

Please see the answers below, by Senior DHS Specialist, Kia Reinis

I. Burkina Faso (Standard DHS-VI 2010)

Ethical review of survey protocols

1. Was the general survey protocol reviewed by an ethics committee? If so, what were the names of those committees(e.g., ICF Macro International IRB, National Ethics Committee, etc.)?

Answer: The Institutional Review Board of ICF Macro reviewed and approved the MEASURE Demographic and Health Surveys Project Phase III. DHS surveys that follow the Standard are categorized under that approval, as is the 2010 Burkina Faso DHS. The Institutional Review Board of ICF Macro complied with the United States Department of Health and Human Services requirements for the "Protection of Human Subjects" (45 CFR 46). (ICF Macro is now known as ICF International).

The 2010 Burkina Faso DHS was also reviewed and approved by the Burkina Faso National Ethical Committee.

2. Aside from ethics committee review and obtaining consent from respondents, were any additional measures taken to ensure ethical requirements were followed (e.g., supervisory visits organized by NECHR in Senegal DHS VI)?

Answer: It is standard operating procedure for DHS survey personnel to carry out the survey in accordance with the ethical requirements outlined in survey protocols.

Treatment for children testing positive for malaria in DHS

1. For children testing positive using RDT, were they informed of their results and offered treatment by survey personnel?

Answer: Yes, the parent or guardian of each child tested was informed of the RDT results and in case of positive result, a treatment was offered or a referral to a health facility for medical attention if the proposed treatment was not accepted. That is why the RDT itself was included in the survey in addition to the thick smears.

Malaria testing

1. Were any internal and external quality control measures used in laboratories when testing malaria blood films? (e.g., use of control wells, having subset of samples tested at external lab).

Answer: Yes, both internal and external quality controls were implemented in the survey. The internal quality control was based on the lab internal protocol and procedures for quality control. Slides were randomly read by different technicians or by the chief technician/supervisor for internal quality control. The external quality control was done at an external lab. The samples for external quality control were taken to Muraz Center in Bobodioulasso. The selection of the samples for external quality control was conducted via a computerized system written by ICF Macro data processing specialists and installed in the Lab at the beginning of the testing process. (note: control wells do not apply to malaria testing.)

II. Mozambique (Standard DHS-VI 2011)

Ethical review of survey protocols

1. Was the general survey protocol reviewed by an ethics committee? If so, what were the

names of those ethics committees (e.g., ICF Macro International IRB, National Ethics Committee, etc.)?

Answer: The Institutional Review Board of ICF Macro reviewed and approved the MEASURE Demographic and Health Surveys Project Phase III. DHS surveys that follow the Standard are categorized under that approval, as is the 2011 Mozambique DHS. The Institutional Review Board of ICF Macro complied with the United States Department of Health and Human Services requirements for the "Protection of Human Subjects" (45 CFR 46). (ICF Macro is now known as ICF International).

2. Was the malaria testing protocol reviewed by an ethics committee? If so, what were the names of those ethics committees(e.g., ICF Macro International IRB, National Ethics Committee, etc.)?

Answer: The IRB approval referred to above in Item #1 included review of malaria testing protocols.

3. Was the HIV testing protocol reviewed by an ethics committee? If so, what were the names of those committees(e.g., ICF Macro International IRB, National Ethics Committee, etc.)?

Answer: There was no HIV testing in the Mozambique DHS 2011 survey.

4. Aside from ethics committee review and obtaining consent from respondents, were any additional measures taken to ensure ethical requirements were followed (e.g., supervisory visits organized by NECHR in Senegal DHS VI)?

Answer: It is standard operating procedure for DHS survey personnel to carry out the survey in accordance with the ethical requirements outlined in survey protocols.

Malaria testing

1. Were any internal and external quality control measures used in laboratories when testing malaria blood films? (e.g., use of control wells, having subset of samples tested at external lab).

Answer: Labs have standard internal quality control measures. (note: control wells do not apply to malaria testing.)

III. Rwanda (Standard DHS-VI 2010)

Ethical review of survey protocols

1. Was the general survey protocol reviewed by an ethics committee? If so, what were the names of those committees(e.g., ICF Macro International IRB, National Ethics Committee, etc.)?

Answer: The ICF Institutional Review Board of ICF Macro reviewed and approved all procedures of the Rwanda 2010 DHS. The IRB of ICF Macro complied with the United States Department of Health and Human Services requirements for the "Protection of Human Subjects" (45 CFR 46). "The protocol for the blood specimen collection and testing for HIV was reviewed and approved by the Rwanda National Ethics Committee, the Institutional Review Board of ICF International, and the Centers for Disease Control and Prevention." page 8 of the Final Report.

2. Was the malaria testing protocol reviewed by an ethics committee? If so, what were the names of those committees(e.g., ICF Macro International IRB, National Ethics Committee, etc.)?

Answer: The ICF approval mentioned above in Item 1 included the review and approval of the malaria testing protocol.

3. Aside from ethics committee review and obtaining consent from respondents, were any additional measures taken to ensure ethical requirements were followed (e.g., supervisory visits organized by NECHR in Senegal DHS VI)?

Answer: It is standard operating procedure for DHS survey personnel to carry out the survey in accordance with the ethical requirements outlined in survey protocols.

Quality control measures for malaria testing

1. Were any internal and external quality control measures used in laboratories when testing malaria blood films? (e.g., use of control wells, having subset of samples tested at external lab).

Answer: Please note that the malaria testing was done by the TRAC/Plus Malaria Unit in Kigali (not the National Reference Lab). The testing lab has standard internal quality control measures that were implemented during the malaria testing. (control wells do not apply to malaria testing.)

HIV testing

1. What is the name of the laboratory that conducted HIV testing of samples?

Answer: Anonymous HIV testing was conducted by The National Reference Laboratory.

2. What is the name of the test used to detect HIV? (e.g., ELISA based assay Vironostika, Enzygnost[®] Anti-HIV ½ plus, Pepti-Lav or InnoLia)

Answer: In Rwanda DHS 2010, the HIV algorithm was Vironostika (Elisa 1), Murex (Elisa 2), and Western Blot (Tie-breaker).

3. Were any internal or external quality control measures used in the laboratory?

Answer: Control wells are used for internal quality control of HIV testing in DHS surveys.

IV. Senegal (Standard DHS-VI 2010-11)

Ethical review of survey protocols

1. Was the general survey protocol reviewed by an ethics committee? If so, what were the names of those committees (e.g., ICF Macro International IRB, National Ethics Committee, etc.)?

Answer: The Institutional Review Board of ICF Macro reviewed and approved the MEASURE Demographic and Health Surveys Project Phase III. DHS surveys that follow the Standard are categorized under that approval, as is the 2010-11 Senegal DHS. The Institutional Review Board of ICF Macro complied with the United States Department of Health and Human Services requirements for the "Protection of Human Subjects" (45 CFR 46). (ICF Macro is now known as ICF International).

In addition, the protocols for anemia, HIV, and parasitemia were also approved by the National Ethics Committee for Health Research (CNERS) of Senegal.

Malaria testing

1. Were any internal and external quality control measures used in laboratories when testing malaria blood films? (e.g., use of control wells, having subset of samples tested at external lab).

Answer: The testing lab has standard internal quality control measures that were implemented during the malaria testing. (control wells do not apply to malaria testing.)