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Are rapid diagnostic tests more accurate in diagnosis of malaria compared to microscopy?



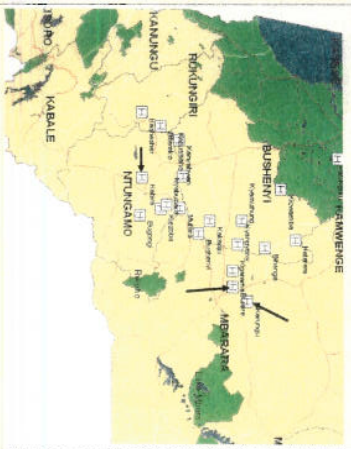
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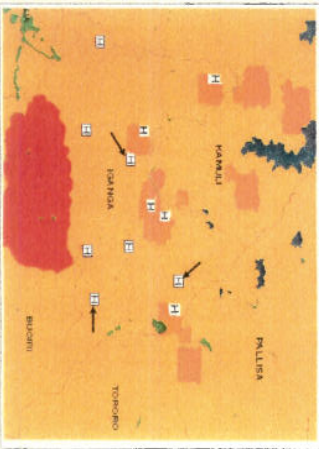
Background

Prompt, accurate diagnosis and treatment with artemisinin combination therapy remains vital to current malaria control. Blood film microscopy the current standard test for diagnosis of malaria has several limitations that necessitate field evaluation of alternative diagnostic methods especially in low income countries of sub-Saharan Africa where malaria is endemic.

Setting 1: Bushenyi – Low transmission



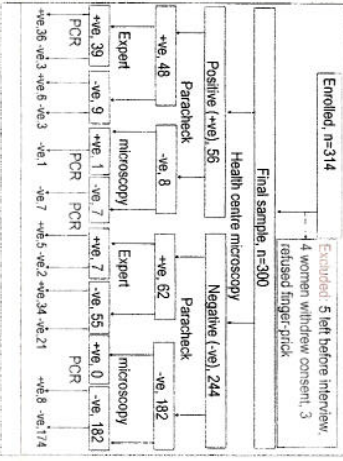
Setting 2: Iganga – High transmission



Methodology

We compared the accuracy of axillary temperature, health centre microscopy, expert microscopy and a HRP2-based rapid diagnostic test (Paracheck) in predicting malaria infection using polymerase chain reaction (PCR) as the gold standard. Three hundred fourteen (314) patients with a clinical suspicion of malaria based on fever and/or history of fever from a low and high transmission setting in Uganda were consecutively enrolled and provided blood samples for all tests. The endpoints were: sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV).

Study profile



Findings

88(29.3%) had fever. 56(18.7%) were positive by health centre microscopy, 47(15.7%) by expert microscopy, 110(36.7%) by Paracheck and 89(29.7%) by PCR. The overall sensitivity >90% was only shown by Paracheck 91.0% [95%CI: 83.1-96.0]. The sensitivity of expert microscopy was 46%, similar to health centre microscopy. The superior sensitivity of Paracheck compared to microscopy was maintained when data was stratified for transmission intensity as well as by age. The overall specificity rates were: Paracheck 86.3% [95%CI: 80.9-90.6], health centre microscopy 93.4% [95%CI: 89.1-96.3] and expert microscopy 97.2% [95%CI: 93.9-98.9]. The NPV >90% was shown by Paracheck 95.8% [95%CI: 91.9-98.2]. The overall PPV was <88% for all methods.

Overall sensitivity, specificity & predictive values

Method	Sensitivity % [95%CI]	Specificity % [95%CI]	PPV % [95%CI]	NPV % [95%CI]
Axillary temp	33.3 [29.1-37.5]	74.5 [68.5-80.6]	39.8 [29.5-50.1]	74.5 [68.5-80.6]
HC microscopy	47.7 [39.5-56.1]	93.4 [89.1-96.3]	75.0 [61.8-88.6]	80.7 [75.2-86.5]
Expert microscopy	46.1 [35.4-57.0]	97.2 [93.9-98.9]	67.2 [43.3-91.2]	81.0 [75.5-86.7]
Paracheck	91.0 [83.1-96.0]	86.3 [80.9-90.6]	73.6 [64.4-81.6]	95.8 [91.9-98.2]

Conclusion

High sensitivity of malaria diagnosis is essential because the infection produces an acute illness in vulnerable populations that can rapidly progress to death. The HRP2-based rapid diagnostic test has shown superior sensitivity compared to microscopy and may be more suitable for screening of malaria infection.

Ethical considerations

The study was approved by Makerere University School of Public Health Institutional Review Board; and the Uganda National Council for Science and Technology (Ref: HS 209). Written informed consent was sought from participants (or parents/legal guardians for minors) at the time of interview.

Study registration

The study is registered with the Clinicaltrials.gov (NCT00565071).

Acknowledgement

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