Data-informed stepped care to improve youth engagement in HIV care in Kenya: a protocol for a cluster randomised trial of a health service intervention

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ABSTRACT

Introduction Adolescents and youth living with HIV (AYLHIV) have lower retention in care, adherence to treatment, and viral suppression compared with adults. Stepped care is a process by which clients are assigned to increasingly intensive services or 'steps' according to level of need. Differentiated care, in which stable clients access less frequent services, can be combined with stepped care to align needs and preferences of youth to promote optimal engagement in care.

Methods and analysis This hybrid type I effectiveness implementation cluster randomised trial aims to evaluate a data-informed stepped care (DiSC) intervention for AYLHIV. AYLHIV ages 10–24 receiving care at 24 HIV treatment facilities in Kisumu, Homabay and Migori counties in Kenya will be enrolled. Twelve facilities will be randomised to the DiSC intervention, and 12 will provide standard care. A clinical assignment tool developed by the study team will be used at intervention sites to assign AYLHIV to one of four steps based on risk for loss to follow-up: differentiated care, standard care, counselling services or intensive support services. The primary clinical outcome is retention in care, specifically missed visits (failure to return within 30 days for any visit) and 12-month loss to follow-up. Implementation outcomes are based on the Reach, Effectiveness, Adoption, Implementation and Maintenance framework. Proportions of missed visits will be compared using mixed effect models clustered by facility and participant.

Ethics and dissemination This study has been approved by the University of Washington Institutional Review Board (STUDY00011096), Maseno University Ethical Review Committee (MUERC/00917/20) and the Kenya National Commission for Science, Technology and Innovation (444824). AYLHIV provide written informed consent when legally permitted, or assent with caregiver permission for minors. Study staff will work with a Community Advisory Board, including youth members, to disseminate results via discussions, presentations, journal publications and local or international conferences.

Trial registration number NCT05007717.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Use of a data-driven approach to match adolescents and youth living with HIV to services according to need.
⇒ Includes implementation outcomes to account for context that will optimise both intervention approach and sustainability.
⇒ Integrates validated survey scales with routinely collected electronic medical records data to assess outcomes.
⇒ Overlap between standard of care and the intervention steps may limit ability to detect a significant difference in outcomes.
⇒ May be subject to routine care interruptions such as strikes, stock outs, the COVID-19 pandemic and workforce turnover that could undermine the intervention.

INTRODUCTION

An estimated 88% of youth, including adolescents and youth living with HIV (AYLHIV) reside in sub-Saharan Africa. Worldwide, 410,000 youth between the ages of 10 and 24 were newly infected with HIV in 2020, and perinatally infected children of the last decade are ageing into adolescence. Compared with adults, youth have lower retention in care, adherence to antiretroviral therapy (ART) and viral suppression, increasing the risk of HIV transmission and disease progression. AYLHIV frequently fail to achieve viral suppression with approximately 30% experiencing non-suppression or failure after 12 months on ART.

Test and Start models, where individuals living with HIV are rapidly initiated on treatment, address loss to follow-up in the pre-ART period, with early evidence of success.
However, there are fears that increasing caseloads, interlinked burdens of disease, sudden epidemic outbreaks and other emerging health challenges will add to healthcare worker (HCW) burdens in already strained healthcare systems. Differentiated models of service delivery have been proposed as a client-centred approach that simplifies and adapts HIV services across the cascade to better serve those in care and reduce unnecessary burdens on the health system. However, due to poor retention outcomes, Kenyan guidelines classify all adolescents as ‘unstable’. Thus, AYLHIV are currently not able to access differentiated approaches, including community-based refills or longer refill durations, which may benefit this population and free up HCW time to provide more intensive care to youth in need.

Stepped care models, a process by which clients are assigned to intervention steps according to level of need, have been used in mental health fields to organise provision of services; and to support clients, HCWs and caregivers to identify the most effective interventions. Models typically start with a low-intensity, evidence-based treatment and systematically progress to higher levels of care or intervention as clients fail to respond. Early studies suggest that stepped care approaches improve access to care, client outcomes and programme efficiencies, including client volume. A key feature of stepped care is outcome monitoring, giving both clients and HCWs feedback to inform care options and service delivery.

One challenge with retention interventions is the ability to identify clients who need more intensive services before they are lost to follow-up. Clinical prediction tools classifying individuals into high and low-risk groups have potential to identify those in need of intervention and support more efficient service delivery prior to poor outcomes occurring. Studies using these tools among key populations in the USA and studies in Kenya found clinical characteristics that were predictive of HIV acquisition. Similarly, tools using a minimal number of variables have been shown to predict virologic failure or mortality in adult cohorts in both the USA and low resource settings. A prediction tool for loss to follow-up could support HCWs to better identify youth at risk for missed visits, rather than waiting until loss occurs, and be used to assign youth into appropriate steps of service delivery. This study aims to evaluate a data-driven, stepped care intervention assigning AYLHIV in Kenya to differentiated or more intensive service steps.

**METHODS AND ANALYSIS**

**Study design**

This hybrid type I effectiveness implementation parallel cluster randomised trial aims to evaluate the effectiveness and implementation of a data-informed stepped care (DiSC) intervention for AYLHIV in Kenya. We hypothesise that the DiSC intervention will result in better retention in care and viral suppression among AYLHIV in intervention sites compared with those in control sites. We hypothesise that the DiSC intervention will be integrated into routine AYLHIV service in a way that is feasible and acceptable for HCWs, reaches a high proportion of youth attending facilities and is able to be implemented with fidelity. Focus group discussions and in-depth interviews will support qualitative understanding and optimisation of study implementation.

**Study sites and population**

We will conduct this study at 24 HIV care facilities located in Kisumu, Homabay and Migori counties in Kenya. Eligible facilities include those with ≥100 AYLHIV enrolled in care, a functioning electronic medical records (EMR) system and interest in participating. Eligible AYLHIV are ages 10–24 and enrolled in HIV treatment at participating clinics. AYLHIV who are not aware of their HIV diagnosis will be excluded. We aim to enrol a minimum of 50 AYLHIV per site, up to a maximum of 6000 AYLHIV total.

**Patient and public involvement**

Grounded in the concept of the stepped care model used in mental health, the DiSC intervention was developed through a combination of: (1) review of stepped care practices in the USA, (2) preliminary data from a longitudinal cohort of >1300 AYLHIV in Kenya and (3) a modified user-centred design (UCD) workshop with key stakeholders (AYLHIV, youth leaders, national and county health officials, HCWs and caregivers of AYLHIV). Cohort data were used to characterise the AYLHIV population and develop a clinical prediction tool for loss to follow-up to aid providers in assigning AYLHIV to care steps. These data, alongside information on stepped care, differentiated care policies, best practices for adolescent care, national guidelines and existing services in clinics in the catchment area, were presented to stakeholders at the UCD workshop. Given COVID-19 social gathering restrictions, the workshop included a series of small group meetings followed by a large group meeting, where participants discussed which services would be appropriate for each step, aligning current practices in facilities. Participants were encouraged to develop the most inclusive and simplest service allocation approach that would work in the largest number of facilities in Kenya. Following the workshops, the study team refined the clinical prediction tool and intervention steps based on the feedback of stakeholders.

**Conceptual framework**

This study uses a socio-ecological framework to understand adolescent care-seeking behaviours and is broadly informed by Andersen’s model of health service use and elements of Pantin’s eco-developmental theory. Andersen’s model describes how environmental factors, including the health system, interact with population factors to motivate individual uptake of health services. The developmental perspective in Pantin’s theory...
further suggests that these factors and relationships change during transition to adulthood. From a theoretical perspective, the stepped care model is grounded in Stages of Change Theory, tailoring different levels of care intensity to different stages of health behaviour change.36

**Intervention components**

The DiSC intervention uses a clinical assessment tool, based on the original prediction tool, to assign AYLHIV to different levels—or steps—of care based on their health and psychosocial needs. As those with lower needs becomes eligible for less frequent contact, this allows more HCW time to concentrate on providing more intensive services (Figure 1). In addition to reinforcing standard of care elements, the intervention also includes HCW training of cognitive behavioural therapy (CBT) and motivational interviewing. These core components address social (transportation, school, social support); individual and family (stigma, depression, self-efficacy and motivation); and health system factors (service availability, quality of care, care coordination) as a holistic approach to promote retention, adherence and ultimately viral suppression.

**Intervention procedures**

At enrolment and at every visit, HCWs will use the assessment tool to determine risk level and assign AYLHIV to a care step. Information will be obtained through self-report and HCW review of the medical record. The tool uses a combination of key loss to follow-up predictors and Kenyan national guidelines to match AYLHIV to one of four steps: differentiated care, standard of care, individual counselling or intensive support (Table 1).

At the lowest step, AYLHIV who adhere well to treatment with no missed visits or health concerns will be assigned to receive differentiated care services, including

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**Table 1** Intervention steps

<table>
<thead>
<tr>
<th>Step</th>
<th>Criteria for step assignment</th>
<th>Intervention steps</th>
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<tbody>
<tr>
<td>1</td>
<td>On ART for 12 months—AND—No opportunistic infection (OI) in last 6 months—AND—Viral suppression at last measure</td>
<td>Differentiated care&lt;br&gt;► Longer visit intervals&lt;br► Pharmacy fast track</td>
</tr>
<tr>
<td>2</td>
<td>Does not meet step 1 criteria (above)—OR—Patient preference for standard care—OR—Pregnant/breastfeeding</td>
<td>Standard care&lt;br&gt;► Job tools for OIs, pregnancy, newly enrolled&lt;br► Support groups&lt;br► Standard visit intervals</td>
</tr>
<tr>
<td>3</td>
<td>PHQ-2 score indicating depression—OR—Missed one or more visits in last 6 months</td>
<td>Individual counselling&lt;br&gt;► Motivational interviewing&lt;br► Cognitive behavioural therapy sessions</td>
</tr>
<tr>
<td>4</td>
<td>Unsuppressed viral load (VL)</td>
<td>Intensive support services&lt;br&gt;► Adherence counselling&lt;br► Facilitated case conference across sites&lt;br► Transportation support or home visits</td>
</tr>
</tbody>
</table>

ART, antiretroviral therapy; PHQ-2, Patient Health Questionnaire-2.
multi-month refills, longer visit intervals and/or fast-track visits. AYLHIV with health concerns (pregnancy, opportunistic infections or TB) or those newly enrolled in care will be assigned to the second step, receiving standard care under Ministry of Health guidelines. AYLHIV with a history of missed visits in the past 6 months or depressive symptoms on standardised Patient Health Questionnaire-2 (PHQ-2) depression screening will be assigned to the third step, individual counselling. Within that step, those with a history of missed visits will receive one motivational interviewing session, and those with depressive symptoms will receive four CBT counselling sessions and referral to further mental health evaluation and treatment where warranted. The last step, intensive support, includes AYLHIV with unsuppressed viral load (VL). They receive services from steps 2 and 3 as needed, and enhanced adherence counselling with case management services such as home visits or transportation support as needed. The study team will guide facility-based quality improvement at intervention sites to monitor unsuppressed clients and support timely return of VL results. Control sites will continue with standard care for AYLHIV clinic visits according to national guidelines.

Recruitment and retention procedures

The sampling frame includes 55 clinics in three high-burden counties in Western Kenya. Among those, 24 clinics that meet eligibility criteria have the highest youth enrolment, and whose leadership is willing to participate will be selected and randomised to intervention or control. AYLHIV in participating facilities who are aware of their HIV status will be identified by facility providers and referred to the study team for eligibility screening and consent. A standard recruitment script with talking points will be used. Recruitment will be conducted during different days and times of the week, during at least two school breaks and ‘youth friendly days’ to maximise enrolment. AYLHIV at intervention sites will be consented for participation in the DiSC intervention and longitudinal surveys. Control sites will be consented for longitudinal surveys only. AYLHIV participants will have 12 months of follow-up time.

Randomisation and blinding

A total of 24 clinics will be randomised in a 1:1 ratio using computer generated random numbers to either intervention or control, using restricted randomisation to balance county representation and facility volume, aiming to balance these variables between arms. Randomisation will be done prior to study initiation at the University of Washington by a biostatistician not involved in study procedures. A list of clinics with their allocation arms will be sent to the study team. The intervention is administered at the clinic level; thus, it is not possible to blind participating clinics or study team members.

Outcome measures

The primary outcome is retention in care, measured as both the proportion of missed visits 1 year after enrolment, and the proportion of AYLHIV who became lost to follow-up with no subsequent return to care during the study period (Table 2). Secondary outcomes are viral non-suppression, defined as HIV VL >1000 copies/mL; receipt of differentiated services (multi-month refills or fast-track visits); and ART adherence defined as a remaining pill count<80% (estimated by days used and inter-visit interval).

Implementation assessment includes barriers, facilitators, and adaptation strategies of intervention implementation. Outcome measures use the Reach, Effectiveness, Adoption, Implementation and Maintenance framework. We will routinely evaluate the proportion of youth enrolled in the intervention (Reach), the proportion of trained HCWs using the intervention (Adoption), proportion of youth assigned to correct step (Fidelity), proportion of youth exposed to correct services in each step (Fidelity), types of HCW adaptations made for optimising delivery (Implementation) and the proportion of

<table>
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<th>Table 2  Study outcomes and data sources</th>
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<tr>
<td><strong>Outcome</strong></td>
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<tr>
<td>Primary outcome—retention in care</td>
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<tr>
<td>Missed visit</td>
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<td>Loss to follow-up</td>
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<tr>
<td>Secondary outcomes</td>
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<tr>
<td>Receiving differentiated care</td>
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<tr>
<td>Adherence</td>
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EMR, electronic medical records; VL, viral load.
facilities using the intervention tools at study end (Maintenance) using study-specific case report forms (table 3). We will also evaluate HCW perceptions of acceptability, feasibility and appropriateness of the DiSC intervention.30,39

Data collection
We will abstract AYLHIV medical record data at baseline, and every 6 months. Data from all enrolled AYLHIV with at least one clinic record within the 12-month period prior to the first data abstraction date will be included. Data will be abstracted at the facility or at the office of the technical partner that supports the EMR system at the facility. The EMR system captures data on client anthropometric measures, demographics, HIV testing history, clinical history, ART adherence data, laboratory data, CD4 count, transfers and discontinuations. If EMR data are unavailable, paper records will be abstracted using mobile REDCap, which enables automatic upload of data to a secure, password-protected study server. Routine HIV VL testing (done 6 months after ART initiation, then annually) will be abstracted from the Kenya National AIDS & STI Control Program database.

Youth surveys will be administered by study staff following intervention assignment by the HCW. Surveys include questions on sociodemographic,40 healthcare use, stigma,41 sexual behaviour and violence using questions adapted from the WHO Multi Country Study,42 social support by the Multidimensional Scale of Perceived Social Support,43 depressive symptoms by PHQ-9,44 anxiety by General Anxiety Disorder-7,45 resilience by Connor-Davidson Resilience Scale-2,46 self-efficacy,47 personal health knowledge, HIV disclosure, and medication adherence by HIV Treatment Adherence Self-Efficacy Scale.48 Surveys will be administered every 6 months either in person or over phone by a trained study staff. Survey visits will coincide with clinic visits whenever possible. At the end of the study, additional surveys will be given to a random sample of youth and caregivers in intervention sites to evaluate satisfaction with care. We will also conduct in-depth interviews (IDIs) or focus group discussions (FGDs) with youth in intervention sites to determine acceptability, feasibility and satisfaction with the intervention.

Facility managers will complete baseline and annual facility surveys to understand baseline resource capacity to implement future interventions and modifiable and non-modifiable health system factors. Variables will include availability of youth-friendly services, management and referral systems, and differentiated care services available. We will conduct pre-trial surveys with HCWs to assess structural readiness for implementation39 and intervention beliefs about acceptability, feasibility and appropriateness of intervention implementation. During the first 6 months of the trial, HCWs will participate in twice-monthly continuous quality improvement (CQI) meetings using plan-do-study-act processes to assess specific adaptations that optimise reach, adoption, fidelity, acceptability and feasibility. Prior to each meeting, HCWs will complete surveys to evaluate changes in implementation. We will conduct FGDs with HCWs in intervention sites at 6 months post-intervention implementation, and FGDs, IDIs and surveys with HCWs post-trial to determine experiences with the DiSC intervention and evaluate barriers and facilitators of intervention utilisation. All FGDs and IDIs will be guided by the Consolidated Framework for Implementation Research.49,50

Sample size calculation
We estimate that participating facilities will have an average of 100–200 AYLHIV in care per clinic. Based on preliminary data, we assume that 75% will remain in care

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<tr>
<th>Outcome</th>
<th>Definition</th>
<th>Timing</th>
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<tr>
<td>Reach</td>
<td>Proportion of youth who are exposed to the intervention among all youth attending clinic</td>
<td>Daily</td>
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<tr>
<td>Adoption</td>
<td>Proportion of trained providers who are using the DISC intervention among youth</td>
<td>Bi-monthly for 6 months and post-trial</td>
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<tr>
<td>Implementation</td>
<td>Characterisation of adaptations and strategies used to optimise early implementation</td>
<td>Bi-monthly for 6 months and post-trial</td>
</tr>
<tr>
<td>Maintenance</td>
<td>Proportion of facilities delivering the DISC intervention with rates of adoption and fidelity at study end; characterisation of barriers and facilitators to sustainability</td>
<td>Post-trial</td>
</tr>
<tr>
<td>Fidelity</td>
<td>Proportion of youth who are correctly assigned to each step; proportion of youth who correctly receive services aligned to assigned step</td>
<td>Bi-monthly for 6 months and post-trial</td>
</tr>
<tr>
<td>Acceptability</td>
<td>Perception among implementation stakeholders and patients that the DISC intervention is agreeable, palatable or satisfactory</td>
<td>Baseline, bi-monthly for 6 months and post-trial</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Perception of the extent to which the DISC intervention can be successfully used or carried out within a given setting</td>
<td>Baseline, bi-monthly for 6 months and post-trial</td>
</tr>
<tr>
<td>Appropriateness</td>
<td>Perception of the perceived fit, relevance, or compatibility of the DiSC intervention for the specific setting, and whether it addresses the issue of loss to follow-up among AYLHIV</td>
<td>Baseline, bi-monthly for 6 months and post-trial</td>
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AYLHIV, adolescents and youth living with HIV; DISC, data-informed stepped care.

Table 3: Implementation outcomes
by the end of the 12-month follow-up period. Assuming 12 facilities per arm, $\alpha=0.05$, a two-sided test, and a coefficient of variation of 0.10, we have 80% power to detect a 14% difference (75%–89%) with $\geq150$ AYLHIV per facility, and a 15% difference (75%–90%) with $\geq50$ AYA per facility. Assuming a coefficient of variation of 0.15, we have 80% power to detect a 17% difference (75%–92%) with $\geq50$ AYLHIV per facility.

**Statistical methods and analysis**

Characteristics of facilities randomised to each arm will be summarised using descriptive statistics. The proportion of missed visits will be compared between study arms using mixed effect models clustered by facility and participant. Time to loss to follow-up will be compared between arms using survival curves and Cox proportional hazards regression, with censoring of deaths or transfers. Proportions of secondary outcomes (viral non-suppression, differentiated care, adherence) will each be compared between study arms using mixed effect models clustered by facility and participant. Exploratory sub-group analyses for missed visits and loss to follow-up will be performed by gender, age-group and step assignment groups. Facility factors including concurrent adolescent-friendly services and high/low performance will be evaluated as moderators of intervention effectiveness. Pre-trial and post-trial survey data will be summarised to evaluate frequencies, variability and associations. Adaptations made to the intervention during the CQI process will be categorised using the Framework for Reporting Adaptations and Modifications Expanded and compared with variations in implementation outcomes to identify modifications associated with sustained improvements in implementation. Qualitative data will be analysed using a combination of thematic and directed content analysis approaches to characterise the determinants of implementation success and explore personal experiences with the DiSC intervention.

**ETHICS AND DISSEMINATION**

This study has been approved by the University of Washington Institutional Review Board (STUDY00011096) and Maseno University Ethical Review Committee (MUERC/00917/20). Protocol modifications will be submitted to both committees. Youth participants will provide written informed consent for study procedures as permitted by law; youth without capacity to consent will provide assent while their caregivers will give consent unless exempted by the two ethics bodies. A sample consent form is provided in the online supplemental appendix. The trial will be monitored by a Data Safety and Monitoring Board (DSMB), as well as by external monitors appointed by the funder. Severe adverse events will be monitored and reported to the DSMB and study monitors in real time. All data will be kept confidential and de-identified by the data manager. Consent documents will be kept separate from study data and secured in a locked cabinet.

Study staff will work with a Community Advisory Board, including youth members, to disseminate results to participants and the community via discussions and presentations. We will further disseminate findings through journal publications and local or international conferences. Data will be submitted to the National Institute of Child Health and Human Development (NICHD) Data and Specimen Hub (DASH) no later than 1 year after acceptance of the primary manuscript or study closure, whichever comes first.

The trial is registered at ClinicalTrials.gov, NCT05007717. Enrolment took place 19 April to 19 July 2022; the trial will conclude by 31 July 2023.

**DISCUSSION**

This study is part of the Prevention and Treatment through a Comprehensive Care Continuum for HIV-affected Adolescents in Resource Constrained Settings (PATCCH) consortium, a NICHD-funded international group of combination individual, family, community, structural and health system intervention studies to improve health outcomes among adolescents and youth at risk for or living with HIV. Our study aims to evaluate a stepped care intervention to tailor service delivery according to AYLHIV needs and ultimately improve retention in care and other clinical and psychosocial outcomes. The intervention has been developed based on a theoretical foundation and informed by pilot data and stakeholder input.

Our multicomponent intervention is based on a combination of evidence-based interventions and recommended but untested strategies to clearly allocate services using a pre-specified algorithm/tool to tailor specific services for AYLHIV. Services include individual motivational interviewing to preemptively improve retention, CBT to address depressive symptoms, and enhanced counseling for adherence. System improvements include facility quality improvement and guideline refreshers. Together, these intensive individual and system-level interventions as elements of higher steps address current gaps in care including resources for mental health treatment and a breakdown in action on unsuppressed VL results. One way our approach differs from US-based stepped care interventions is that we include risk for non-retention, rather than waiting for non-retention outcomes alone, to assign AYLHIV to steps.

The use of a data-driven tool to identify AYLHIV at highest risk of loss to follow-up is consistent with stepped care principles of using routine data to inform care needs. The risk assessment provides a systematic way to identify AYLHIV who are most likely to be safe to initiate on differentiated services, despite being classified by Kenya’s MOH as a high-risk group overall. Currently, differentiated services like longer visit intervals are only applied to stable adults, due to concerns that AYLHIV may not be able to sustain adherence and retention without
more frequent contact. Our approach will emulate adult standards for differentiated care in terms of identifying eligible AYLHIV. Data from this study will provide important evidence for Ministries of Health who seek to extend differentiated care to AYLHIV. Simultaneous measurement of implementation outcomes throughout the trial will help to determine best practices to ensure sustainability and inform issues of setting and context, which may contribute to eventual scale-up if the intervention is found effective.

This trial has limitations. Elements of several care steps are offered in control settings, which may limit our ability to detect a difference between intervention and control arms, and there is a possibility of transfer of enrolled clients between facilities. The study is operating through routine care programmes in Kenya, which are subject to strikes, stock outs, the COVID-19 pandemic, and workforce turnover and may undermine fidelity of the intervention over the study course. Furthermore, the age range represents a heterogeneous group of AYLHIV, and our sample size may limit our ability to detect differences in effectiveness among key subgroups. Finally, there are social factors that influence AYLHIV uptake of services and may not be addressed within the health system alone.

In summary, this a data-driven, provider-led, health system intervention aims to identify young people most at risk for loss to HIV care, sub-optimal adherence and viral failure. Our stepped care approach, combined with a clinical prediction tool, is a timely and flexible intervention in the context of differentiated care and numerous ongoing care initiatives. By improving engagement in care and optimising provision of limited resources, this intervention may ultimately improve health among adolescents and youth in Kenya and provide support for testing stepped care approaches in other settings.

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Contributors PK, GJ-S and KA are principal investigators. PK, GJ-S, KA, BAR and KB-S designed the study and supervised trial protocol development, IN, JD, WJ, SS, II, NC and JB contributed to the study protocol, BAR and WJ were responsible for statistical design; KB-S and NC were responsible for implementation science approaches. PK drafted the initial manuscript and all authors critically revised, read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

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REFERENCES


Data-informed Stepped Care (DiSC) to Improve Adolescent HIV Outcomes

CONSENT FORM FOR ADOLESCENTS AGED 15–17 and YOUNG ADULTS 18-24 or EMANCIPATED MINORS or MATURE MINORS

Investigators

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<th>NAME</th>
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Emergency telephone number:
Local Site IRB contact:
US Site IRB contact:

1. Researcher’s Statement
We are asking you to volunteer for a research study. This study is being done by a US-based university and Kenyan-based organization. Before you decide to take part in this study, we would like to explain the purpose, risks, and benefits of the study. It is important that you understand that it is your choice to take part in this study. If you join the study, you can withdraw from the study at any time. If you decide not to take part in the study, it will not affect any care or services that you receive from this clinic. We will retain a copy of this consent form and give you a copy to take with you.

2. Purpose of Study
The purpose of this study is to test a model of care - called “Stepped Care” - that matches health services to the needs of young people receiving care at clinics. For example, people experiencing depression or missing clinic visits will be offered more services, and people needing less support may be able to come to clinic less often. This study will be conducted in 20-24 clinics. Half of the clinics will use this approach and half will not. A random process will be used to put the clinics in the two groups. If you receive care at a clinic that is using this approach, you will be placed into a health care “step” depending on your needs. If you receive care at a clinic that is not using this approach, you will receive the care you would usually receive. In all clinics, we also want to learn more about your social life and behaviors that may affect your health, and your views about the care you receive at this clinic, by asking you questions in a survey. We aim to enroll about 3,000 adolescents in this study. This study will last for about 1 year. What we learn from these surveys may help to improve health care for young people like you.
3. Study Procedures

This is what will happen if you agree to take part in this study. We will ask you to read, discuss, and sign or make your mark on this form. After this form is signed or marked, you will be eligible to be placed into a “step” to receive health services personalized to you, if you are in a facility that offers these services. We will also ask you to complete a survey. You can take this survey during your normal clinic visits or at another time convenient to you. We will not ask you to put your name on the survey. The survey will ask about your background, social support, mental health, sexual partners and behaviors, substance use, any experience with violence, and satisfaction with care. A trained study staff member will take you to a private place at the clinic where you can take the survey. A study staff will ask you questions and record your responses on a tablet. The enrollment survey will take between 30 and 60 minutes.

We will ask you to take follow-up surveys every 6 months after enrollment for a total of 1 year. All surveys will ask similar questions. The follow-up surveys will be a little shorter because they will only ask about things that may have changed in your life since you took the last survey. These surveys should take about 40 minutes. Once you have taken the surveys, your participation in this study will end. We will not share with you information about what we think of your responses to the survey.

We will also link information from your medical records including clinic visit dates, medications, and health status to your survey data. This is information that we cannot collect easily through surveys.

We are also interested in learning about caregivers. When you enroll in this study, we may ask your permission to speak with your caregiver about whether they want to take a survey also, if your caregiver came with you. We would then speak with them about their interest in this study. We will not share with your caregiver any information you give with us during the survey.

4. Risks, Stress, and Discomfort

Answering questions about yourself: We may ask things on the surveys that make you feel embarrassed or uncomfortable. Some questions on the surveys about sexual behavior, violence, mental health, or drug use might make you feel uncomfortable because they are personal or sensitive. You do not have to answer any questions that make you feel uncomfortable. You can end the survey at any time if you do not want to talk to us anymore. You do not have to take all the surveys if you do not want to. Your answers will be confidential.

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

5. Alternatives to Taking Part in this Study

There may be other studies going on here or in the community that you may be eligible for. If you wish, we will tell you about other studies that we know about. There also may be other places where you can go for medical care. We will tell you about those places if you wish. Whether or not you decide to participate in this study, you can receive care services at a facility of your choice.

6. Benefits of the Study

By participating in the study, you will help our understanding of how to improve clinical services for young people like you.

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7. **Source of Funding**

The study receives funding from the United States Government, National Institutes of Health.

8. **Confidentiality of Research Information**

We will keep your identity as a research participant confidential. Your responses to questions will be kept private. We will not share this information with a caregiver or your partner. None of your identifying information will be shared with any person or agency outside this study without your permission in writing. Your surveys will not have your name or patient ID. Your survey data and medical record data will be linked only by a study ID. We will not publish or discuss in public anything that could identify you. All of your information, including the link between your name and study ID will be kept in a secure location at the study office. Study documents will be stored in a secure place for 6 years after the study ends. Any publications of this study will not use your name or identify you. However, if we learn that you intend to harm yourself or others, we must report that to the authorities. We will make every effort to keep your information confidential. However, it is possible that someone could find out you were in this study and could find out information about you.

We plan to take away any information that may identify you in the data – this is called ‘de-identified data’. This de-identified data will be stored indefinitely and may be used for future research or distributed to other investigators for future research. Because the data is not identifiable, there is no risk to you of sharing the data and the data may benefit other people like you by answering research questions relevant to you.

If we find out from the responses you give us that you are being abused, neglected or have been seriously injured, under Kenyan law, we may be required to report this to authorities.

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

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

- Kenyan University ethics review board
- US-based University Institutional Review Board
- National Institutes of Health (NIH) in the United States

We have a Certificate of Confidentiality from the United States National Institutes of Health. These protections only apply to data held in the United States. This helps up protect your privacy. The certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law in the United States. We will use the Certificate to refuse any demands for identifying information.

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

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

- a member of the United States government who needs it in order to assess the research;
• individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
• individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
• to relevant authorities as required by other Federal, State, or local laws

The Certificate expires when the NIH funding for this study ends. Currently this is August 31, 2023. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9. Other Information

Your participation is voluntary:

• You do not have to be in this study if you do not want to.
• You may withdraw from the study or decide not to answer any question without losing access to routine medical care in this clinic or elsewhere.
• No one will be angry or upset with you if you do not want to be in this study. You can also change your mind about being in this study at any time.

Reasons why you may be withdrawn from the study without your consent if:

• The research study is stopped or cancelled
• The study staff feels that participating in the study would be harmful to you.

Costs to you: There is no cost to you for your participation in the study.

Reimbursement: You will receive some light refreshment for participating in this survey.

10. Research-Related Injury

If you think you have been harmed or think you have a medical problem related to this research, please contact Dr. Kawango Agot at 0736-505046 or Jacinta Badia at 0791-575733. There is no program for monetary compensation or other forms of compensation for injuries. You do not give up any legal rights by signing this consent form. If you need further medical assistance, we will refer you to care at Jaramogi Oginga Odinga Teaching and Referral Hospital (formerly known as Russia Hospital or PGH). If we refer you, you may be asked to pay for some services.

11. Problems or Questions

If you ever have any questions about this study or if you have any problems, you should contact the Site Lead or Study Coordinator.

If you have questions about your rights as a research participant, you should contact the Kenyan University Ethics and Research Committee.

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Do you have questions about the survey itself or about taking part in this study? Yes ☐ No ☐

**Subject’s statement**
This study has been explained to me. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research participant, I should contact the Kenyan University Ethics and Research Committee.

I give permission to the researchers to use my data as described in this consent form. I will receive a copy of this consent form if I wish.

I agree to take part in this study ☐

Printed name of subject  Signature of subject  Date

If needed:

Printed name of witness  Signature of witness  Date

Printed name of study staff obtaining consent  Signature of staff person  Date