

RDT Field Trials

Malaria RDTs are designed predominantly for use in malaria endemic areas beyond the reach of good quality microscopy. The ultimate test of their performance is therefore accuracy attained in such an environment, after enduring probable conditions of transport and storage, in the hands of the intended end-users, in high-quality field trials. Performance in such conditions may be affected by the quality of manufacture and packaging, exposure to high temperatures, preparation and interpretation by the end-user, and characteristics of the host population and parasites in the area where they are used.

- [Reviews of published malaria RDT field trials](#)
- [Recommended Methods for Field Trials of Malaria RDTs](#)

Requirements and Limitations of Field Trials

Field trials are useful in confirming that high levels of performance observed in the laboratory is maintained in the field, and in investigating certain aspects of RDT use such as ease of use and safety, or outcomes in populations with specific characteristics. Good field trials are relatively expensive to implement, and are unsuited to comparison of many RDTs as it is logistically difficult to test many RDTs in parallel in their intended conditions of use, and variation within the study population makes testing in series inappropriate.

Field trials of malaria RDTs are further limited by the requirement for a reference standard that is clearly better performing than the expected performance of the RDT under evaluation. This is difficult to achieve with light microscopy, as RDTs may potentially out-perform microscopy in some aspects of parasite detection. The use of more sensitive methods such as PCR is usually necessary to obtain reliable estimates of sensitivity and specificity.

In order to allow comparison of results between various field trials, it is essential that field trials of malaria RDTs are planned, performed and documented meticulously according to the standards necessary for comparative trials of any diagnostic method. Without strict adherence to standardized protocols and clear documentation of conditions and standards used, it is difficult or impossible to draw firm conclusions from results. Poorly designed or documented trials will have, or should have, little impact on implementation policy. Well planned, performed, and documented trials can be of major benefit to public health.

Reviews of published malaria RDT field trials

The reviews of malaria rapid diagnostic test (RDT) trials are intended to summarize published trials, highlighting information that is relevant to guide decisions on whether to use RDTs and what to procure, aimed particularly at malaria programme personnel in endemic countries.

The list of trial reviews will be progressively updated as soon as reviews are completed which will include most trials back in 2000.

[Search reviews of RDT trials](#)

Method of Review

Reviews

The review criteria are developed by consultation from criteria used elsewhere (Bossuyt, Reitsma et al. 2003; Whiting, Rutjes et al. 2004) and modified for malaria RDT trials in light of trial recommendations from the 2003 WHO Informal Consultation on Malaria RDT (WHO 2003). Each paper is reviewed by a review coordinator according to a standardized questionnaire (coordinator reviewer). The summary and original paper are then reviewed by two co-reviewers drawn from a pool of experts in operational aspects of malaria management in endemic countries (co-review notes) and a final review prepared by the review coordinator. The review coordinator is varied where necessary to avoid conflict of interest.

Each paper is rated according to relevance to malaria control personnel in endemic countries. Although this takes into account the quality of the paper, it is not a reflection of quality alone but is intended to guide prioritizing of reading for malaria programme personnel with procurement and field use in mind. High quality papers with limited direct relevance to field use of RDT could therefore rate lower than reports of lower quality but demonstrating issues of high relevance to field implementation.

Trial selection

Peer-reviewed published trials listed in MEDLINE® (Medical Literature Analysis and Retrieval System Online of the U.S. National Library of Medicine) are included, if they fit the following criteria:

- Assess commercially-available products, or products formerly commercially
- available and with relevance to the use of current products
- Full text version available in English
- Assess test accuracy, or other aspects relevant to use in the field
- Sufficiently detailed to allow review of the quality of the methods and results.

Trials and studies of components of RDTs are not included, unless directly relevant to field use. Trials published from 2003 to 2005 will be reviewed initially, with inclusion of earlier papers periodically.

Acknowledgements

The WHO gratefully acknowledges the following for contributing to this project:

Review coordinator: Anthony Moody (United Kingdom)

Co-reviewers: Elizabeth Streat (Mozambique), Daniel Masiga (Kenya), Walter Jaoko (Kenya), Eldirdieri Salim Ahmed (Sudan), Olugbenga Mokuolu (Nigeria), Jenny Luchavez (Philippines), Helen Counihan (United Kingdom), Neena Valecha (India), Salim Abdulla (Tanzania), Christa Hook (United Kingdom), Ferdinand J Laihad (Indonesia), Armindo Tiago (Brazil), Willis Simon Akhwale (Kenya), Dr Martin Meremikwu (Nigeria), Modest Mulenga (Zambia), Akin Sowunmi (Nigeria), Chris Membi (Tanzania), Masela Chinyama (Zambia), Patrick Devenand Moonesar (South Africa), Leigh Dini (Sweden), Myers Lugemwa (Uganda), Damiel Kyabayainze (Uganda), Heidi Hopkins (Uganda), Carol Asiimwe (Uganda), Sheikh Oumar (Burkina Faso), Pongwit Buolumbai (Thailand), Busika (Zambia), Siv Sovannaroth (Cambodia).

Recommended Methods for Field Trials of Malaria RDTs

The WHO guide to field trials was developed by WHO/WPRO and WHO/TDR through the [Informal Consultation on Field Trials and Guidelines for Malaria Rapid Diagnostic Tests, Manila, 2003](#) and by the WHO/TDR Diagnostics Expert Evaluation Panel (DEEP), and published with Nature Reviews Microbiology in Nature Reviews Microbiology Supplement – Evaluating diagnostics: the malaria guide in September 2006, the first of a series of guides for field trials of diagnostic tests for tropical diseases. The guide is presented in two sections: (Links given below).

Relevant Links and Documents

- [Generic Trial Guide](#)
- [Malaria RDT Trial Guide](#)
- Ensuring quality and access for malaria diagnosis: how can it be achieved? Nat Rev Microbiol. 2006 Sep;4(9 Suppl):S21-40