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Title: Evaluation of 3 rapid diagnostic tests (CareStart[®] Malaria 3 line pLDH (Pan, Pf), OptiMAL-IT[®] pLDH (Pan, Pf) and CareStart[®] 2 line pLDH (Pan) for the diagnosis of malaria in Myanmar

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Background

Obtaining biological confirmation of the diagnosis is considered an essential element of the detection and treatment of malaria in MSF programmes. Several Rapid Diagnosis Tests (RDTs) using monoclonal antibodies against histidine-rich protein 2 (HRP-2) produced by *P. falciparum* (Pf), have shown reliable results when evaluated. A second type of RDT, targeting parasite lactate dehydrogenase (pLDH), produced by all *Plasmodia* species, is appearing on the market increasingly, but few studies support the use of these new tests.

Methods

In an MSF-Switzerland programme in Dawei, Myanmar, 3 pLDH based RDTs were evaluated in patients presenting with clinically suspected malaria. A subset of patients with microscopically confirmed malaria had their RDTs repeated on days 2, 7 and then weekly until negative. Each RDT was read twice. At the end of the study samples of study RDTs were sent for temperature stability and quality control testing.

Results

Between Aug and Nov 2007, 1004 patients were enrolled in the study. Slide microscopy diagnosed 214 *P. vivax* (Pv), 99 Pf and no malaria in 650 cases. The sensitivities (Se) and specificities (Sp), of the RDTs for the detection of malaria were: **OptiMAL-IT[®]**: Pf: Se 95.2% [CI⁹⁵ 87.5-98.2], Sp 94.7% [92.8-96.2]; non-Pf: Se 89.6% [83.6-93.6], Sp 96.5% [94.8-97.7]; Pv alone: Se 91.4% [85.3-95.2]. **CareStart Malaria[®] 3 line**: Pf: Se 93.5% [CI⁹⁵85.4-97.3], Sp 97.4% [95.9-98.3]; non-Pf: Se 78.5% [71.1-84.4], Sp 97.8% [96.3-98.7]; Pv alone: Se 80.6% [72.9-86.5]. **CareStart Malaria[®] 2 line**: Pf: Se 89.1% [CI⁹⁵ 84.2-92.6], Sp 94.7% [92.5-96.3]; Pf alone: Se 95.6% [87.7-98.5]; Pv alone: Se 91.0% [92.5-96.3]. Inter-observer agreement was excellent for all tests (kappa > 0.9). The median time for the RDTs to become negative was 2 days for the CareStart[®] tests and 7 days for OptiMAL-IT[®]. Only **CareStart Malaria[®] 2 line** passed all heat stability evaluation.

Conclusion

In this study OptiMAL-IT[®] RDT and the CareStart[®] 2 line pLDH (Pan) test met the 95% threshold of Se for detection of falciparum malaria set by WHO. The Se of both tests to detect vivax malaria exceeded 90%. However any decision to implement one of these tests should take into account the heat stability results, positive predictive value in the context in which it would be deployed and cost-effectiveness.

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