# FIELD REPORT

## Developing and testing a generic job aid for malaria rapid diagnostic tests (RDTs)

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# KEY TO ROUNDS AND JOB AID VERSIONS

This document makes reference to various rounds of data collection during which both manufacturer's instructions and various versions of job aids were tested in the Philippines and the Lao People's Democratic Republic. The key below summarizes the relationships between rounds and the type of instructions / job aid used in each round. It may be useful to refer back to this key while reading different sections of the document.

### Philippines

| Round | Instructions / job aid used | Comments |
|---|---|---|
| - | Job aid version 1 | Preliminary evaluation using job aid drafted by WHO Western Pacific Regional Office. |
| 1 | Original manufacturer's instructions | Instructions on test packet plus Tagalog translation on a separate sheet of paper. |
| - | Job aid version 2 – pilot test | Test round to determine necessary changes. Data not collected for analysis. Job aid was modified through focus group discussions in multiple rounds. |
| 2 | Job aid version 3 | Final revision of job aid tested in the Philippines. |

### Lao People's Democratic Republic

| Round | Instructions / job aid used | Comments |
|---|---|---|
| - | Job aid version 4 | Revisions were made to job aid version 3 while en route to the Lao People's Democratic Republic. This version was developed subsequent to the last round of data collection in the Philippines and so was not field-tested there. This version served as the basis for initial translation into Lao then underwent two further revisions before ending as version 7, the final version used for data collection in the Lao People's Democratic Republic (see below). |
| 1 | Original manufacturer's instructions | High-education participants using the instructions on the test packet plus Lao translation on a separate sheet of paper. |
| - | Job aid version 5 | Job aid version 4 translated into Lao. |
| - | Job aid version 6 | Revisions to job aid version 5 based on a few observations. Test round. Data not collected for analysis. |
| 2 | Job aid version 7 | Final Lao version (incorporates changes from versions 5 and 6; only version used during actual observations in the Lao People's Democratic Republic). Low-education participants using job aid only. |
| 3 | Job aid version 7 | Low-education participants using job aid after a one-hour orientation. |
| 4 | Job aid version 7 | Test round. Non-literate participants were asked if they understood how to perform the test using only the drawings (no words). This was for exploratory purposes. Step-by-step results were not recorded. |
| 5 | Job aid version 7 | High-education participants using job aid only. The results of round 5 were compared with those of round 1 (cassette test only). |

# EXECUTIVE SUMMARY

## Background

The traditional approach to malaria diagnosis has been examination by microscope of a thick blood smear from the individual suspected of being infected. In an attempt to provide a more rapid alternative, companies worldwide have developed malaria rapid diagnostic tests (RDTs).

Although RDTs can be effectively used in clinical settings by trained personnel, their greatest potential use is in rural areas with limited access to health and laboratory facilities. Using RDTs for diagnosis at the community level will shorten the delay between the onset of symptoms and the beginning of appropriate treatment. It will also slow development of resistance and lead to significant cost savings by avoiding unnecessary use of antimalarials. However, achieving a high level of sensitivity and specificity with RDTs in this context will require a product designed, labelled, and explained so that community health workers (CHWs) can use it accurately with minimal formal training and supervision.

In partnership with the WHO Regional Office for the Western Pacific, the Quality Assurance Project (QAP) carried out quality-design research in the Philippines and the Lao People's Democratic Republic to develop and test a generic RDT job aid, mainly pictorial, that could be adapted with little modification for use with different RDT products and in different cultural settings by health workers with low literacy skills and with little or no prior training in product use.

## Methods

During October and November 2003, QAP worked with WHO, the Philippine Research Institute for Tropical Medicine (RITM), and the Lao Ministry of Health to assess the usability of existing RDT instructions and a prototype job aid, to develop more detailed line-drawing-based job aids, and to test the change in user performance when using the detailed job aids. The rapid diagnostic tests used for this project were the **Paracheck Pf Rapid One Step device for *P. falciparum* specific HRP 2 antigen in whole blood** (hereinafter referred to as the "cassette test") and the **Paracheck Pf Rapid One Step dipstick for *P. falciparum* specific HRP 2 antigen in whole blood** (hereinafter referred to as the "dipstick test"). Both tests are manufactured by Orchid Biomedical Laboratories.

The research team collected both quantitative and qualitative data. Techniques comprised:

(1) an observation checklist of RDT use and interpretation by CHWs or villagers;

(2) individual structured interviews with CHWs, patients, and observers; and

(3) group discussions with CHWs and observers.

Data collection instruments for these activities were based on those used by Tavrow et al. and adapted to suit the needs of this study.[1] A detailed description of data collection methods and activities appears in the full report below.

## Results

### *Performance of RDT steps*

Participants in both the Philippines and the Lao People's Democratic Republic performed significantly better using the job aid than using the manufacturer's instructions (Table 1, columns 1–2). Levels of performance represent the percentage of total test steps performed correctly. [a] However, overall performance was still unacceptably low. In both countries, participants rarely performed three steps initially classified as crucial: checking the package for expiration date, checking the desiccant for signs of exposure to humidity, and waiting 15 minutes to read the test results. Scores improved when the first two of these steps were excluded from analysis on the assumption that quality control might be better handled by ministry of health officials than by CHWs (Table 1, columns 3–4).

**Table 1: Performance with job aid compared to manufacturer's instructions (percentage of steps completed correctly)**

| | **Score including all test steps** | | **Score *excluding* steps 1 and 2 *** | |
|---|---|---|---|---|
| **Philippines** | **Manufacturer's instructions** | **Improved job aid version 3** | **Manufacturer's instructions** | **Improved job aid version 3** |
| Cassette | 50.8% (n=45) | 66.9% (n=30; p<0.001) | 57.6% | 74.4% (p<0.001) |
| Dipstick | 42.8% (n=46) | 59.5% (n=31; p<0.004) | 47.1% | 65.9% (p<0.001) |
| **Lao People's Democratic Republic** | **Manufacturer's instructions** | **Improved job aid version 7** | **Manufacturer's instructions** | **Improved job aid version 7** |
| Cassette | 67.4% (n=30) | 79.0% (n=27; p<0.001) | 78.6% | 91.3% (p<0.001) |
| Dipstick** | N/A | N/A | N/A | N/A |

* Test steps 1 and 2, the most frequently missed by all participants, were (1) check the date on the outside of the package to confirm that the test was not expired, and (2) check the desiccant inside the package to confirm that the test had not been damaged by exposure to humidity. Scores were calculated excluding these two steps on the assumption that RDT quality might better be managed by ministry of health officials, thus relieving CHWs of this responsibility.

** Participants in round 1 (manufacturer's instructions) were approximately five years younger than those in round 2 (job aid), and had significantly more education. Since age and education are both likely confounders, a comparison was not made between the two groups.

Additional problems in the Philippines included the tendency of the barangay health workers (BHWs) to collect a larger amount of blood than needed (step 8) and their habit of wiping the finger with alcohol after the finger stick (step 7) but immediately before collecting the blood. [b] Both habits—learned as part of collecting thick blood smears—could theoretically affect the accuracy of RDT results. (In the near future, WHO plans to conduct a small study in the Philippines to determine if mixing blood and alcohol does, in fact, affect results.) Most study participants in the Lao People's Democratic Republic were villagers with little or no previous health experience. Since they had not been trained to take blood smears, they did not have to break old habits as was the case in the Philippines.

[a] Most RDTs involve 15–20 discrete steps that must be carried out carefully and in the same order with every patient. Changing the order of a step, missing a step, or performing a step incompletely or incorrectly can lead to flawed test results and incorrect diagnoses.

[b] A barangay is the smallest local government unit in the Philippines and is similar to a village. A 'barangay health worker' (BHW) is the Philippine term for a 'community health worker' (CHW).

**Table 2: Performance with job aid only versus job aid plus orientation (percentage of steps completed correctly)** [a]

| | Improved job aid version 7 only | Improved job aid version 7 plus orientation | p-value |
|---|---|---|---|
| **Cassette** | 69.8% (n=32) | 79.5% (n=32) | 0.0007 |
| **Dipstick**** | N/A | N/A | - |

[a] Low-education group in the Lao People's Democratic Republic.

Low-education Lao participants showed a small but significant improvement when given an hour-long orientation prior to their first use of the cassette RDT (Table 2). However, most still failed to check the expiration date, check for exposure to humidity, and wait 15 minutes to read test results. As a result, overall performance was still unsatisfactory. Interestingly, low-education Lao villagers with no previous health experience carried out almost 70% of the test steps correctly using the job aid alone. This was as well as or better than the better-educated Filipino BHWs. The only important gain in test performance from the orientation was using the correct amount of buffer. While use of the job aid led to performance improvement on many individual test steps, performance on checking the expiration date, checking for exposure to humidity, and waiting a full 15 minutes before reading RDT results never reached acceptable levels.

### *Interpreting RDT results*

There were two different measures of participant ability to interpret RDT results. First, step 13 of the RDT trial measured whether the user correctly read the test they had just performed (Table 3). For the cassette test, both Philippine and Lao participants using the job aid interpreted results correctly from the test they had just performed significantly more often than participants using the manufacturer's instructions. For the dipstick test, Philippine participants using the job aid also interpreted test results correctly more often, but the difference was not statistically significant. It was not possible to measure this difference with the high-education group in Laos. Laotian low-education participants showed no improvement in reading test results when the job aid was accompanied by orientation. Given the scarcity of malaria in the Lao project area, almost all tests performed were negative. As a result, step 13 really only measured the ability to correctly read a negative test. The orientation seemed to help significantly in reading positive test results, as discussed below.

**Table 3: Correctly read test results (step 13)**

| **Philippines** | **Manufacturer's instructions** | **Improved job aid version 3** |
|---|---|---|
| Cassette | 51.1% (n=45) | 86.7% (n=30) (p<0.01) |
| Dipstick | 58.7% (n=46) | 71.0% (n=31) (NS) |
| **Lao People's Democratic Republic*** | **Manufacturer's instructions** | **Improved job aid version 7** |
| Cassette | 67.4% (n=30) | 79.0% (n=27) (p=0.0001) |
| Dipstick** | N/A | N/A |

*High-education group

** Participants in round 1 (manufacturer's instructions) were approximately five years younger than those in round 2 (job aid), and had significantly more education. Since age and education are both likely confounders, a comparison was not made between the two groups.

As a second measure, participants were asked to read and interpret a battery of 10 previously performed tests. The battery included nine positives (some only weakly positive) and one negative. There was no significant change in the users' ability to read the battery of test results using the job aid as compared to using the manufacturer's instructions. In the Lao People's Democratic Republic, however, there was a significantly improved ability to read the battery of 10 tests when the job aid was accompanied by a practical orientation that included examples of actual positive and negative test results in addition to the drawings on the job aid. The 32 villagers who received the orientation read 9.5 out of 10 tests correctly, compared to a high of 7.8 out of 10 for those who did not receive the orientation. This difference may be due to the fact that during the orientation, the actual examples of positive and negative tests included both weak and strong positives so that the users were better able to identify weak positives in the battery of tests.

### *Comparison of dipstick and cassette*

The research seems to confirm previous anecdotal evidence that users have more trouble correctly using the dipstick than the cassette. As shown in Table 4, participants performed better on the cassette test than the dipstick test in every situation where a comparison was possible.

## Discussion

Using the manufacturer's instructions, performance was far below any acceptable levels. Using the improved job aid, most groups were able to significantly improve performance, although the job aid—even with an hour orientation given to one group—did not seem to affect correct performance of certain steps. The steps that remained below acceptable levels were: checking the expiration date, checking for exposure to humidity, and waiting for 15 minutes before reading test results. However, participants using the improved job aid were able to complete the test with near acceptable precision when these two steps (checking for expiration date and humidity) were removed from analysis, page 27.

**Table 4: Cassette versus dipstick performance**

| | Cassette | Dipstick | Difference | p-value* |
|---|---|---|---|---|
| **Philippines** [a] | | | | |
| Manufacturer's instructions | 50.8% | 42.1% | – 8.7% | 0.012 |
| Improved job aid version 3 | 66.9% | 59.5% | – 7.5% | 0.162 |
| **Lao People's Democratic Republic** [b] | | | | |
| Manufacturer's instructions | 67.4% | 58.2% | – 9.2% | 0.052 |
| Improved job aid version 7 | 79.0% | NA | N/A | N/A |
| **Lao People's Democratic Republic** [c] | | | | |
| Manufacturer's instructions | N/A | N/A | N/A | N/A |
| Improved job aid version 7 | 69.8% | 62.5% | – 7.3% | 0.061 |

* p-value for difference in scores between cassette test and dipstick test
[a] Barangay health workers
[b] High-education participants
[c] Low-education participants

It may be that that supervisors will need to take responsibility for quality control issues such as test integrity. The test manufacturer reports a useful shelf-life of up to two years. If turnaround of stock is sufficiently rapid, correct user performance of these two steps may not be crucial. However, the

manufacturer's instructions also specify that test packets must be stored between 4°C and 30°C, a condition unlikely to be met in at least some field sites.

The issue of waiting a full 15 minutes before interpreting test results is more problematic. Early reading of the test results would tend to decrease test sensitivity (more false negatives), meaning that more patients with malaria infections would remain undiagnosed and, presumably, untreated. The manufacturer should be consulted about what, if any, tolerance exists in the 15-minute waiting period. If such studies have not been carried out, it will be important to determine the minimum wait necessary to ensure maximum test sensitivity. Still, a change in product design or issuing of timers may be necessary to ensure compliance with the 15-minute wait before reading.

# FIELD REPORT

Developing and testing a generic job aid for malaria rapid diagnostic tests (RDTs)

# 1. BACKGROUND

## 1.1 Problem statement

Around 2.5 billion people—at least 40% of the world's population—are at risk of contracting malaria in over 90 countries. Up to 500 million acute clinical cases and 1.5–3 million malaria-related deaths occur each year. Children account for the majority of these deaths. Other high-risk groups include pregnant women, refugees, migrant workers, and non-immune travellers.[2]

The traditional approach to malaria diagnosis has been examination by microscope of a thick blood smear from the individual suspected of being infected. This method depends on the availability of a microscope and a trained microscopist. Unfortunately, many malaria-endemic areas of Africa, Asia, and Latin America lack both. In some cases this leads to presumptive treatment based on clinical diagnosis of symptoms which in turn leads to over-prescription of antimalarials and contributes to drug resistance. Alternatively, it may lead to long delays in treatment while a sick client and perhaps a village health worker wait from several days to more than a week for microscopy results.

## 1.2 Development of malaria diagnostic kits

In an attempt to provide an effective alternative to diagnosis by microscopy, companies worldwide have developed malaria rapid diagnostic tests (RDTs). While only two or three RDTs were on the market as recently as five years ago, the WHO RDT website now lists 21 different manufacturers.[3] Some are intended for diagnosis of *P. falciparum* only, some for *P. falciparum* and *P. vivax* and some for *P. falciparum* and all three other human forms of the plasmodium parasite. At present malaria RDTs are used widely in Asia and southern Africa, and less so in South America. Use is expected to increase rapidly with money from the Global Fund to Fight AIDS, Tuberculosis and Malaria. Most of the tests on the market are cassettes or dipsticks; WHO is promoting the use of cassettes as they are simpler to use.

Although RDTs can be effectively used in clinical settings by trained personnel, their greatest potential use is in rural areas with limited access to health and laboratory facilities. If RDTs can be used with a high level of sensitivity and specificity by community health workers (CHWs) at the village level, it will be possible to rapidly and accurately diagnose, and hence appropriately treat, a much greater proportion of febrile cases. Using RDTs for diagnosis at the community level will shorten the time between onset of symptoms and initiation of appropriate treatment, leading to less suffering by the infected individual and less potential to spread the parasite to others when the infected individual is bitten by more anopheline mosquitoes. RDT use should also help slow development of resistance and reduce costs by avoiding unnecessary use of antimalarials.

These last two factors are increasingly important with the introduction of artemisinin-based combination therapy (ACT) in sub-Saharan Africa. Presumptive treatment is cost-effective for individual consumers and health systems while chloroquine (CQ), sulfadoxine/pyramethamine (SP), and amodiaquine (AQ) are available at around US$ 0.15 per child dose. With ACT costing about

US$ 1.50 per child dose, presumptive treatment becomes less feasible and the need for diagnosis more urgent.

However, RDT sensitivity depends greatly on user ability to correctly prepare and carry out the test and interpret the results.[4-8] [4-7, 9] Studies show up to 30% errors in preparation and interpretation with measurable improvement through simple modification of instructions.

For example, the Quality Assurance Project (QAP) redesigned and tested job aids for two malaria RDTs in Malawi in 1998.[4] To establish a baseline measure for correct use of the kits, nine health workers were observed using the first kit a total of 10 times each; another 10 health workers were observed using the second kit a total of 10 times each. Both groups were guided by pre-printed manufacturer's instructions. Only three of the nine workers were able to follow the steps indicated for the first kit 100% correctly in each of their 10 applications. None of the 10 workers using the second kit used it 100% correctly in each of their 10 applications. After two rounds of redesign and testing of revised instructions, 20 different health workers were observed using each of the two kits a total of 10 times. This time, 17 out of the 20 performed all the steps 100% correctly in each of their 10 applications: nine out of 10 for the first kit and eight out of 10 for the second. This experience shows that providing simple clear instructions for test kit use can dramatically improve performance.

## 1.3 Rationale for developing a generic RDT job aid

As stated earlier, RDT use by community health workers at the village level presents a tremendous opportunity to improve malaria diagnosis and treatment. However, it also presents a major challenge, since in many areas CHWs have only the most limited training in health, limited or no formal education and may even be non-literate. Further, CHWs may work in settings that lack resources for training and supervision. Achieving a high level of sensitivity and specificity with RDTs used in this context will depend on a product designed, labelled, and explained so that CHWs can use it accurately with minimal training and supervision.

Research demonstrates that job aids can improve health care provider performance in both preventive and acute care. Job aids can be particularly helpful when procedures involve pre-defined concrete steps to be followed the same way each time the procedure is performed. [10] RDT use is one such example. Most RDTs involve 15–20 discrete steps that must be carried out carefully and in the same order with every patient. Changing the order of a step, missing a step, or performing a step incompletely or incorrectly can lead to flawed test results and incorrect diagnoses.

Some RDT product instructions provided by the manufacturers are of poor quality, fail to list in one easy reference panel the necessary steps and cautions for use, contain large amounts of irrelevant fine print, or actually miss vital information on preparation. As these products are likely to be used in remote areas by health workers with limited literacy, little or no training in RDT use, and little supervision, it is vital that instructions be clear, simple, and easy to follow. The presence of more than 20 different RDT products on the market makes it difficult for WHO or ministries of health to develop an improved product instruction leaflet for each product. Hence, WHO recognizes the need to design effective, generic instructions for the use of RDTs in different field settings. Participants in WHO's malaria RDT initiative have established as one important priority

the design of a job aid to be included as an RDT package insert "including diagrams and text adaptable to different cultural backgrounds".[11]

# 2. PROJECT RATIONALE

## 2.1 Quality-design project

In partnership with the WHO Regional Office for the Western Pacific, the Philippine Research Institute for Tropical Medicine (RITM), and the Lao Ministry of Health, QAP carried out quality-design research in the Philippines and the Lao People's Democratic Republic to develop and test a generic RDT job aid, mainly pictorial, that could be easily adapted to different RDT products in different cultural settings. If successful, this generic job aid could later be tested for usability in Africa. This research also allowed investigators to see which aspects of RDT use were amenable to change through the use of line-drawing-based job aids and/or brief training, and which would need to be influenced through photograph-based job aids, product redesign, longer training, supervision, or other interventions.

## 2.2 Use of quality-design results

Solid quantitative evidence about the ability of CHWs to use and interpret RDT tests accurately, and factors affecting this ability, can inform many decisions. WHO can use the evidence to influence RDT product design and choice, to develop a web-based job aid available for download by national malaria control programmes and other public health entities, and to make recommendations about RDT use by low-literacy health workers. Manufacturers can use these results to improve product design and make product instructions more user-friendly, thereby encouraging correct use. The Philippine and Lao Ministries of Health can use the results to help choose appropriate RDTs, to design training, supply and supervision systems for low-literacy health workers, to boost diagnostic accuracy and coverage, and to increase the proportion of fevers rapidly and appropriately treated.

Obtaining solid quantitative evidence showing that CHWs can use and interpret RDTs with a high degree of accuracy will increase RDT credibility. This credibility, in turn, should increase the likelihood of adherence to treatment prescribed on the basis of RDT results.

# 3. RESEARCH OBJECTIVES

This project had several quality-design goals.

(1) Evaluate the comprehensibility and usefulness of a draft RDT job aid previously developed by WHO as well as the package instructions provided by the product manufacturers.

(2) Use the resulting information to develop two generic line-drawing-based job aids, one for cassette tests and one for dipstick tests, both readily adaptable to different products and settings.

(3) Test user performance improvement achieved by use of these job aids compared to existing package instructions.

(4) Test user performance improvement achieved by use of these job aids accompanied by a brief orientation.

(5) Assess CHW and client perceptions of RDT credibility as compared to microscopy.

# 4. METHODS

## 4.1 Design

During October and November 2003, QAP carried out quality-design research in the Philippines and the Lao People's Democratic Republic to assess the usability of existing RDT instructions and a prototype job aid, develop more detailed line-drawing-based job aids, and test the change in user performance between them.

The rapid diagnostic tests used for this project were the **Paracheck Pf Rapid One Step device for *P. falciparum* specific HRP 2 antigen in whole blood** (hereinafter referred to as the "cassette test") and the **Paracheck Pf Rapid One Step dipstick for *P. falciparum* specific HRP 2 antigen in whole blood** (hereinafter referred to as the "dipstick test"). Both tests are manufactured by Orchid Biomedical Systems of Goa, India. As of this writing, the technical information and package insert for both the cassette and dipstick tests were available on the Orchid Medical Systems website. The manufacturer reports that—presumably under ideal conditions—both tests, compared to microscopy, can achieve a sensitivity of >99% and a specificity of 100% for detecting *P. falciparum* HRP 2. The manufacturer also reports that both tests remain stable for up to two years when stored at 4–30 °C. [a]

A pre-test was carried out in the Philippines to determine the number of trials needed per CHW, to assess the learning curve for RDT users by describing the change in performance as number of trials per user increases. Four users repeated the test 10 times each. Some improvement in performance was observed between the first and second or third trial, but not much change after that. Given logistical constraints, the research team decided that the third trial would represent the plateau of the performance learning curve. This was confirmed by the performances seen in the actual research—performance tended to be poorer on the first attempt, but remained essentially unchanged between trials two and three.

In addition to performing RDTs, the CHWs read the results of 10 previously performed RDTs, in order to test the effectiveness of the package insert or the improved job aid at explaining how to interpret RDT results. The battery included nine positives of varying intensity and one negative.

[a] Orchid Biomedical Systems, Plot Nos. 88/89, Phase II C, Verna Industrial Estate, Verna, Goa, India.

The first round tested the manufacturer's instruction leaflet. Findings from a pre-test (using a simple job aid developed by WHO Western Pacific Regional Office) and the first round (manufacturer's instructions) were then incorporated into the first detailed job aid, tested in round 2.

#### *4.1.1 Study sites and study population*

The research teams worked in several health facilities in each country in order to enrol enough febrile patients to be able to adequately test RDT use. Patient flow at health centres in both countries was quite low. In the Philippines, in some health facilities researchers found only few febrile patients, so non-febrile volunteers were recruited. This was also the case in the Lao People's Democratic Republic, where an intensive malaria project had taken place in the area selected for field work.

In the Philippines, barangay health workers (BHWs), almost all with finger stick experience and almost none with RDT experience, participated. Two research teams were used so that two health facilities could be visited per day. The number of BHWs and volunteer "patients" available near each health facility were fairly low. On some days the teams had to visit additional facilities or try to find BHWs at home in order to include the desired number of BHWs per round. In accordance with Philippine national norms, a confirmatory blood slide was prepared for each patient tested.

In the Lao People's Democratic Republic, it was not possible to identify enough village health volunteers. Thus, the research team members agreed to recruit low-literacy villagers with no previous health experience to perform RDTs. As described above, volunteers were also recruited in lieu of febrile patients.

As planned, each Philippine BHW performed three trials (performance data from each CHW's first and second RDT trial represent the user's learning curve; the third trial represents likely performance over time). Near the end of the research in the Lao People's Democratic Republic, there were insufficient numbers of RDT test kits available to allow each participant to complete three trials; some completed only two. Thus data analysed and results presented for the Lao People's Democratic Republic are based on the second trial for each participant rather than the third.

#### *4.1.2 Job-aid revisions*

The initial WHO- and QAP-devised job aids were revised based on trials using the package inserts (round 1) and on interviews with BHWs about the proposed job aids. Revised job aids were then further tested in various forms (with and without text) with the BHWs. This allowed development of the final version tested with Philippine BHWs (round 2). Based on the final round results in the Philippines, the job aids were revised a final time in the Lao People's Democratic Republic before being tested with low- and high-educated villagers.

### 4.2 Data collection techniques

The research team collected both quantitative and qualitative data. Techniques comprised:

- an observation checklist of RDT use and interpretation by CHWs (or villagers);
- individual, structured interviews with CHWs and observers; and
- group discussions with CHWs and observers.

Table 6 provides an overview of data collection techniques by source.

**Table 6: Summary of data collection techniques**

| Source | Technique |
|---|---|
| Trained health workers | Individual interviews |
| Trained observers | Group discussions |
| CHWs | Observation checklist |
| | Individual interviews |
| | Group discussions |

Data collection instruments for these activities were based on those used by Tavrow et al. and adapted to suit the needs of this study.[4] Two research teams were used in the Philippines in order to find enough CHWs, but in the Lao People's Democratic Republic only one team was used since the participants were villagers, not CHWs. In the Philippines, both teams conducted research concurrently after undergoing training to standardize research techniques. The principal investigator and a WHO specialist supervised the two teams to ensure consistency of technique. Evening feedback sessions were held at the end of each day's work. Each team in the Philippines consisted of four to five members, tasked as follows:

- One team member registered CHWs and patients or volunteers, administered the informed consent forms, managed patient and CHW flow to the observers, and ensured that blood slides were collected when finger pricks for RDTs were done.
- Two observers documented participant RDT use and interpretation. Each observed one CHW at a time, but the two worked simultaneously to maximize the number of RDT trials observed. Having two observers also left sufficient time for some group interviews with CHWs.
- A supervisor monitored observation quality, assigned record numbers, re-checked data collection forms, and oversaw confirmatory RDTs, patient treatment, and interviews. When necessary, the supervisor also administered the battery of RDTs for CHW interpretation.
- In some instances, a microscopist accompanied the team to read blood slides.

The team in the Lao People's Democratic Republic consisted of a registrar, four observers, a supervisor and a microscopist. As available, team members also carried out exit interviews with patients, participants, and health staff to learn their attitudes towards the RDTs. Test users were also asked for feedback on how to improve the job aids or product design. The teams were too small to assign one person to conduct these interviews full time, so team members did this in addition to their other tasks.

Each round of testing was carried out as follows:

- The supervisor assigned a record number to the CHW or volunteer to be observed, and sometimes completed the demographic information at the top of the observation checklist.

- The CHW was sent to the observer's station where he/she applied the RDT with three different patients or volunteers using the job aid appropriate to each test and to each stage of the investigation (e.g. original package insert, WHO prototype job aid, revised draft job aid).
- The observer evaluated the CHW's ability to correctly use the RDT, completing a separate checklist for each observation.
- The observer then had the CHW read a battery of 10 pre-prepared RDTs and recorded the CHW's interpretation of results. At times, a supervisor carried out this portion of the observation, enabling the observer to begin observing another CHW or volunteer.
- In observations involving a febrile patient, a trained health professional using blood from the same finger stick, collected a blood slide.
- Appropriate treatment was provided to patients according to national policy. Both febrile and asymptomatic patients were treated if found to be either RDT- or slide-positive.
- Research team members conducted exit interviews with a convenience sample of patients. The interviews took place after patients had been informed of their diagnoses and received treatment if appropriate. Due to time constraints and the fact that most participants were volunteers rather than patients, these interviews were conducted only during the first few days of field work in the Philippines.
- Research team members conducted structured interviews with a sample of CHWs after their last RDT use.
- The team conducted group discussions (with four to eight CHWs at a time) to discuss understandability, acceptability, and appropriateness of the kit instructional inserts.
- Based on the results of each round, the technical team, with assistance of the local artist, made required changes to illustrations and text.

# 5. RESULTS

## 5.1 The Philippines

### *5.1.1 Cassette test*

Of the 75 BHWs included in cassette test rounds 1 and 2, 74 were female. Only one BHW had less than complete primary education; 22 (29.3%) had complete primary, 12 (16.0%) had some secondary, and 40 (53.3%) had complete secondary or higher. The average age was 41.6 years (standard deviation (SD) 9.75, range 20–67). An overwhelming majority had at least some experience treating malaria (mean 5.84 years, SD 5.42, range 0–21) and handling blood (mean 5.3 years, SD 5.27, range 0–28). Very few had experience working in a laboratory and fewer still had previously used RDTs. Table 7 summarizes the characteristics of the sample overall and by type of instruction used (package instructions versus job aid version 3).

**Table 7: Characteristics of Philippine BHWs using cassette RDTs**

| | Manufacturer's instructions (n=45) | Improved job aid version 3 (n=30) | Total (n=75) | Test statistic (p value) |
|---|---|---|---|---|
| **Mean age** | 40.2 | 43.8 | 41.6 | t=1.59 (0.117) |
| **Level of education completed **** | | | | |
| Incomplete primary | 0 (0.0%) | 1 (3.3%) | 1 (1.3%) | |
| Complete primary | 10 (22.2%) | 12 (40.0%) | 22 (29.3%) | $\chi^2$ =11.54 (0.009) |
| Some secondary | 12 (26.7%) | 0 (0.0%) | 12 (16.0%) | |
| Complete secondary | 24 (51.1%) | 17 (56.7%) | 41 (53.3%) | |
| **Mean years treating malaria *** | 4.8 | 7.3 | 5.8 | t=1.95 (0.055) |
| **Mean years handling blood *** | 4.3 | 6.8 | 5.3 | t=2.03 (0.046) |
| **Have treated malaria *** | 43 (95.6%) | 25 (83.3%) | 69 (90.67%) | $\chi^2$ =3.30 (0.069) |
| **Have handled blood** | 45 (100%) | 29 (96.7%) | 75 (98.7%) | $\chi^2$ =1.52 (0.218) |
| **Have laboratory experience** | 4 (8.9%) | 3 (10.0%) | 7 (9.33%) | $\chi^2$ =0.03 (0.871) |
| **Have used an RDT** | 3 (6.7%) | 0 (0.0%) | 3 (4.0%) | $\chi^2$ =2.08 (0.149) |

* difference significant at p < 0.10; ** difference significant at p < 0.05

## Applying the test

Using only the manufacturer's instructions as a guide, BHWs correctly carried out 50.8% of the 14 individual test steps for the cassette RDT (SD 14.1%, 95% confidence interval (CI) 46.6%–55.1%). With the revised job aid in round 2, the BHWs correctly completed 66.9% of the steps (SD 17.6%, 95% CI 60.3%–73.5%). This amounts to a 16% improvement over performance with the manufacturer's instructions alone. The difference is highly significant (t=4.39, p<0.001).

The results are a good deal less encouraging when the score is based only on the seven pre-determined "crucial" steps. If scores are calculated on the assumption that all seven of these "crucial" steps must be completed correctly for the RDT to be considered valid, the BHWs relying on the manufacturer's instructions were not able to correctly complete even a single test. With the revised job aid, only one BHW completed all seven steps correctly.

This outcome led us to examine the step-by-step differences between use of the manufacturer's instructions and use of job aid version 3. The results of this examination appear in Table 8. It shows that the three most problematic steps were step 1 (check expiration date), step 2 (check colour of the desiccant in the package to be sure the test has not been damaged by humidity), and step 12 (wait 15 minutes after adding buffer before reading the test results). In the case of step 1, 20% of the BHWs using the job aid checked the expiration date on the package, compared to only 4.4% of those using the manufacturer's instructions. The improvement is significant ($\chi^2$=4.56, p=0.033), but the level of performance is still unacceptably low (for purposes of this study, "acceptable performance" = steps performed correctly ≥80% of the time). With step 2 (desiccant), the difference between 15.6% correct (manufacturer's instructions) to 23.3% correct (job aid) is insignificant. The test statistic and p-value ($\chi^2$=0.72, p=0.397) indicate that any apparent improvement may well have occurred by chance. The same can be said for the apparent improvement from 17.8% to 30.0% in step 12. As with step one, the difference, even if not due to chance still results in unacceptably low performance.

**Table 8: Performance on individual test steps (cassette RDTs, Philippines)** [a]

| Test step | Number (%) of BHWs who performed this step correctly | | | |
|---|---|---|---|---|
| | Manufacturer's instructions (n=45) | Improved Job Aid version 3 (n=30) | Improvement | $c^2$ (p value) |
| **1. Check expiration date** | 2 (4.4%) | 6 (20.0%) | * 15.6% | 4.57 (0.033) |
| **2. Check desiccant colour (should be blue)** | 7 (15.6%) | 7 (23.3%) | 7.7% | 0.72 (0.397) |
| 3. Place cassette on level surface | 42 (93.3%) | 30 (100.0%) | 6.7% | 2.08 (0.149) |
| 4. Select finger to puncture | 45 (100.0%) | 30 (100.0%) | 0.0% | N/A |
| 5. Clean finger with antiseptic | 44 (97.8%) | 30 (100.0%) | 2.2% | 0.68 (0.411) |
| 6. Allow finger to air dry | 32 (71.1%) | 21 (70.0%) | -1.1% | 0.011 (0.918) |
| 7. Use sterile lancet to puncture | 45 (100.0%) | 30 (100.0%) | 0.0% | N/A |
| 8. Collect 5 ul of blood with pipette | 11 (24.4%) | 19 (63.3%) | ** 38.9% | 11.34 (0.001) |
| **9. Blot blood on sample well A** | 21 (46.7%) | 23 (76.7%) | ** 30.0% | 6.68 (0.010) |
| **10. Hold bottle vertically and dispense buffer into well B** | 3 (6.7%) | 9 (30.0%) | ** 23.3% | 7.29 (0.007) |
| **11. Dispense 6 drops of buffer** | 26 (57.8%) | 26 (86.7%) | ** 28.9% | 7.07 (0.008) |
| **12. Wait 15 minutes** | 8 (17.8%) | 9 (30.0%) | 12.2% | 1.53 (0.216) |
| **13. Read results correctly** | 23 (51.1%) | 26 (86.7%) | ** 35.6% | 10.05 (0.002) |
| 14. Dispose of test safely | 11 (24.4%) | 15 (50.0%) | * 25.6% | 5.19 (0.023) |

* difference significant at $p < 0.05$; ** difference significant at $p < 0.01$

[a] Steps in bold are "crucial.

On the other hand, use of the revised job aid led to highly significant improvements in the performance of steps 8, 9, 10, 11, and 13, although steps 8–10 were still at a less than adequate performance level. Steps 9–13 were all part of the group initially defined as "crucial," so the significant performance improvement seen in these steps indicates that test outcomes could be expected to be more accurate with the job aid than with the original manufacturer's instructions.

One possible explanation for the low score on step 10 was an error in the observation checklist. Step 10 actually involves two separate tasks: holding the buffer bottle upright and dispensing the buffer solution into the correct well (well B) on the cassette. Holding the bottle upright was deemed to be important to ensure a reasonably consistent volume in each drop of buffer dispensed, although it is not absolutely essential for test accuracy. Dispensing the buffer into the correct well is important because the test has two wells: one for blood, the second for buffer. If the user of the test puts the blood or buffer into the wrong well, the test will not function properly. Given the concern about both issues, step 10 should have been divided into two separate steps to avoid confusion about what to do if a participant did not hold the bottle upright but did dispense the buffer into the correct well or vice versa.

In the field, it was decided that putting the buffer in the correct well was the more crucial of the two issues and therefore that participants should receive credit for completing the step correctly if they dispensed the buffer into the correct well regardless of the position in which they held the bottle. However, in some cases, the step was continuously scored as incorrect if the participant did not hold the bottle upright, even if the participant used the correct well. It is highly likely that more participants would have received credit for completing this step correctly had the instrument error been corrected before field work began and the recording been more consistent. This is supported by the fact that, when the instrument was simplified in the Lao People's Democratic Republic to check only on whether buffer was dispensed into well B, the majority of users received credit for the step.

Reading the battery of test results

A total of 76 BHWs participated in this phase of the study, 46 using the manufacturer's instructions; 30 using the revised job aid. The battery of 10 cassettes used to test BHW ability to interpret RDT results contained nine positive tests and one negative test. There were no missing values in this data set. All 10 tests were scored either "correct" or "incorrect" for all 76 participants. On average, BHWs using the manufacturer's instructions read 7.8 out of 10 tests correctly; those using the job aid read 6.8 out of 10 correctly. The 1% difference was not statistically significant, indicating no overall change in BHW ability to accurately interpret the cassette RDT.

Controlling for education did not affect performance in interpreting RDT cassette results. Only one participant had incomplete primary education, so it was not possible to compare results between original instructions and job aid for this education level. Likewise, the 12 participants with incomplete secondary education all used the original instructions; there was no comparison group using the job aid. However, comparison between participants with complete primary education showed a pattern similar to that of the overall results: a mean score of 6.5 with the original instructions compared to 5.7 for the job aid, a non-significant difference of –0.83 (p=0.57). Participants with complete secondary education or higher scored an average of 8.4 with original instructions compared to 7.5 with the job aid. This difference of –0.85 is also non-significant (p=0.32). For those with complete primary education, there were no significant differences between original instructions and job aid in percentage of participants correctly interpreting any one test.

### *5.1.2 Dipstick test*

A total of 77 BHWs participated in the dipstick tests, 72 women and five men. Three (4.0%) had less than complete primary education, 17 (22.4%) had complete primary, 18 (23.7%) had some secondary, and 38 (50.0%) had complete secondary or higher. The average age was 42.3 years (SD 10.1, range 23–69). All but seven had experience treating malaria (mean 6.61 years, SD 5.77, range 0–22). All but four had experience handling blood (mean 6.25 years, SD 5.77, range 0–23). As with the cassette group, very few had experience working in a laboratory or using RDTs. Table 9 summarizes the characteristics of dipstick participants overall and by type of instructions used.

**Table 9: Characteristics of Philippine BHWs using dipstick RDTs**

| | Manufacturer's instructions (n=46) | Improved job aid version 3 (n=31) | Total (n=77) | Test statistic (p value) |
|---|---|---|---|---|
| **Mean age** | 40.8 | 44.4 | 42.3 | t=1.52 (0.133) |
| **Level of education completed *** | | | | |
| Incomplete primary | 1 (2.2%) | 2 (6.7%) | 3 (3.95%) | |
| Complete primary | 6 (13.0%) | 11 (36.7%) | 17 (22.4%) | $\chi^2$ = 7.48 (0.058) |
| Some secondary | 13 (28.3%) | 5 (16.7%) | 18 (23.7%) | |
| Complete secondary | 26 (56.5%) | 12 (40.0%) | 38 (50.0%) | |
| **Mean years treating malaria** | 7.4 | 5.5 | 6.6 | t=1.46 (0.149) |
| **Mean years handling blood *** | 7.1 | 5.0 | 6.2 | t=1.68 (0.097) |
| **Have treated malaria **** | 46 (100.0%) | 24 (77.4%) | 70 (90.9%) | $\chi^2$ =11.43 (0.001) |
| **Have handled blood **** | 46 (100.0%) | 27 (87.1%) | 73 (94.8%) | $\chi^2$ = 6.26 (0.012) |
| **Have laboratory experience** | 4 (8.7%) | 3 (9.7%) | 7 (9.1%) | $\chi^2$ = 0.02 (0.883) |
| **Have used an RDT** | 2 (4.4%) | 0 (0.0%) | 2 (2.6%) | $\chi^2$ = 1.38 (0.239) |

* difference significant at p < 0.10; ** difference significant at p < 0.05

Applying the test

With only the manufacturer's instructions, participating BHWs correctly completed an average 42.8% of the steps for the dipstick RDT (SD 18.0, 95% CI 36.7-47.4%). With the revised job aid, participating BHWs correctly completed an average 59.5% of the steps correctly (SD 23.0%, 95% CI 51.0–67.9%). This amounts to a 17.4% improvement over the original instructions (t=3.71, p=0.004).

Similar to the cassette RDT, however, the pre-post difference for the previously defined crucial steps only were small (a 3.2% improvement) and not statistically significant (t=1.22, p=0.2255). None of the BHWs using the manufacturer's instructions and only one of those using the revised job aid completed all 7 crucial steps correctly. Once again, the differences for each individual step of the test were examined (Table 10). Of the 7 "crucial" steps, by far the most problematic was step 1 with a non-significant improvement from 2.2% to 9.7%.

**Table 10: Performance on individual test steps (dipstick RDTs, Philippines) [a]**

| Test Step | Number (%) of BHWs who performed this step correctly | | | |
|---|---|---|---|---|
| | Manufacturer's instructions (n=46) | Improved job aid version 3 (n=31) | Improvement | $c^2$ (p value) |
| **1. Check expiration date** | 1 (2.2%) | 3 (9.7%) | 7.51% | 2.12 (0.146) |
| 2. Check desiccant colour (should be blue) | 10 (21.7%) | 10 (32.3%) | 10.6% | 1.07 (0.302) |
| 3. Do not touch membrane | 25 (54.4%) | 13 (41.9%) | -12.5% | 1.14 (0.285) |
| 4. Clean finger with antiseptic | 44 (95.7%) | 31 (100.0%) | 4.3% | 1.38 (0.239) |
| 5. Allow finger to air dry | 31 (67.4%) | 26 (83.9%) | 16.5% | 2.62 (0.106) |
| 6. Use sterile lancet to puncture | 46 (100.0%) | 31 (100.0%) | 0.0% | N/A |
| 7. Collect 5 ul of blood with pipette | 9 (19.6%) | 20 (64.5%) | *** 44.9% | 15.94 (<0.001) |
| 8. Blot blood on dipstick pad | 15 (32.6%) | 22 (71.0%) | *** 38.4% | 10.92 (0.001) |
| **9. Squeeze buffer into test tube, holding dropper vertically** | 2 (4.4%) | 10 (32.3%) | *** 27.9% | 10.97 (0.001) |
| **10. Dispense 4 drops of buffer** | 25 (54.4%) | 21 (67.7%) | 13.3% | 1.38 (0.240) |
| **11. Place dipstick in test tube, arrows down** | 16 (34.8%) | 20 (64.5%) | ** 29.7% | 6.58 (0.010) |
| **12. Wait 15 minutes** | 11 (23.9%) | 16 (51.6%) | ** 27.7% | 6.24 (0.012) |
| **13. Read results correctly** | 27 (58.7%) | 22 (71.0%) | 12.3% | 1.21 (0.272) |
| 14. Dispose of test safely | 9 (19.6%) | 13 (41.9%) | ** 22.3% | 4.54 (0.033) |

* difference significant at p < 0.10; ** difference significant at p < 0.05; *** difference significant at p < 0.01

[a] Steps in bold are "crucial.

Results improve slightly if step 1 is removed from consideration. The improvement between original instruction and revised job aid is still only a non-significant 6.7% from 2.1% at baseline to 8.8% at follow-up. If the first *two* steps are removed from consideration (checking to make sure the test is not expired *and* checking that it has not been damaged by humidity), the mean score improves 15.1% from 2.0% correct with the manufacturer's instructions to 17.1% correct with the revised job aid (t=2.6, p=0.011). Participants seemed to have a particularly hard time grasping the need to hold the buffer bottle vertically when dispensing drops (necessary to achieve a uniform drop volume, although not critical to test accuracy) and the need to wait 15 minutes before interpreting the test. As with the cassette test, the job aid produced more accurate performance than the manufacturer's instructions. Still, though performance exceeded 50% correct on four of the seven "crucial" steps, and 60% on three of the seven, the performance level did not come close to achieving the ≥80% target.

Reading the test

The same 77 BHWs tested the manufacturer's instructions (n=46) and revised job aid (n=31) for interpreting the battery of 10 RDT dipsticks. As with the cassettes, the battery of 10 dipstick RDTs contained nine positives and 1 negative. On average, BHWs using original instructions read 7.0 out of 10 tests correctly, while those using the job aid read 7.5 out of 10 correctly. This half-point difference was not statistically significant (t=1.13, p=0.263). Stratifying for education showed no potential confounding. At each grade level, there was a slight but non-significant increase in accurate interpretation.

## 5.2 The Lao People's Democratic Republic

Characteristics of the participants in the Lao People's Democratic Republic differed considerably from those of the Filipino BHWs. First, while nearly all the BHWs were female, approximately one third of the Laotian participants were male. Second, while most BHWs had completed primary education or higher, educational levels were much lower among the Laotian group. In fact, in the Lao People's Democratic Republic, the educational categories developed for use in the Philippines could not be applied (incomplete primary, complete primary, incomplete secondary, and complete secondary or higher). Since it was difficult to get reliable information even about the number of years of education completed by the Laotian participants, the participants were divided into three new educational categories: (1) cannot read well (one to three years of education); (2) can read a newspaper; and (3) "well educated" (can read with ease, completed primary education or higher). Third, while most BHWs had considerable experience diagnosing and treating malaria, most of the Laotian participants had no experience with any type of health care work. In fact, due to the scarcity of CHWs in the Lao People's Democratic Republic, the team worked with "ordinary" villagers. Finally, due to limited time and a limited supply of both cassette and dipstick RDTs, it was not possible for each Laotian participant to complete three tests as had been the case with the BHWs. For this reason, the results presented below represent the second test for each participant rather than the third.

### *5.2.1 Cassettes*

The project carried out five rounds of testing with RDT cassettes in the Lao People's Democratic Republic. Round 1 included mainly "well educated" (category 3) villagers using only the manufacturer's instructions. Round 2 included mainly less educated villagers (more than two thirds with 3 years of education or less and ) using the job aid version 7. Round 3 included mainly villagers with a similar (low) educational background (categories 1 and 2) using job aid version 7 after having received an hour orientation from the principal investigator (PI) and the field team.[*] Round 4 was used as a qualitative diagnostic exercise to test some potential changes to the job aid, so no observations were recorded. Round 5 consisted of mostly "well educated" villagers using only version 7 of the job aid with no orientation provided.

[*] The orientation consisted of a step-by-step demonstration of how to carry out the test using the revised job aid (version 7). Field staff first demonstrated each step, then asked participants to complete each step themselves using the job aid. Once all participants had practised each step, field staff members distributed several tests showing strong positive, weak positive and negative results. Participants reviewed these tests and received one-on-one feedback on their diagnoses from field staff members and from fellow participants.

Below, we present two comparisons: (1) round 1 (well educated using manufacturer's instructions) versus round 5 (well educated using the job aid); and (2) round 2 (less educated using only the job aid) versus round 3 (less educated using the job aid plus an hour orientation).

A total of 121 Lao villagers participated in the cassette tests, 57 (47.1%) female and 64 (52.89%) male. Forty-three (35.5%) of the total sample had three years or less education and could read with difficulty. Twenty-seven (22.3%) could read a newspaper, while 51 (42.2%) were categorized as well educated (complete primary or higher). Average age was 33.6 years (SD 9.5, range 17–64). Only four (3.3%) reported ever having treated malaria, six (5.0%) had experience handling blood, none had laboratory experience, and 12 (9.9%) reported having ever seen or used an RDT. Table 11 summarizes the characteristics of cassette participants overall and by round.

## Applying the test

When all steps are included in the performance score, round 1 users (well educated using only the manufacturer's instructions) correctly completed an average 67.4% of the steps for the cassette RDT (SD 12.8%, 95% CI 62.6%–72.2%). Meanwhile, round 5 users (well educated using improved job aid version 7) correctly completed 79.0% of the steps (SD 7.9% 95% CI 75.9%–82.2%), an improvement of 11.7% (t=4.1, p=0.0001). However, all participants in both rounds scored zero when the evaluation criteria was the correct completion of all seven "crucial" steps. Here the principal problem occurred in the first two steps. Not a single participant in either round checked the expiration date and only three (11.1%) in round 5 checked the colour of the desiccant.

**Table 11: Characteristics of Lao villagers using cassette RDTs**

| | Higher-education group[a] | | | Lower-education group[b] | | |
|---|---|---|---|---|---|---|
| | Manufacturer's instructions (n=30) | Improved job aid version 7 (n=27) | Test statistic (p value) | Improved job aid version 7 only (n=32) | Improved job aid version 7 + orientation (n=32) | Test statistic (p value) |
| **Mean age** | 33.9 | 34.0 | t = 0.04 (0.967) | 35.0 | 31.3 | t = 1.48 (0.144) |
| **Sex = female: **** | 18 (60%) | 7 (25.9%) | $\chi^2$ = 6.7 (0.010) | 11 (34.4%) | 21 (65.6%) | $\chi^2$ = 6.25 (0.012) |
| **Level of education completed:** | | | | | | |
| 1-3 years (can read with difficulty) | 1 (3.3%) | 0 (0.0%) | | 23 (71.9%) | 19 (59.4%) | |
| Can read newspaper | 6 (20.0%) | 3 (11.1%) | $\chi^2$ = 1.87 (0.393) | 9 (25.0%) | 10 (31.3%) | $\chi^2$ = 1.6 (0.449) |
| Well educated (complete primary +) | 23 (76.7%) | 24 (88.9%) | | 1 (3.1%) | 3 (9.4%) | |
| **Have treated malaria:** | 3 (10.0%) | 1 (3.7%) | $\chi^2$ = 0.86 (0.353) | 0 | 0 | N/A |
| **Have handled blood:** | 1 (3.3%) | 1 (3.7%) | $\chi^2$ = 0.006 (0.940) | 2 (6.25%) | 2 (6.25%) | $\chi^2$ = 0 (1.00) |
| **Have laboratory experience:** | 0 | 0 | N/A | 0 | 0 | N/A |
| **Have seen or used an RDT: **** | 2 (6.7%) | 1 (3.7%) | $\chi^2$ = 0.25 (0.617) | 0 (0.0%) | 9 (28.1%) | $\chi^2$ = 10.47 (0.001) |

[a] The higher education group consisted mainly of villagers from education category 3 (page 22).

[b] The lower education group consisted mainly of villagers from education categories 1 and 2 (page 22)..

* difference significant at p < 0.10; ** difference significant at p < 0.05

Table 12 presents the results of the step-by-step comparison between rounds 1 and 5. In addition to the first two steps, the problem areas for both groups were waiting a sufficient amount of time before reading the test (step 12) and disposing of the test safely after use (step 14). With the job aid, there was a marginally significant improvement for step 5 (clean finger with antiseptic before puncturing) and highly significant improvements with the job aid for steps 6 and 8 (allowing the finger to air dry and collecting no more than the necessary amount of blood).

**Table 12: Performance on individual test steps (cassette RDTs, Lao People's Democratic Republic, higher education)** [a]

| Test step [b] | Number (%) of users who performed this step correctly | | | |
|---|---|---|---|---|
| | Manufacturer's instructions (n=30) | Improved job aid version 7 (n=27) | Improvement | $\chi^2$ (p value) |
| **1. Check expiration date** | 0 (0.0%) | 0 (0.0%) | - | N/A |
| **2. Check desiccant colour** (should be blue) | 0 (0.0%) | 3 (11.1%) | 11.1% | 3.52 (0.061) |
| 3. Place cassette on level surface | 29 (96.7%) | 27 (100.0%) | 3.3% | 0.92 (0.339) |
| 4. Select finger to puncture | 30 (100.0%) | 27 (100.0%) | - | N/A |
| 5. Clean finger with antiseptic * | 23 (76.7%) | 25 (92.6%) | 15.9% | 2.71 (0.100) |
| 6. Allow finger to air dry *** | 20 (66.7%) | 26 (96.3%) | 29.6% | 8.01 (0.005) |
| 7. Use sterile lancet to puncture | 28 (93.3%) | 26 (96.3%) | 3.0% | 0.25 (0.617) |
| 8. Collect 5 ul of blood with pipette *** | 7 (23.3%) | 26 (96.3%) | 73.0% | 31.0 (< 0.001) |
| **9. Blot blood on sample well A** | 28 (93.3%) | 26 (96.3%) | 3.0% | 0.25 (0.617) |
| **10. Dispense buffer into well B** | 30 (100.0%) | 27 (100.0%) | - | N/A |
| **11. Dispense 6 drops of buffer** | 29 (96.7%) | 26 (96.3%) | 0.4% | 0.006 (0.94) |
| **12. Wait 15 minutes** | 19 (63.3%) | 18 (66.7%) | 3.4% | 0.07 (0.792) |
| **13. Read results correctly *** | 24 (80.0%) | 26 (96.3%) | 16.3% | 3.5 (0.061) |
| 14. Dispose of test safely | 16 (53.3%) | 15 (57.7%) | 4.4% | 0.11 (0.743) |

* difference significant at $p \leq 0.10$; ** difference significant at $p < 0.05$; *** difference significant at $p < 0.01$

[a] The higher education group consisted mainly of villagers from education category 3 (page 22)..

[b] Steps in bold are "crucial"

In the comparison between rounds 2 (less educated with job aid only) and 3 (less educated with job aid plus an hour orientation), those working with the job aid alone correctly carried out an average 69.8% of the test steps (SD 14.3%, 95% CI 64.7%–74.9%) while those who received the one hour orientation correctly carried out an average 79.5% (SD 5.4%, 95% CI 77.5%–81.4%). Though statistically significant (t=3.6, p=0.0007), this improvement was relatively small (9.7%, 95% CI 4.3–15.0%). As with the first group, there were no correct scores when the evaluation criteria became correct completion of all seven "crucial" steps. Also as with the first group, the biggest problem areas were steps 1 and 2: checking the expiration date and the desiccant. As shown in Table 13, the percentage of participants waiting 15 minutes before reading the test results improved from 43.8% in group 2 to 56.3% in group 3, but the difference was not significant ($\chi^2$=1.00, p=0.317). There was a marginally significant improvement from 90.6% to 100% of participants correctly completing step 9 and significant improvements on steps 6–8 and steps 10 and 11.

**Table 13: Performance on individual test steps (cassette RDTs, Lao People's Democratic Republic, lower education) [a]**

| Test step | Number (%) of users who performed this step correctly | | | |
|---|---|---|---|---|
| | Improved job aid version 7 only (n=32) | Improved job aid version 7 plus orientation (n=32) | Improvement | $c^2$ (p value) |
| **1. Check expiration date** | 1 (3.1%) | 0 (0.0%) | - | N/A |
| **2. Check desiccant colour (should be blue)** | 1 (3.1%) | 3 (9.4%) | 6.3% | 1.1 (0.302) |
| 3. Place cassette on level surface | 31 (96.9%) | 32 (100.0%) | 3.1% | 1.0 (0.313) |
| 4. Select finger to puncture | 31 (96.9%) | 32 (100.0%) | 3.1% | 1.0 (0.313) |
| 5. Clean finger with antiseptic | 30 (93.8%) | 32 (100.0%) | 6.2% | 2.1 (0.151) |
| 6. Allow finger to air dry ** | 28 (87.5%) | 32 (100.0%) | 12.5% | 4.3 (0.039) |
| 7. Use sterile lancet to puncture ** | 27 (84.4%) | 32 (100.0%) | 15.6% | 5.4 (0.020) |
| 8. Collect 5 ul of blood with pipette ** | 26 (81.3%) | 31 (96.9%) | 15.6% | 4.01 (0.045) |
| **9. Blot blood on sample well A *** | 29 (90.6%) | 32 (100.0%) | 9.4% | 3.2 (0.076) |
| **10. Dispense buffer into well B **** | 28 (87.5%) | 32 (100.0%) | 12.5% | 4.3 (0.039) |
| **11. Dispense 6 drops of buffer ***** | 21 (65.6%) | 32 (100.0%) | 34.4% | 13.3 (< 0.001) |
| **12. Wait 15 minutes** | 14 (43.8%) | 18 (56.3%) | 12.5% | 1.0 (0.317) |
| **13. Read results correctly** | 28 (87.5%) | 30 (93.8%) | 6.3% | 0.7 (0.391) |
| 14. Dispose of test safely | 17 (54.8%) | 18 (56.3%) | 1.5% | 0.01 (0.910) |

* difference significant at $p \leq 0.10$; ** difference significant at $p < 0.05$; *** difference significant at $p < 0.01$

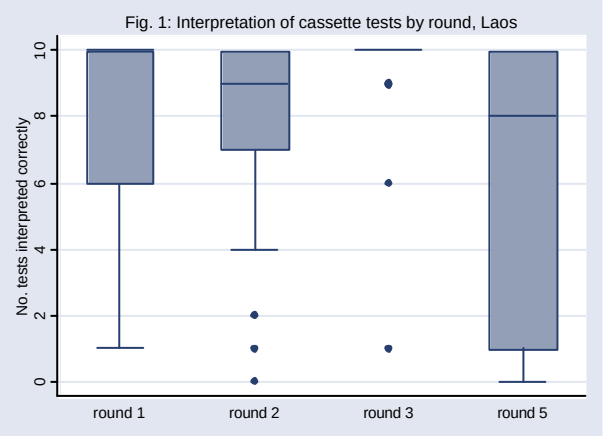
[a] The lower education group consisted mainly of villagers from education categories 1 and 2 (page 22)..

[b] Steps in bold are "crucial".

## Reading the test

The same number of Laotian users participated in each round of interpreting the battery of 10 RDTs as had participated in carrying out the tests. The battery of 10 cassettes was identical to that used in the Philippines and described previously. Once again, there were no missing values: All 10 tests were scored as either "correct" or "incorrect" for all participants in each round. On average, round 1 participants read 7.8 out of the 10 tests correctly compared to 6.5 out of 10 for round 5 participants, but the difference was not significant (t=1.4, p=0.158). As shown in Figure 1, the wide dispersion of scores in round 5 indicates considerable overall variation in scores within the round rather than undue influence of one or two extreme scores.

**Figure 1: Interpretation of cassette tests by round (Lao People's Democratic Republic) [a]**



[a] The graph shows the number of tests correctly read by each participant in each round. Each box spans the 25th to the 75th percentile and contains scores for 50% of the participants in each round. A shorter box (e.g. in round 2), shows that the middle 50% of participants read approximately the same number of tests correctly (in this case, the middle 50% read 7–10 tests correctly). A longer box (e.g. in round 5) shows more variation in scores: the middle 50% of participants ranged from reading only one to reading as many as 10 tests correctly. There is no box in round three because almost all participants (28/31) read all 10 tests correctly, thus the middle 50% of participants all had the same score: 10 correct. The dots below rounds 2 and 3 represent outliers: participants whose scores were extremely low compared to others in their round. The horizontal lines inside the boxes for rounds 2 and 5 are median scores. The boxes for rounds 1 and 3 do not show separate median scores because in both cases the median score was equal to 10, the upper limit of the box.

Participants in round 2 read 7.9 out of the 10 tests correctly compared to 9.5 out of 10 for those participating in round 3. This difference was statistically significant (t=2.67, p=0.0092).

### *5.2.2 Dipsticks*

Due to the limited number of test kits available, only 50 participants could be included in RDT dipstick tests in the Lao People's Democratic Republic. The 50 participants were divided into two rounds. Round 1 included 21 participants using only the manufacturer's instructions; round 2 included 29 participants using only the Lao version of the job aid with no prior orientation.

The overall sample had 25 males and 25 females. Twenty-six participants (52.0% of the total sample) had three years or less education and could read with difficulty, 10 (20.0%) could read a newspaper, and 14 (28.0%) had complete primary education or higher ("well educated"). Average age was 32.9 years (SD 8.9, range 17–50). Only one reported ever having treated malaria, and three (6.0%) had experience handling blood. None had laboratory experience, but nine (18.0%) reported having ever seen or used an RDT. Table 14 summarizes Lao dipstick participant characteristics overall and by type of instructions used.

As can be seen in Table 14, the participants in round 1 (manufacturer's instructions) were approximately five years younger than those in round 2 (job aid). Also, participants in round 1 had significantly more education. This makes comparison between the two groups difficult since age and education are both likely confounders when looking at differences in score.

**Table 14:Characteristics of Lao participants using dipstick RDTs**

| | Manufacturer's instructions | Improved job aid version 7 | Test statistic (p value) |
|---|---|---|---|
| **Mean age*** | 29.8 | 35.1 | t = 2.17 (0.035) |
| **Sex = female:** | 11 (52.4%) | 14 (48.3%) | $\chi^2$ = 0.08 (0.774) |
| **Level of education completed:)*** | | | |
| 1–3 years (can read with difficulty) | 1 (4.8%) | 25 (86.2%) | |
| Can read newspaper | 8 (38.1%) | 2 (6.9%) | $\chi^2$ = 32.45 (<0.001) |
| Well educated (complete primary +) | 12 (57.1%) | 2 (6.9%) | |
| **Have treated malaria:** | 0 (0.0%) | 1 (3.5%) | $\chi^2$ = 0.74 (0.390) |
| **Have handled blood:** | 0 (0.0%) | 3 (10.3%) | $\chi^2$ = 2.31 (0.128) |
| **Have laboratory experience:** | 0 (0.0%) | 0 (0.0%) | N/A |
| **Have used an RDT:** | 5 (23.8%) | 4 (13.8%) | $\chi^2$ = 0.83 (0.363) |

* difference significant at p < 0.05

## Applying the test

Participants using only the manufacturer's instructions completed an average 58.2% of the 14 dipstick test steps correctly (SD 20.2%, 95% CI 49.0%–67.4%). Participants using the improved

job aid version 7 with no orientation completed an average 62.5% of the steps correctly (SD 15.7%, 95% CI 56.5%–68.5%). This 4.3% difference was not statistically significant (t=0.85, p=0.402).

Table 15 presents step-by-step scores. As with previous groups, participants in these two rounds of testing scored poorly at checking expiration date and desiccant colour. Waiting the full 15 minutes before reading test results also remained a problem for both groups.

Participants using the improved job aid performed 37.8 percentage points better than those using the manufacturer's instructions at step 7: collecting the correct amount of blood (75.9% versus 38.1% correct, respectively, p=0.007). Participants using the job aid also performed 20.2 percentage points better at step 11: correctly placing the dipstick in the test tube with the buffer solution (respectively 96.4% versus 76.2% correct, p=0.032). There were no significant differences between the two groups on any other steps.

When the scores are calculated based on the assumption that all steps predetermined to be "crucial" must be completed correctly, none of the participants in either round scored above zero. However, when the two most troublesome steps (1 and 2, checking expiration date and desiccant) were removed from the set of "crucial" steps, about 25% of the participants in each group were able to perform the test adequately. When the next most problematic step (step 12, waiting 15 minutes before reading the test results) was removed from consideration, the number of participants performing adequately (all other "crucial" steps completed correctly) jumped to 47.6% in the manufacturer's instructions group and 51.7% in the job aid group (difference not significant, p=0.774).

**Table 15: Performance on individual test steps (dipstick RDTs, Lao People's Democratic Republic) [a]**

| Test step | Number (%) participants who performed this step correctly | | | |
|---|---|---|---|---|
| | Manufacturer's instructions (n=21) | Job aid version 7 (n=29) | Difference | $c^2$ (p value) |
| **1. Check expiration date** | 0 (0.0%) | 0 (0.0%) | - | N/A |
| **2. Check desiccant colour (should be blue)** | 0 (0.0%) | 4 (13.8%) | 13.8% | 3.15 (0.076) |
| 3. Do not touch membrane | 7 (33.3%) | 12 (41.4%) | 7.1% | 0.33 (0.563) |
| 4. Clean finger with antiseptic | 20 (95.2%) | 24 (82.8%) | -12.4% | 1.79 (0.180) |
| 5. Allow finger to air dry | 17 (81.0%) | 25 (86.2%) | 5.2% | 0.25 (0.617) |
| 6. Use sterile lancet to puncture | 19 (90.5%) | 23 (79.3%) | -11.2% | 1.13 (0.288) |
| 7. Collect 5 ul of blood with pipette*** | 8 (38.1%) | 22 (75.9%) | 37.8% | 7.24 (0.007) |
| 8. Blot blood on dipstick pad | 17 (81.0%) | 26 (89.7%) | 8.7% | 0.77 (0.381) |
| **9. Hold dropper vertically** | 18 (85.7%) | 26 (96.3%) | 10.6% | 1.73 (0.188) |
| **10. Dispense 4 drops of buffer** | 16 (76.2%) | 17 (63.0%) | -13.2% | 0.96 (0.327) |
| **11. Place dipstick in test tube, arrows down ** ** | 16 (76.2%) | 27 (96.4%) | 20.2% | 4.57 (0.032) |
| **12. Wait 15 minutes** | 6 (28.6%) | 10 (34.5%) | 5.9% | 0.20 (0.658) |
| **13. Read results correctly** | 14 (66.7%) | 21 (72.4%) | 5.7% | 0.19 (0.662) |
| 14. Dispose of test safely | 13 (61.9%) | 13 (44.8%) | -19.1% | 1.42 (0.233) |

* difference significant at p < 0.10; ** difference significant at p < 0.05; *** difference significant at p < 0.01

[a] Steps in bold are "crucial"

## Reading the test

All participants in both rounds also read the battery of 10 tests, nine positive and one negative. On average, participants using the manufacturer's instructions read 6.3 out of 10 tests correctly; those using

the improved job aid version 7 read 6.6 out of 10 correctly. This difference was not significant (t=0.37, p=0.712).

## 5.3 Provider and population attitudes towards RDTs

A small convenience sample of providers, CHWs, and villagers was interviewed about their impression of the RDT, and their level of confidence in an RDT compared to a blood slide as a diagnostic method. Participant and patient responses to the RDTs were overwhelmingly positive. Representative comments from health workers include: "This is convenient since you do not need electricity or sun-light [as you do for the microscopes] or slides and chemicals, since sometimes they are not available"; and, "Sometimes the microscopist is not available, so this is helpful to have easy tests any of us can use."

BHWs said: "This test is fast and easy, you don't have to send it to the microscopist who may not be available"; and, "We can do this test ourselves, so patients do not have to wait for the results. We will know immediately whether the patient needs treatment for malaria or not." (Apparently blood slides are sometimes sent or read in batches, making definitive diagnosis very slow. In these cases, treatment may be given presumptively while waiting for the slide results.)

One villager said, "With this test, you know it is your blood that they are testing. They have not mixed up your slide with another person's." Another said, "There is no doubt about what the result is. With a slide, you don't know what they are looking at in the microscope. With this test, you can see the lines. Even we can see."

Most of the respondents expressed their desire to have these tests available in the communities. Several villagers stated their willingness to purchase or pay for these tests as a more precise, reliable, and rapid means of diagnosing fever and deciding whether to take antimalarial drugs or not. They felt that the time and effort saved was worth the price of a test and suggested that these tests be made available either through BHWs or simply through village shops and pharmacies.

## 5.4 Comparison of dipstick to cassette tests

Results seem to confirm previous anecdotal evidence that users have more trouble correctly using the dipstick than using the cassette (Table 16). In the Philippines, many BHWs tried to peel off the section of the dipstick where the arrow pointed to the blotter pad on which the blood was supposed to be placed. In addition, the dipsticks often fell over once placed in the tube wells, spilling the buffer on the table. Some BHWs placed the collection tube parallel to the dipstick, or placed the blood collection tube directly into the tube well with the buffer.

**Table 16: Cassette versus dipstick performance (percentage of steps performed correctly)**

| | Cassette | Dipstick | Difference | p-value* |
|---|---|---|---|---|
| **Philippines** [a] | | | | |
| Manufacturer's instructions | 50.8% | 42.1% | – 8.7% | 0.012 |
| Improved job aid version 3 | 66.9% | 59.5% | – 7.5% | 0.162 |
| **Lao People's Democratic Republic** [b] | | | | |
| Manufacturer's instructions | 67.4% | 58.2% | – 9.2% | 0.052 |
| Improved job aid version 7 | 79.0% | NA | N/A | N /A |
| **Lao People's Democratic Republic** [c] | | | | |
| Manufacturer's instructions | N/A | N/A | N/A | N/A |
| Improved job aid version 7 | 69.8% | 62.5% | – 7.3% | 0.061 |

* p-value for difference in scores between cassette test and dipstick test

[a] Barangay health workers

[b] High-education participants

[c] Low-education participants

## 5.5 Challenges to study implementation

Challenges to research implementation included:

- The PI was accompanied by a fluent English speaker for only the first three days of field work in the Lao People's Democratic Republic, leading to communication difficulties during data collection.
- Scheduling and logistical difficulties (holidays, floods, the need to work by flashlight in a few health centres, a BHW convention) all required deviations from the established protocol.
- Payment of honoraria to participants in the Lao People's Democratic Republic led to a change in the socioeconomic profile of these participants. The protocol called for a baseline trial of the manufacturer's insert with villagers wit a low education. However, since the Lao field coordinator felt that honoraria should be distributed to village headmen and other leaders, initial participants had significantly more education than anticipated. This made it necessary to carry out an additional round of testing (round 5) to measure the effectiveness of the job aid with more highly educated participants.
- Recruitment obstacles in both countries limited the ability to test job aid effectiveness under different conditions. The Philippines protocol stipulated a fourth round of testing preceded by a brief orientation if the revised job aid did not produce acceptable performance by round 3. This would have made it possible to compare performance with the job aid plus orientation to performance with the job aid alone. However, it was not possible to complete this round. In the Lao People's Democratic Republic, it would have been useful to recruit more participants with a low level of education, but there were insufficient RDT kits available.

The limitations of the research include the constraints listed above plus the fact that the research was conducted with only one type of CHW, those in the Philippines, who are more highly educated than CHWs found in many other countries. On the other hand, the research in the Lao People's Democratic Republic showed the level of success that ordinary villagers with limited education could have using the manufacturer's instructions or a job aid. Even though demographic

characteristics were different between rounds and countries, the investigators feel justified in making the conclusions that follow.

# 6. DISCUSSION

This research offers some indication of the extent to which a line-drawing-based job aid can enable health volunteers or laypersons with relatively low levels of education to correctly use dipstick and cassette RDTs. It also suggests what aspects of performance might require a different type of job aid or a different intervention. Additional information garnered during the research includes user and client perceptions of the tests and which type of test seems more appropriate for use by lay users.

## 6.1 Type of RDT

As noted above, performance was slightly better with cassette RDTs than with dipsticks. The dipstick seemed more confusing to participants because there are more choices about where to put the blood and where to place the dipstick. In terms of logistics, dipsticks present the additional challenge of ensuring that tube wells are available, since they are not included in the test kit package; whereas with the cassette, a lancet is the only additional supply needed. Also, with the dipstick tests, the buffer has a tendency to spill out of the tube well. The researchers recommend that cassettes be the preferred test kit for community use, due to their greater ease of use, better performance, and simpler logistics.

## 6.2 Product redesign issues

The study findings raise several issues related to product design and instructions (kit inserts, job aids or training on use).

### *6.2.1 Blood collection*

Both RDTs included straws to collect blood from the finger stick. Manufacturer's instructions indicate that users should collect only a thin film of blood (5 µl). BHWs in the Philippines tended to collect much more blood than necessary, attempting to partially fill the capillary tube instead of collecting just a thin film. In interviews, BHWs explained that, based on their experience preparing thick blood smears for diagnosis by microscopy, they believed the more blood they collected the better the test would function. This was less of a problem in the Lao People's Democratic Republic, where most study participants had no experience preparing blood slides. Still, many participants in both countries had difficulty understanding how to use the straw: Some tried sucking blood into the tube to collect blood, others tried scraping to collect more blood. This experience suggests that a different product design may be more successful than further changes to the job aid in collecting the correct amount of blood. Some manufacturers currently use other blood transfer devices, including plastic loops, pipettes and capillary tubes. In view of the difficulties with using the straw, it is important to evaluate if one of these alternative devices is better.

#### *6.2.2 Waiting 15 minutes to interpret test results*

Despite many attempts to communicate the importance of waiting 15 minutes before reading the test results, participants rarely followed this instruction, apparently for several reasons. First, many of the users did not have a watch, and only a few asked to use the watches that the observers had available. Second, those who did use a watch often rounded up or down to the nearest five-minute interval or miscalculated the time completely. Third, many users contented themselves with waiting a few minutes without actually timing the interval or simultaneously checked several tests performed at different times rather than waiting 15 minutes after each test.

This problem was not simply absence of watches or lack of ability to calculate or remember the time. Rather, 15 minutes seemed to be a somewhat flexible concept for many users. Our observations suggest that it may be impossible to effectively communicate the importance of the 15-minute wait through the job aid alone. The issue would likely respond better to product redesign or provision of a timer. It is recommended that the manufacturer clarify the tolerance levels for the test, specifying how much sensitivity and specificity are lost when results are read in less than 15 minutes. If it is feasible, redesigning the product to include some sort of built-in timing device, perhaps something that changes colour, makes a sound, or pops out of the device 15 minutes after the buffer is added is also recommended. Another alternative might be to design the product so that it is difficult to read the results when the proper waiting time is not respected. If a product redesign of this type is not feasible, it is recommended to test the use of a low-cost 15 minute timer. If the definitive ring of a bell leads to a sufficient increase in compliance with the requisite waiting period, such a timer could be distributed to health volunteers who will apply the RDTs.

It is interesting to note that in Malawi trained health workers with much higher education levels also had difficulty complying with the 15-minute wait. The Malawi study authors concluded that the issue of test timing was probably not amenable to change with a job aid alone. For this reason, they also recommended that timers be included with the test kits. [4]

### 6.3 Role of job aid in attaining correct performance

Given the results from Malawi, a more substantial performance improvement in this study was expected. In retrospect, the two studies have at least two important differences that may help explain the differing results. First, the Malawi study participants were not CHWs or villagers but paid health personnel. The *least* educated of these participants, the health surveillance assistants, had an average of eight years of formal education plus eight weeks of clinical training. Other participants included health assistants (average 14 years formal education, two years clinical training) and enrolled nurses and medical assistants (average 15 years formal education, three years clinical training).[4] Second, Tavrow and colleagues did not include "checking for expiration date" or "exposure to humidity" in their performance criteria.[4] The absence of these steps plus the higher level of formal education and the clinical training probably accounts for a significant part of the performance improvement seen in Malawi compared to that observed here. Tavrow et al. did, however, report the same difficulty experienced in this study with communicating the importance of waiting a full 15 minutes before reading test results. Tavrow et al. recommended that to address this problem, the manufacturers should consider including timers in the test kit.[4][1]

With a line-drawing job aid, BHWs in the present study did show significant overall improvement, and Lao participants correctly performed almost 80% of test steps. But the important question is whether correctly performing a *certain combination of steps* is necessary to achieve acceptable sensitivity and specificity and what—if any—margin of error is tolerable in which steps. In the present research, significant variability in quantity of blood and buffer used and in timing was observed. More clarity is needed on how much the test accuracy is affected by this type of variability. For example, how much sensitivity and specificity is lost if a CHW uses more than the specified volume of blood, adds four or five drops of buffer instead of six, or reads the test at 10 minutes instead of 15? To answer this, the test manufacturer should be invited to review these results and provide guidance on whether performance levels observed with the job aid are sufficient. From the information available on the manufacturer's website, it is not clear whether reported sensitivity and specificity (99% and 100%, respectively) are based on tests of efficacy (use under ideal conditions) or effectiveness (use under field conditions). If the reported levels are based on efficacy testing, additional trials may be necessary to determine effectiveness. Even if the reported levels are based on effectiveness testing with trained health personnel, it may be worth doing additional testing with lower-level health workers (or simulating in the laboratory commonly observed errors from the field) to more clearly determine acceptable margins of error.

#### *6.3.1 Expiration date and exposure to humidity*

Two of the three steps that were consistently skipped or performed incorrectly were checking the expiration date and checking for exposure to humidity. However, as illustrated below (Table 17, columns 3 and 4), participants using the job aid were able to complete the test with near acceptable precision when these two steps were removed from analysis. Performing these steps may not be essential for individual users under normal field conditions. If the unopened test packet has a two-year shelf life as reported by the manufacturer, turnover should be rapid enough that large stocks of expired tests are unlikely to accumulate. Based on the observations carried out in this study, it seems unlikely that a job aid could successfully address these issues. It is recommended that RDT kit integrity and freshness be monitored by ministries of health at the distribution level rather than by individual users in the field.

The manufacturer also specifies that test packets must be stored between 4 °C and 30 °C prior to use. In areas where temperatures routinely rise above 30 °C, CHWs may make erroneous diagnoses by continuing to use tests whose accuracy has been compromised by exposure to excessive heat.

**Table 17: RDT performance with job aid compared to manufacturer's instructions (percentage of steps completed correctly)**

| | Score including all test steps | | Score *excluding* steps 1 and 2 [a] | |
|---|---|---|---|---|
| **Philippines** | **Manufacturer's instructions** | **Improved job aid version 3** | **Manufacturer's instructions** | **Improved job aid version 3** |
| Cassette | 50.8% (n=45) | 66.9% (n=30; p<0.001) | 57.6% | 74.4% (p<0.001) |
| Dipstick | 42.8% (n=46) | 59.5% (n=31; p<0.004) | 47.1% | 65.9% (p<0.001) |
| **Lao People's Democratic Republic** | **Manufacturer's instructions** | **Improved job aid version 7** | **Manufacturer's instructions** | **Improved job aid version 7** |
| Cassette | 67.4% (n=30) | 79.0% (n=27; p<0.001) | 78.6% | 91.3% (p<0.001) |
| Dipstick** | N/A | N/A | N/A | N/A |

[a] Test steps 1 and 2, the most frequently missed by all participants, were (1) check the date on the outside of the package to confirm that the test was not expired, and (2) check the desiccant inside the package to confirm that the test had not been damaged by exposure to humidity. Scores were calculated excluding these two steps on the assumption that RDT quality might better be managed by Ministry of Health officials, thus relieving CHWs of this responsibility.

**Participants in round 1 (manufacturer's instructions) were approximately five years younger than those in round 2 (job aid), and had significantly more education. Since age and education are both likely confounders, a comparison was not made between the two groups..

## 6.4 Role of job aid in correct interpretation of results

The key issue with correct interpretation is the correct identification of weak positives. Malaria control programmes want to ensure that all cases are identified and treated. Incorrect reading of tests with weak positive results will result in false negative diagnoses leading to an increased burden of disease at both the individual and population levels.

With the job aid, most users could correctly interpret most of the individual tests they had carried out. However, almost all these tests were negative. The difficulty in correctly interpreting the battery of 10 tests indicates that user performance is insufficiently accurate to ensure adequate sensitivity. Given the difficulty with reading the weak positives in the Philippines, the job aid used in the Lao People's Democratic Republic was modified to include four drawings of results: one negative, one with a dark positive line, one with a paler line to indicate a weak positive, and one without a control line to indicate a defective test. These additional drawings did not seem to help users to interpret the battery of results, since those using the job aid alone in the Lao People's Democratic Republic did not score better than those using the job aid in the Philippines. Only users who also received an hour orientation read the test battery with a high degree of success, correctly interpreting 9.5 out of 10 results. The orientation focused on learning to read results by seeing actual positive and negative RDTs, including some weak positives.

## 6.5 Which job aid to use?

The main choices for job aids are line-drawing-based and photograph-based job aids. Some advantages of using line drawings for job aids and other education materials are:

- revising images based on pre-testing is straightforward and there is no need to re-photograph;
- simplifying images and eliminating irrelevant details is easy;
- it is possible to produce fairly generic images not specific to any one ethnic group;

- printing line drawings is usually cheaper than printing photographs; and
- printing in black and white is cheaper than printing in colour.

Photograph-based job aids, though more expensive, offer greater attractiveness, realism, and precision. Technological improvements now allow editing, revision, and simplification as needed. Each option has implications for ease of development, adaptation, and interpretation and for cost.

### *6.5.1 Text alone*

Based on the results of the research, it was clear that the manufacturer's instructions, which were in text alone, with an image of the positive and negative results, were not sufficient to enable most participants to correctly use and interpret the tests.

### *6.5.2 Line drawings*

Low-literacy villagers and health workers had difficulty with black and white line drawings, particularly those showing test results. Most could follow the steps for carrying out the test, but had difficulty understanding that some of the black lines on the drawing represented pink or red lines that would form on the RDT itself. If line drawings are to be used, they should be black, white, and red, to show clearly where blood goes on the RDT and where diagnostic lines appear.

### *6.5.3 Photographs*

In addition to comparing text- versus line-drawing-based job aids, the research team held some discussions with participants and community members about their preference for photographs versus line drawings or other graphic approaches. The researchers also discussed user preferences between black and white (either photo or illustration) and colour.

Given Philippine participants' difficulties with the line drawings, researchers printed some small digital photographs of the steps for carrying out and interpreting the test. These were shown to a few participants who had already tried the line-drawing-based job aids. Responses were mixed about whether the photos or the line drawings were clearer. This is understandable given that the photos were small, in black and white, and of relatively poor resolution.

While preparing to test the latest version of the line-drawing job aid in the Lao People's Democratic Republic, the researchers obtained a copy of a Laotian training manual prepared to train health workers in RDT use. The manual contained medium-sized colour photos illustrating RDT use and interpretation. Participants who had tried the text-only or line-drawing job aid expressed a clear preference for the large, good quality colour photos, which are much more expensive than black and white line drawings.

It was not within the scope of the research to carry out a comparison between photograph-based and line-drawing-based job aids, but given the difficulties the participants had in interpreting some of the instructions for use, and particularly in reading the results, this seems to be a necessary next step.

Though it was appropriate to start with black and white line drawings, the least expensive alternative, it seems likely that low literacy users will perform better with spot colour drawings, full colour drawings, photos with spot colour (red), or colour photographs. Alternately, actual tests could be used for initial training, as was done with the orientation group in this study. It is worth noting that Tavrow et al., based on their Malawi experience, also recommended the use of spot colour to improve RDT job aid comprehensibility.[4]

The researchers recommend that WHO or country programmes test differences in performance with the following different types of job aids (listed from least to most expensive):

- black and white drawings as used in this research
- spot colour drawing (adding red to indicate blood and the results lines)
- full colour drawings
- colour photographs.

These different options should also be compared to performance using a job aid accompanied by a brief orientation with actual tests showing strong and weak positive, negative, and defective results. This test of performance could include groups of villagers or CHWs with similar education levels to ensure comparability of results or groups with differing levels of education to ascertain if certain threshold levels of education produce performance high enough to ensure accurate results. This test should also include a comparison of which job aid produced the most correct interpretations of weak positives. Any test battery should include negative and weak and strong positive examples, since most test results will be negative, even in highly endemic areas.

## 6.6 Job aid alone or job aid plus orientation?

Our recommendations about the need for orientation would differ depending on the target user group. Results suggest that community agents with experience doing blood smears need significant orientation on RDT use to overcome existing habits and beliefs. Relatively well-educated lay persons, in contrast, seemed able to perform most steps correctly using only the job aid. Even users with only three years of primary education performed fairly well using the job aid alone.

Most participants using the job aid alone had difficulty remembering to check the expiration date, checking the desiccant colour, waiting 15 minutes, and correctly interpreting results, regardless of education level or type of instructions. Orientation did not improve the first three, but did increase the correct interpretation of results. Thus, the main role for orientation might be to improve users' ability to recognize weak positives by showing actual examples of tests. A job aid with colour photographs of strong and weak positives might eliminate the need for such orientation. Additional research comparing performance using photo-based job aids versus performance using photo-based job aids plus orientation could help answer this question.

## 6.7 Packaging job aids

There are several potential audiences for instructions on RDT use: trained health personnel, CHWs, private vendors, and individual users who acquire RDTs through the private sector. Trained health personnel might use RDTs if they lack laboratory facilities but wish to correctly diagnose fevers before prescribing treatment. Once these health workers have mastered proper RDT use, they may

have less need for a job aid since they will likely perform these tests fairly frequently. Job aids for facility-based health workers could take the form of a laminated wall chart or desk aid.

Job aids for CHWs might also take the form of a detailed, illustrated, and (ideally) laminated wall chart. In many countries, the national malaria control programme provides periodic training of community malaria volunteers who would be using these RDTs. This periodic training could be used to introduce the test kits and their use, and the job aid could be used to reinforce the training. The advantage of this approach is that it makes unnecessary the inclusion of detailed job aids with costly colour graphics or photographs in each RDT package.

However, if RDTs are made available in the retail sector (e.g. in shops or pharmacies), each test kit would need to be packaged with a complete set of instructions or a job aid, as well as all necessary supplies (buffer, lancet, tube wells for dipsticks, etc.). Though pharmacists, for instance, might be able to apply RDTs using a wall-based job aid, individual consumers would need instructions with each test unit purchased.

### 6.8 Final job aid

Illustrations of the most recent versions of the job aids for the cassette and the dipstick tests are in Appendices A and B. Graphics files in both JPG and CorelDraw© format are available for downloading on the WHO RDT website at http://www.wpro.who.int/rdt/link11.cfm. However, given the results of the research, the investigators do not recommend that this type of line drawing be used as the definitive job aid. Performance with photo-based and line-drawing-based job aids should be compared before making a decision on mass production.

Once a decision is made whether to recommend photo- or drawing-based job aids, adapting the generic job aids for other malaria RDT products should be a relatively simple task for each manufacturer. Each RDT is different, but certain steps will be the same or similar for all tests. Other RDT manufacturers will need to analyse which steps differ from those portrayed in the generic job aid; which are the same but require slight changes in the drawings, photos, or text; and which steps should be eliminated/added. However, as with any set of instructions or communication materials, it is *essential* that all changes be tested with end-users before being produced for large-scale use.

## ACKNOWLEDGEMENTS

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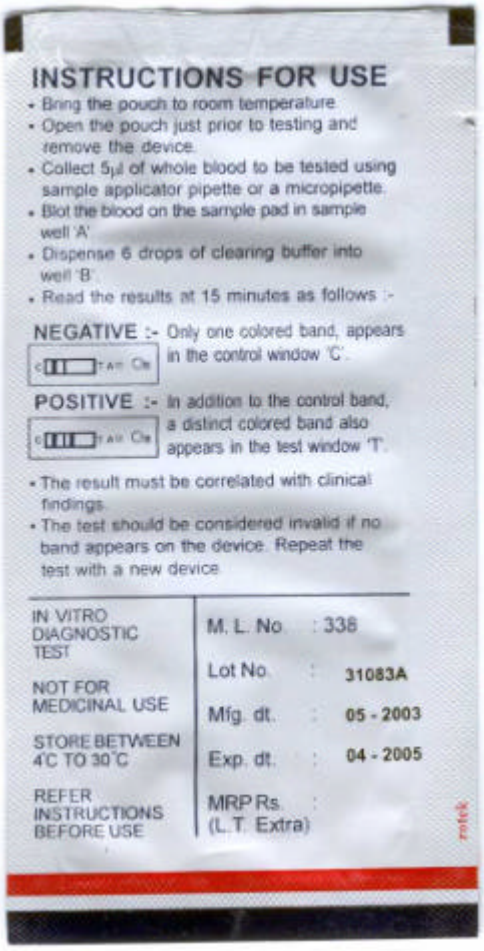
Phonekeo in Lao People's Democratic Republic. Funding was provided by the UNICEF-UNDP-World Bank-WHO Special Programme for Research and Training in Tropical Diseases/Product Research and Development/Diagnostic Research and the Australian Agency for International Development (AusAID) (through WHO-Roll Back Malaria), and the Quality Assurance Project.

# ANNEXES

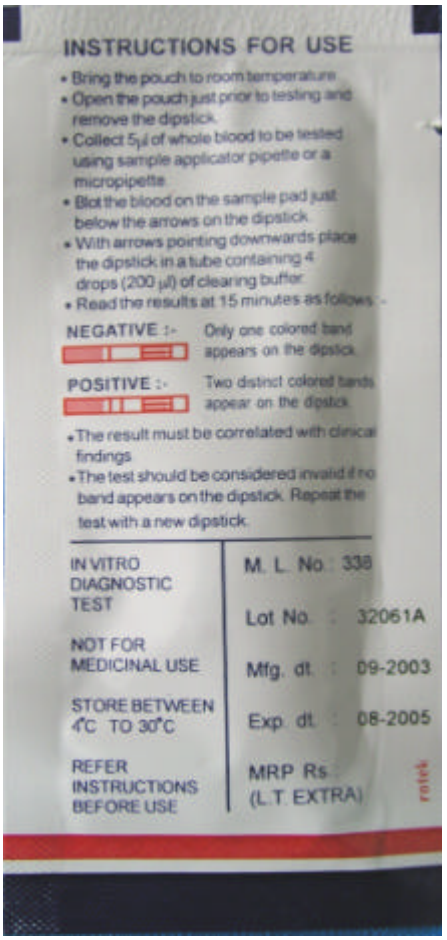
*A. Original instructions and final job aid for cassette and dipstick RDT*
*B. Observation instrument: Dipstick test, Philippines*
*C. Observation instrument: Cassette test, Philippines*
*D. Observation instrument: Dipstick test, Laos*
*E. Observation ins trument: Cassette test, Laos*
*F. Rapid diagnostic tests used in this trial*

# ANNEX A:
# ORIGINAL INSTRUCTIONS AND FINAL JOB AID FOR CASSETTE AND DIPSTICK RDT

This page contains a copy of the cassette test packet with the manufacturer's original instructions. The image is approximately actual size: the packet measures 2.5 x 5 inches and the text of the instructions is in 6 point type. Participants in this study were provided with both the test packet itself (with instructions in English) and a separate piece of paper with the same images of the test kit in black and white and the instructions in the same size type translated into the local language (Tagalog and Lao, respectively). Before beginning observations, observers showed each participant both the packet itself and the translated instructions, and explained that the content was identical in English and the local language.



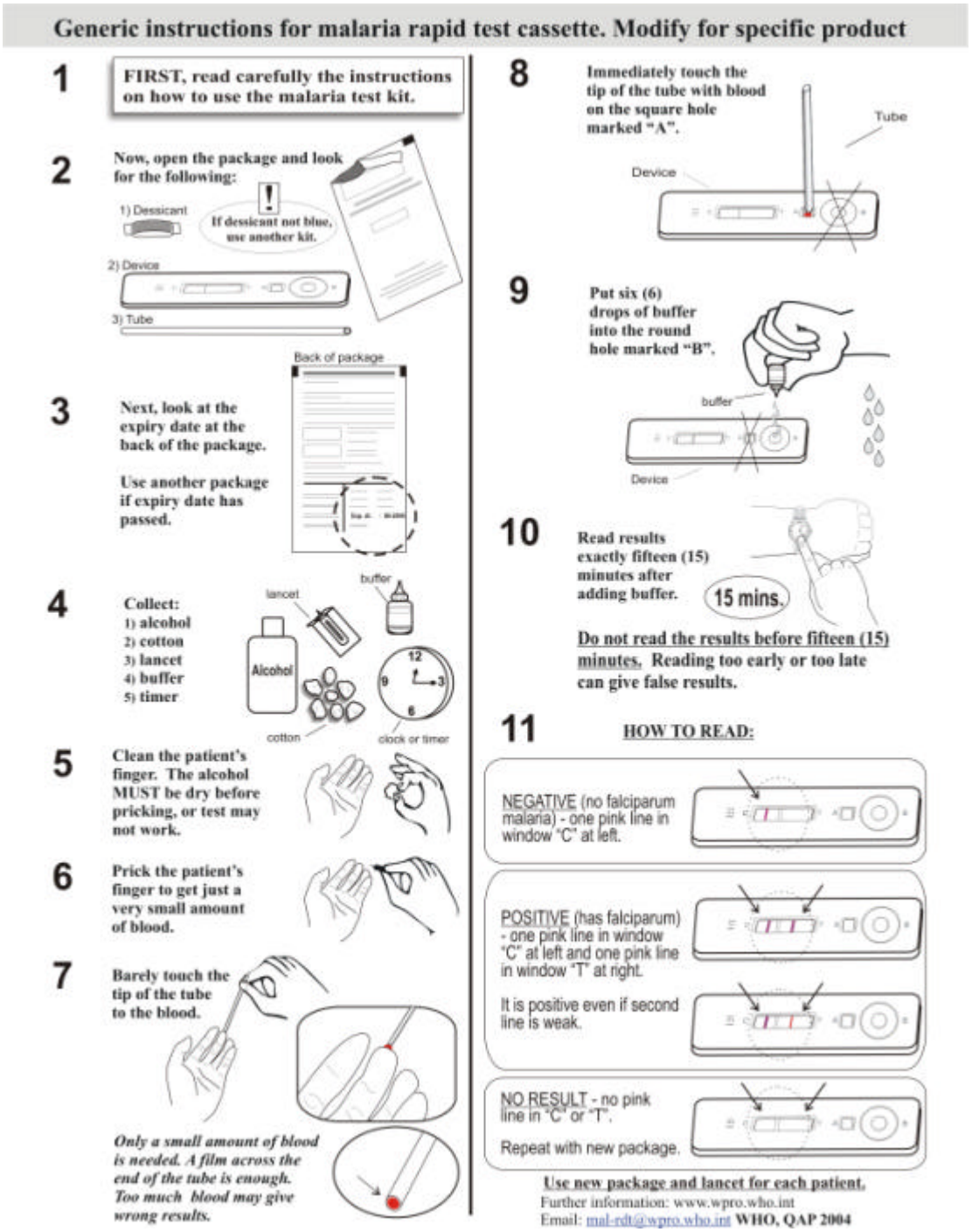

Cassette instructions




Dipstick instructions

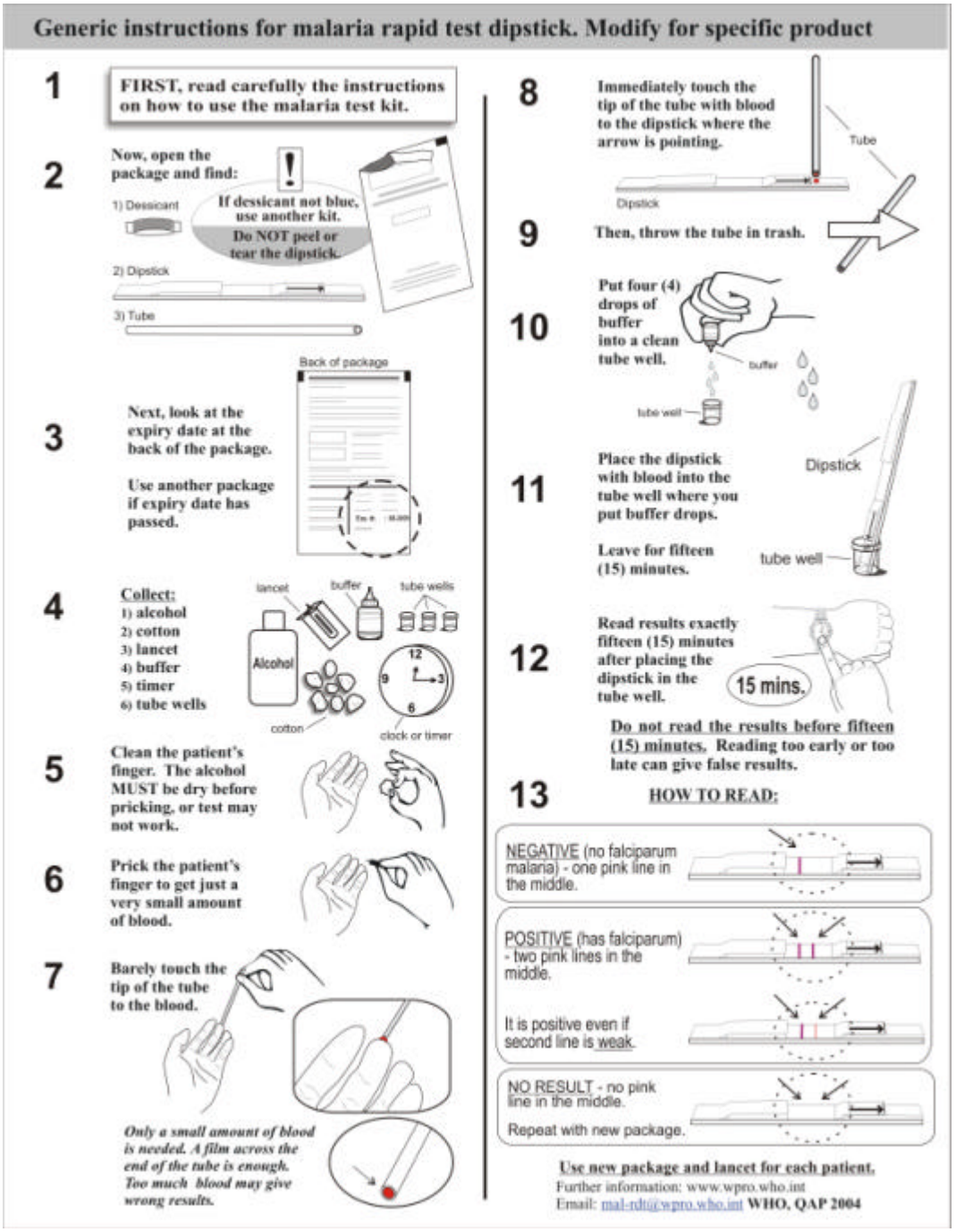
## FINAL JOB AID FOR CASSETTE RDT

This page contains an illustration of the final cassette RDT job aid. Please note that the image here is for ***illustration only***. It appears at 65% actual size and is ***not*** meant to be reproduced. Graphics files in both JPG and CorelDraw© format are available for downloading on the RDT website at http://www.wpro.who.int/rdt/link11.cfm



## FINAL JOB AID FOR DIPSTICK RDT

This page contains an illustration of the final dipstick RDT job aid. Please note that the image here is for ***illustration only***. It appears at 65% actual size and is ***not*** meant to be reproduced. Graphics files in both JPG and CorelDraw© format are available for downloading on the RDT website at http://www.wpro.who.int/rdt/link11.cfm.



## **ANNEX B**: *Observation of use and interpretation – Dipstick RDT – Philippines*

ANNEX C

***Table A: Observation of three tests***

| Observer | Date observed | BHW # | BHW sex | BHW age | Education | Malaria tx experience | Blood use | Laboratory experience | RDT use |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | [1] Incomplete primary | [1] Y | [1] Y | [1] Y | Y [1] |
| | | BHW first name | [1] M | | [2] Complete primary | [2] N | [2] N | [2] N | N [2] |
| Site | Day Month Year | | [2] F | | [3] Incomplete secondary | # years | # years | # years | # years |
| | | | | | [4] Complete secondary + | | | | |

| Observation number | 1 | | | 2 | | | 3 | | | Comments |
|---|---|---|---|---|---|---|---|---|---|---|
| **Was this test done on a real patient?** ***Circle the correct answer: 1=Yes 2=No*** | 1 Y | 2 N | | 1 Y | 2 N | | 1Y | 2 N | | |
| **Was patient febrile?** ***Circle the correct answer: 1=Yes 2=No 3=Not applicable (if not a real patient)*** | 1 Y | 2 N | 3 | 1 Y | 2 N | 3 | 1Y | 2 N | 3 | |
| ***For each step below, circle* Y *if the BHW performed the step correctly, circle* W *if the BHW performed the step incorrectly, circle 3 if the BHW skipped the step.*** | | | | | | | | | | **Ask at end if they knew:** |
| **1. Check expiration date on package to be sure kit has not expired.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | **Date Y N** |
| **2. Check desiccant colour and confirm that it is blue. If it is light blue, colourless, or pink, discard the kit and use another kit.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | **Colour Y N** |
| 3. Do not touch the membrane area in the middle of dipstick or the pad below the arrows. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 4. Clean finger with antiseptic/alcohol. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 5. **Allow finger to air dry**. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 6. Use a sterile lancet to puncture the side of the ball of the finger. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 7. **Collect 5 µl of blood with the enclosed micropipette.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 8. **Using the micropipette, immediately blot blood on the pad just below the arrows on the end of the dipstick. Be sure blood has not clotted.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **9. Squeeze clearing buffer into clean test tube by holding the plastic dropper bottle vertically.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **10. Dispense 4 drops of clearing buffer.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **11.** Place the dipstick with the sample into the tube, with the arrows on the dipstick pointing downwards and ensuring that the buffer level is below the blood sample for the entire duration of the test. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **12. Read at 15 minutes (15–20 minutes is correct; more than 20 minutes or less than 15 minutes is incorrect).** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **13. Read results correctly.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 14. Safely dispose of lancet, cotton, dipstick, and micropipette tube. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **Row total:** | | | /14 | | | /14 | | | /14 | |

***Table B: Interpretation of results***

| **Battery #** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** |
|---|---|---|---|---|---|---|---|---|---|---|
| **Test result** | *(Write an **"X"** in the appropriate box below each test number to indicate if the BHW interprets the test result as "positive", "negative" or "ambiguous".)* | | | | | | | | | |
| **Positive** | | | | | | | | | | |
| **Negative** | | | | | | | | | | |
| **Ambiguous** | | | | | | | | | | |

## ANNEX C: *Observation of use and interpretation – Cassette RDT – Philippines*



***Table A: Observation of three tests***

| Observer | Date observed | BHW # | BHW sex | BHW age | Education | Malaria tx experience | Blood use | Laboratory experience | RDT use |
|---|---|---|---|---|---|---|---|---|---|
| | | | [1] M | | [1] Incomplete primary | [1] Y | [1] Y | [1] Y | Y [1] |
| | | BHW first name | | | [2] Complete primary | [2] N | [2] N | [2] N | N [2] |
| Site | Day Month Year | | [2] F | | [3] Incomplete secondary | # years | # years | # years | # years |
| | | | | | [4] Complete secondary + | | | | |

| Observation number | 1 | | | 2 | | | 3 | | | Comments |
|---|---|---|---|---|---|---|---|---|---|---|
| **Was this test done on a real patient?** ***Circle the correct answer: 1=Yes 2=No*** | 1 Y | 2 N | | 1 Y | 2 N | | 1Y | 2 N | | |
| **Was patient febrile?** ***Circle the correct answer: 1=Yes 2=No 3=Not applicable (if not a real patient)*** | 1 Y | 2 N | 3 | 1 Y | 2 N | 3 | 1Y | 2 N | 3 | |
| ***For each step below, circle* Y *if the BHW performed the step correctly, circle* W *if the BHW performed the step incorrectly, circle 3 if the BHW skipped the step.*** | | | | | | | | | | **Ask at end if they knew:** |
| **1. Check expiration date on package to be sure kit has not expired.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | **Date Y N** |
| **2. Check desiccant colour and confirm that it is blue. If it is light blue, colourless, or pink, discard the kit and use another kit.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | **Colour Y N** |
| 3. Place cassette on a level surface. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 4. Select the finger to puncture (usually the third or fourth finger). | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 5. Clean area with antiseptic/alcohol. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 6. **Allow finger to air dry**. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 7. Using a sterile lancet, puncture the side of the ball of the finger. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 8. **Collect 5 ml of blood with the enclosed micropipette.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **9. Using the micropipette, immediately blot blood on the pad in sample well A. Be sure blood has not clotted. Be sure sample pad has completely absorbed blood from the micropipette.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **10. Squeeze clearing buffer into well 'B' by holding the plastic dropper bottle vertically.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **11. Dispense six drops of clearing buffer.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **12. Read at 15 minutes (15–20 minutes is correct; more than 20 minutes or less than 15 minutes is incorrect).** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **13. Read results correctly.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 14. Safely dispose of lancet, cotton, test strips and tube. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **Row total:** | | | /14 | | | /14 | | | /14 | |

***Table B: Interpretation of results***

| **Battery #** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** |
|---|---|---|---|---|---|---|---|---|---|---|
| **Test result** | *(Write an **"X"** in the appropriate box below each test number to indicate if the BHW interprets the test result as "positive", "negative" or "ambiguous".)* | | | | | | | | | |
| **Positive** | | | | | | | | | | |
| **Negative** | | | | | | | | | | |
| **Ambiguous** | | | | | | | | | | |

## **ANNEX D:** *Observation of use and interpretation – Dipstick RDT – Lao People's Democratic Republic* ANNEX E

***Table A: Observation of three tests***

| Observer | Date observed | | | User # | User sex | | User age | Education | Malaria tx experience | Blood use | Laboratory experience | RDT use |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | [1] M | | [1] No formal education | [1] Y | [1] Y | [1] Y | Y [1] |
| | | | | User first name | | | | [2] 1–3 years of school but cannot read well | [2] N | [2] N | [2] N | N [2] |
| Site | Day | Month | Year | | | [2] F | | [3] Can read a newspaper | # years | # years | # years | # years |
| | | | | | | | | [4] Well educated | | | | |

| Observation number | 1 | | | 2 | | | 3 | | | Comments |
|---|---|---|---|---|---|---|---|---|---|---|
| **Was this test done on a real patient?** ***Circle the correct answer: 1=Yes 2=No*** | 1 Y | 2 N | | 1 Y | 2 N | | 1Y | 2 N | | |
| **Was patient febrile?** ***Circle the correct answer: 1=Yes 2=No 3=Not applicable (if not a real patient)*** | 1 Y | 2 N | 3 | 1 Y | 2 N | 3 | 1Y | 2 N | 3 | |
| ***For each step below, circle* Y *if the BHW performed the step correctly, circle* W *if the BHW performed the step incorrectly, circle 3 if the BHW skipped the step.*** | | | | | | | | | | **ASK at end- if they knew** |
| **1. Check expiration date on package to be sure kit has not expired.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | **Date Y N** |
| **2. Check desiccant colour and confirm that it is blue. If it is light blue, colourless, or pink, discard the kit and use another kit.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | **Colour Y N** |
| 3. Do not touch the membrane area in the middle of dipstick or the pad below the arrows. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 4. Clean finger with antiseptic/alcohol. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **5. Finger is dry before collecting blood.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 6. Use a sterile lancet to puncture the side of the ball of the finger | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **7. Collect 5 ml of blood with the enclosed micropipette.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **8. Using the micropipette, immediately blot blood on the pad just below the arrows on the end of the dipstick. Be sure blood has not clotted.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **9. Put buffer into one tube.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **10. Put 4 drops of clearing buffer into well.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 11. Place the dipstick with the sample into the tube, with the arrows on the dipstick pointing downwards and ensuring that the buffer level is below the blood sample for the entire duration of the test. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **12. Read at 15 minutes (15–20 minutes is correct; more than 20 minutes or less than 15 minutes is incorrect).** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **13. Read results correctly.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 14. Safely dispose of lancet, cotton, dipstick and micropipette tube. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **Row Total:** | | | /14 | | | /14 | | | /14 | |

***Table B: Interpretation of results***

| **Battery #** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** |
|---|---|---|---|---|---|---|---|---|---|---|
| **Test result** | *(Write an **"X"** in the appropriate box below each test number to indicate if the BHW interprets the test result as "positive", "negative" or "ambiguous".)* | | | | | | | | | |
| **Positive** | | | | | | | | | | |
| **Negative** | | | | | | | | | | |
| **Ambiguous** | | | | | | | | | | |

## ANNEX E: *Observation of use and interpretation – Cassette RDT – Lao People's Democratic Republic*



***Table A: Observation of three tests***

| Observer | Date observed | User # | User sex | User age | Education | Malaria tx experience | Blood use | Laboratory experience | RDT use |
|---|---|---|---|---|---|---|---|---|---|
| | | | [1] M | | [1] No formal schooling | [1] Y | [1] Y | [1] Y | Y [1] |
| | | User first name | | | [2] 1–3 years school but cannot read well | [2] N | [2] N | [2] N | N [2] |
| Site | Day Month Year | | [2] F | | [3] Can read a newspaper<br>[4] Well educated | # years | # years | # years | # years |

| Observation number | 1 | | | 2 | | | 3 | | | Comments |
|---|---|---|---|---|---|---|---|---|---|---|
| **Was this test done on a real patient?** ***Circle the correct answer: 1=Yes 2=No*** | 1 Y | 2 N | | 1 Y | 2 N | | 1Y | 2 N | | |
| **Was patient febrile?** ***Circle the correct answer: 1=Yes 2=No 3=Not applicable (if not a real patient)*** | 1 Y | 2 N | 3 | 1 Y | 2 N | 3 | 1Y | 2 N | 3 | |
| ***For each step below, circle* Y *if the BHW performed the step correctly, circle* W *if the BHW performed the step incorrectly, circle 3 if the BHW skipped the step.*** | | | | | | | | | | **Ask at end if they knew:** |
| **1. Check expiration date on package to be sure kit has not expired.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | **Date Y N** |
| **2. Check desiccant colour and confirm that it is blue. If it is light blue, colourless, or pink, discard the kit and use another kit.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | **Colour Y N** |
| 3. Place cassette on a level surface. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 4. Select the finger to puncture (usually the third or fourth finger). | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 5. Clean area with antiseptic/alcohol. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **6. Finger is dry before blood is collected.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 7. Using a sterile lancet, puncture the side of the ball of the finger. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **8. Collect 5 ml of blood with the enclosed micropipette.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **9. Using the micropipette, immediately blot blood on the pad in sample well A. Be sure blood has not clotted. Be sure sample pad has completely absorbed blood from the micropipette.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **10. Dispense clearing buffer into well B.** | | | | | | | | | | |
| **11. Dispense six drops of clearing buffer.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **12. Read at 15 minutes (15–20 minutes is correct; more than 20 minutes or less than 15 minutes is incorrect).** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **13. Read results correctly.** | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| 14. Safely dispose of lancet, cotton, test strips and tube. | 1 Y | 2W | 3 | 1Y | 2 N | 3 | 1Y | 2 N | 3 | |
| **Row Total:** | | | /14 | | | /14 | | | /14 | |

***Table B: Interpretation of results***

| **Battery #** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** |
|---|---|---|---|---|---|---|---|---|---|---|
| **Test result** | *(Write an **"X"** in the appropriate box below each test number to indicate if the BHW interprets the test result as "positive", "negative" or "ambiguous".)* | | | | | | | | | |
| **Positive** | | | | | | | | | | |
| **Negative** | | | | | | | | | | |
| **Ambiguous** | | | | | | | | | | |

## ANNEX F: RAPID DIAGNOSTIC TESTS USED IN THIS TRIAL


**Figure 1: Paracheck Pf Rapid One Step device for *P. falciparum* specific HRP 2 antigen in whole blood, Orchid Biomedical Systems** ( "cassette test")


**Figure 2: Paracheck Pf Rapid One Step dipstick for *P. falciparum* specific HRP 2 antigen in whole blood, Orchid Biomedical Systems,** ("dipstick test") . **Wells are not provided with the test.**

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