

Initial Accuracy of HIV Rapid Test Kits Stored in Suboptimal Conditions and Validity of Delayed Reading of Oral Fluid Tests

Data Creators

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Data Description

An anonymised dataset produced as part of a study on initial accuracy of commonly used HIV rapid diagnostic tests (RDT) when stored in suboptimal conditions and the validity of delayed reading of OraQuick oral fluid tests. It contains HIV results for each RDT, age, sex, previous testing data and an indication of whether or not there was a change in the reading of OraQuick oral RDT over the 12 month period of re-reading. It may be used to validate results related to analysis of sensitivity and specificity of each sub-optimally-stored test kit compared with optimally stored Determine and Uni-Gold conducted in parallel.

Methods

This was a quality assurance study enrolling participants who presented to the HIV testing centre and ART centre of Ndirande Health Centre in urban Blantyre sequentially. Participants gave a blood sample and also used OraQuick oral swab to collect oral mucosal transudate sample. A nurse then performed HIV testing using optimally-stored (stored within manufacturer-recommended temperature of 2-28 degrees Celsius) RDTs: Determine 1/2, Uni-Gold (Alere, Waltham, USA and Uni-Gold Recombigen HIV, Trinity Biotech, Bray, Ireland); and OraQuick (OraSure Technologies, Bethlehem, USA) and also sub-optimally-stored RDTs (pre-incubated at 37 degrees Celsius for 28 days). The diagnostic reference standard was Determine and Uni-Gold conducted in parallel with a repeat of all optimally-stored RDTs in case of discordance. Each sub-optimally-stored RDT was then compared to this reference standard in order to compute sensitivity and specificity a measure of initial accuracy. All used optimally-stored and sub-optimally-stored OraQuick oral RDTs were sent to the laboratory located at the College of Medicine in Blantyre for immediate and subsequent monthly re-reading up to 12 months after use in order to assess stability of the visual read over time.

Spatial Coverage

Blantyre, Malawi.

Temporal Coverage

Data collected between 14th January 2012 and 30th April 2013.

Quality Controls

All oral rapid diagnostic tests were read by two independent laboratory technicians.

Species:

Human population

Privacy:

No individual participant identifiers were collected as part of this study and all oral RDTs were given a numerical identifier which was used throughout the 12 month re-reading period.

Ethics

Ethical approval was obtained from the College of Medicine Ethics Review Committee, University of Malawi (Approval number: P.03/12/1186). All participants provided written (or witnessed thumbprint) informed consent.

HIV Rapid Test Kits

Keywords

HIV; diagnosis; rapid diagnostic tests; near-patient tests; diagnostic accuracy

Language of written material

English

Additional Information

Data collection tools used in the study can be provided upon request (Augustine.Choko@lshtm.ac.uk).

Project

Part of the parent project titled: Intensified HIV/TB prevention linking home-based HIV testing, including the option of self-testing, with HIV care: a cluster-randomised trial in Blantyre, Malawi (ISRCTN02004005).

Funder/Sponsor

Wellcome Trust, UK.

Grant Number

WT091769

Associated Roles

Role	Forename	Surname	Faculty / Dept	Institution
Project Leader, Data Creator & Contact Person	Augustine	Choko	Epidemiology & Population Health > Infectious Disease Epidemiology	London School of Hygiene & Tropical Medicine
Data Creator	Emily	Webb	Epidemiology & Population Health > Infectious Disease Epidemiology	London School of Hygiene & Tropical Medicine
Researcher, Rights holder	Elizabeth	Corbett	Infectious & Tropical Diseases > Clinical Research	London School of Hygiene & Tropical Medicine

File Description

Title	Filename	File type	Description
Rapid diagnostic tests accuracy	rdt_accuracy.txt	Tab delimited	Demographic, HIV results and indicator of change of result from oral RDT
Data dictionary	data_dictionary_rdt_Tab.txt data_dictionary_rdt_PDF.pdf	Tab delimited Adobe PDF/A	Variable name, data type and description, as well as code meanings.
User Guide	UserGuide.pdf	Adobe PDF/A	This document