hospital. During year two, we will recruit and randomize study sites, and begin implementation of the intervention. The intervention will be rolled out in waves, completing measurement and intervention cycles during year 4. Year 5 will be dedicated to statistical outcome analyses, cost effectiveness analyses and modeling, and dissemination of study findings both locally and internationally.

**Table 4. Overview of SPEED Study 2015 - 2020**

| | 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 | | | | | | | | | | | | | | | | | | | | |
| Actor Training | | | | | | | | | | | | | | | | | | | | |
| Pilot phase | | | | | | | | | | | | | | | | | | | | |
| Consents & Randomization | | | | | | | | | | | | | | | | | | | | |
| Baseline OR EMR data pull | | | | | X | | | | X | | | | X | | | | X | X | | |
| Wave 1 | | | | | | | | | | | | | | | | | | | | |
| Training | | | | | | | | | | | | | | | | | | | | |
| Exposure time & data pull (X) | | | | | | | | | X | | | | | | | | | | | |
| Wave 2 | | | | | X | | | | | | | | | | | | | | | |
| Training | | | | | | | | | | | | | | | | | | | | |
| Exposure time & data pull (X) | | | | | | | | | | | | X | | | | | | | | |
| Wave 3 | | | | | X | | | | | | | | | | | | | | | |
| Training | | | | | | | | | | | | | | | | | | | | |
| Exposure time & data pull (X) | | | | | | | | | | | | | | | X | | | | | |
| Wave 4 | | | | | X | | | | | | | | | | | | | | | |
| Training | | | | | | | | | | | | | | | | | | | | |
| Exposure time & data pull (X) | | | | | | | | | | | | | | | | | | X | | |
| Post-trial data pull | | | | | | | | | | | | | | | | | | | X | |
| **Analysis** | | | | | | | | | | | | | | | | | | | | |
| Data Analysis | | | | | | | | | | | | | | | | | | | | |
| **Dissemination** | | | | | | | | | | | | | | | | | | | | |
| Reports to stakeholders | | | | | | | | | | | | | | | | | | | | |
| Manuscript development | | | | | | | | | | | | | | | | | | | | |

# 9. ASSESSMENT OF SAFETY

The SPEED study is a randomized trial of a clinical training intervention. 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 HIV counseling and treatment (client surveys and HCWs in training), breech of patient confidentiality during data extraction (adolescent clinic records), and fear of or actual loss of employment associated with disclosure of grades checklists (HCWs in training).

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

## 9a. Specification of Safety Parameters

The risks in this study fall under 'unanticipated problems,' as defined by the Office for Human Research Protections (OHRP) and the University of Washington (UW). Unanticipated problems are defined as a problem or event that meets all of the following criteria:

- Unexpected
- Related or possibly related to participation in the research
- Suggests that the research places (or could have placed) participants or others at a greater risk of harm than was previously known or recognized. This includes physical, psychological, economic or social harm

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

## 9b. 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.

## 10. STUDY OVERSIGHT

In addition to the PI's responsibility for oversight, study oversight will be under the direction of an External Advisory Panel (EAP) composed of members with expertise in stepped-wedge trial design, HIV research, and pediatric/adolescent health. The EAP will meet once yearly to assess unanticipated problems, study conduct, and progress. If major concerns arise, more frequent meetings may be held.

## 11. DATA COLLECTION

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

Data sources for HCW participants

- *Audio-visual recordings:* Video-recordings, locally recorded on a web-camera and uploaded to the SPEED learning management system (LMS), will be made of each HCW-SP interaction for training, scoring, and debriefing/feedback purposes in the pilot and in the RCT. The LMS will utilize Canvas software, a program available only to the Study Team and HCW participants. Each HCW will have a study ID number assigned to them and will log in to the LMS using a user name and private password.

- *Surveys:*
    - *Actor feedback checklist (used in training only)*: Actors will complete an actor feedback checklist and review it with each HCW during the training.

    - *Faculty checklist (used in training only)*: Faculty experts will review the videos and complete a faculty checklist with a final competency score for each HCW immediately after the training. These scores will be stored with each user record.

    - *HCW sociodemographic and satisfaction survey*: HCW participants will complete the sociodemographic and satisfaction questions at baseline and in the SPEED training.

    - *HCW self-rated competency:* HCW participants will complete the competency survey immediately after their training and at the end of each wave to assess perceived competency to care for adolescent patients. The survey will be repeated to assess changes in competency over time during the trial. The final survey will be conducted by telephone due to COVID-19.

    - *Exit interviews:* A purposeful sample of HCW participants from each wave will take part in one semi-structured exit interview each at the end of the RCT to better understand barriers and facilitators to applying the skills they learned in the SPEED intervention to their routine practice. The interview will follow a structured interview guide.

    - *Facility survey:* This survey will be administered to a health facility representative at baseline and at the end of each wave of the RCT to capture facility characteristics, including turn-over of SPEED-trained HCWs, patient volume, and any relevant changes in HIV policies and procedures.

- *Program records:*
    - *Cost data:* Direct and indirect cost data for the CEA/CUA analyses will be obtained from clinic program data (e.g. HCW salaries from employment records)

using an Excel spreadsheet. These data will be collected at baseline assessment. Cost data will be updated, as needed, at the end of the trial.

Data sources from adolescents

- *Clinic records:* De-identified adolescent clinic records from the EMR system will extracted at baseline, and at the end of each wave to assess primary and clinical outcomes, according to our data use agreement with NASCOP. Data from each pull will capture all records until the previous data pull. Examples of data will be visit dates, enrollment status (newly enrolled or existing), date of birth/age, sex, viral load and CD4 counts, pharmacy records, and referrals to family planning/TB/STI services.

- *Adolescent satisfaction, cost, and sexual behavior surveys*: Anonymous post-visit surveys will be conducted with adolescents using electronic tablets. These surveys will be conducted at baseline and at the end of each wave in all sites. Information will include basic demographics (age, schooling), type of service received/reason for visit, satisfaction with services received, perception of judgment by the health HCWs, and intent to return for services. Questions will also ask about direct and indirect costs associated with seeking care that the facility (e.g. cost of transportation, lost wages). The last section of the survey will be self-administered and ask questions about sexual behavior and sexual partners using electronic tablets. These surveys will be conducted at immediately after the satisfaction and costs surveys.

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 statistical team for reporting, data cleaning, study monitoring, and interim analyses. Study data uploaded to the secure study cloud server using Open Data Kit (ODK). Open Data Kit is a secure, web-based application designed by UW faculty 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

- *Video-recordings* will be stored on Canvas, a secured learning management system (LMS) utilized by the University of Washington. HCW participants will be able to log in to view the SP encounter videos and faculty scores. The LMS uses industry standard security will be password protected.

- *HCW surveys, adolescent surveys, and the facility survey* will be carried out by trained study staff members using ODK on tablets, 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 NASCOP. We will provide a list of variables and records for

a NASCOP-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 data base accessible only to authorized members of the study team.

- Program cost data (excluding the facility survey) will be stored in an Excel file for use in the CEA/CUA analyses. These data will not contain personal identifiers.

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 (i.e. surveys and videos) 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 participant identifiers and study ID codes will be retained for 6 years following completion of the study. Video data will be destroyed after 6 years, unless a waiver has been signed. HCW 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. No identifying data will be collected for the adolescent satisfaction surveys.

## 12. STATISTICAL CONSIDERATIONS

### 12a. Sample Size Considerations

For the Aim 2 RCT, we based our sample size and power calculations on the primary outcome of retention in care, obtained from EMR data. This outcome is binary on the individual level. We used the methods described by Hussey and Hughes [32] to determine power assuming an evaluation with 24 clusters and 5 time points (including baseline). We include 24 clinics in this study to account for the possibility that 15% drop-out without replacement. We assumed that only a small proportion of the 40 HIV-positive adolescents enrolled in HIV care per clinic may be newly enrolled or recently re-engaged in care. As such, we estimated the minimum number of records per clinic for 80% power to detect a 15% difference between control and intervention periods. We assumed a coefficient of variation ($\tau/\mu$) of 0.25 and calculated the power for a two-tailed test with α=0.05. Based on relevant published data [7], we assumed that 75% of adolescents in the control period will return to clinic after first visit. Under these assumptions, we estimate needing at least 5 adolescents per clinic. As such, the lower bound of the sample size required is estimated to be 720 clinic records (6 records/site X 24 sites X 5time points). If N=20

clinics are retained, we would need 7 adolescents per site, per time point, or a minimum of 700 records total.

In the optimal scenario with an average of 40 adolescents in care at each facility, our estimated analysis sample size would be at least 4,800 (5 time points). Under the same assumptions described above, we would have >99% power to detect a 15% difference in retention between the intervention and control periods.

We expect to have adequate power to detect an intervention effect for the analysis with a broader definition of retention in care (return for any follow-up visit within 6 months), because this is likely a more common pattern of follow-up than either return among newly enrolled or return after re-engagement in care .

## 12b. Planned interim analyses (if applicable)

Because this is a randomized trial with a stepped-wedge (staggered roll-out) design, there will be no interim analyses or stopping rules.

## 12c. Overview of analysis plan

Pilot phase

Qualitative feedback from participants, actors, and faculty experts will be used to finalize the case scripts, actor checklist, and HCW satisfaction survey.

Data from the completed faculty checklists will be used to establish competency scores. Participants, faculty experts, and actors will be asked to provide qualitative feedback on the checklist indicators. Inter-rater reliability of the faculty checklist will be determined using Cohen's kappa. We will assess correlation of checklist variables and utilize principal component analysis to reduce the number of variables, using a scree test method to plot eigenvalues. Pass/fail cut-off scores will utilize relative and absolute standard-setting processes [33]. In relative processes, initial pass/fail determinations will depend on the performance of the cohort, such that all scoring less than 1 standard deviation below the mean receives a fail. Relative standards are useful with new trainings where there is no prior performance data. Subsequently we will explore standard-setting using an iterative combination of the Angoff item-based method and the Hofstee whole-test method. The Angoff method establishes the probability of a borderline student to accomplish each item on the checklist. The sum of probabilities across items is then equal to a passing score. A team review process is convened in which reviewers discuss outlier ratings, assess performance data after pilot testing, and revision of ratings if necessary. The Hofstee whole-test method combines normative and absolute judgments, in that checklist reviewers make four determinations: the minimum and maximum acceptable passing scores, and the minimum and maximum proportions of students failing. A final cut-off determination will be made by averaging the Hofstee and Angoff scores.

Stepped-Wedge Randomized Controlled Trial

The primary analysis will be an intent-to-treat (ITT) analysis, assuming that adolescents who receive care at clinics after the SPEED training will be 'exposed' to HCWs trained in the SPEED intervention until the end of the study.

A CONSORT diagram, adapted for a stepped-wedge design [34] will be used to show the number of HCW-participants within clusters and flow of randomized stepped wedge clusters though the five time periods. We will report the number of clinics selected for inclusion, assignment to intervention or control at each time period, and the number of HCWs trained at each facility. We will report number of excluded clusters and any reasons for exclusion. No replacement will be used. Facility-specific information – adolescent patient volume, number of HCWs and presence of any adolescent-specific service (peer groups, clinics etc.) prior to the intervention – will be grouped by clinic and recorded. Baseline values of primary and process outcomes, and socio-demographic characteristics of adolescents and HCWs will be presented in a descriptive table.

We will use generalized linear mixed models (GLMM), which are more efficient than paired t-tests and linear mixed models (LMMs) in the analysis of cluster RCTs when the size of clusters is unequal [32] to compare the probability of an adolescent returning to clinic after enrollment visit OR second visit after >3 months LTFU between the intervention and control periods [35]. To estimate the effect of the intervention (*Xij*) on the individual level, we will use a GLMM model with a Poisson distribution and robust standard errors, allowing for random effects for clusters (*ui)* and fixed effects for time (*j)*. This approach models individual level outcomes, adjusts for temporal trends and accounts for correlation of outcomes within a cluster (clinic). We will estimate adjusted risk ratios (ARR), adjusted risk differences (ARDs) and 95% confidence intervals at the 5% significance level (two-sided). Adjusted risk ratios will be estimated for secondary outcomes: initiating and adherent to ART (≥80% in the dosing period by pharmacy records), 12-month retention in care; viral suppression (<100 copies/ml, <1000 copies/ml), and referred for ancillary services (family planning and TB screening). Models will be adjusted for facility type, patient volume, and exposure to prior adolescent health interventions (c).

The equation for a generic model is: $Y_{ijk} = \beta_0 + \beta j_{time} + \beta_{effect} X_{ij,} + \beta c Xij,\ ui + \varepsilon ij$

- *Analyses of process outcomes to understand intervention mechanisms will include:*
    - Mean HCW competency (passing score proportion per clinic) before and after the intervention
    - Association between mean HCW competency scores per facility and adolescent satisfaction scores
    - Associations between mean adolescent satisfaction scores and 1) retention in care (binary), 2) referral to APS services (binary), 3) ART adherence (binary or mean percent), and 4) viral suppression (binary) comparing the exposed and unexposed periods.

- *Evaluation of temporal trends:* Temporal trends that change over time (e.g. introduction of new HIV treatment guidelines, COVID-19) and potentially impact study outcomes can lead to a biased effect estimate in a stepped-wedge trial design [34]. To assess this possibility, we will repeat the primary analyses including an interaction term between a time indicator (e.g. coded as ‘pre’ versus ‘post’ policy/program change) and the variable for the main effect. A p-value for the interaction <0.1 will be evidence of interaction. We will report these results in a separate table showing any differences in intervention effect by this temporal change.

- *Lag effects of SPEED intervention:* Because the effect of the intervention may not be immediate or it may diminish over time, we will evaluate these possibilities in two ways. HCWs may take time to put skills they learned in the training into practice. In addition, trained HCWs may decrease or stop using these new skills. Intervention lag will be modeled by re-coding the first month after the intervention as a control period, as recommended by Davey *et al.* [34]. We will model the reduction of the intervention effect over time by using a fractional term for the coefficient of primary effect estimate, which will have a value of 1 (assumes 100% exposure) and get smaller at each time step (e.g. 75%, 50%, 25%).

- *Qualitative analysis of exit interviews*: Qualitative data from the HCW exit interviews will be coded in Atlas.ti. Data will be analyzed by two reviewers using thematic analysis according to the interview guide. These results will be utilized to complement results from the structured HCW satisfaction surveys.

Cost-effectiveness Analysis (CEA) and Cost Utility Analysis (CUA)

We will develop a cost-effectiveness analysis (CEA) and mathematical model to determine cost-effectiveness of the SP intervention. Costing data will be sourced from actual study costs using local rates, as well as primary data collection from adolescents supplemented by published literature to estimate direct medical costs, direct non-medical costs and indirect costs. Direct costs include laboratory tests, and personnel. Direct non-medical costs include transportation costs and field allowances. We will estimate the cost-effectiveness of the SP intervention in terms of cost per additional HIV-infected adolescent identified and retained in care.

We will also model the cost-utility of the intervention in terms of cost per life year saved and disability-adjusted life year (DALY) averted by maintaining HIV-infected adolescents in care, including subsequent decreases in HIV transmission/acquisition.

We will examine how these estimates vary through one-way and probabilistic sensitivity analyses in settings with varying adolescent HIV prevalence, health care HCW wages, population density, and linkage to care rate; identifying scenarios where the intervention is most cost-effective, allowing policymakers to determine incremental costs and net benefits of the intervention. Analyses will be performed both from the programmatic perspective of the Kenyan government and from the societal perspective. All benefits and costs will be discounted at 3% per year.

# 13. ETHICS/PROTECTION OF STUDY PARTICIPANTS

## 13a. Informed Consent Process

Clinic participation

This intervention will be at facility level therefore, we will engage with the Kenyan Ministry of Health, relevant 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 not seek individual consent of adolescent patients for de-identified clinic records.

HCW participants

HCW participants will provide standard written informed consent. A consent form describing in detail the study procedures and risks will be provided. For the wave 4 surveys, participants who have already provided informed consent will be read a telephone script and asked to provide verbal permission to take the final survey by telephone. Verbal permission will be documented in the tablet survey and in the call log.

*Waiver to release SP encounter videos*: HCWs will also have the opportunity to sign waivers to authorize use of SP encounter videos for educational purposes by UW and UoN (e.g. dissemination activities, examples for future SP trainings, on-line courses, conference presentations). Waivers will be signed before the start of the pilot phase and the RCT. Actors are study staff and will sign a waiver as condition of employment. Only videos where participants have signed waivers will be used for these purposes. ***Videos where a participant has not signed the waiver will not be used.***

Participants will be informed that they are free to decline signing a waiver, 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. Videos will not be altered (e.g. blurring of faces). As such, participants may be identifiable in the recordings. Participants who sign the waiver will understand that, due to logistical reasons, they will not be able to review the videos prior to their release.

Adolescent patients – rationale for procedures for adolescents and caregivers

Adolescent patients will be provided with an information sheet and have the opportunity to provide oral consent to participate in surveys. If a caregiver is present and the adolescent is <18, the caregiver will also provide oral consent. An oral consent is appropriate because the only risk associated with the anonymous survey is the possible breach of confidentiality due to written documentation of consent. Kenyan guidelines allow mature minors (married, sexually active, pregnant) to consent for their own HIV test, a far riskier procedure than an anonymous survey. In addition, completion of the survey would present no risk beyond what would occur as part of routine HIV care. Finally, many adolescents present to HIV testing and care alone or accompanied by a non-parent support person.

The consent and assent process by age is described below:

1) Adolescents ages 10-17 who come with a caregiver: Oral consent will be sought from the caregiver and oral assent will be sought from the minor. We will not enroll any adolescent between ages 10 and 13 who is unaccompanied by a caregiver.

2) Adolescents ages 14-17 who come without any caregiver: A waiver of parental consent is sought. Oral consent will be sought only from the adolescent.

3) Adolescents 18-19: Regardless of whether they are accompanied, adolescents will provide oral consent.

Justification for a waiver of parental consent for adolescents ages 14-17 who are unaccompanied:

For adolescents ages 14-17 who present at the clinic without a caregiver, there will be a waiver of parental/caregiver consent. Our justifications are: 1) Many adolescents 14-17 come for HIV testing without a caregiver, specifically because they do not want a caregiver present; 2) Some adolescents are orphaned, married, and/or do not have a caregiver, 3) Getting a caregiver's signature would pose an added logistical challenge, including scheduling a follow-up visit when both caregivers and adolescents can present at the clinic; 4) There would be a strong possibility of selection bias if we are limited to adolescents 14-17 who have caregivers present and willing to provide consent.

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 (HCWs) or provide oral consent (adolescent patients) 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 or information sheet 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.

Documentation of Oral Consent and Assent

We will document informed consent with a consent log, which will be completed by our study staff member who recruits participants. This log will contain numbered rows for each person (adolescents in HIV care) who is approached to take part in the survey. No identifying information will be recorded. For each row there will be two columns "oral consent obtained" and "declined to give consent." The study staff member will tick the appropriate box for each row to document whether the individual gave oral consent or declined to take part in the study. This log will be maintained in a secure filing cabinet at our study office.

Exclusion of Women, Minorities, and Children

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

## 13b. Participant Confidentiality

Study staff will take strict measures to maintain confidentiality for participants. Data collected will be kept confidential and access restricted to study staff. All video-recordings of the SP encounters will be kept in an encrypted cloud server. 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.

## 13c. 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 or adolescents.

- *Other:* Other study risks include emotional distress associated with the sensitive nature of HIV counseling and treatment (client surveys and HCWs in training), breach of patient confidentiality during data extraction (adolescent clinic records), and fear of or actual loss of employment associated with disclosure of grades checklists (HCWs in training). We are not directly enrolling adolescent clients other than to take part in anonymous cost, and sexual behavior 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 enrollment or subsequent clinic visits. However, the possibility of this social harm would exist if this intervention were not conducted. In addition, there is a risk of discomfort related to answering sensitive questions about sexual behavior. However, these questions are similar to what would be asked as part of routine HIV care.

- *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. Trained facilitators will oversee debriefing sessions with health care HCWs. Each clinical training intervention will open with a session on professional standards, expectations, and confidentiality, building an atmosphere of peer-support and collaboration. All HCW participants will agree to not share individual performance information outside of the learning group. Kenyan study personnel experienced in research with AYA will conduct the adolescent surveys. Adolescent participants will be informed that they can skip any question or stop the questionnaire altogether at any time. The questions on sexual behavior will be self-administered. Participants will be offered support or referral to additional services, as needed, according to standard procedures.

- *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

confidentially. 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. Adolescent participants will be assured that their sensitive information will not be shared with anyone outside the study team, including a parent, caregiver, or partner who may be present. In the rare situation that an AYA participant tells the study nurse that they are experiencing violence or threat of violence by a sexual partner, the study nurse will offer a referral to the appropriate clinic staff member according to study SOPs. Study staff will be trained in the importance of confidentiality during human participants training prior to study implementation. We will not share individual-level HCW data with health facilities in order to minimize risk of a negative reaction by an employer if they choose to participate or not participate in this study. In the event of reported social harm, we have developed standard operating procedures for referrals to local social agencies that will be incorporated into the HCW training.

- The adolescent survey will not include any reference to HIV status. The survey is designed to collect data on satisfaction with the patient-HCW experience overall and not specific HIV-related services. In addition, this 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 anonymous adolescent satisfaction surveys. These protections will depend on adolescents' age and whether they are accompanied by a caregiver.

Potential Benefits

- *HCWs:* Health care workers (HCW) will receive direct and immediate benefit in receipt of training to improve their skills in delivery of adolescent friendly HIV services. HCWs in previous studies have specifically requested this training.

- *Adolescent clients (surveys)*: Adolescent clients participating in the surveys will be able to inform study personnel and program leaders about their experiences in accessing testing and treatment services, which may in turn improve the way care is delivered and make it more acceptable to them. The benefit is direct, but is not likely to be immediate.

- *Adolescent client (clinic attendees)*: Adolescent clients who do not participate in the surveys but are clients of participating health facilities may benefit directly from the improved care and counseling services they receive from trained HCWs.

**Budget summary for SPEED Study (2015-2020)**

| **CATEGORY** | **COST (USD)** |
|---|---|
| Salaries | 451,246 |
| Consultants/Country Staff | 320,826 |
| Other Svcs | 73,831 |
| Subcontracts | 299,571 |
| Travel | 63,888 |
| Supplies | 21,300 |
| Benefits | 119,163 |
| TOTAL DIRECT COSTS | 1,352,601 |
| TOTAL INDIRECT COSTS | 503,050 |
| **TOTAL COSTS** | **1,855,650** |

## REFERENCES

1. UNAIDS. Global report: UNAIDS report on the global AIDS epidemic 2013. In; 2013.
2. UNICEF. Turning the tide against AIDS will require more concentrated focus on adolescents and young people. In.
3. UNAIDS. Fact sheet: Adolescents, young people and HIV - UNAIDS. In; 2012.
4. Idele P, Gillespie A, Porth T, Suzuki C, Mahy M, Kasedde S*, et al.* Epidemiology of HIV and AIDS Among Adolescents: Current Status, Inequities, and Data Gaps. *J Acquir Immune Defic Syndr* 2014,**66 Suppl 2**:S144-153.
5. Kasedde S, Kapogiannis BG, McClure C, Luo C. Executive Summary: Opportunities for Action and Impact to Address HIV and AIDS in Adolescents. *J Acquir Immune Defic Syndr* 2014,**66 Suppl 2**:S139-143.
6. UNAIDS. Global Report: UNAIDS Report on the Global AIDS Epidemic 2013. In; 2013.
7. 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.
8. Godia PM, Olenja JM, Lavussa JA, Quinney D, Hofman JJ, van den Broek N. Sexual reproductive health service provision to young people in Kenya; health service providers' experiences. *BMC Health Serv Res* 2013,**13**:476.
9. WHO U. Adolescents falling through gaps in HIV services. In; 2013.
10. WHO. Adolescent HIV testing, counselling and care. Implementation guidance for health providers and planners. 2013.
11. WHO. Strengthening the health sector response to care, support, treatment and prevention for young people living with HIV. In; 2006.
12. Mavhu W, Berwick J, Chirawu P, Makamba M, Copas A, Dirawo J*, et al.* Enhancing psychosocial support for HIV positive adolescents in Harare, Zimbabwe. *PLoS One* 2013,**8**:e70254.
13. World Health Organization. Making health services adolescent friendly. In; 2012.
14. Scott KW, Jha AK. Putting quality on the global health agenda. *N Engl J Med* 2014,**371**:3-5.
15. Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century. In; 2001.
16. Makoul G. Essential elements of communication in medical encounters: the Kalamazoo consensus statement. *Acad Med* 2001,**76**:390-393.
17. Wachira J, Naanyu V, Genberg B, Koech B, Akinyi J, Kamene R*, et al.* Health facility barriers to HIV linkage and retention in Western Kenya. *BMC Health Serv Res* 2014,**14**:646.
18. Weaver M, Erby L. Standardized patients: a promising tool for health education and health promotion. *Health Promot Pract* 2012,**13**:169-174.

19. Peabody JW, Luck J, Glassman P, Dresselhaus TR, Lee M. Comparison of vignettes, standardized patients, and chart abstraction: a prospective validation study of 3 methods for measuring quality. *Jama* 2000,**283**:1715-1722.

20. Rowe AK, Onikpo F, Lama M, Deming MS. Evaluating health worker performance in Benin using the simulated client method with real children. *Implementation Science* 2012,**7**:95.

21. Wright B, McKendree J, Morgan L, Allgar VL, Brown A. Examiner and simulated patient ratings of empathy in medical student final year clinical examination: are they useful? *BMC Med Educ* 2014,**14**:199.

22. Mugo PM, Duncan S, Mwaniki SW, Thiong'o AN, Gichuru E, Okuku HS*, et al.* Cross-sectional survey of treatment practices for urethritis at pharmacies, private clinics and government health facilities in coastal Kenya: many missed opportunities for HIV prevention. *Sex Transm Infect* 2013,**89**:583-589.

23. García PJ, Carcamo CP, Garnett GP, Campos PE, Holmes KK. Improved STD syndrome management by a network of clinicians and pharmacy workers in Peru: The PREVEN Network. *PLoS One* 2012,**7**:e47750.

24. Walker D, Fritz J, Olvera M, Lamadrid H, Cohen S, Fahey J. PRONTO Low-Tech Obstetric Simulation and Team Training in Mexico Improves Patient Outcomes, and Evidence-Based Care at Birth. *Obstet Gynecol* 2014,**123 Suppl 1**:176s-177s.

25. Walker D, Cohen S, Fritz J, Olvera M, Lamadrid H, Carranza L. PRONTO Low-Tech Obstetric Simulation and Team-Training for Obstetric and Neonatal Emergencies in Mexico Leads to a Decrease in Cesarean Delivery Rates. *Obstet Gynecol* 2014,**123 Suppl 1**:177s.

26. Walker D, Cohen S, Fritz J, Olvera M, Lamadrid-Figueroa H, Cowan J*, et al.* Team training in obstetric and neonatal emergencies using highly realistic simulation in Mexico: impact on process indicators. *BMC Pregnancy Childbirth* 2014,**14**:367.

27. Eid A, Petty M, Hutchins L, Thompson R. "Breaking bad news": standardized patient intervention improves communication skills for hematology-oncology fellows and advanced practice nurses. *J Cancer Educ* 2009,**24**:154-159.

28. Baer JS, Wells EA, Rosengren DB, Hartzler B, Beadnell B, Dunn C. Agency context and tailored training in technology transfer: a pilot evaluation of motivational interviewing training for community counselors. *J Subst Abuse Treat* 2009,**37**:191-202.

29. Chipman JG, Beilman GJ, Schmitz CC, Seatter SC. Development and pilot testing of an OSCE for difficult conversations in surgical intensive care. *J Surg Educ* 2007,**64**:79-87.

30. Denno DM, Hoopes AJ, Chandra-Mouli V. Effective Strategies to Provide Adolescent Sexual and Reproductive Health Services and to Increase Demand and Community Support. *J Adolesc Health* 2015,**56**:S22-s41.

31. Ivers NM, Halperin IJ, Barnsley J, Grimshaw JM, Shah BR, Tu K*, et al.* Allocation techniques for balance at baseline in cluster randomized trials: a methodological review. *Trials* 2012,**13**:120.

32. Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. *Contemp Clin Trials* 2007,**28**:182-191.

33. Downing SM, Tekian A, Yudkowsky R. Procedures for establishing defensible absolute passing scores on performance examinations in health professions education. *Teach Learn Med* 2006,**18**:50-57.

34. Davey C, Hargreaves J, Thompson JA, Copas AJ, Beard E, Lewis JJ*, et al.* Analysis and reporting of stepped wedge randomised controlled trials: synthesis and critical appraisal of published studies, 2010 to 2014. *Trials* 2015,**16**:358.

35. Chi BH, Yiannoutsos CT, Westfall AO, Newman JE, Zhou J, Cesar C*, et al.* Universal definition of loss to follow-up in HIV treatment programs: a statistical analysis of 111 facilities in Africa, Asia, and Latin America. *PLoS Med* 2011,**8**:e1001111.