patients. For pLDH, in children under 5 years, NPV ranged from a peak of 98.9% at a low-transmission site, to just 49.0% at a high-transmission site; in patients aged 5 years and older, the NPV fell from 98.1% to 69.3%. The NPV of expert microscopy was very similar to that of pLDH across all sites and age ranges. In conclusion, considering diagnosis based on PCR as a gold standard, microscopy or pLDH are likely to provide the best diagnostic utility at sites with low transmission, while HRP2 is recommended for medium- and high-transmission areas.

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EVALUATION OF THE NEW MALARIA RAPID DIAGNOSTIC TEST *FIRST RESPONSE*® PF/PV, WHEN USED AS A SCREENING TOOL FOR MALARIA DURING PREGNANCY IN CENTRAL INDIA

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We evaluated a new pLDH malaria rapid diagnostic test (First Response Malaria Pf/Pv Antigen Strips by Premier Medical Corporation Ltd, India) as a potential screening tool for *Plasmodium falciparum* (Pf) and *P. vivax* (Pv) infection in pregnant women attending for antenatal care. Two 6 week cross-sectional surveys were conducted in 3 districts in Central India, one in the dry hot season (March-April) and one post monsoon (October-November), the later representing the peak prevalence of *P. vivax* and *P. falciparum*, respectively. Overall, 1812 pregnant women (815 in the dry season and 997 in the post-monsoon survey) attending routine antenatal care were screened for malaria with the RDT and conventional light microscopy, irrespective of clinical symptoms. Based on microscopy, the prevalence of Pf and Pv was 0.8% and 1.2% in the dry season and 5.7% and 0.7% post-monsoon season, respectively, with marked variations of Pf prevalence between the 3 sites in the latter survey (0%, 2.7% and 18.1%). The overall geometric mean parasite densities (GMPDs) of Pf (n=62) and Pv (n=16) infections were 1380 (95% CI 795-2395) and 908 (95% CI 449-1838), respectively. The GMPDs for *P. vivax* were significantly lower in the dry season survey than the post monsoon survey (422 vs 2434). Using microscopy as the gold standard, the overall sensitivity and specificity of the RDT test were 95.2% and 99.6% for Pf and 68.8% and 99.4% for Pv, respectively. The positive and negative predictive values were 90.8% and 99.8% for Pf, respectively, and 52.4% and 99.7% for Pv. Four out of 7 *P. falciparum* infections with densities <250 parasites/ul were detected by RDT, but this was 1 of 5 for Pv. Confirmation using PCR is ongoing. The First Response Pf/Pv antigen strips test was easy to learn and is a potential alternative to microscopy where the facilities for microscopy are poor or non existent. It was highly sensitive and specific in the screening of mainly asymptomatic pregnant women for *P. falciparum* infection, but was less accurate as screening test for low density *P. vivax* infections.

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CHALLENGES IN ROUTINE IMPLEMENTATION AND QUALITY CONTROL OF RAPID DIAGNOSTIC TESTS FOR MALARIA - RUFIJI DISTRICT, TANZANIA

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Rapid diagnostic tests (RDTs) represent an alternative to microscopy for malaria diagnosis and have shown high sensitivity and specificity in a variety of study settings. Current WHO guidelines for quality control of RDTs provide detailed instructions on pre-field testing, but offer little guidance for quality assurance once RDTs are deployed in health facilities. From September 2006 to April 2007, we introduced HRP2-based RDTs (Paracheck Pf) for suspected malaria cases in 9 health facilities with existing microscopy services in Rufiji District, Tanzania. Rufiji District is a rural setting with holoendemic malaria transmission. Thick blood smears were collected for all patients tested with RDTs and stained and read by laboratory personnel in each facility. Thick smears were subsequently reviewed by a reference microscopist to determine RDT sensitivity and specificity. In all 9 health facilities there were significant problems with the quality of staining and microscopy. Intensive refresher training did not result in substantial improvements in the quality of slide preparation. Sensitivity and specificity of RDTs were difficult to assess given the poor quality of routine blood smear staining. Mean operational sensitivity of RDTs based upon reference microscopy was 64.8%, but varied greatly by health facility, range 18.8-85.9%. Sensitivity of RDTs increased with increasing parasite density. Specificity remained high at 87.8% despite relatively poor slide quality. Institution of quality control of RDTs based on poor quality blood smear staining may impede reliable measurement of sensitivity and specificity and undermine confidence in the new diagnostic. Reliable staining and microscopy for quality control must be a prerequisite to the introduction of RDTs.

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MODELLING COSTS AND BENEFITS OF RDTS FOR THE DETECTION OF *PLASMODIUM FALCIPARUM* IN UGANDA

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With the increasing variety of RDTs on the market, policy makers must identify the most appropriate test, and circumstances where presumptive treatment remains the preferred strategy. This choice is likely to vary widely not only in response to test characteristics but also to characteristics of the population where RDTs are to be deployed. An economic model was developed as a decision aid, adaptable to different scenarios of ACT and RDT costs, and test accuracies. The model also enables the user to vary estimates for other factors, such as the potential harm of treatment, including risk of adverse events and drug resistance, and the probability that clinicians will adhere to test results. In a recent trial the accuracy of two RDTs (detecting either pLDH or HRP2 antigens) was evaluated in 7 sites across Uganda. The data on costs and accuracies were entered into the model to illustrate its use and results. Output was then obtained at increasing levels of comprehensiveness, starting with direct expenditure on diagnostics and treatment alone, and then introducing patient health outcomes, compromised adherence with test results, and the broader societal costs associated with overprescription of antimalarials. Results suggest that given current RDT and ACT prices, use of the HRP2 RDT would be justifiable across most prevalences and age groups. This however depends to a great extent on whether factors such as the harm associated with use of antimalarials and the probability clinicians adhere to results is included in the analysis. Excluding the harm of treatment, presumptive treatment is justified for younger children, and the benefit in the use of RDTs for older patients is also limited. Results also indicate to the need to ensure that clinicians adhere to negative test result if RDTs are to remain an efficient use of resources. Results are expected to vary widely by location and over time as prices and effectiveness of RDTs and ACTs change, therefore the model was designed for easy incorporation of local and up to date parameter estimates for identification to support local decision making.