### Summary Table 6.09

<table>
<thead>
<tr>
<th>Challenges in Routine Implementation and Quality Control of Rapid Diagnostic Tests for Malaria-Rufiji District Tanzania</th>
<th>Meredith I. McMorrow, M. Irene Masanja, Salim M. K. Abdulla, Elizeus Kahigwa and S. Patrick Kachur</th>
</tr>
</thead>
<tbody>
<tr>
<td>RDT product(s):</td>
<td>Paracheck, Orchid Biomedical Systems, Mumbai, India</td>
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<td>Target antigens:</td>
<td>HRP2</td>
</tr>
<tr>
<td>Comparative standard(s):</td>
<td>Thick blood films</td>
</tr>
<tr>
<td>Trial type:</td>
<td>Accuracy / Cost-benefits / public health impact / ease of use / behavioral: Quality control of RDT introduction</td>
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</tbody>
</table>

*Usefulness of paper (rated by reviewers): 5

**Major findings/implications:**
- Many technical difficulties occurred during implementation of RDT in rural Tanzania
- Performance of blood smears remained poor and RDT sensitivity was very variable
- Supervisory visits reported adequate performance of RDT despite poor sensitivity
- Using poor quality microscopy as standard may impede reliable measure of sensitivity and undermine confidence in a new diagnostic

**Country:** Tanzania

**Trial type**

Introduction and Implementation of RDT for malaria diagnosis, Quality control challenges. The proposal was reviewed by the institutional review boards of CDC and Ifakara Health Research and Development Centre.

From September 2006 to April 2007 HRP2 based RDT (Paracheck) were introduced into 9 health Districts of Rufiji District for the diagnosis of suspected malaria cases. Rufiji District is a rural area of subsistence farming with holoendemic malaria transmission. 89% of population live within 5 Km of a health centre and acute febrile illness including malaria is a major cause of death in the district.

Healthcare workers were trained to perform Paracheck RDT according to the manufacturer’s instructions. Blood smears were collected for all patients tested with RDT and stained with 10% Giemsa stain for 30 minutes and read by the laboratory personnel in each facility. Thick smears were reviewed by a reference experienced microscopist blinded to RDT and first microscopist reading. The reference microscopist counted the parasitaemia against 200 wbc and examined 100 fields before declaring negative. Expected sensitivity for the RDT was ≥ 80% sensitivity and specificity for the RDT.

**Results and analysis:**

**Data analysis:** Data and blood smears were collected weekly from each centre Data included number of patients seen, number of positive/negative RDT’s, treatment received. Individual RDT results were compared with reference microscopist results to calculate the sensitivity and specificity. Supervisory visits included a checklist evaluating health workers RDT performance.

Data was entered into Epi Info version 3.3.2 database for descriptive analysis. The SAS 9.1 PROC GENMOD was used to perform log-binomial regression to model the change in RDT sensitivity with increasing parasite density.

**Results**

Number of tests performed during the 7 months of implementation.
58685 patients seen at the 9 health facilities
16779 patients diagnosed with malaria
3650 patients diagnosed with malaria had positive RDT performed
13129 patients were diagnosed clinically.

Demographic: Among patients diagnosed with malaria 8121 were <5yrs (outside the age group recommended for study)
In Adults and children > 5yrs 2874 had a positive RDT and 5784 were clinically diagnosed.
All positive RDT received treatment and only 183 negative RDT received treatment.

Laboratory data:
15661 RDT’s and 12539 blood smears were performed during this period.
32650 RDT’s were read as positive in the health facility and 2134 of 10765 suitable blood smears were read as positive by the reference microscopist.
20.8% of RDT’s read from older children and adults and 41.6% of <5yrs were positive.

Poor quality blood films were evident in all health centres (stain contamination, immersion oil poor, slides not read and RDT result used for slide reading). Intensive repeat training did not result in much improvement.

RDT performance: Strict timing not adhered too. Loop device for blood transfer was difficult to manage, blood deposited into wrong hole in device. Job aides were inconsistently used and cassette labelling errors occurred.

Sensitivity and specificity were compromised by poor slide quality but using reference readers results mean operational RDT sensitivity was 64.8%. (range 18.8%-85.9%)
Health facility performance of RDT had a consistent sensitivity but did not reach the 80% target. Specificity remained at 87.8% in spite of poor slide quality.
RDT sensitivity increased with increasing parasite density in a statistically significant trend

RDT device: Paracheck lots were pre-checked by WHO and again in Ifakara for detection of 200 and 5000 parasites/µl. Some post check errors were seen (failure to detect 5000 parasites in 1 case and device manufacturing defect for buffer flow).
Test line was narrower than control line introducing reading errors

Generalised comments on QA for RDT usage

Many technical difficulties occurred during implementation of RDT in rural Tanzania
Performance of blood smears remained poor and RDT sensitivity was very variable
Supervisory visits reported adequate performance of RDT despite poor sensitivity
Health care workers accepted RDT result over reading blood films
Clinical diagnosis of malaria did not match RDT result
Possible overloading of the laboratory may have decreased diagnostic compliance.
Health care acceptance of RDT may reduce the frequency of appropriate treatment.
Using poor quality microscopy as gold standard may impede reliable measure of sensitivity and undermine confidence in a new diagnostic.

Other proposals and suggestions on quality control of RDT implementation are discussed and new proposals are put forward to ensure that adequate quality control procedures are implemented at all levels of health care system

Usefulness of paper (rated by reviewers): 5

* 1. No direct relevance. 2. Very unlikely to influence current practice. 3. Likely to influence current practice in some settings. 4. Likely to influence current practice in many areas. 5. Highly likely to influence current practice in many areas.

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