Index Patient
Adult/Guardian/EM
Consent/Assent
English version

MAKERERE UNIVERSITY COLLEGE OF HEALTH SCIENCES

YALE UNIVERSITY

Study Title: Interrupting HIV and TB stigma in the household during TB contact investigation in Uganda

Principal Investigator (Uganda):
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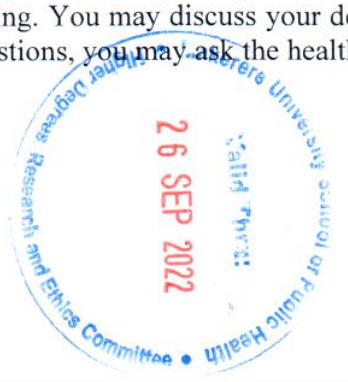
Summary

We are inviting you/your child to join a research study. The purpose of this research study is to evaluate an intervention to increase uptake of home HIV testing and linkage to HIV and TB care among household members undergoing TB investigation. Study activities will include a survey during a visit by community health workers. Your involvement will require about one hour. There may be some risks from participating in this study, such as disclosure of private information like place of residence, TB diagnosis, HIV status. The study may have no benefits to you. However, taking part in this study may improve your/your child's knowledge about TB and HIV.

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with this health center. Even if you don't participate in the research, you can still receive free home contact investigation services.

If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Introduction: You/your child are being asked to participate in this study because you/your child have been diagnosed with TB, and there is a chance that people in your household may have TB and or HIV. You can choose whether or not you want to participate in this study. Take your time when making your decision about participating. You may discuss your decision with your family and friends, if you wish. If you have any questions, you may ask the health worker at any time.



Sponsor: This study is sponsored by the National Institutes of Health.

Purpose: The study seeks to develop and evaluate an intervention to increase uptake of home HIV testing and linkage to HIV and TB care among household members undergoing TB contact investigation.

Procedures: This study will be carried out during contact investigation activities initiated at Kiswa, Kisenyi and Kawaala Health Centres. About 152 TB patients identified at health clinics and about 304 household contacts older than 14 years old will take part in one of the two study arms.

If you/your child choose to take part in the study, the following procedures will occur:

- Before visiting your household, the community health worker will ask you/your child to participate in this study.
- After study enrolment a CHW will work with you/your child and, if available, treatment supporter to schedule a home visit.
- Households will be randomly assigned to one of the two CHW teams to receive the intervention or the routine care.
- After being notified by the clinic-based CHW, the assigned CHW team will then accompany the index patient to the household to conduct both routine household contact investigation and study procedures. This is a systematic process for identifying previously undiagnosed people with TB among the contacts of an index patient.
- Upon arrival, the CHWs will enrol all eligible consenting household contacts in the study. But before doing this, at the start, CHWs will introduce themselves and ask for introduction of contacts.
- They will introduce the reason for their visit and the services they will offer (TBCI, oral HIV testing) using the introductory script for either Intervention or routine care depending on household assignment. For the oral HIV testing, we shall use the Oral HIV self-testing kits from Orasure technologies (Oraquick HIV self-test kit) which are approved by FDA, WHO and MoH in Uganda. This type of kits are also available in some of the public primary health facilities. The CHW will hand over the kit to you/your child and guide you through the testing process.
- For the intervention arm, one CHW will take the index case to a private area to ask the influence questions. The CHW will also collect patient demographoic data and information about your household. After completing this exercise, the CHW will then embark on conducting household contact screening interviews followed by HIV testing and any other study related activities.

- Meanwhile, the other CHW will be conducting routine TB contact investigation activities and any other clinical procedures in household TB contact investigation.

- After 3 (three) months, the community health worker may contact your household to schedule a follow-up visit to ask each participating member about their attitudes about TB and HIV.

Duration of study: If you/your child choose to take part in the study, a researcher will join the routine contact investigation visit to your home. The research procedures will take about one hour.

Risks: There are minimal risks to participating in this study. The primary risks to you/your child is the psychological and social risks of disclosure of private information such as place of residence, or of disclosure of your/your child's TB diagnosis and/or HIV status. As in routine practice, community health workers will make every effort to preserve the privacy and confidentiality of you/your child's information (that is, keep it a secret.) No other adverse effects are expected. Furthermore, we will not publish any identifying information and we will only use personal information like your name and phone number to communicate with you.

Benefits: Taking part in this study could improve your/your child's knowledge about TB and HIV.

Confidentiality: If you/your child agree to join this study, we will collect some personal information from you/your child, but only the people working on the study will see it. We will assign a code to your/your child's information. The key to the code will be stored in a safe place. Your/your child's name will not be used in any published reports from research using your health information. Research staff will have access to information about you/your child but they will not release any identifying information about you/your child to others. We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission.

To make sure the project follows good research practices, the Makerere University School of Makerere University School of Public Health Higher Degree of Research and Ethics Committee, the Yale University Human Investigation Committee, the Uganda National Council for Science and Technology, or the U.S. National Institutes of Health may look at or copy records that show your/your child's name or study number. We will comply with all laws that protect your/your child's confidentiality.

Voluntary participation: Participating in this study is voluntary. It is your/your child's choice whether to participate or not. If you no longer wish to participate you may ask the study team to leave at any time. You/your child may refuse to answer any questions you/your child do not want to answer. If you/your child choose not to participate in the study, you/your child can still receive health care and TB treatment at this or any other clinic. You/your child may change your mind later and stop participating even if you/your child agreed earlier. Tell the LHW if you/your child are thinking about stopping or if you/your child decide to stop. If you/your child decide after the study that you do not wish to be in the study, you can contact the study staff and you/your child will be removed from the study. We will tell you/your child about any new information or changes in the study that may affect you/your child's willingness to continue in the study.

The study staff may also stop you/your child from taking part in this study at any time if the study is stopped, or if they believe that it is in you/your child's best interest.

Costs: You will not be charged for any of the study activities.

Payment: You/your child will not be paid for taking part in the study.

Questions: You/your child can talk to the study staff about any questions, concerns, or complaints you have about this study. You can also contact Dr. Achilles Katamba, the Principal Investigator on +256-414-530-021 or 0753-040-922.

If you wish to ask questions about the study or you/your child's rights as a research participant to someone other than the researchers, or if you wish to voice any problems or concerns you may have about the study, please call Dr Suzanne Kiwanuka, chairman of School of Public Health Higher Degree of Research and Ethics Committee at 0701-273-378.

You can ask questions any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else.

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Summary

We are inviting you/your child to join a research study to evaluate an intervention to increase uptake of home HIV testing and linkage to HIV and TB care among household members undergoing home-based TB contact investigation.

The purpose of this research study is to evaluate an intervention to increase uptake of home HIV testing and linkage to HIV and TB care among household members undergoing TB investigation. Study activities will include a survey during a visit by community health workers. Your involvement will require about one hour. There may be some risks from participating in this study, such as disclosure of private information like place of residence, TB diagnosis, HIV status. The study may have no benefits to you. However, taking part in this study may improve your/your child's knowledge about TB and HIV.

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with this health center. Even if you don't participate in the research, you can still receive free home contact investigation services.

If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate.

Introduction: You/your child are being asked to participate in this study because you/your child is a household contact of TB and there is a chance that you/your child may have TB and or HIV. You can choose whether or not you/your child want to participate in this study. Take your time when making your decision about participating. If you have any questions, you may ask the community health worker at any time.

Sponsor: This study is sponsored by the National Institutes of Health.

Purpose: The study seeks to develop and evaluate an intervention to increase uptake of home HIV testing and linkage to HIV and TB care among household members undergoing home-based TB contact investigation.

Procedures: This study will be carried out during contact investigation activities initiated at Kiswa, Kisenyi, and Kawaala Health Centres. About 304 adult household contacts eligible for HIV testing will be enrolled into the study.

If you/your child choose to take part in the study, the following procedures will occur:

- Community health workers will provide household contact investigation services, including TB education, screening, sputum collection, and clinic referral, according to routine public heath protocols. This is a systematic process for identifying previously undiagnosed people with TB among the contacts of an index patient.
- A community health worker will offer free, optional oral HIV testing. We shall use the Oral HIV self-testing kits from Orasure technologies (Oraquick HIV self-test kit) which are approved by FDA, WHO and MoH in Uganda. This type of kits are also available in some of the public primary health facilities. The CHW will hand over the kit to you/your child and guide you through the testing process.
- A CHW may ask you a few questions when you are just the two of you.
- For newly identified people living with HIV, they will be linked to care at the preferred facility. Engagement in care will be assessed at month one and month three by facility register review and phone follow-up.
- After 3 (three) months, the community health worker might contact your household to schedule a follow-up visit to ask each participating member about their attitudes about TB and HIV.

Duration of study: If you/your child choose to take part in the study, today's visit will last about 1 hour. There might be follow-up home visits which might last about 1 hour for each visit.

Risks: There are minimal risks to participating in this study. The primary risks to you/your child is the psychological and social risks of disclosure of private information such as place of residence, or of disclosure of your/your child's TB diagnosis and/or HIV status. As is done in routine practice, community health workers will make every effort to preserve the privacy and confidentiality of you/your child's information (that is, keep it a secret.) No other adverse effects are expected. Furthermore, we will not publish any identifying information and we will only use personal information like your name and phone number to communicate with you.

Benefits: Taking part in this study could improve your/your child's knowledge about TB and HIV. In case you/your child has TB and or HIV, your/your child's participation

could help them be diagnosed with TB and or HIV earlier than if you/your child did not take part in the study. This means they would be able to start treatment sooner and be less likely to transmit the disease to others.

Confidentiality: If you/your child agree to join this study, we will collect some personal information, possibly including a voice recording if we choose you/your child to participate in the follow-up household discussions. Only the people working on the study will see/hear these. We will assign a code to your/your child's information. The key to the code will be stored in a safe place. We will not use your sputum for any purposes other than to test for TB. Your/your child's name will not be used in any published reports from research using your health information. Research staff will have access to information about you/your child but they will not release any identifying information about you/your child to others. We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission.

To make sure the project follows good research practices, the Public Health Higher Degree of Research and Ethics Committee, the Yale University Human Investigation Committee, the Uganda National Council for Science and Technology, or the U.S. National Institutes of Health may look at or copy records that show your/your child's name or study number. We will comply with all laws that protect your/your child's confidentiality. Health workers in the clinic may be required to report information about your/your child's TB and HIV evaluation to the National TB and Leprosy Programme (NTLP) using standard forms.

Voluntary participation: Participating in this study is voluntary. It is your/your child's choice whether to participate or not. If you are providing consent for your child to participate, and your child does not want to participate, we will not include your child in the study. If you no longer wish to participate you may ask the study team to leave at any time. You/your child may refuse to answer any questions you/your child do not want to answer. If you/your child choose not to participate in the study, you/your child can still receive health care and TB treatment at the clinic. You/your child may change your mind later and stop participating even if you agreed earlier. Tell the LHW if you are thinking about stopping or if you decide to stop. If you/your child decide after the study that you do not wish to be in the study, you/your child can contact the study staff and you will be removed from the study. We will tell you/your child about any new information or changes in the study that may affect your willingness to continue in the study.

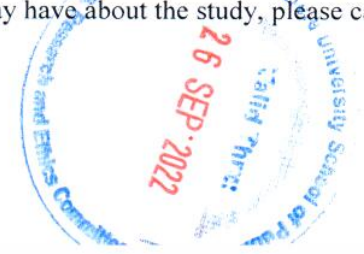
The study staff may also stop you/your child from taking part in this study at any time if the study is stopped, or if they believe that it is in your/your child's best interest. Whether or not you/your child is in this study, it is important to follow the instructions of the health care workers regarding clinic visits and to take medication if needed.

Costs: You will not be charged for any of the study activities, but there may be some costs associated with routine care, such as traveling to the health facility.

Payment: You/your child will not be paid for taking part in this study.

Questions: You/your child can talk to the study staff about any questions, concerns, or complaints you/your child have about this study. You can also contact Dr. Achilles Katamba, the Principal Investigator on +256-414-530-021 or 0753-040-922.

If you wish to ask questions about the study or your/your child's rights as a research participant to someone other than the researchers, or if you wish to voice any problems or concerns you may have about the study, please call Dr Suzanne



Kiwanuka, chairman of School of Public Health Higher Degree of Research and Ethics Committee at 0701-273-378.