



Investigating current and future national policy and regulation of HIV self-testing

1. Why are we doing this study?

This study is designed to find out ways to make it easier for people in Malawi to test themselves for HIV (“self-testing”). We are interested in your opinions about the regulation and implementation of HIV self-testing. This will help us to prioritise issues that need to be considered by policy-makers when developing a national pathway for the regulation of HIV self-testing devices.

2. Why are we asking you to take part in this study?

Regular HIV testing is very important in Malawi and worldwide because it helps people with HIV get treatment when they are still healthy and it may also help to cut down the spread of HIV. But it is important for people to get the rights results, and we do not yet know how easy it will be to scale up access to quality-assured HIV self-testing products in Malawi. For this study, we want to find ways to regulate the quality of HIV self-testing kits on a national scale and introduce policies that can expand accessibility of these products to all Malawians.

3. What will happen if you decide to take part in this study?

You would take part in an interview and be asked questions about the following topics:

1. Your thoughts about areas of policy that support or hinder the implementation of HIV self-testing, and any existing policy gaps.
2. Your opinions on issues of counselling, consent, coercion and confidentiality in relation to HIV self-testing.
3. Your thoughts on how HIV self-testing can be distributed.
4. Your thoughts on the key stakeholders in HIV self-testing.
5. Your opinions on the regulation of HIV self-testing.
6. Your opinions on the scale-up and monitoring of HIV self-testing.

There are no correct or incorrect answers. We would audio-record the interview in order to have an accurate record of your responses for review. The interview will take about 45 minutes.

4. Who are we asking to participate?

We are interviewing government officials and other decision-makers involved in HIV testing and/or the regulation of medical devices to better understand some of the issues around introducing HIV self-testing. You have been invited to participate as you have been identified as a decision maker involved in HIV testing or regulation.

5. Where do we come from?

We work at the Malawi-Liverpool-Wellcome Trust Clinical Research programme (MLW) and Population Services International (PSI). MLW and PSI conduct research and implement projects on diseases of local importance to Malawi and the region.

6. What are the risks and benefits of the study?

There are no risks associated with the study.

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Your responses will help identify challenges and opportunities for the effective regulation and implementation of HIV self- testing in Malawi. Participating in this interview will not benefit you personally.

7. Do I have to participate in this study?

Your participation is voluntary. You may withdraw from the study at any time and without giving a reason. You can also decide to answer some questions, and not to answer other questions.

8. Confidentiality

All information obtained from the study will be stored securely on a voice-recorder and on paper and computer files and only researchers in this study will have access to them. Data entry will only be performed by the study team and confidentiality will be maintained throughout this and all data handling and storage processes.

When we publish information from this interview, we will not identify you by your name or other information so that your responses cannot be linked to your identity. We will show any reports using information from this interview to you before we use it in any published materials (e.g. reports or scientific publications) and will not use it without your approval.

9. Costs

It will not cost you anything to participate and you will not receive payment for your participation.

10. The Ethics Committees that have approved the study are:

Committee for Medical Research Ethical Considerations [COMREC], London School of Hygiene and Tropical Medicine, and Liverpool School of Tropical Medicine.

11. What if I have any questions?

If you have any questions about the disease or about this study please feel free to ask them. If you think of any questions after we have gone please feel free to contact us by calling the following number and asking for Pitchaya Indravudh or Dr Nicola Desmond.

Tel: 01874628 / 01876444

Please contact the COMREC Secretariat should you wish further information about your rights, safety, and wellbeing in research:

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