







# BMJ Open Assessing knowledge, acceptability and social implications of a peer-to-peer HIV self-testing kit distribution model among adolescents aged 15–24 in Zambia and Uganda – HISTAZU: a mixed-method study protocol

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## ABSTRACT

**Introduction** HIV self-testing (HIVST) across sub-Saharan African countries may be acceptable as it overcomes significant barriers to clinic-based HIV testing services such as privacy and confidentiality. There are a number of suggested HIVST distribution models. However, they may not be responsive to the testing service needs of adolescents and young people (AYP). We will investigate the knowledge, acceptability and social implications of a peer-to-peer distribution model of HIVST kits on uptake of HIV prevention including pre-exposure prophylaxis, condoms, and voluntary medical male circumcision and testing services and linkage to anti-retroviral therapy among AYP aged 15–24 in Zambia and Uganda.

**Methods and analysis** We will conduct an exploratory mixed methods study among AYP aged 15–24 in Uganda and Zambia. Qualitative data will be collected using audio-recorded in-depth interviews (IDIs), focus group discussions (FGDs), and participant observations. All IDIs and FGDs will be transcribed verbatim, coded and analysed through a thematic-content analysis. The quantitative data will be collected through a structured survey questionnaire derived from the preliminary findings of the qualitative work and programme evaluation quantitative data collected on uptake of services from a Zambian trial. The quantitative phase will evaluate the number of AYP reached and interested in HIVST and the implication of this on household social relations and social harms. The quantitative data will be analysed through bivariate analyses. The study will explore any social-cultural and study design barriers or facilitators to uptake of HIVST.

**Ethics and dissemination** This study is approved by the Uganda Virus Research Institute Research and Ethics committee, Uganda National Council for Science and Technology, University of Zambia Biomedical Ethics Committee, Zambia National Health Research Authority and the London School of Hygiene and Tropical Medicine. Dissemination activities will involve publications in peer-reviewed journals, presentations at conferences and stakeholder meetings in the communities.

## STRENGTH AND LIMITATIONS OF THIS STUDY

- ⇒ This study protocol outlines a multicountry exploratory study to understand views on HIV self-testing (HIVST) among adolescents and young people aged 15–24 years in different settings.
- ⇒ Engaging adolescents and young people who are potential users of HIVST will ensure a comprehensive exploration of knowledge, feasibility, acceptability and social implications of a peer-to-peer distribution model.
- ⇒ Using the mixed-method approach will provide breadth and depth of understanding of the research questions.
- ⇒ The use of focus group discussions and interviews affords the opportunity to gather detailed information on the topic providing the basis for the survey questionnaire development.
- ⇒ The selective sample from ongoing randomised control trials may not reflect the representativeness of a wider study population in both settings.

## BACKGROUND

HIV infection is the leading cause of death among adolescents and young people (AYP) (aged 10–24 years) in Africa and the second most common cause of death among adolescents globally.<sup>1–3</sup> Timely detection of HIV is an important step for linking individuals living with HIV to early initiation and access to anti-retroviral therapy (ART) to prevent reinfection and protect their partners. However, AYP are less likely to test for HIV and if seropositive, less likely to immediately link to age-appropriate HIV specialty care, yet they represent a growing share of people living with HIV worldwide.<sup>4–6</sup> It is important to note that reaching zero new infections in

this group requires increased coverage of all HIV prevention methods: pre-exposure prophylaxis (PrEP), voluntary medical male circumcision (VMMC), condom use, counselling, testing, and care services including linkage to ART and adherence support among AYP in sub-Saharan Africa.<sup>7–10</sup>

Uptake of HTS among AYP remains relatively low with only 25% of adolescent girls and 17% of adolescent boys aged 15–19 having tested for HIV in Eastern and Southern Africa in 2020.<sup>11</sup> Zambia and Uganda have young populations and in both countries uptake of HTS among AYP is reported to be low yet adolescence is a period when behaviours associated with HIV risk are common thereby increasing their chance of HIV acquisition.<sup>12–16</sup>

One potential strategy is HIV self-testing (HIVST), a process in which a person collects their specimen, performs the test and interprets their results.<sup>17 18</sup> Studies of HIVST across sub-Saharan African countries have shown it to be acceptable as it overcomes significant barriers to clinic-based HTS such as privacy and confidentiality.<sup>19–25</sup> Previous studies have revealed that people are motivated to self-test due to the rapid turnaround of results, the opportunity to test in private spaces, and the sense of empowerment, control, and being in charge of their health.<sup>20 21 24 26</sup> Current models of distributing HIVST include distributing HIVST kits through the clinic, community-based models such as the community health worker-led door-to-door distributing model, and secondary distribution (distribution through a primary recipient that is, partner).<sup>26–29</sup> However, research has shown that these approaches to distribution have the potential to miss AYP who hardly ever attend health facilities and are absent from home due to mobility and many other reasons.<sup>30 31</sup>

A community-based peer-to-peer/social network (P2P/SN) distribution model has the potential to effectively reach more AYP. This model uses trained young people to distribute HIVST to fellow young people. In addition, the model also leverages social networks to promote distribution, access and uptake of HIVST. A similar model was piloted among men who have sex with men and fishermen in Uganda.<sup>32–36</sup> However, there is a lack of evidence on whether this model can effectively reach AYP of Uganda and Zambia and the social implication of the model on accessibility, acceptability, the usability of self-test kits, linkage to confirmatory testing and care. Additionally, there is a need for evidence on the social implications of this model on social harms like internalised and experienced stigma. This study will assess the knowledge, feasibility, acceptability and social implications of a peer-to-peer distribution model of HIVST kits as a prevention strategy, on uptake of HIV prevention and testing services, and linkage to ART and HIV prevention services (PrEP, condoms, and VMMC) among AYP aged 15–24 in Zambia and Uganda. The study will further explore any social-cultural and study design barriers or facilitators to uptake HIVST.

## STUDY AIMS

- ▶ To elucidate the perceptions and contextual factors likely to influence the implementation, feasibility, and acceptability of a P2P/SN distribution models of HIVST among AYP in Lusaka and Entebbe (qualitative methods).
- ▶ To investigate the perceptions, facilitators and barriers of self-testing among AYP in Lusaka and Entebbe (qualitative methods).
- ▶ To investigate the number of AYP reached with HIVST through the P2P/SN model in Zambia and the number of AYP who would be interested in HIVST in Uganda and the implication of this on household social relations and social harms (quantitative methods).

## THEORETICAL ORIENTATION

HIV-ST in low-resource settings is still a novel and emerging HIV testing strategy intended to address challenges of several persisting barriers associated with current HIV testing models and increasing access to preliminary knowledge of one's HIV status.<sup>37 38</sup> In order to explore the knowledge, acceptability and social implications of HIVST in the two low-resource countries, we will adopt the technology acceptance model<sup>39 40</sup> that has evolved to become a key behavioural model in understanding predictors of human behaviour towards potential end-user acceptance or rejection of new technology.<sup>41 42</sup> It posits that perceived usefulness and perceived ease of use of a new technology predicts the behavioural intention to use technology, which subsequently correlates with its actual use.<sup>41</sup>

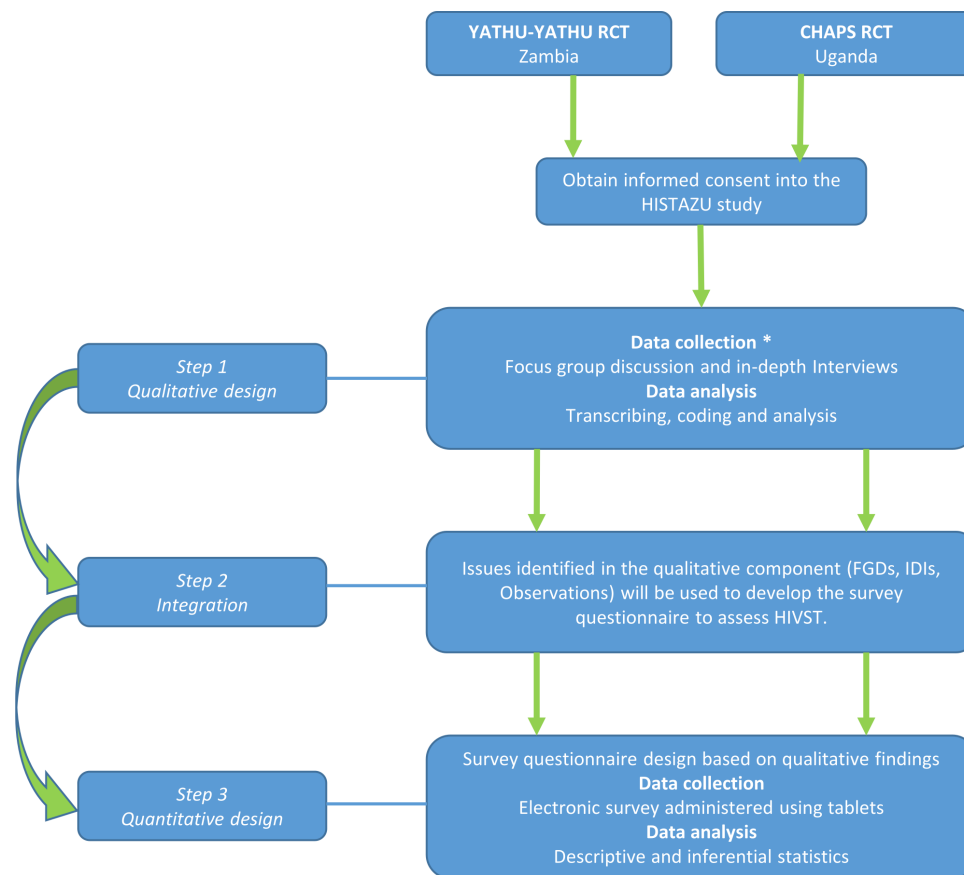
## METHODS

We will conduct a cross-country mixed methods study drawing on a sample of AYP participating in two different ongoing randomised control trials (RCTs) being implemented in Uganda and Zambia. In this study, we will build on the exploratory qualitative findings detailing individuals' experiences and perceptions to inform the development of the quantitative survey (figure 1).

## DESCRIPTION OF THE STUDY SETTING

### Description of Zambian RCT and study setting

The 'Yathu-Yathu' ('For us, By us') study is a cluster randomised trial codesigned with AYP that aims to evaluate the impact of a comprehensive community-based, peer-led sexual reproductive health (SRH) service on the knowledge of HIV status and coverage of key SRH services among AYP aged 15–24 years old.<sup>43 44</sup> Using peer support workers (PSW), the study also provides adolescents with HIVST kits and support for testing and linkage to confirmatory testing and ART. Services are delivered through the Yathu-Yathu hubs which are fixed spaces in the community linked to but located away from the local health facilities. The day-to-day management of the hubs is by PSWs who are themselves young people, with support



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#### Zambia

- Adolescents and young people accessing HIVST services from the Yathu-Yathu hubs
- AYP testing positive through the model
- young couples accessing testing kits through secondary distribution
- Peer support workers (PSWs)
- PSW Supervisors
- Nurses working with AYP

#### Uganda

- AYP residing in the 3 CHAPS communities
- Peer mobilisers working with the AYP

**Figure 1** HISTAZU study flow diagram. AYP, adolescents and young people; CHAPS, Combined HIV Adolescent PrEP and Prevention Study; FGD, focus group discussion; HIVST, HIV self-testing; IDI, in-depth interview.

from supervisors and rotating nurses who are trained in the provision of adolescent-friendly health services.

The Yathu-Yathu study is being conducted in Kanyama and Chipata communities based in Lusaka, Zambia. These two communities were part of the HPTN 071 (PopART) trial, a large community randomised trial that evaluated the impact of a door-to-door universal test and treat<sup>20</sup> intervention on HIV incidence.<sup>45</sup> Details of these settings and the PopART study have been provided elsewhere.<sup>43 46</sup>

#### Description of the Ugandan RCT and study setting

The Combined HIV Adolescent PrEP and Prevention study<sup>47</sup> is a multisite, open-label, randomised controlled trial assessing oral PrEP to protect men from HIV infection using

foreskin tissue to estimate protection.<sup>47</sup> The study involves community sampling of young people aged 13–24 years from areas of Kigungu, Gerenge, Nakawuka and Entebbe municipality in Wakiso district. These fishing communities have a big vibrant young population with a known presence of transient sex workers and fisherfolk populations operating in mini commercial and residential towns characterised by a notable lack of urban planning and poor housing.<sup>48</sup> Local community-based organisations provide sporadic HIV prevention outreach services like information dissemination, condom distribution, mobile HIV counselling, and testing and male circumcision services. Details of these settings have been provided elsewhere.<sup>47 49</sup>

The study is based on the premise that currently, HIV prevention programmes within sub-Saharan Africa have had limited effect, despite high levels of HIV/AIDS awareness. One of the key concerns is that few studies assess the cultural context within which adolescents practice risk behaviour and the gender dynamics influencing risk behaviour decisions. It is important to note that HIVST has been rolled out and is available in public health facilities in Zambia<sup>50 51</sup> while based on evidence from research studies and pilot programmes, the Uganda Ministry of Health is currently considering introducing oral HIVST kits.<sup>33 34 52 53</sup>

## STUDY DESIGN

### Qualitative study design

In both countries, an exploratory qualitative research design will be employed to guide research activities and provide deeper insight into the perceptions and opinions of the participants about HIVST. Qualitative research methods will be appropriate for this study because of their ability to collect data on health, which is embedded in the social, political and economic factors that influence health and disease among individuals.<sup>54 55</sup> Using this line of inquiry, the study will provide a better understanding of experiences of AYP accessing HIVST through the peer-to-peer model and their decision-making process including factors influencing linkage to care for those AYP testing HIV-positive. This will provide a rich understanding of factors influencing linkage to confirmatory testing and care for those testing positive after an HIVST.

### Quantitative study design

A cross-sectional quantitative survey will be conducted in Uganda among 200 young people and adolescents aged 15–24 years (n=200; 100 males and 100 females). The survey will be designed and developed based on the preliminary findings from the qualitative work and therefore a precise definition of the outcome will be defined post qualitative data analysis. In Zambia, as part of the parent study, a process evaluation is being used to collect quantitative data through the Yathu-Yathu hubs regarding the utilisation of SRH services and HIVST uptake. This data are collected using the hubs' standardised electronic data collection system and will be used as comparative data.

### Study population

The primary population for this study will consist of AYP both male and female, aged between 15 and 24 years of age accessing HIVST services being provided through the Yathu-Yathu intervention in Zambia and the participants residing in areas where the CHAPS study is being conducted in Uganda.<sup>50 56</sup> The second study population will comprise hub supervisors and PSWs distributing HIVST kits in the Yathu-Yathu intervention in Zambia and the peer mobilisers involved and supporting the Ugandan CHAPS trial.

## SAMPLING PROCEDURE AND SAMPLE SIZE

### Qualitative study

Purposive sampling will be used to recruit participants.<sup>57 58</sup>

The participants are chosen according to defined criteria, specifically to provide information on the subject of investigation from their viewpoint/position. We have two principal aims in this selection: the first is to ensure that all the key constituencies of relevance to the subject matter are covered. The second is to ensure that, within each of the key criteria, some diversity is included so that the impact of the characteristics concerned can be explored.<sup>57 58</sup>

The sample units will be chosen because they have particular features or characteristics that will enable detailed exploration and understanding of the central themes and outstanding questions relating to HIVST that we wish to study. In Zambia, we will work together with PSWs and their supervisors and nurses to select participants coming to hubs from different zones, ages and gender groups to have representation across the range of study recipients. In Uganda, participants will be identified following the village information meetings and peer mobilisation with support from the Community Health Extension Workers formerly Village Health Teams supporting the CHAPS trial.<sup>56</sup> Participants will be purposively sampled to obtain data representing the different adolescents and young people enrolled into the CHAPS study. Some participants may also be selected from those who volunteer to take part. Where possible, partners of participants will be invited to participate and the safety and privacy of these participants will be paramount.

### Quantitative study

In Zambia, through a process evaluation, quantitative data which is being collected routinely on the number of AYP accessing HIVST and linking to care will be used to answer research questions for this study. In Uganda, 200 participants (100 males and 100 females) for the quantitative survey will be randomly selected to participate and to provide sufficient precision when estimating study summary measures. The sample size to be recruited will help us determine whether it is possible to recruit sufficient numbers of participants to participate in the planned replication study similar to the Zambia study in the future. We will identify and invite the maximum possible number of participants to participate in the quantitative survey, to generate the most robust estimate of recruitment rates possible. Being an exploratory study, we hope to generate new hypotheses from the qualitative findings that can then be formally tested. Qualitatively, we aim to look for patterns of response that will be verified quantitatively.

### Data collection

In Zambia, qualitative activities will include one audio recorded FGD in each community with two groups of AYP (AYP 15–17 years and 18–24 years) accessing HIVST services from the hubs will be conducted to elucidate the experiences and contextual factors influencing

**Table 1** Qualitative data collection activities for the Zambian sites

Sn	Category of participants	Number of participants
1	FGDs with AYP accessing HIVST services from the hubs—two FGDs per community with two separate groups (AYP 15–17 years and 18–24 years) and each FGD with approximately 8–10 participants.	40
2	AYP testing positive through the model in the two age categories (AYP 15–17 years and 18–24 years).	12
3	IDIs with young couples (aged 18–24 years) accessing testing kits through secondary distribution (distribution through a primary recipient that is, partner) within 1 year.	15
4	Peer support workers (PSWs) to participate in group discussions.	20
5	Nurses working with AYP.	2
6	PSW Supervisors.	2

AYP, adolescents and young people; FGD, focus group discussion; HIVST, HIV self-testing; IDI, in-depth interview.

the implementation, feasibility and acceptability of the peer-led model of HIVST among AYP in Lusaka. Additional audio recorded in-depth interviews (IDIs) with AYP testing positive through the model (n=12 participants, with each participant interviewed twice) will be conducted to document the effectiveness of the peer-led model to support linkage to confirmatory testing and clinic-based or hub-initiated ART in two urban communities in Lusaka. These participants testing HIV positive will be identified purposively through peer counsellors providing HIVST in the hubs.

To explore the perception and experiences of young couples with a secondary distribution of HIVST and the implication of this on household social relations, social harms, linkage to confirmatory testing and clinic-based or hub-initiated ART, IDIs with a group of young couples aged 18–24 years (n=10 participants) accessing testing kits through secondary distribution within 1 year will also be conducted. To triangulate data sources, audio-recorded interviews with PSW (n=2 participants), PSW supervisors (n=2 participants), and nurses (n=2 participants) will also be conducted across the two sites. Additionally, longitudinal observation of HIVST service delivery (n=10 participants) by PSW through the Yathu-Yathu hubs will be done by a social science research assistant. Field notes will be taken during these observations. See [table 1](#) for details of the research activities.

Quantitative data for this study will be collected through the main Yathu-Yathu study data collection procedures.

In Uganda, six audio-recorded group discussions (n=60 participants) and up to 20 audio-recorded IDIs will be conducted with AYP (n=14 participants) and peer mobilisers (n=6 participants) to explore possible barriers and facilitators, perceptions around a preference for distribution models, points of access, type of test kit (blood-based or oral) and interviews to access usability of test kits among AYP in Uganda. Group discussion is a useful method for collecting general community perspectives and shared experiences of a given research issue. This method allows the researcher to elicit a wide variety of different views about a particular issue while providing the opportunity for the researcher to observe how individuals collectively make sense of a phenomenon and construct meanings around it.<sup>59</sup> This will be instrumental in starting the discussion concerning how people talk about HIVST and the meanings they attach to it. In all group discussions across the two countries, a topic guide with semi-structured questions and probes will be used (see online supplemental file 1). Each group discussion will comprise 8–10 participants. Each FGD will be conducted by two researchers: one moderating the discussion with the other observing and taking notes of the proceedings. See [table 2](#) for details of the research activities. Researchers will also follow-up on issues as they emerge and these will be further explored during the IDIs.

Additionally, the survey will be pilot tested among the adolescent peer mobilisers of the CHAPS trial. Feedback from the pilot will be used to make additional necessary

**Table 2** Data collection activities for the Ugandan sites

Sn	Category of participants	Number of participants
1	AYP residing in three communities where CHAPS study is being implemented will participate in the FGDs: Two FGDs per community with two separate groups and each FGD with approximately 8–10 participants.	60
2	AYP residing in communities where CHAPS study is being implemented will participate in the in-depth interviews.	14
3	AYP residing in communities where CHAPS study is being implemented will participate in the survey.	200
4	Peer mobilisers working with AYP in communities where CHAPS study is being implemented.	06

AYP, adolescents and young people; CHAPS, Combined HIV Adolescent PrEP and Prevention Study; FGD, focus group discussion.



adjustments to the survey tools. The final survey will be translated into Luganda; the main language spoken at the study sites. Participant consent or assent will be obtained from eligible participants, who will be asked to complete a once-off interviewer-administered structured survey, using an electronic data capture device using a tablet or laptop. The survey will be expected to last approximately 45 min. Surveys will be completed at a private venue that is convenient for the participant.

## DATA ANALYSIS

### Qualitative data management and analysis

All audio-recorded interviews and FGDs will be transcribed verbatim and during the transcription process, translated from local languages into English. The transcripts, alongside the audio recordings and notes taken during the data collection, will be reviewed to ensure consistency and make sure meaning is not lost during the translation. Observations noted will also be typed and saved in Microsoft Word and saved on a password-protected computer.

Using the thematic-content data analysis approach, all parts of the data transcripts and notes from observations will be managed through ATLAS.ti version 9, and open coded to inductively identify possible codes.<sup>54 60</sup> The full transcripts will be read several times to ensure the context of the data is understood. Similar codes emerging from the data will then be merged and a final codebook, which will have a list of all codes related to knowledge, feasibility, acceptability, and social implications of a peer-to-peer distribution model, will be developed. Each code in the codebook will be given a definition. This definition will facilitate consistent coding of all transcripts across the two countries. After this, all codes in ATLAS.ti V.9 will then be renamed and redefined following those coded in the codebook. A second (final) coding phase of all the data using the redefined final codebook will then be conducted by the team. Once the coding of all the data is completed, data outputs from ATLAS.ti V.9 using the query tool for specific themes will then be produced and shared among the two cross country teams and these will act as units of analysis. Each team will read the outputs and conference calls will be held to discuss the outputs including emerging themes from the data followed by writing up themed summaries that will act as units of analysis.

### Quantitative analysis plan

Quantitative data generated from the survey in Uganda and the process evaluation in Zambia will be analysed using Statistical Package for the Social Sciences (SPSS) or Stata. A statistical analysis plan will be developed; preliminary analyses will include a check for missing values, data range and outliers. Normality will be examined using Q-Q plots and continuous data will be assessed for transformations or categorisations. Bivariate analyses will include  $\chi^2$  and Fisher's exact tests to compare categorical

variables, and t-tests or Wilcoxon tests for continuous variables. Descriptive statistics will be used to describe the study sample and assess factors associated with the perceptions, facilitators and barriers to self-testing among AYP. The precise definition of the outcome will be defined during the formative research. Multivariate logistic regression will be used to estimate OR and 95% CI for associations with HIVST acceptability. In all analyses, p values will be two sided and considered statistically significant at  $p < 0.05$ . Additional detail is shown in online supplemental file 2.

## DISCUSSION

HIV testing is an entry point for all HIV-related prevention, care and treatment services and an essential step in achieving 'the UNAIDS 90–90–90 targets'.<sup>61</sup> Adolescence is one of life's critical transitions and encouraging and reaching many AYP who do not know their HIV serostatus is an urgent global priority.<sup>62</sup> While both the Zambian and Ugandan governments are keen to have more people, including AYP, know their HIV status, the overall uptake of HTS among AYP is currently suboptimal in both countries.

As countries move towards integrating HIVST into national policies and regulations, additional evidence is needed on different community-based models of distributing HIVST that will complement facility-based HTS. This study will provide this additional evidence for the Ministries of Health in both countries on whether a community-based peer-to-peer/social network (P2P/SN) distribution model can improve uptake of HIVST and support linkage to confirmatory testing and ART care among adolescents accessing HIV services. It will further bring to the fore perceptions and contextual factors likely to influence the implementation and acceptability of a P2P/SN distribution models of HIVST among AYP in Entebbe Uganda.

There is a global interest in appropriate, innovative and responsive strategies in providing HIV testing to AYP that can supplement health facility-based models. Evidence from this study therefore will provide this much-needed information to shape the integration and scaling up of an appropriate and youth-friendly model of delivering HIVST services in Zambia and Uganda. In addition, this study will provide evidence that will influence policies that will enhance appropriate community-based HIVST distribution models that will effectively reach adolescents, improve linkage to care and support as well as minimise stigma experiences and social harms. This will lead to more adolescents knowing their status and being able to act on it in both Uganda and Zambia. The study will collect much-needed data to develop, advocate, plan, implement and monitor HIVST interventions for AYP. We will support the scale-up of HIV testing, counselling and linkage to care among AYP.

## ETHICS AND DISSEMINATION

This study has received approval from the Uganda Virus Research Institute Research and Ethics committee (GC/127/20/05/767), Uganda National Council for Science and Technology (SS446ES), University of Zambia Biomedical Ethics Committee, Zambia National Health Research Authority (1251–2020) and the London School of Hygiene and Tropical Medicine (Ethics ref 22588).

Participants will be informed of their rights to confidentiality, voluntary participation and the right to withdraw before or during the data collection. Qualitative and quantitative data will be anonymised with pseudonyms and unique identifier codes, and any personally identifiable information will be removed. Dissemination activities will involve publications in peer-reviewed journals, presentations at regional and international conferences, and dissemination workshops for the communities where the study will be conducted.

### Patient and public involvement statement

The patients were not involved in the design of the study. The study will utilise participants from CHAPS trial - ClinicalTrials.gov Identifier: NCT03986970 in Uganda and the Yathu Yathu intervention - ClinicalTrials.gov Identifier: NCT04060420 in Zambia.

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