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# **BMJ Open**

Assessing the knowledge, acceptability and social implications of a peer-to-peer HIV Self-testing kit distribution model among adolescents aged 15 to 24 in Zambia and Uganda: a mixed methods study protocol.

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Assessing the knowledge, acceptability and social implications of a peer-to-peer HIV Self-testing kit distribution model among adolescents aged 15 to 24 in Zambia and Uganda: a mixed methods 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 (HTS) such as privacy and confidentiality. There are a number of suggested HIVST distribution models. However, theymay not be responsive to the testing services needs of Adolescents and Young People (AYP). We will investigate the knowledge, acceptability, and social implications of a peer-to-peer distribution model of HIV self-testing kits on uptake of HIV testing services and linkage to ART among Adolescent and Young People aged 15 to 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. The quantitative data will be collected through a structured survey questionnaire derived from the preliminary findings of the qualitative work and process evaluation quantitative data collected on uptake of services. All IDIs and FGDs will be transcribed, coded and analysed through a thematic-content analysis approach while the quantitative data will be analysed through bivariate analyses. Defining the prevention uptake needs for AYP who find it difficult to access prevention services is critical and HIVST can be a valuable addition to the prevention tools for AYP. 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.

**Keywords:** HIV, self-testing, adolescents, young people, sub-Saharan Africa, knowledge, acceptability, social implications, peer-to-peer, Uganda, Zambia

## Strength and Limitations of this study

This study protocol outlines a a multi-country exploratory mixed methods study to achieve a comprehensive overview of HIVST among adolescents and young people aged 15-24 years in Uganda and Zambia.

By studying adolescents in two sub-Saharan African countries, we will be able to understand AYP's vulnerabilities and barriers to HIVST and accessing healthcare systems necessary for prevention support.

Using the mixed-methods approach, we are able to provide real-life contextual understandings and multilevel perspectives and allows for a rich understanding of the views and experiences of adolescents and young people on HIVST.

The findings of this study will guide the development of AYP friendly strategies to facilitate the successful implementation and delivery of HIVST in adolescent HIV prevention and care.

A selective sample from on-going RCTs may not reflect representativeness of the 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 [1-3]. 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 re-infection and protect their partners. However, AYP are less likely to test for HIV and when sero-positive, immediately link to age-appropriate HIV specialty care yet they represent a growing share of people living with HIV worldwide.[4-6]

In 2020, AYP aged 10-24 accounted for over 410,000 (194,000-690,000) new HIV infections, with young women aged 15-24 years having the highest HIV incidence rates in Africa.[7, 8] Access to ART has significantly improved the survival of AYP on ART and can significantly contribute to reduced onward transmission.[9, 10] However, reaching zero new infections in this group requires increased coverage of all HIV prevention, HIV testing and care services including linkage to ART and adherence support among AYP in sub-Saharan Africa.[11]

Uptake of HTS amongst 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.[7] 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 sexual risk taking behaviour is common.[12-16] In Zambia, a number of studies and surveys estimate that 55.4% of AYP aged 15-24 know their HIV status.[17-19] The situation is no different in Uganda.[20-24] Results from a National representative survey in Uganda reported that 218 (80%) HIV positive AYP 15-24 years reported themselves as HIV negative or unknown despite high general HIV and sexual reproductive knowledge.[25]

However, even in places where HIV services have been scaled up, AYP still face unique challenges when accessing clinic-based and community HTS. Barriers to testing include: perceived low risk of HIV infection, the emotional burden of dealing with a positive result, absence of support from family and friends, daily mobility linked to livelihood options, social recreation and school, and, health system barriers such as stigma, perceived lack of confidentiality and fear of disrespect by health staff.[26-31] Thus, novel HIV testing strategies are needed with appropriate distribution approaches that can reach adolescents and overcome these challenges that adolescents face when accessing HTS.

One potential strategy is HIV self-testing (HIVST), a process in which a person collects their specimen, performs the test, and interprets their results.[32, 33] Studies of HIVST across sub-Saharan African countries have shown it to beacceptable as it overcomes significant barriers to

clinic-based HTS such as privacy and confidentiality.[34-40] 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 related to HIVST.[35, 36, 39, 41] 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 i.e. partner).[41-44] 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.[45, 46]

Youth-friendly and responsive models of HIVST distribution are needed to provide testing services to AYP who have been underserved by current HIVST distribution models but are still at risk of getting HIV infections.[2, 7] There is a need for effective and age appropriate and responsive HIVST distribution models that can reach AYP that are being missed by the existing distribution approaches.

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 (MSM) and fishermen in Uganda.[47-51] 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 implication of this model on social harms like internalised and experienced stigma. This study will assess the knowledge, acceptability, and social implications of a peer-to-peer distribution model of HIV self-testing kits on uptake of HIV testing services and linkage to ART among adolescents aged 15 to 24 in Zambia and Uganda. The study will further explore any social cultural and study design barriers or facilitators to uptake HIVST.

#### Methods

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

## **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 co-designed 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 to 24 years old.[52, 53] Using peer support workers, 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 hubs that 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 peer support workers (PSWs) who are themselves, young people, with support from supervisors and rotating nurses who are trained in the provision of adolescent-friendly health services.

The 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 (UTT) intervention on HIV incidence.[54] Details of these settings and the PopART study have been provided elsewhere.[27, 52]

## Description of the Ugandan RCT and study setting

The Combined HIV Adolescent PrEP and Prevention study (CHAPS) study is a multi-site, open-label, randomised controlled trial assessing oral PrEP to protect men from HIV infection using foreskin tissue to estimate protection.[55] 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.[56] Local community-based organizations 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.[55, 57] The study is based on the premise that currently, HIV prevention programs 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.

## Study design

## Qualitative study design

In both countries, an exploratory qualitative research design will be employed to guide research activities. 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.[58, 59] 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 amongst 200 young people and adolescents aged 15-24 years (N=200; N=100 males and N= 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 utilization of SRH services and HIVST uptake. This data is 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' resident in areas where the CHAPS study is being conducted in Uganda.[60, 61] The second study population will be comprised of hub supervisors and peer support workers 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**

In Zambia, purposive sampling will be used to recruit participants.[62, 63] We will work together with peer support workers and their supervisors and nurses to select participants coming to hubs from the 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 (CHEWs) formerly Village Health Teams (VHTs) supporting the CHAPS trial [61]. 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 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 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. 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.

#### **Data collection**

In Zambia, qualitative activities will include, one audio-recorded focus group discussion in each community with two groups of AYP (AYP 15-17 years & 18-24 years) accessing HIVST services from the hubs will be conducted to elucidate the experiences and contextual factors influencing the implementation and acceptability of the peer-led model of HIVST amongst AYP in Lusaka. Additional audio recorded in-depth interviews with AYP testing positive though the model (n=12, 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.

To explore 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, in-depth interviews with a group of young couples aged 18 to 24 years (n=10) accessing testing kits through secondary distribution within one year will also be conducted. To triangulate data sources, audio-recorded interviews with PSW (n=2), PSW-supervisors (n=2), and nurses (n=2) will also be conducted across the two sites. Additionally, longitudinal observation of HIVST service delivery (n=10) 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 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) and up to 20 audio-recorded in-depth interviews will be conducted with AYP (n=14) and peer mobilisers (n=6) 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.[64] This will be instrumental in starting the discussion concerning how people talk about HIV self-testing 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 supplementary file). Researchers will also follow up on issues as they emerge. 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 research activities.

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 adjustments to the survey tools. The final survey will be translated into Luganda; the main langue spoken in 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 minutes. Surveys will be completed at a private venue that is convenient for the participant.

Sample size for qualitative and quantitative methods

Table 1: Qualitative data collection activities for the Zambian sites

Sn	Category of participants	Sample size
1	FGDs with AYP accessing HIVST services from the hubs - Two FGDs per	40
	community with two separate groups (AYP 15-17 years & 18-24 years.)	
	with each FGD with approximately 8-10 participants.	
2	AYP testing positive through the model in the two age categories (AYP	12
	15-17 years & 18-24 years).	

3	IDIs with young couples (aged 18 to 24 years) accessing testing kits	15
	through secondary distribution (distribution through a primary recipient i.e.	
	partner) within one year.	
4	Peer support workers (PSWs) to participate in group discussions	20
5	Nurses working with AYP.	2
6	PSW-Supervisors	2

Table 2: Data collection activities for the Ugandan sites

Sn	Category of participants	Sample size
1	AYP residing in communities where CHAPS study is being implemented	14
	will participate in the in-depth interviews.	
2	AYP residing in communities where CHAPS study is being implemented	60
	will participate in FGDs	
3	AYP residing in communities where CHAPS study is being implemented	200
	will participate in the survey	
3	Peer mobilisers working with AYP in communities where CHAPS study is	06
	being implemented	

## **Data analysis**

## Qualitative Data management and analysis

All audio recorded interviews and FGDs will be transcribed and during the transcription process, translated from local languages into English. Observations noted will also be typed and saved in Microsoft Word and saved on a password protected computer.

Using the thematic 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.[58, 65] 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, 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 version 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 version 9 using the query tool for specific themes will then be produced and shared amongst 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 categorizations. Bivariate analyses will include Chi-square 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 of 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 odds ratios (OR) and 95% Cumulative Interval (CI) for associations with HIV self-testing acceptability. In all analyses, p-values will be two-sided and considered statistically significant at p<0.05.

#### **Discussion**

HIV testing is an entry point for all HIV-related care and treatment services and an essential step in achieving "the UNAIDS 90–90-90 targets".[66] Adolescence is one of life's critical transitions and encouraging and reaching many AYP who do not know their HIV sero-status is an urgent global priority [10]. 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 amongst 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 upon 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.

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We acknowledge the studies and participants within which the study will be conducted.

#### **Authors' contributions**

All authors contributed to the overall study design and specific methodologies. All authors approved the final version for submission.

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## **Competing interests**

The authors declare that they have no competing interests.

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#### References

- 1. Gore, F.M., et al., *Global burden of disease in young people aged 10–24 years: a systematic analysis.* The Lancet, 2011. **377**(9783): p. 2093-2102.
- Joint United Nations Programme on HIV/AIDS. All In to #EndAdolescentAIDS. 2015 [cited 2019 29 September]; Available from: http://www.unaids.org/sites/default/files/media asset/20150217 ALL IN brochure.pdf.
- 3. World Health Organization, *Global accelerated action for the health of adolescents (AA-HA!):* guidance to support country implementation. . 2017, World Health Organization,: Geneva.
- 4. Committee on Pediatric AIDS, *Adolescents and HIV infection: the pediatrician's role in promoting routine testing.* 2011, Am Acad Pediatrics.
- 5. Staveteig, S., et al., Reaching the 'first 90': Gaps in coverage of HIV testing among people living with HIV in 16 African countries. PLoS One, 2017. **12**(10): p. e0186316.
- 6. Kidman, R., J. Waidler, and T. Palermo, *Uptake of HIV testing among adolescents and associated adolescent-friendly services.* BMC Health Serv Res, 2020. **20**(1): p. 881.
- 7. UNICEF. *HIV and AIDS in adolescents*. Turning the tide against AIDS will require more concentrated focus on adolescents and young people 2021 July 2021 [cited 2021 12 August]; Available from: https://data.unicef.org/topic/adolescents/hiv-aids/.
- 8. UNAIDS. Global HIV statistics Fact sheet 2021. Preliminary UNAIDS 2021 epidemiological estimates 2021 [cited 2021 02 September]; Available from:

  <a href="https://embargo.unaids.org/static/files/uploaded\_files/UNAIDS\_2021\_FactSheet\_en\_em.pd">https://embargo.unaids.org/static/files/uploaded\_files/UNAIDS\_2021\_FactSheet\_en\_em.pd</a>
  f.
- 9. Johnson, L.F., et al., *Life expectancies of South African adults starting antiretroviral treatment: collaborative analysis of cohort studies.* PLoS medicine, 2013. **10**(4): p. e1001418.
- 10. Johnson, C., et al., *Realizing the potential for HIV self-testing*. AIDS and Behavior, 2014. **18**(4): p. 391-395.
- 11. Joint United Nations Programme on HIV/AIDS, HIV Prevention among Adolescent Girls and Young Women: Putting HIV Prevention among Adolescent Girls and Young Women on the Fast-Track and Engaging Men and Boys Fast-Tracking HIV Prevention Among Adolescent Girls and Young women. 2016, UNAIDS.
- 12. Joint United Nations Programme on HIV/AIDS, 90-90-90: An ambitious treatment target to help end the AIDS epidemic. 2014, UNAIDS: Geneva, Switzerland.
- 13. Wong, V.J., et al., *Adolescents, young people, and the 90–90–90 goals: a call to improve HIV testing and linkage to treatment.* AIDS (London, England), 2017. **31**(Suppl 3): p. S191.
- 14. Govender, K., et al., HIV Prevention in Adolescents and Young People in the Eastern and Southern African Region: A Review of Key Challenges Impeding Actions for an Effective Response. Open AIDS J, 2018. 12: p. 53-67.
- 15. Govindasamy, D., et al., *Uptake and yield of HIV testing and counselling among children and adolescents in sub-Saharan Africa: a systematic review.* J Int AIDS Soc, 2015. **18**(1): p. 20182.
- 16. Shanaube, K., et al., HIV Care Cascade Among Adolescents in a "Test and Treat" Community-Based Intervention: HPTN 071 (PopART) for Youth Study. J Adolesc Health, 2021. **68**(4): p. 719-727.
- 17. Ministry of Health Zambia, *Zambia Population-based HIV Impact Assessment (ZAMPHIA)* 2017, Ministry of Health: Lusaka.
- 18. Asiimwe, S., et al., *Accuracy of un-supervised versus provider-supervised self-administered HIV testing in Uganda: a randomized implementation trial.* AIDS and behavior, 2014. **18**(12): p. 2477-2484.
- 19. Heri, A.B., et al., Changes over time in HIV testing and counselling uptake and associated factors among youth in Zambia: a cross-sectional analysis of demographic and health surveys from 2007 to 2018. BMC Public Health, 2021. **21**(1): p. 456.

- 20. Siu, G.E., et al., *HIV serostatus disclosure and lived experiences of adolescents at the Transition Clinic of the Infectious Diseases Clinic in Kampala, Uganda: a qualitative study.* AIDS Care, 2012. **24**(5): p. 606-11.
- 21. Mutumba, M., et al., *Disclosure of HIV Status to Perinatally Infected Adolescents in Urban Uganda: A Qualitative Study on Timing, Process, and Outcomes.* J Assoc Nurses AIDS Care, 2015. **26**(4): p. 472-84.
- 22. Nabunya, P., et al., Factors Associated With HIV Disclosure and HIV-Related Stigma Among Adolescents Living With HIV in Southwestern Uganda. Front Psychiatry, 2020. **11**: p. 772.
- 23. Doat, A.R., R. Negarandeh, and M. Hasanpour, *Disclosure of HIV Status to Children in Sub-Saharan Africa: A Systematic Review.* Medicina (Kaunas), 2019. **55**(8).
- 24. Butler, L., et al., *Increasing pediatric HIV disclosure to children in Uganda, Project SOAR Results Brief.* 2017, Population Council.: Washington, DC.
- 25. Kenyon, C.R., et al., Who Knows Their Partner's HIV Status? Results From a Nationally Representative Survey in Uganda. J Acquir Immune Defic Syndr, 2015. **69**(1): p. 92-7.
- 26. Musheke, M., et al., A systematic review of qualitative findings on factors enabling and deterring uptake of HIV testing in Sub-Saharan Africa. BMC public health, 2013. **13**(1): p. 220.
- 27. Bond, V., et al., "The difference that makes a difference": highlighting the role of variable contexts within an HIV Prevention Community Randomised Trial (HPTN 071/PopART) in 21 study communities in Zambia and South Africa. AIDS care, 2016. **28**(sup3): p. 99-107.
- 28. Shanaube, K., et al., What works—reaching universal HIV testing: lessons from HPTN 071 (PopART) trial in Zambia. AIDS (London, England), 2017. **31**(11): p. 1555.
- 29. Mwisongo, A., et al., *Barriers and facilitators associated with HIV testing uptake in South African health facilities offering HIV Counselling and Testing*. Health SA Gesondheid, 2016. **21**(1): p. 86-95.
- 30. Bagchi, A.D. and T. Davis, *Clinician Barriers and Facilitators to Routine HIV Testing: A Systematic Review of the Literature*. Journal of the International Association of Providers of AIDS Care (JIAPAC), 2020. **19**: p. 2325958220936014.
- 31. Qiao, S., et al., Facilitators and barriers for HIV-testing in Zambia: A systematic review of multi-level factors. PLoS One, 2018. **13**(2): p. e0192327.
- 32. World Health Organization, *Consolidated Guidelines on HIV Testing Services: 5Cs: consent, confidentiality, counselling, correct results and connection 2015.* 2015.
- 33. World Health Organization, *Guidelines on HIV self-testing and partner notification:* supplement to consolidated guidelines on HIV testing services. 2016: World Health Organization.
- 34. Kalibala, S., et al., Factors associated with acceptability of HIV self-testing among health care workers in Kenya. AIDS and Behavior, 2014. **18**(4): p. 405-414.
- 35. Kumwenda, M., et al., Factors shaping initial decision-making to self-test amongst cohabiting couples in urban Blantyre, Malawi. AIDS and Behavior, 2014. **18**(4): p. 396-404.
- 36. Kurth, A.E., et al., *Accuracy and acceptability of oral fluid HIV self-testing in a general adult population in Kenya*. AIDS and Behavior, 2016. **20**(4): p. 870-879.
- 37. Pant Pai, N. and M.B. Klein, Are we ready for home-based, self-testing for HIV? 2008.
- 38. Vara, P.A., et al., Level of knowledge, acceptability, and willingness to use oral fluid HIV self-testing among medical students in Kilimanjaro region, Tanzania: a descriptive cross-sectional study. AIDS Res Ther, 2020. **17**(1): p. 56.
- 39. Harichund, C. and M. Moshabela, *Acceptability of HIV Self-Testing in Sub-Saharan Africa: Scoping Study.* AIDS Behav, 2018. **22**(2): p. 560-568.
- 40. Harichund, C., et al., *Acceptability of HIV self-testing among men and women in KwaZulu-Natal, South Africa*. AIDS Care, 2019. **31**(2): p. 186-192.
- 41. Hensen, B., et al., Frequency of HIV-testing and factors associated with multiple lifetime HIV-testing among a rural population of Zambian men. BMC public health, 2015. **15**(1): p. 960.
- 42. Choko, A.T., et al., Acceptability of woman-delivered HIV self-testing to the male partner, and additional interventions: a qualitative study of antenatal care participants in Malawi. Journal of the International AIDS Society, 2017. **20**(1): p. 21610.

- 43. Offorjebe, O.A., et al., *Acceptability of index partner HIV self-testing among HIV-positive clients in Malawi: A mixed methods analysis.* PLoS One, 2020. **15**(7): p. e0235008.
- 44. Hensen, B., et al., Who Accepts and Who Uses Community-Based Secondary Distribution HIV Self-Testing (HIVST) Kits? Findings From the Intervention Arm of a Cluster-Randomized Trial of HIVST Distribution Nested in Four HPTN 071 (PopART) Communities in Zambia. J Acquir Immune Defic Syndr, 2020. **84**(4): p. 355-364.
- 45. Ministry of Health Zambia, Zambia Country Report (UNGASS): Monitoring the declaration of commitment on HIV and AIDS and the Universal access-Biennial Report January 2013-December 2014. 2015, Ministry of Health & National AIDS Council Zambia: Lusaka.
- 46. Mulubwa, C., et al., Community based distribution of oral HIV self-testing kits in Zambia: a cluster-randomised trial nested in four HPTN 071 (PopART) intervention communities. The Lancet HIV, 2019. **6**(2): p. e81-e92.
- 47. Choko, A.T., et al., *A pilot trial of the peer-based distribution of HIV self-test kits among fishermen in Bulisa, Uganda.* PloS one, 2018. **13**(11): p. e0208191.
- 48. Okoboi, S., et al., *Acceptability, perceived reliability and challenges associated with distributing HIV self-test kits to young MSM in Uganda: a qualitative study.* Journal of the International AIDS Society, 2019. **22**(3): p. e25269.
- 49. Ortblad, K.F., et al., Acceptability of HIV self-testing to support pre-exposure prophylaxis among female sex workers in Uganda and Zambia: results from two randomized controlled trials. BMC infectious diseases, 2018. **18**(1): p. 503.
- 50. Ortblad, K.F., et al., Female sex workers often incorrectly interpret HIV self-test results in Uganda. Journal of acquired immune deficiency syndromes (1999), 2018. **79**(1): p. e42.
- 51. Matovu, J.K.B., et al., Formative research to inform the development of a peer-led HIV self-testing intervention to improve HIV testing uptake and linkage to HIV care among adolescents, young people and adult men in Kasensero fishing community, Rakai, Uganda: a qualitative study. BMC Public Health, 2020. **20**(1): p. 1582.
- 52. Simuyaba, M., et al., Engaging young people in the design of a sexual reproductive health intervention: Lessons learnt from the Yathu Yathu ("For us, by us") formative study in Zambia. BMC Health Serv Res, 2021. **21**(1): p. 753.
- 53. Hensen, B., et al., *Uptake of HIV Testing Services Through Novel Community-Based Sexual and Reproductive Health Services: An Analysis of the Pilot Implementation Phase of the Yathu Yathu Intervention for Adolescents and Young People Aged 15-24 in Lusaka, Zambia.* AIDS Behav, 2021.
- 54. Hayes, R., et al., HPTN 071 (PopART): rationale and design of a cluster-randomised trial of the population impact of an HIV combination prevention intervention including universal testing and treatment—a study protocol for a cluster randomised trial. Trials, 2014. **15**(1): p. 57.
- 55. Nash, S., et al., Combined HIV Adolescent Prevention Study (CHAPS): comparison of HIV preexposure prophylaxis regimens for adolescents in sub-Saharan Africa—study protocol for a mixed-methods study including a randomised controlled trial. Trials, 2020. **21**(1): p. 900.
- 56. Sileo, K.M., et al., "Such behaviors are not in my home village, I got them here": A qualitative study of the influence of contextual factors on alcohol and HIV risk behaviors in a fishing community on Lake Victoria, Uganda. AIDS and Behavior, 2016. **20**(3): p. 537-547.
- 57. Muhumuza, R., et al., *Exploring Perceived Barriers and Facilitators of PrEP Uptake among Young People in Uganda, Zimbabwe, and South Africa*. Arch Sex Behav, 2021. **50**(4): p. 1729-1742.
- 58. Pope, C., S. Ziebland, and N. Mays, *Qualitative research in health care: analysing qualitative data.* BMJ: British Medical Journal, 2000. **320**(7227): p. 114.
- 59. Cresswell, W.J. and N.C. Poth, *Qualitative Inquiry & Research Design: Choosing Among Five Approaches*. 4th ed. 2018, Thousand Oaks, California: Sage publications. 646.
- 60. Mulubwa, C., et al., Community based distribution of oral HIV self-testing kits in Zambia: a cluster-randomised trial nested in four HPTN 071 (PopART) intervention communities. Lancet HIV, 2019. **6**(2): p. e81-e92.

- 61. Nash, S., et al., Combined HIV Adolescent Prevention Study (CHAPS): comparison of HIV preexposure prophylaxis regimens for adolescents in sub-Saharan Africa-study protocol for a mixed-methods study including a randomised controlled trial. Trials, 2020. **21**(1): p. 900.
- 62. Robinson, O.C., Sampling in interview-based qualitative research: A theoretical and practical guide. Qualitative research in psychology, 2014. 11(1): p. 25-41.
- 63. Robinson, R.S., Purposive sampling. Encyclopedia of Quality of Life and Well-Being Research, 2014: p. 5243-5245.
- Bryman, A., Social research methods. 2016: Oxford university press. 64.
- Nowell, L.S., et al., Thematic analysis: Striving to meet the trustworthiness criteria. 65.
- 66. Joint United Nations Programme on HIV/AIDS, Ending AIDS: progress towards the 90-90-90



## **Supplement 1**

HIV Self-testing among young people: Assessing the knowledge, acceptability and social implications of a peer-to-peer HIVST distribution model among adolescents aged 15 to 24 in Zambia and Uganda.

(HISTAZU)

## **Qualitative Interview Guide**

#### **Background information**

- Please tell me a little bit about yourself? (hobbies, friends, where you hangout for fun)
- Tell me about the last time you tested for HIV. Why did you decide to test for HIV? Where did you test for HIV? What was your experience of testing for HIV? If NEVER tested for HIV. What are the reasons you have never tested for HIV?

HIV RISK PERCEPTIONS

- How do you think young people that you know are at risk of contracting HIV?
   Probe: which group of people do you think are more at risk: sex, gender, age?
- How do you think you are/ are not at risk of contracting HIV?
- Please tell me about ways that young people (including yourself) are using to protect against HIV.

## Perceptions and motivations of self-testing

- What are your opinion about self-testing? Probe for where to get the kits, price of the kits, ability to read the correct results, who to distribute them, feasibility of young people adapting self-testing
- Please share with some of the perceptions that other young people like you have about self-testing
- What are some of the motivations/facilitators of self-testing?
- Please share with me some of the barriers to self-testing among young people. Probe for counselling needs, fear of the needle prick....
- How can these barriers be overcome?

## **Group Discussion guide for HIVST for AYP**

- 1. What are the current HIV testing services available in this community? **Probe** what is the perception and level of acceptance and use of the existing services by adolescents and young people (AYP)?
- 2. Please share with me what you know or have heard about HIVST and HIVST procedures. *Probe* where they heard it from, their thoughts about HIVST
- 3. What are your views about HIVST? *Probe* for comparison between current routine HIV testing and HIVST?
- 4. When made available, where and how do you think HIVST kits should be accessed and distributed? *Probe* for location i.e. facilities, vendors, peers, clinic, pharmacy, mobile clinics and community centres.

**Probe** for reasons for the selected point of dissemination. Probe for person to disseminate.

Where would you recommend a friend to get HIVST kits? **Probe** Why?

- 5. What are your feelings about receiving them from peers or using a peer to peer distribution model? **Probe** best ways to share information among peers and adolescent and the facilitators and barriers of using peer distributors
- 6. Would you be willing to pay for the Kit? How much would you be willing to pay for it and why? *Probe* what would motivate you to pay?
- 7. What would be the possible challenges associated with using and distributing HIV self-test kits?
- 8. What aspects would encourage you to take up HIVST? *Probe* Potential for a dramatic increase in knowledge of HIV status, increased confidentiality, increased convenience, Autonomy and empowerment).
- 9. What are your concerns about HIVST? **Probe** Greater potential for inaccurate results, Psychological danger when decoupling testing and counselling, Greater difficulty ensuring referral to treatment and care, Potential unethical use of HIV self-testing, Self-testing as justification for unprotected sex, Concern for safe disposal of biohazard materials)
- 10. [Demonstrate for participant the use of the OraQuick kit] then ask What is your comment on the design of the kit and the testing procedures? **Probe** if this is something that would be acceptable to AYP.

- 11. What are your perception /opinions on test accuracy? **Probe** How would you perceive the results, what would you do if the result was negative positive, unclear or you are uncertain?
- 12. Is there anything else you would love to share with me about what we have been discussing or HIV testing in general?

Thank you for accepting to participate in this research study



- 1. What are the current HIV testing services available in this community? **Probe** what is the perception and level of acceptance and use of the existing services by adolescents and young people (AYP)?
- 2. Please share with me what you know or have heard about HIVST and HIVST procedures. **Probe** where they heard it from, their thoughts about HIVST
- 3. What are your views about HIVST? **Probe** for comparison between current routine HIV testing and HIVST?
- 4. When made available, where and how do you think HIVST kits should be accessed and distributed to AYP in your community? Probe for location i.e. facilities, vendors, peers, clinic, pharmacy, mobile clinics and community centres.
  Probe for reasons for the selected point of dissemination. Probe for person to disseminate.

Where would you recommend AYP in your community to get HIVST kits? **Probe** Why?

- 5. What are your thoughts about using a peer to peer distribution model or being a distributor/ contact person for the kits? **Probe** best ways to share information among peers and adolescent and the facilitators and barriers of using peer distributors
- 6. What would be the possible challenges associated with using and distributing HIV self-test kits?
- 7. Would AYP in your community be willing to pay for the Kit? How much would they be willing to pay for it and why? **Probe** what would motivate them to pay?
- 8. What aspects would encourage you to promote uptake HIVST? **Probe** Potential for a dramatic increase in knowledge of HIV status, increased confidentiality, increased convenience, Autonomy and empowerment).
- 9. What are your concerns about HIVST? **Probe** Greater potential for inaccurate results, Psychological danger when decoupling testing and counselling, Greater difficulty ensuring referral to treatment and care, Potential unethical use of HIV self-testing, Self-testing as justification for unprotected sex, Concern for safe disposal of biohazard materials)
- 10. [Demonstrate for participant the use of the OraQuick kit] then ask What is your comment on the design of the kit and the testing procedures? **Probe** if this is something that would be acceptable to AYP.

- 11. What are your perception /opinions on test accuracy? **Probe** How would you perceive the results, what would you do if the result was negative positive, unclear or you are uncertain?
- 12. What strategies can be put in place to support and promote uptake of HIVST among AYP in your community.
- 13. Is there anything else you would love to share with me about what we have been discussing or HIV testing in general?

What would be the best strategies to use to reach out to adolescent boys, adolescent girls; married couples/ those in relationships?

What strategies or distribution channels can we use to effectively reach AYP in your community?

Thank you for accepting to participate in this research study

# **BMJ Open**

Assessing knowledge, acceptability, and social implications of a peer-to-peer HIV self-testing kit distribution model among adolescents aged 15 to 24 in Zambia and Uganda (HISTAZU): a mixed-methods study protocol.

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Assessing knowledge, acceptability, and social implications of a peer-to-peer HIV self-testing kit distribution model among adolescents aged 15 to 24 in Zambia and Uganda - HISTAZU: a mixed-methods 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 (HTS) such as privacy and confidentiality. There are a number of suggested HIVST distribution models. However, they may not be responsive to the testing services needs of adolescents and young people (AYP). We will investigate the knowledge, acceptability, and social implications of a peer-to-peer distribution model of HIV self-testing kits on uptake of HIV prevention: PrEP, condoms, and voluntary medical male circumcision (VMMC) and testing services and linkage to ART among AYP aged 15 to 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 indepth 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.

**Keywords:** HIV, self-testing, adolescents, young people, sub-Saharan Africa, knowledge, acceptability, social implications, peer-to-peer, Uganda, Zambia

## Strength and Limitations of this study

- This study protocol outlines a multi-country exploratory study to understand views on 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-methods approach will provide breadth and depth of understanding of the research questions.
- The use 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 RCTs 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. 1-3. 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 re-infection and protect their partners. However, AYP are less likely to test for HIV and if sero-positive, less likely to immediately link to age-appropriate HIV specialty care, yet they represent a growing share of people living with HIV worldwide. 4-6 It is important to note that reaching zero new infections in this group requires increased coverage of all HIV prevention methods: PrEP, VMMC, condom use, counselling, testing, and care services including linkage to ART and adherence support among AYP in sub-Saharan Africa. 7-10

Uptake of HTS amongst 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</sup> <sup>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</sup> <sup>21</sup> <sup>24</sup> <sup>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 i.e. 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</sup> <sup>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 (MSM) and fishermen in Uganda. 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 implication 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 HIV self-testing 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 to 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 amongst 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 (TAM) <sup>39 40</sup> that has evolved to become a key behavioural model in understanding predictors of human behaviour toward 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 co-designed 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 to 24 years old. 43 44 Using peer support workers, 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 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 peer support workers (PSWs) who are themselves, young people, with support from supervisors and rotating nurses who are trained in the provision of adolescent-friendly health services.

The 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</sup> <sup>46</sup>

## Description of the Ugandan RCT and study setting

The Combined HIV Adolescent PrEP and Prevention study <sup>47</sup> study is a multi-site, 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 organizations 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</sup> <sup>49</sup>

The study is based on the premise that currently, HIV prevention programs 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 HIV self-testing 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</sup> <sup>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 amongst 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 is 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</sup> The second study population will be comprised of hub supervisors and peer support workers 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</sup> <sup>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 peer support workers 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 (CHEWs) formerly Village Health Teams (VHTs) 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 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 focus group discussion in each community with two groups of AYP (AYP 15-17 years & 18-24 years) accessing HIVST services from the hubs will be conducted to elucidate the experiences and contextual factors

influencing the implementation, feasibility, and acceptability of the peer-led model of HIVST amongst AYP in Lusaka. Additional audio recorded in-depth interviews with AYP testing positive though 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 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, in-depth interviews with a group of young couples aged 18 to 24 years (n=10 participants) accessing testing kits through secondary distribution within one 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 in-depth interviews 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 HIV self-testing 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 supplementary 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 adjustments to the survey tools. The final survey will be translated into Luganda; the main langue 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 minutes. Surveys will be completed at a private venue that is convenient for the participant.

The sample groups for qualitative and quantitative methods

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	40
	community with two separate groups (AYP 15-17 years & 18-24 years.)	
	and each FGD with approximately 8-10 participants.	
2	AYP testing positive through the model in the two age categories (AYP	12
	15-17 years & 18-24 years).	
3	IDIs with young couples (aged 18 to 24 years) accessing testing kits	15
	through secondary distribution (distribution through a primary recipient i.e.	
	partner) within one year.	
4	Peer support workers (PSWs) to participate in group discussions	20
5	Nurses working with AYP.	2
6	PSW-Supervisors	2

Table 2: Data collection activities for the Ugandan sites

Sn	Category of participants	Number of
		participants
1	AYP residing in 3 communities where CHAPS study is being implemented	60
	will participate in the FGDs: Two FGDs per community with two separate	
	groups and each FGD with approximately 8-10 participants.	

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	200
3	will participate in the survey	200
3	Peer mobilisers working with AYP in communities where CHAPS study is	06
	being implemented	

## 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 makes 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. 54 60 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 version 9 will then be re-named 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 version 9 using the query tool for specific themes will then be produced and shared amongst 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 categorizations. Bivariate analyses will include Chi-square 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 odds ratios (OR) and 95% Cumulative Interval (CI) for associations with HIV self-testing acceptability. In all analyses, p-values will be two-sided and considered statistically significant at p<0.05. Additional detail is shown in supplementary 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 amongst 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 upon 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.

## **Acknowledgments**

We acknowledge the studies and participants within which the study will be conducted.

### **Authors' contributions**

ASS, CB and RM conceived the idea for the study.

ASS, CB, RM, DN, MM, VB, MS and JS made substantial contributions to the design.

JS, VB and MS helped in study conceptualization, methodology, writing review, supervision and final editing. DN, MM revised the manuscript critically for important intellectual content.

ASS wrote the manuscript. All authors approved the final version of the manuscript to be published.

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### **Competing interests**

The authors declare that they have no competing interests.

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# **Footnotes**

Figure 1 legend: HISTAZU study flow diagram

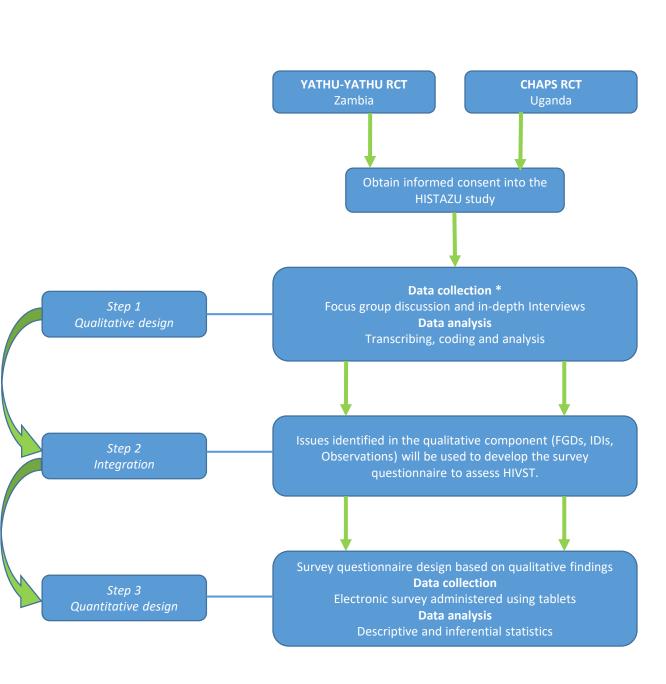
### References

- 1. Gore FM, Bloem PJ, Patton GC, et al. Global burden of disease in young people aged 10–24 years: a systematic analysis. *The Lancet* 2011;377(9783):2093-102. doi: 10.1016/S0140-6736(11)60512-6 [published Online First: 2011/06/10]
- Joint United Nations Programme on HIV/AIDS. All In to #EndAdolescentAIDS.: UNAIDS; 2015
   [Available from:
   <a href="http://www.unaids.org/sites/default/files/media\_asset/20150217\_ALL\_IN\_brochure.pdf">http://www.unaids.org/sites/default/files/media\_asset/20150217\_ALL\_IN\_brochure.pdf</a>
   accessed 29 September 2019.
- 3. World Health Organization. Global accelerated action for the health of adolescents (AA-HA!): guidance to support country implementation. . Geneva: World Health Organization,, 2017.
- 4. Committee on Pediatric AIDS. Adolescents and HIV infection: the pediatrician's role in promoting routine testing: Am Acad Pediatrics, 2011.
- 5. Staveteig S, Croft TN, Kampa KT, et al. Reaching the 'first 90': Gaps in coverage of HIV testing among people living with HIV in 16 African countries. *PLoS One* 2017;12(10):e0186316. doi: 10.1371/journal.pone.0186316 [published Online First: 2017/10/13]
- 6. Kidman R, Waidler J, Palermo T. Uptake of HIV testing among adolescents and associated adolescent-friendly services. *BMC Health Serv Res* 2020;20(1):881. doi: 10.1186/s12913-020-05731-3 [published Online First: 2020/09/19]
- 7. Joint United Nations Programme on HIV/AIDS. HIV Prevention among Adolescent Girls and Young Women: Putting HIV Prevention among Adolescent Girls and Young Women on the Fast-Track and Engaging Men and Boys Fast-Tracking HIV Prevention Among Adolescent Girls and Young women: UNAIDS, 2016.
- 8. The impact of HIV self-testing on recent testing, status knowledge, and linkage to care among female sex workers in Kampala, Uganda: a randomized controlled trial. 9th International AIDS Society Conference on HIV Science Paris, France; 2017.
- 9. Spielberg F, Levine RO, Weaver M. Self-testing for HIV: a new option for HIV prevention? *The Lancet infectious diseases* 2004;4(10):640-46.
- 10. Wurm M, Neumann A, Wasem J, et al. Barriers to Accessing HIV Testing Services A Systematic Literature Review. *Gesundheitswesen* 2019;81(3):e43-e57. doi: 10.1055/a-0668-5621 [published Online First: 2018/10/16]
- 11. UNICEF. HIV and AIDS in adolescents Geveva: UNICEF; 2021 [updated July 2021. Available from: <a href="https://data.unicef.org/topic/adolescents/hiv-aids/">https://data.unicef.org/topic/adolescents/hiv-aids/</a> accessed 12 August 2021.
- 12. Joint United Nations Programme on HIV/AIDS. 90-90-90: An ambitious treatment target to help end the AIDS epidemic. Geneva, Switzerland: UNAIDS, 2014.
- 13. Wong VJ, Murray KR, Phelps BR, et al. Adolescents, young people, and the 90–90–90 goals: a call to improve HIV testing and linkage to treatment. *AIDS (London, England)* 2017;31(Suppl 3):S191. doi: 10.1097/QAD.000000000001539 [published Online First: 2017/07/01]
- 14. Govender K, Masebo WGB, Nyamaruze P, et al. HIV Prevention in Adolescents and Young People in the Eastern and Southern African Region: A Review of Key Challenges Impeding Actions for an Effective Response. *Open AIDS J* 2018;12:53-67. doi: 10.2174/1874613601812010053 [published Online First: 2018/08/21]
- 15. Govindasamy D, Ferrand RA, Wilmore SM, et al. Uptake and yield of HIV testing and counselling among children and adolescents in sub-Saharan Africa: a systematic review. *J Int AIDS Soc* 2015;18(1):20182. doi: 10.7448/ias.18.1.20182
- 20182 [published Online First: 2015/10/17]
- 16. Shanaube K, Macleod D, Chaila MJ, et al. HIV Care Cascade Among Adolescents in a "Test and Treat" Community-Based Intervention: HPTN 071 (PopART) for Youth Study. *J Adolesc Health* 2021;68(4):719-27. doi: 10.1016/j.jadohealth.2020.07.029 [published Online First: 2020/10/17]
- 17. World Health Organization. Consolidated Guidelines on HIV Testing Services: 5Cs: consent, confidentiality, counselling, correct results and connection 2015. 2015

- 18. World Health Organization. Guidelines on HIV self-testing and partner notification: supplement to consolidated guidelines on HIV testing services: World Health Organization 2016.
- 19. Kalibala S, Tun W, Cherutich P, et al. Factors associated with acceptability of HIV self-testing among health care workers in Kenya. *AIDS and Behavior* 2014;18(4):405-14.
- 20. Kumwenda M, Munthali A, Phiri M, et al. Factors shaping initial decision-making to self-test amongst cohabiting couples in urban Blantyre, Malawi. *AIDS and Behavior* 2014;18(4):396-404. doi: 10.1007/s10461-014-0817-9 [published Online First: 2014/06/16]
- 21. Kurth AE, Cleland CM, Chhun N, et al. Accuracy and acceptability of oral fluid HIV self-testing in a general adult population in Kenya. *AIDS and Behavior* 2016;20(4):870-79. doi: 10.1007/s10461-015-1213-9 [published Online First: 2015/10/07]
- 22. Pant Pai N, Klein MB. Are we ready for home-based, self-testing for HIV? 2008
- 23. Vara PA, Buhulula LS, Mohammed FA, et al. Level of knowledge, acceptability, and willingness to use oral fluid HIV self-testing among medical students in Kilimanjaro region, Tanzania: a descriptive cross-sectional study. *AIDS Res Ther* 2020;17(1):56. doi: 10.1186/s12981-020-00311-1 [published Online First: 2020/09/11]
- 24. Harichund C, Moshabela M. Acceptability of HIV Self-Testing in Sub-Saharan Africa: Scoping Study. *AIDS Behav* 2018;22(2):560-68. doi: 10.1007/s10461-017-1848-9 [published Online First: 2017/07/13]
- 25. Harichund C, Moshabela M, Kunene P, et al. Acceptability of HIV self-testing among men and women in KwaZulu-Natal, South Africa. *AIDS Care* 2019;31(2):186-92. doi: 10.1080/09540121.2018.1503638 [published Online First: 2018/07/31]
- 26. Hensen B, Lewis J, Schaap A, et al. Frequency of HIV-testing and factors associated with multiple lifetime HIV-testing among a rural population of Zambian men. *BMC public health* 2015;15(1):960.
- 27. Choko AT, Kumwenda MK, Johnson CC, et al. Acceptability of woman-delivered HIV self-testing to the male partner, and additional interventions: a qualitative study of antenatal care participants in Malawi. *Journal of the International AIDS Society* 2017;20(1):21610. doi: 10.7448/IAS.20.1.21610 [published Online First: 2017/07/12]
- 28. Offorjebe OA, Hoffman RM, Shaba F, et al. Acceptability of index partner HIV self-testing among HIV-positive clients in Malawi: A mixed methods analysis. *PLoS One* 2020;15(7):e0235008. doi: 10.1371/journal.pone.0235008 [published Online First: 2020/07/11]
- 29. Hensen B, Schaap AJ, Mulubwa C, et al. Who Accepts and Who Uses Community-Based Secondary Distribution HIV Self-Testing (HIVST) Kits? Findings From the Intervention Arm of a Cluster-Randomized Trial of HIVST Distribution Nested in Four HPTN 071 (PopART) Communities in Zambia. *J Acquir Immune Defic Syndr* 2020;84(4):355-64. doi: 10.1097/qai.0000000000002344 [published Online First: 2020/03/21]
- 30. Ministry of Health Zambia. Zambia Country Report (UNGASS): Monitoring the declaration of commitment on HIV and AIDS and the Universal access-Biennial Report January 2013-December 2014. Lusaka: Ministry of Health & National AIDS Council Zambia, 2015.
- 31. Mulubwa C, Hensen B, Phiri MM, et al. Community based distribution of oral HIV self-testing kits in Zambia: a cluster-randomised trial nested in four HPTN 071 (PopART) intervention communities. *The Lancet HIV* 2019;6(2):e81-e92.
- 32. Choko AT, Nanfuka M, Birungi J, et al. A pilot trial of the peer-based distribution of HIV self-test kits among fishermen in Bulisa, Uganda. *PloS one* 2018;13(11):e0208191.
- 33. Okoboi S, Twimukye A, Lazarus O, et al. Acceptability, perceived reliability and challenges associated with distributing HIV self-test kits to young MSM in Uganda: a qualitative study. Journal of the International AIDS Society 2019;22(3):e25269. doi: 10.1002/jia2.25269 [published Online First: 2019/04/02]
- 34. Ortblad KF, Chanda MM, Musoke DK, et al. Acceptability of HIV self-testing to support preexposure prophylaxis among female sex workers in Uganda and Zambia: results from two randomized controlled trials. *BMC infectious diseases* 2018;18(1):503.
- 35. Ortblad KF, Musoke DK, Ngabirano T, et al. Female sex workers often incorrectly interpret HIV self-test results in Uganda. *Journal of acquired immune deficiency syndromes (1999)* 2018;79(1):e42.

- 36. Matovu JKB, Nambuusi A, Nakabirye S, et al. Formative research to inform the development of a peer-led HIV self-testing intervention to improve HIV testing uptake and linkage to HIV care among adolescents, young people and adult men in Kasensero fishing community, Rakai, Uganda: a qualitative study. *BMC Public Health* 2020;20(1):1582. doi: 10.1186/s12889-020-09714-1 [published Online First: 2020/10/22]
- 37. Harichund C, Moshabela M. Acceptability of HIV Self-Testing in Sub-Saharan Africa: Scoping Study. *AIDS and behavior* 2018;22(2):560-68. doi: 10.1007/s10461-017-1848-9
- 38. Sundararajan R, Ponticiello M, Nansera D, et al. Interventions to Increase HIV Testing Uptake in Global Settings. *Curr HIV/AIDS Rep* 2022 doi: 10.1007/s11904-022-00602-4 [published Online First: 2022/04/21]
- 39. Venkatesh V, Davis FD. A model of the antecedents of perceived ease of use: Development and test. *Decision sciences* 1996;27(3):451-81.
- 40. Venkatesh V, Davis FD. A theoretical extension of the technology acceptance model: Four longitudinal field studies. *Management science* 2000;46(2):186-204.
- 41. Campbell JI, Aturinda I, Mwesigwa E, et al. The Technology Acceptance Model for Resource-Limited Settings (TAM-RLS): A Novel Framework for Mobile Health Interventions Targeted to Low-Literacy End-Users in Resource-Limited Settings. *AIDS Behav* 2017;21(11):3129-40. doi: 10.1007/s10461-017-1765-y [published Online First: 2017/04/20]
- 42. Nadal C, Sas C, Doherty G. Technology Acceptance in Mobile Health: Scoping Review of Definitions, Models, and Measurement. *J Med Internet Res* 2020;22(7):e17256. doi: 10.2196/17256 [published Online First: 2020/07/07]
- 43. Simuyaba M, Hensen B, Phiri M, et al. Engaging young people in the design of a sexual reproductive health intervention: Lessons learnt from the Yathu Yathu ("For us, by us") formative study in Zambia. *BMC Health Serv Res* 2021;21(1):753. doi: 10.1186/s12913-021-06696-7 [published Online First: 2021/07/31]
- 44. Hensen B, Phiri M, Schaap A, et al. Uptake of HIV Testing Services Through Novel Community-Based Sexual and Reproductive Health Services: An Analysis of the Pilot Implementation Phase of the Yathu Yathu Intervention for Adolescents and Young People Aged 15-24 in Lusaka, Zambia. *AIDS Behav* 2021 doi: 10.1007/s10461-021-03368-9 [published Online First: 2021/07/25]
- 45. Hayes R, Ayles H, Beyers N, et al. HPTN 071 (PopART): rationale and design of a cluster-randomised trial of the population impact of an HIV combination prevention intervention including universal testing and treatment—a study protocol for a cluster randomised trial. Trials 2014;15(1):57. doi: 10.1186/1745-6215-15-57 [published Online First: 2014/02/15]
- 46. Bond V, Chiti B, Hoddinott G, et al. "The difference that makes a difference": highlighting the role of variable contexts within an HIV Prevention Community Randomised Trial (HPTN 071/PopART) in 21 study communities in Zambia and South Africa. AIDS care 2016;28(sup3):99-107.
- 47. Nash S, Dietrich J, Ssemata AS, et al. Combined HIV Adolescent Prevention Study (CHAPS): comparison of HIV pre-exposure prophylaxis regimens for adolescents in sub-Saharan Africa—study protocol for a mixed-methods study including a randomised controlled trial. *Trials* 2020;21(1):900. doi: 10.1186/s13063-020-04760-x [published Online First: 2020/10/31]
- 48. Sileo KM, Kintu M, Chanes-Mora P, et al. "Such behaviors are not in my home village, I got them here": A qualitative study of the influence of contextual factors on alcohol and HIV risk behaviors in a fishing community on Lake Victoria, Uganda. *AIDS and Behavior* 2016;20(3):537-47.
- 49. Muhumuza R, Ssemata AS, Kakande A, et al. Exploring Perceived Barriers and Facilitators of PrEP Uptake among Young People in Uganda, Zimbabwe, and South Africa. *Arch Sex Behav* 2021;50(4):1729-42. doi: 10.1007/s10508-020-01880-y [published Online First: 2021/05/07]
- 50. Mulubwa C, Hensen B, Phiri MM, et al. Community based distribution of oral HIV self-testing kits in Zambia: a cluster-randomised trial nested in four HPTN 071 (PopART) intervention communities. *Lancet HIV* 2019;6(2):e81-e92. doi: 10.1016/s2352-3018(18)30258-3 [published Online First: 2018/12/26]

- 51. Zanolini A, Chipungu J, Vinikoor MJ, et al. HIV Self-Testing in Lusaka Province, Zambia:
  Acceptability, Comprehension of Testing Instructions, and Individual Preferences for Self-Test Kit Distribution in a Population-Based Sample of Adolescents and Adults. *AIDS Res Hum Retroviruses* 2018;34(3):254-60. doi: 10.1089/aid.2017.0156 [published Online First: 2017/10/04]
- 52. Ortblad K, Musoke DK, Ngabirano T, et al. Direct provision versus facility collection of HIV self-tests among female sex workers in Uganda: a cluster-randomized controlled health systems trial. *PLoS medicine* 2017;14(11):e1002458.
- 53. Ortblad KF, Musoke DK, Ngabirano T, et al. HIV self-test performance among female sex workers in Kampala, Uganda: a cross-sectional study. *BMJ open* 2018;8(11)
- 54. Pope C, Ziebland S, Mays N. Qualitative research in health care: analysing qualitative data. *BMJ: British Medical Journal* 2000;320(7227):114. doi: 10.1136/bmj.320.7227.114 [published
  Online First: 2000/01/22]
- 55. Cresswell WJ, Poth NC. Qualitative Inquiry & Research Design: Choosing Among Five Approaches. 4th ed. Thousand Oaks, California: Sage publications 2018.
- 56. Nash S, Dietrich J, Ssemata AS, et al. Combined HIV Adolescent Prevention Study (CHAPS): comparison of HIV pre-exposure prophylaxis regimens for adolescents in sub-Saharan Africastudy protocol for a mixed-methods study including a randomised controlled trial. *Trials* 2020;21(1):900. doi: 10.1186/s13063-020-04760-x [published Online First: 2020/10/31]
- 57. Robinson OC. Sampling in interview-based qualitative research: A theoretical and practical guide. *Qualitative research in psychology* 2014;11(1):25-41.
- 58. Robinson RS. Purposive sampling. *Encyclopedia of Quality of Life and Well-Being Research* 2014:5243-45.
- 59. Bryman A. Social research methods: Oxford university press 2016.
- 60. Nowell LS, Norris JM, White DE, et al. Thematic analysis: Striving to meet the trustworthiness criteria. *International Journal of Qualitative Methods* 2017;16(1):1609406917733847.
- 61. Joint United Nations Programme on HIV/AIDS. Ending AIDS: progress towards the 90–90–90 targets. AIDS. Geneva: Joint United Nations Programme on HIV, 2017.
- 62. Johnson C, Baggaley R, Forsythe S, et al. Realizing the potential for HIV self-testing. *AIDS and Behavior* 2014;18(4):391-95. doi: 10.1007/s10461-014-0832-x [published Online First: 2014/07/06]



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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

## Supplement 1

HIV Self-testing among young people: Assessing the knowledge, acceptability and social implications of a peer-to-peer HIVST distribution model among adolescents aged 15 to 24 in Zambia and Uganda.

(HISTAZU)

# **Qualitative Interview Guide**

## **Background information**

- Please tell me a little bit about yourself? (hobbies, friends, where you hangout for fun)
- Tell me about the last time you tested for HIV. Why did you decide to test for HIV? Where did you test for HIV? What was your experience of testing for HIV? If NEVER tested for HIV. What are the reasons you have never tested for HIV?

HIV RISK PERCEPTIONS

- How do you think young people that you know are at risk of contracting HIV?
   Probe: which group of people do you think are more at risk: sex, gender, age?
- How do you think you are/ are not at risk of contracting HIV?
- Please tell me about ways that young people (including yourself) are using to protect against HIV.

# Perceptions and motivations of self-testing

- What are your opinion about self-testing? Probe for where to get the kits, price of
  the kits, ability to read the correct results, who to distribute them, feasibility of
  young people adapting self-testing
- Please share with some of the perceptions that other young people like you have about self-testing
- What are some of the motivations/facilitators of self-testing?
- Please share with me some of the barriers to self-testing among young people. Probe for counselling needs, fear of the needle prick....
- How can these barriers be overcome?

# **Group Discussion guide for HIVST for AYP**

- 1. What are the current HIV testing services available in this community? **Probe** what is the perception and level of acceptance and use of the existing services by adolescents and young people (AYP)?
- 2. Please share with me what you know or have heard about HIVST and HIVST procedures. *Probe* where they heard it from, their thoughts about HIVST
- 3. What are your views about HIVST? *Probe* for comparison between current routine HIV testing and HIVST?
- 4. When made available, where and how do you think HIVST kits should be accessed and distributed? *Probe* for location i.e. facilities, vendors, peers, clinic, pharmacy, mobile clinics and community centres.

**Probe** for reasons for the selected point of dissemination. Probe for person to disseminate.

Where would you recommend a friend to get HIVST kits? **Probe** Why?

- 5. What are your feelings about receiving them from peers or using a peer to peer distribution model? **Probe** best ways to share information among peers and adolescent and the facilitators and barriers of using peer distributors
- 6. Would you be willing to pay for the Kit? How much would you be willing to pay for it and why? *Probe* what would motivate you to pay?
- 7. What would be the possible challenges associated with using and distributing HIV self-test kits?
- 8. What aspects would encourage you to take up HIVST? *Probe* Potential for a dramatic increase in knowledge of HIV status, increased confidentiality, increased convenience, Autonomy and empowerment).
- 9. What are your concerns about HIVST?

  Probe Greater potential for inaccurate results, Psychological danger when decoupling testing and counselling, Greater difficulty ensuring referral to treatment and care, Potential unethical use of HIV self-testing, Self-testing as justification for unprotected sex, Concern for safe disposal of biohazard materials)
- 10. [Demonstrate for participant the use of the OraQuick kit] then ask What is your comment on the design of the kit and the testing procedures? **Probe** if this is something that would be acceptable to AYP.

- 11. What are your perception /opinions on test accuracy? **Probe** How would you perceive the results, what would you do if the result was negative positive, unclear or you are uncertain?
- 12. Is there anything else you would love to share with me about what we have been discussing or HIV testing in general?

Thank you for accepting to participate in this research study



## Interview guide for HIVST for Peer mobilisers

- 1. What are the current HIV testing services available in this community? **Probe** what is the perception and level of acceptance and use of the existing services by adolescents and young people (AYP)?
- 2. Please share with me what you know or have heard about HIVST and HIVST procedures. *Probe* where they heard it from, their thoughts about HIVST
- 3. What are your views about HIVST? **Probe** for comparison between current routine HIV testing and HIVST?
- 4. When made available, where and how do you think HIVST kits should be accessed and distributed to AYP in your community? Probe for location i.e. facilities, vendors, peers, clinic, pharmacy, mobile clinics and community centres.
  Probe for reasons for the selected point of dissemination. Probe for person to disseminate.

Where would you recommend AYP in your community to get HIVST kits? **Probe** Why?

- 5. What are your thoughts about using a peer to peer distribution model or being a distributor/ contact person for the kits? **Probe** best ways to share information among peers and adolescent and the facilitators and barriers of using peer distributors
- 6. What would be the possible challenges associated with using and distributing HIV selftest kits?
- 7. Would AYP in your community be willing to pay for the Kit? How much would they be willing to pay for it and why? **Probe** what would motivate them to pay?
- 8. What aspects would encourage you to promote uptake HIVST? **Probe** Potential for a dramatic increase in knowledge of HIV status, increased confidentiality, increased convenience, Autonomy and empowerment).
- 9. What are your concerns about HIVST? **Probe** Greater potential for inaccurate results, Psychological danger when decoupling testing and counselling, Greater difficulty ensuring referral to treatment and care, Potential unethical use of HIV self-testing, Self-testing as justification for unprotected sex, Concern for safe disposal of biohazard materials)
- 10. [Demonstrate for participant the use of the OraQuick kit] then ask What is your comment on the design of the kit and the testing procedures? **Probe** if this is something that would be acceptable to AYP.

- 11. What are your perception /opinions on test accuracy? **Probe** How would you perceive the results, what would you do if the result was negative positive, unclear or you are uncertain?
- 12. What strategies can be put in place to support and promote uptake of HIVST among AYP in your community.
- 13. Is there anything else you would love to share with me about what we have been discussing or HIV testing in general?

What would be the best strategies to use to reach out to adolescent boys, adolescent girls; married couples/ those in relationships?

What strategies or distribution channels can we use to effectively reach AYP in your community?

Thank you for accepting to participate in this research study

# Qualitative and Quantitative Procedures and outcomes

Qualitative	Procedure	Outcomes/End results
Qualitative data	Participants:	Transcripts for easy
	Uganda	coding (in Microsoft
	Adolescents and young people (15-	word from the group
	24 years old) (n=74)	discussions and
	• Village health Teams (n=06)	interviews
	Zambia	
	• AYP (15-24) (n=67)	
	• Peer support Staff (n=20)	
	• Nurses working with AYP (n=2)	
	• PSW Supervisors (n=2)	
	Data collection tool: Semi structured	
	Interviews	
	Sampling procedure: Purposive sampling	
	Main phenomena: perceptions and	
	contextual factors likely to influence the	
	implementation, feasibility and	
	acceptability of a P2P/SN distribution	
	models as well as facilitators and barriers	
	of HIVST amongst AYP as well linkage to	
	care and support	
Qualitative data	Transcription	List of codes, themes
analysis (Thematic-	Familiarisation	and excerpts with
content analysis)	Inductive and deductive Identifying	support of ATLAS.ti.
	a codes for the coding framework	
	• Indexing	
	• Charting	
	Mapping and interpretation	
Quantitative data	Participants: Adolescents and young	Data set including all
	people (n=200)	the 200 survey