ISRCTN15197669 https://doi.org/10.1186/ISRCTN15197669

Measuring HIV-related mortality during surveys in Africa

Submission date
09/09/2018

Recruitment status
No longer recruiting

Registration date
12/10/2018

Overall study status
Completed

Last Edited
10/11/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Reducing HIV/AIDS deaths is one of the clearest indicators of success in HIV prevention and treatment programs. It is thus crucial to collect the best possible data on HIV/AIDS mortality to monitor progress towards this target and evaluate the impact of HIV programs. Unfortunately, the vast majority of countries most affected by HIV epidemics often lack well-functioning civil registration and vital statistics (CRVS) systems. Instead, reliable data on causes of death in sub-Saharan countries are currently only available for small and highly selected populations. The researchers propose to address this lack of representative data by assessing the feasibility of collecting information on HIV mortality during household surveys such as the Demographic and Health Surveys (DHS). Declines in HIV stigma and increasingly confidential interviewing techniques such as audio computer-assisted self-interviewing (ACASI) may also improve respondents' willingness to report such data. The researchers have developed an enhanced adult mortality questionnaire, which includes direct questions on the HIV status and the engagement in HIV care and treatment of each deceased relative. The aim of this study is to test whether the accuracy of the enhanced survey questionnaire in classifying recently deceased relatives of respondents according to their HIV status can be further improved by the use of ACASI.

Who can participate?
People aged 15 – 59 years residing in the Karonga health and demographic surveillance system (KHDSS) area

What does the study involve?
The enhanced questionnaire is used to collect data on respondent characteristics, sibling survival and HIV testing history of the respondent. Participants are randomly allocated to undergo either a face-to-face interview or an ACASI interview.

What are the possible benefits and risks of participating?
There are no direct benefits for the respondents. However, information gathered from the study respondents will help to improve the measurement of adult mortality in Malawi and possibly in sub-Saharan countries. As a result, better-targeted HIV care and treatment programs may result, which will eventually improve the health of local populations. The risks associated with the study

are minimal and consist of possible breach of confidentiality, and possible discomfort/sadness associated with recalling deceased siblings.

Where is the study run from?
The study is run by Johns Hopkins University School of Public Health, and Malawi Epidemiolgical and Intervention Research Unit. Recruitment will take place in the KHDSS area in Malawi.

When is the study starting and how long is it expected to run for?
June 2017 to May 2019

Who is funding the study?
National Institute of Allergy and Infectious Diseases (NIAID) (USA)

Who is the main contact?
Dr Stephane Helleringer

Contact information

Type(s)
Public

Contact name
Dr Stephane Helleringer

ORCID ID
http://orcid.org/0000-0002-5921-9651

Contact details
Department of Population, Family, and Reproductive Health
Johns Hopkins Bloomberg School of Public Health
615 North Wolfe Street
Baltimore
United States of America
21205

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R21AI127286

Study information

Scientific Title

Feasibility of measuring HIV-related mortality during population-based surveys in African countries: a randomized controlled trial

Study objectives
Audio computer-assisted self-interview (ACASI) reduces social desirability bias, but it has not been used to collect mortality data. It may help increase the sensitivity of survey data on the HIV status of deceased relatives. This study will evaluate whether ACASI improves the accuracy of an enhanced questionnaire in recording HIV-positive deaths relative to standard face-to-face interviews. More specifically, the study will test two hypotheses:
1. ACASI increases the sensitivity of an enhanced questionnaire in recording HIV-positive deaths due to lower social desirability bias
2. ACASI does not reduce the specificity of the enhanced questionnaire in recording deaths not related to HIV

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institutional Review Board of the Johns Hopkins University Bloomberg School of Public Health in the United States, 05/09/2018, ref: IRB00007944
2. National Health Sciences Research Committee (NHSRC) in Malawi, 21/06/2018, Protocol #18 /03/1996

Study design
Interventional single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
HIV status of deceased sibling

Interventions
The trialists will enroll a sample of individuals aged 15-59 years old who have ever resided in the Karonga Health and Demographic Surveillance Systems (KHDSS) area and whose deceased sibling death was either HIV-related or not related to HIV. Individuals meeting the eligibility

criteria will be randomized to either the face-to-face interview or the ACASI interview. Randomization will be stratified by a) gender of the respondent, b) time since the death, and c) level of engagement of the deceased sibling on the HIV care cascade (for HIV-related deaths).

The face-to-face interviews will consist of a) the section on respondent characteristics of the DHS questionnaire (e.g., age, education), b) the enhanced mortality questionnaire, and c) a few questions about the HIV testing history of the respondent (similar to questions asked during Demographic and Health Surveys (DHS) or Population-based HIV Impact Assessment (PHIA) surveys). All data collection will be on mobile devices using open data kit (ODK).

The ACASI interviews will consist of the exact same questions asked during face-to-face interviews. It will also be conducted with ODK, which allows associating an audio-file with each survey question. It will be preceded by a small set of training questions so that the respondent can become familiarized with the device.

Intervention Type
Other

Primary outcome measure
1. Sensitivity in recording the HIV status of deceased siblings in the ACASI and face-to-face groups. Sensitivity is defined as the proportion of HIV positive deaths according to KHDSS that were correctly reported as such by survey respondents.
2. Specificity in recording the HIV status of deceased siblings in the ACASI and face-to-face groups. Specificity is defined as the proportion of HIV-negative deaths according to KHDSS that were correctly reported as such by survey respondents.
There will be one planned study visit per participant, with no planned follow-up. As such the outcomes will be measured at the one study visit. The trialists will measure the level of agreement between survey data and KHDSS data using Cohen’s Kappa in each study arm.

Secondary outcome measures
1. The sensitivity/specificity of the survey in recording the respondent's own HIV status
2. The amount of time spent answering HIV-related questions, as measured internally by ODK
3. The accuracy of the enhanced questionnaire in assessing the engagement of deceased siblings identified as HIV-infected on the HIV care cascade
There will be one planned study visit per participant, with no planned follow-up. As such the outcomes will be measured at the one study visit.

Overall study start date
01/06/2017

Completion date
31/05/2019

Eligibility

Key inclusion criteria
1. Aged 15-59 years old at the time of the study
2. Residing in the Karonga Health and Demographic Surveillance System (HDSS) area

Participant type(s)
All

Age group
Adult

Sex
Both

Target number of participants
490

Total final enrolment
535

Key exclusion criteria
1. Younger than 15 years old at the time of enrollment
2. Older than 59 years old at the time of enrollment
6. Not residing in the Karonga Health and Demographic Surveillance System (HDSS) area

Date of first enrolment
10/10/2018

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Malawi

Study participating centre
Malawi Epidemiolgical and Intervention Research Unit
PO Box 46
Chilumba, Karonga District
Malawi
N/A

Sponsor information

Organisation
National Institute of Allergy and Infectious Diseases (NIAID)

Sponsor details
5601 Fishers Lane
MSC 9806
Bethesda, MD

United States of America
20892-2425
+1 (0)866 284 4107
ocpostoffice@niaid.nih.gov

Sponsor type
Government

Website
https://www.niaid.nih.gov/

ROR
https://ror.org/043z4tv69

Funder(s)

Funder type
Government

Funder Name
National Institute of Allergy and Infectious Diseases

Alternative Name(s)
Instituto Nacional de Alergias y Enfermedades Infecciosas, National Institute of Allergy & Infectious Diseases, NIAID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
Findings will be shared with health officials, researchers, policymakers, donors and other stakeholders through submissions to open access journals and presentation at scientific conferences, with a view to informing future research and programming aimed at improving the performance of HIV programs. Participants' names or identifying information will not appear in any study outputs.

2020 results in preprint https://doi.org/10.1101/2020.06.01.20118810 (added 10/11/2020)

Intention to publish date
01/03/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Stephane Helleringer. Type of data: Deidentified participant level data. Date data will become available: 01/03/2019 onwards for an unlimited period of time. Access criteria: open to all for all types of analyses. Consent from participants: being obtained. Data anonymization: Data will be deidentified. Ethical or legal restrictions: None.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		14/09/2018	12/10/2018	No	Yes