



WHO policy recommendation on malaria diagnostics in low transmission settings

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In recent years, the application of nucleic acid amplification (NAA)-based diagnostic tools to detect malaria in the context of epidemiological surveys and in research endeavours has increased significantly. Many different assays are available with a superior diagnostic performance to microscopy and rapid diagnostic tests. Based on a recent evidence review,¹ the following are recommendations on the role of molecular diagnostic tests for malaria in low transmission areas.²

Recommendation 1

Quality assured RDT and microscopy are the primary diagnostic tools for the confirmation and management of suspected clinical malaria in all epidemiological situations, including areas of low transmission, due to their high diagnostic performance in detecting clinical malaria, their wide availability and relatively low cost. Similarly, RDT and microscopy are appropriate tools for routine malaria surveillance (of clinical cases) in the majority of malaria-endemic settings.

Recommendation 2

A number of nucleic acid amplification techniques are available and are more sensitive in detection of malaria compared to RDTs and microscopy. Generally, the use of more sensitive diagnostic tools should be considered only in low transmission settings where there is already widespread implementation of malaria diagnostic testing and treatment and low parasite prevalence rates (e.g. < 10%). Use of nucleic acid amplification (NAA)-based methods should not divert resources away from malaria prevention and control interventions and strengthening of the health care services, including the surveillance system.

Recommendation 3

Submicroscopic *Plasmodium falciparum* and *P. vivax* infections are common in low as well as high transmission settings. The use of NAA methods by malaria programs should be considered for epidemiological research and surveys aimed at mapping submicroscopic infections at low transmission intensity. There may also be a use for NAA methods for identifying foci for special intervention measures in elimination settings.

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1 Report available on the WHO-GMP website at the following URL:

www.who.int/malaria/mpac/mpac_mar2014_diagnosis_low_transmission_settings_report.pdf

2 Defined according to WHO (2012) *Disease surveillance for malaria elimination: an operational manual* www.who.int/malaria/publications/atoz/9789241503334/en/

Recommendation 4

The majority of infections with asexual parasites have gametocytes detectable by molecular amplification methods, at low density not detectable by microscopy or RDTs. Most malaria infections (microscopic and submicroscopic) should be considered as potentially infectious and able to contribute to ongoing transmission. There is no need for routine detection of gametocytes using sensitive NAA methods in malaria surveys or clinical settings.

Recommendation 5

Common standards for nucleic acid based assays should be developed, including use of the WHO International Standard for *P. falciparum* DNA NAA assays and development of standards for other Plasmodium species, particularly *P. vivax* should be undertaken. A standard operating procedure should be developed which defines methods for sample collection, extraction, and the recommended equivalent quantity of blood to be added to the assay.

Development of an international, external quality assurance system is strongly recommended to ensure that data obtained from nucleic acid amplification assays are reliable and comparable.

Recommendation 6

In order to establish the role of serological assays in epidemiological assessments, there is a need for standardisation and validation of reagents (antigens and controls), assay methodologies and analytical approaches.