QUALITY
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Using Quality Design To Improve Malaria Rapid Diagnostic Tests in Malawi

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OPERATIONS RESEARCH RESULTS

Using Quality Design To Improve Malaria Rapid Diagnostic Tests in Malawi

Abstract

Malaria rapid diagnostic kits (MRDTs) have the potential of significantly improving the diagnosis of malaria in developing countries, especially where microscopic diagnosis is not available. But, in order for them to be effective, the informational inserts and product design must be clearly understood by the health workers in rural developing country facilities. Using quality design principles, a team composed of technical experts and local researchers developed and tested a job aid in Malawi designed to improve health workers' ability to use the kits properly without training.

Two manufacturers of the kits, PATH and FLOW, provided kit samples and product inserts to a quality design team, which included an expert in the use of diagnostic kits. With the assistance of the manufacturers, the team developed an observation checklist for evaluating whether 20 end users (representing different cadres of health workers) were following the steps in using the diagnostic kits. The team trained 50 percent of the end users in the kits' use, and gave the others the kits without any introduction. They noted where users seemed to be having trouble with the products, and interviewed them about the products and instructions. Next, the team redesigned the instructions, pre-tested them, and

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then redesigned them again. For the second phase, the team selected a new group of 20 end users, and again equally divided them between the two products, making sure that equal proportions of users from the various cadres were represented. However, during this phase, none of the end users were given training beforehand. They also developed an interview guide for querying providers about their experiences using the kit.

Relying on the kits and job aids supplied by the manufacturers, only one in five providers in Malawi was able to use the kits properly to diagnose malaria, even though half had been trained in using the kits. After the job aids were modified, four in five providers used the kits properly without training. The team was also able to recommend that manufacturers make important modifications to the kit design and packaging that could increase the kits' usability.

Acknowledgements

This paper was written by Paula Tavrow and Elisa Knebel of QAP. It is based on the research findings of Lynne Cogswell, consultant to QAP.

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About this series

The *Operations Research Results* series presents the results of QAP country or area research to encourage discussion and comment within the international development community. If you would like to obtain the full research report of this study containing all relevant data collection instruments, please contact qapdissem@urc-chs.com.

Using Quality Design To Improve Malaria Rapid Diagnostic Tests in Malawi

Paula Tavrow, Elisa Knebel, and Lynne Cogswell

Abbreviations

CDC	Centers for Disease Control and Prevention
HSA	Health Surveillance Assistant
MOH	Ministry of Health
MRDT	Malaria Rapid Diagnostic Test
QAP	Quality Assurance Project
USAID	United States Agency for International Development

Introduction

New medical products and procedures often meet resistance from providers. For providers to accept a new product, it is important that they perceive the product to be safe, effective, valuable, and trustworthy. Design of a product based on clients' needs—what is generally referred to as "quality design"—could increase the likelihood that the product is used safely, regularly, and correctly. This could translate into fewer medical errors or patient injuries. Also, quality design of medical products could lead to considerable savings for program managers, because training of providers could be scaled back, and waste associated with improper product use would be minimized.

Contents of OptiMAL® MRDT

Malaria rapid diagnostic tests (MRDTs) are new products that could significantly improve the diagnosis of malaria in developing countries, especially where microscopic diagnosis is not available. For maximum impact, all cadres of health personnel—including village health workers—should be able to use the tests properly. The tests would not be cost-effective unless providers correctly perform all of the procedures, interpret the results accurately, and persuade clients to take appropriate actions based on the results.

This report summarizes a study in Malawi that led to improvements in two different MRDTs. Using quality design principles, a research team sponsored by the Quality Assurance Project (QAP) developed a user-friendly job aid that dramatically improved health workers' ability to use the tests properly without training. The team was also able to recommend to the manufacturers some modifications to the kit design and packaging that could increase the likelihood that the kit would be used correctly every time.

Background to the Study

Plasmodium falciparum malaria is a leading cause of morbidity and mortality in Eastern and Southern Africa, including Malawi. For decades, developing countries have relied on microscopic analysis of blood smears for malaria diagnosis. Unfortunately, microscopy is time consuming, requires trained personnel and laboratory equipment, and is largely unavailable in small health facilities. Consequently, patients are often diagnosed and treated based only on clinical symptoms without use of the more accurate microscopic method. Some experts estimate that 35–60 percent of malaria in Africa is wrongly diagnosed.

The potential benefits of a sensitive, specific, quick, simple, and inexpensive diagnostic test for malaria are considerable. The amount of anti-malarial drugs dispensed could be reduced significantly, especially in countries such as Malawi where malaria prevalence is very high and all fevers are presumptively treated as malaria. More rational anti-malaria drug use, in turn, could be expected to reduce the rate of increase in resistance to these drugs. In addition, more accurate diagnosis could result in more timely treatment of non-malarial illnesses. However, if a rapid malaria test is not very usable in rural clinical settings, it could deplete scarce resources without increasing diagnostic accuracy.

In the past decade, several companies have produced MRDTs for use in clinical settings to provide an alternative to microscopic testing. The tests use whole blood, rather than smears, and take only about 10 minutes to provide an accurate diagnosis. The United States Agency for International Development (USAID) has been reviewing two of these MRDTs for potential widespread use in developing countries:

- **PATH:** The Falciparum Malaria IC Strip Test from the Program for Appropriate Technology in Health (PATH) is an antigen-capture assay of P. falciparum-specific, histidine-rich protein II (PfHRP-II), a soluble protein contained in and released from parasitized red cells. The kit contains 50 test strips in plastic envelopes, a sample buffer, a clearing buffer, 50 reaction tubes, 1 reaction stand, and instructions. It does not require refrigeration.
- **FLOW:** The OptiMAL Assay from FLOW, Incorporated, is an immunological assay of parasite lactate dehydrogenase (pLDH) in the blood. The kit contains 100 test strips in a desiccant container, a conjugate buffer, a wash buffer, 100 disposable 10 ml pipettes, 100 test wells, 1 test well stand, and instructions. Its conjugate buffer requires refrigeration.

In 1997, USAID commissioned the Centers for Disease Control and Prevention (CDC) to study the specificity and sensitivity of these MRDTs in Peru and Malawi. Recognizing that these studies would not provide information on how usable these products would be in actual clinical settings, USAID requested QAP to assess their acceptablity and usability in Malawi.

The Quality Design Approach

Step 1 Set Design Objectives
Step 2 Identify Clients and Determine Their Needs
Step 3 Create Design
Step 4 Test and Revise
Step 5 Implement and Monitor

Description of the Study

Through its operations research program in developing countries, QAP tests various techniques to improve health workers' compliance with clinical and laboratory standards. Quality design research systematically assesses the usability of the product from the end user or client's viewpoint and identifies ways to change the product and its instructions to reduce error and increase the likelihood of regular use. The purpose of this study was to assess the current usability of the two MRDTs and test whether employing quality design principles could lead to higher levels of performance.

In collaboration with the CDC and the Ministry of Health's (MOH) Community Health Services Unit, QAP analyzed the following aspects of the two products:

- Suitability, acceptability, functionality, and ease of use
- Level of expertise and type of training needed by the end user
- Comprehensibility and usefulness of the instructions insert
- Consistency of end-user performance over time
- Technical problems with use
- End-user ability to interpret test results accurately
- Attitudes of end users and patients toward the tests

Study design

The study was conducted in Machinga District in southern Malawi during mid-1998. The MOH in Malawi has made the prevention and effective treatment of malaria its top priority. Eleven Malawian research assistants with qualitative research experience were selected by the QAP lead investigator, who was a job aid expert. The Malawians received an intensive four-day training in interviewing and direct observation techniques, using forms developed by the lead investigator. During the training, a representative from PATH instructed them in the use of both tests. They were then divided into two teams.

Research was conducted at 16 selected health facilities along the Machinga/Chikweo corridor, which is known for its high incidence of malaria, and at two mobile clinics that operated south and west of Machinga district. Study locations included MOH facilities, which offer free services, and Christian Health Association of Malawi clinics, which charge for services.

Health providers who participated in the study met the following criteria:

- Worked in a rural hospital, health center, mobile clinic, or dispensary
- Signed an informed consent agreement to participate in the study
- Were willing to perform finger pricks (with training, if necessary)

The health workers assessed were medical assistants, enrolled nurses, health assistants, and health surveillance assistants (HSAs). More than half the providers participating in the study were HSAs, who had had only eight weeks of clinical training (see Table 1). An effort was made to include significant numbers of HSAs because they were reported to be the largest group of health workers and thus most likely to use the tests.

The study used a mix of rapid, qualitative research techniques that allowed for an assessment of learning curves, consistency of use over time, and the ability to use the tests with no training (see Table 2). Due to time and resource constraints, QAP chose to use convenience sampling (e.g., decide how many observations or interviews would be made and then observe/interview until the numbers had been met). Sample size was determined by the number of health workers available to the researchers and the number of potential malaria cases present on any given day.

During the first phase of the study, the team introduced the two products to 19 end users. Half of the end users received training prior to receiving the tests, and the other half did not. Different cadres of end users were in each group. The research team observed how the

Table 1

Educational/Training Background of End Users Observed in Study

(Average, in Years, Unless Noted)

Cadre	Formal Education	Clinical Training	Malaria Diagnostic Experience
Medical assistants	15	3	13
Enrolled nurses	15	3	7
Health assistants	14	2	5
Health surveillance assistants	8	8 weeks	2

Table 2
Data Collection Techniques

Data Source	Methodology	Sample Size
Clinic records	Records review	4 rural clinics
Patient flow	Observation	4 rural clinics, 1 rural hospital, 1 rural dispensary, 2 rural health posts
End users	Initial observations (10 tests per user) during first phase	2 medical assistants, 1 health assistant, 5 enrolled nurses, 11 HSAs (19 total)
	Structured interviews (2 per user: before and after using tests)	2 medical assistants, 1 health assistant, 5 enrolled nurses, 11 HSAs (19 total)
	In-depth interviews	4 clinic in-charges
	Pretest of improved job aid (first draft)	2 clinical officers, 2 medical assistants, 2 enrolled nurses, 6 laboratory technicians, 1 health assistant, 8 HSAs in two rounds (42 total)
	Field pretest of improved job aid (second draft)	2 medical assistants, 2 enrolled nurses, 2 health assistants, 4 HSAs (10 total)
	Final observation	2 clinical officers, 4 registered nurses, 6 enrolled nurses, 8 HSAs (20 total)
Patients	Structured exit interview	20 patients over 8 years old, and 32 caregivers of patients under 8 years (52 total)

users performed and noted where users seemed to be having trouble with the products. The researchers then interviewed the end users about the products and instructions. Next, the team redesigned the instructions, pretested them, and then redesigned them again.

For the final phase, the team selected a new group of 20 end users. Half received the PATH test and half received the FLOW test. Again, equal proportions of users from the various cadres were represented in each group. During this phase, no training was provided, but the redesigned instructional insert was used.

During all phases of the study, the lead investigator collected the completed forms daily and looked for trends in learning curves, consistency of use over time, ability to use the tests with no training, and user needs. Pretesting of revised instructions continued until at least 80 percent comprehension and acceptablity was achieved. Users were queried on: (1) text alone, (2) illustration alone, and (3) text and illustration together.

The research was purposely kept simple so that it could be replicated in-country. No computer statistical software was used for analysis. As part of the usability study, in one health center CDC compared blood smear results with test strip results as interpreted by providers. This helped the research team to assess the extent of providers' ability to read and interpret results accurately.

Findings

Suitability, acceptability, functionality, and ease of use before redesign

During the first phase, only about one in six providers were able to use the products without making any errors. However, because many of these errors were small, senior medical staff felt that all levels of health personnel could use the tests. While both products performed equally, none of the PATH users followed all of the steps correctly using the original instructions (see Table 3).[1]

Level of expertise and type of training needed by the end user before redesign

If the data is disaggregated by cadre rather than product, education and experience with malaria diagnostics does not correlate with performance. No cadre performed consistently well with the original instructions.

Among end users who received training before using the MRDTs, two in eight followed all of the steps correctly, as compared to one in 11

[1] There was no weighting of steps; all had equal value.

of the untrained users. Neither level of performance is acceptable, although those who were trained seemed to perform better with the original instructions (see Table 3).

Performance after redesign

As shown in Table 3, 11 out of 19 providers using the original instructions insert (Figure 1) had difficulty in performing all of the steps correctly. After the instructions had been revised twice (Figure 2), a new group of providers were given the MRDTs to use without training. Their performance using the revised instructions was dramatically better than the first group. As shown in Table 4, more than four in five end users were now able to use the products without any errors, even though none of the users had been trained in advance. Both products yielded almost equally good results.

Similarly, there were no significant differences by cadre. All cadres performed very well, and no end user missed more than 20 percent of the steps.

Table 3

Performance During First Phase by Product Type, Cadre, and Training in Product Use

	Performance Level			
	100%[1]	80–99%[2]	<80%	Total
Product Type				
FLOW Kit	3	1	5	9
PATH Kit	0	4	6	10
Cadre				
Medical assistant	0	1	2	3
Enrolled nurse	2	0	2	4
Health assistants	0	1	0	1
Health surveillance assistants	1	3	7	11
Trained in MRDT Use				
Yes	2	3	3	8
No	1	2	8	11
Total Users	3	5	11	19

[1] 100% means the end user performed every step correctly (as per manufacturer's original instructions) for each of his/her 10 uses.

[2] 80–99% means that the end user performed correctly at least 9 or 10 of 11 steps for each of his/her 10 FLOW uses, or 13–15 out of 16 steps correctly for each of his/her 10 PATH uses.

Consistency of end-user performance over time

Using the original instructions, about one in four providers who received training in the MRDTs performed the tests correctly throughout. The remaining made at least one mistake on the first try and continued to do so for all 10 uses. Among providers who received no training, about one-fourth never noticed that they were making a mistake, and about half corrected their mistakes by the fifth try.

Technical problems with use

Several technical problems arose during the use of the kits. Collection of blood with both tests was the biggest challenge, whether with the FLOW pipette or on the PATH strip, especially with children. Timing of results was also a problem, since most providers did not have a watch or other timing device. Another difficulty observed was that all items needed to conduct the test (e.g., lancets) were not included and are not necessarily available in the rural areas. The providers complained that the areas for labeling strips were too small. Also, expiration dates and type of kit were not clearly labeled on the outside of the box. Finally, the need for refrigeration of the FLOW MRDT would cause problems. Most sites have no electricity and only sporadic fuel for petrol refrigerators.

Because health workers usually see patients at a fixed location (such as an office), having a kit available right on their desk would improve their diagnostic ability and increase the likelihood that they would use it.

Table 4

Performance after Redesign by Cadre and Product Type

	Performance Level			
	100%[1]	80–99%[2]	<80%	Total
Product Type				
FLOW Kit	9	1	0	10
PATH Kit	8	2	0	10
Cadre				
Medical assistant	2	1	0	3
Enrolled nurse	2	1	0	3
Health assistants	3	0	0	3
Health surveillance assistants	10	1	0	11
Total Users	17	3	0	20

[1] 100% means the end user performed every step correctly (as per manufacturer's original instructions) for each of his/her 10 uses.

[2] 80–99% means that the end user performed correctly 9 or 10 out of 11 steps for each of his/her 10 FLOW uses, or 13 out of 16 steps correctly for each of his/her 10 PATH uses.

Since FLOW tests cannot be kept on a desk because they require refrigeration, this limits their usability. If tests had to be set up in a separate room, using the tests would probably disrupt patient flow and be less efficient.

End-user ability to interpret test results accurately

During the first phase, observers found that 85 percent of all results read by providers corresponded to the actual result indicated on the strip and that 15 percent were incorrectly interpreted. These misrepresentations were significantly reduced with the revised inserts.

Attitudes of end users and patients toward the tests

Providers expressed a need for more accurate, easier, and convenient means to diagnose malaria as well as something that would allow field health workers to effectively diagnose malaria. Providers felt that with no electricity and no lab technicians, these tests could help ensure that diagnosis is timely and treatment is appropriate.

The majority of providers liked the MRDTs because they gave accurate, safe, and clear malaria diagnoses. There was an overwhelming preference of PATH to FLOW, with 19 out of 20 providers preferring PATH, mostly because it did not require refrigeration.

One major drawback of the MRDTs appears to be provider reluctance to "believe" negative test strip results. Providers reportedly felt that one strip test was sufficient if the results were positive, thereby confirming their initial diagnosis. However, if the results were negative, they seemed to feel that another test should be run to confirm the disagreement with the clinical diagnosis. This attitude, if widespread, could significantly increase the cost per patient. However, it is likely that with greater exposure to the MRDTs, both providers and patients would be more inclined to trust them and only run repeat tests when they strongly suspected malaria.

Paying and nonpaying patients liked the tests equally and commented that they would be willing to pay for them. Patients seemed to be happiest when the test confirmed they had malaria; they were not very happy when the test showed no malaria if they believed that they had it.

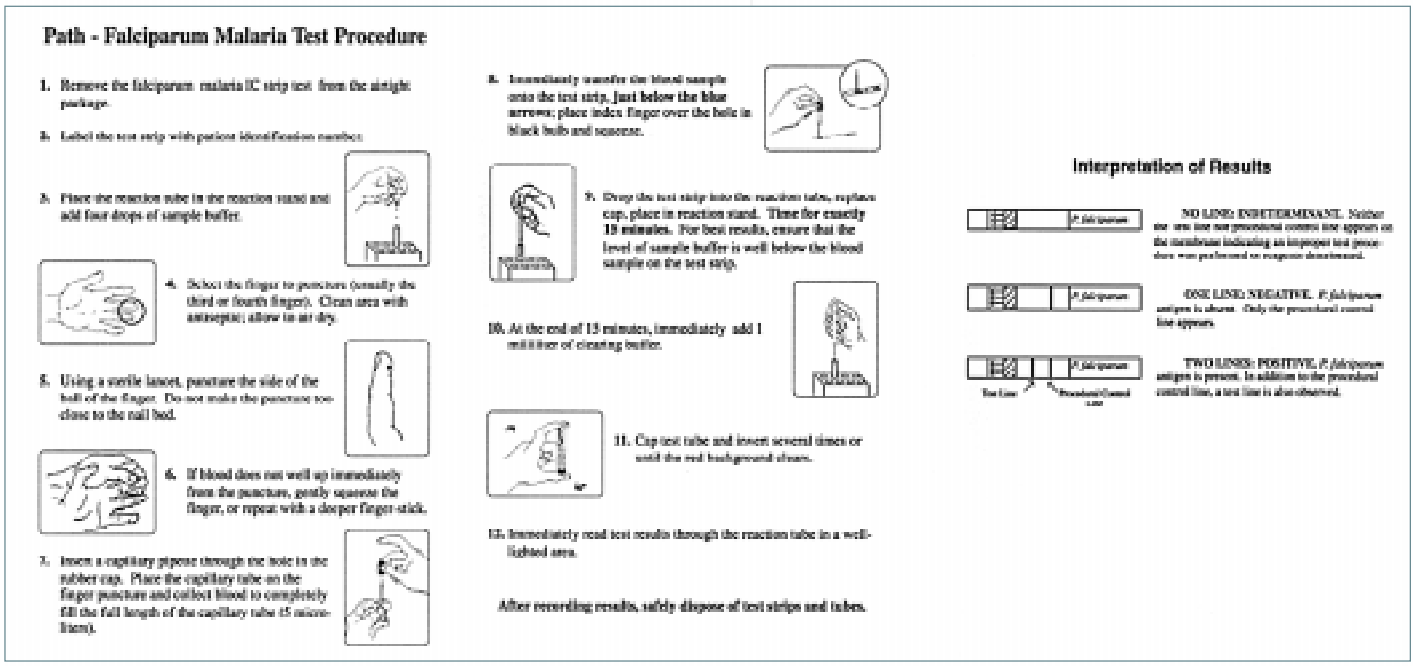
Job Aid Recommendations

Product instructional inserts should:

- Include instructions on how to use a sterile needle to do a finger prick
- Include suggestions for when to do a repeat test
- Show clocks for explaining times
- Have red color when possible to indicate blood and blood on strips
- Have clear illustration that provider is wearing gloves
- Have an illustration to emphasize proper disposal
- Be laminated

Figure 1

Original Product Instructional Insert for PATH Kit



Path - Falciparum Malaria Test Procedure

1. Remove the falciparum malaria IC strip test from the airtight package.
2. Label the test strip with patient identification number.
3. Place the reaction tube in the reaction stand and add four drops of sample buffer.
4. Select the finger to puncture (usually the third or fourth finger). Clean area with antiseptic; allow to air dry.
5. Using a sterile lancet, puncture the side of the ball of the finger. Do not make the puncture too close to the nail bed.
6. If blood does not well up immediately from the puncture, gently squeeze the finger, or repeat with a deeper finger-stick.
7. Insert a capillary pipette through one hole in the rubber cap. Place the capillary tube on the finger puncture and collect blood to completely fill the full length of the capillary tube (5 microliters).
8. Immediately transfer the blood sample onto the test strip, just below the blue arrows; place index finger over the hole in black bulb and squeeze.
9. Drop the test strip into the reaction tube, replace cap, place in reaction stand. Time for exactly 15 minutes. For best results, ensure that the level of sample buffer is well below the blood sample on the test strip.
10. At the end of 15 minutes, immediately add 1 milliliter of clearing buffer.
11. Cap test tube and invert several times or until the red background clears.
12. Immediately read test results through the reaction tube in a well-lighted area.

After recording results, safely dispose of test strips and tubes.

Interpretation of Results

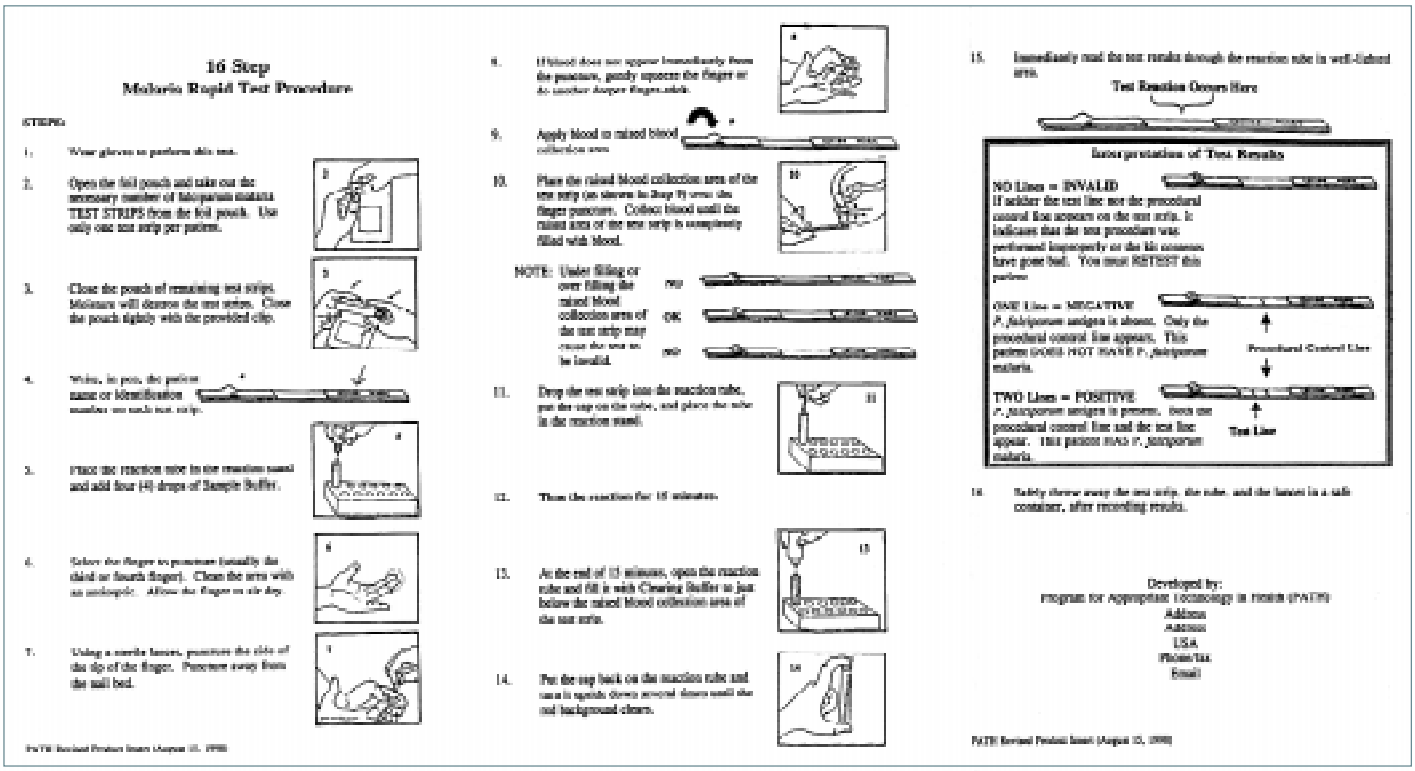
NO LINE: INDETERMINANT. Neither the test line nor procedural control line appears on the membrane indicating an improper test procedure was performed or reagents deteriorated.

ONE LINE: NEGATIVE. *P. falciparum* antigen is absent. Only the procedural control line appears.

TWO LINES: POSITIVE. *P. falciparum* antigen is present. In addition to the procedural control line, a test line is also observed.

Figure 2

Revised Product Instructional Insert for PATH Kit



16 Step
Malaria Rapid Test Procedure

STEPS:

1. Wear gloves to perform this test.
2. Open the foil pouch and take out the necessary number of falciparum malaria TEST STRIPS from the foil pouch. Use only one test strip per patient.
3. Close the pouch of remaining test strips. Moisture will destroy the test strips. Close the pouch tightly with the provided clip.
4. Write, in pen, the patient name or identification number on each test strip.
5. Place the reaction tube in the reaction stand and add four (4) drops of Sample Buffer.
6. Select the finger to puncture (usually the third or fourth finger). Clean the area with an antiseptic. Allow the finger to air dry.
7. Using a sterile lancet, puncture the side of the tip of the finger. Puncture away from the nail bed.
8. If blood does not appear immediately from the puncture, gently squeeze the finger or the another deeper finger-stick.
9. Apply blood to raised blood collection area.
10. Place the raised blood collection area of the test strip (as shown in Step 9) over the finger puncture. Collect blood until the raised area of the test strip is completely filled with blood.

NOTE: Under filling or over filling the raised blood collection area of the test strip may cause the test to be invalid.

11. Drop the test strip into the reaction tube, put the cap on the tube, and place the tube in the reaction stand.
12. Time the reaction for 15 minutes.
13. At the end of 15 minutes, open the reaction tube and fill it with Clearing Buffer to just below the raised blood collection area of the test strip.
14. Put the cap back on the reaction tube and turn it upside down several times until the red background clears.
15. Immediately read the test results through the reaction tube in well-lighted area.

Test Reaction Occurs Here

Interpretation of Test Results

NO Lines = INVALID
If neither the test line nor the procedural control line appears on the test strip, it indicates that the test procedure was performed improperly or the kit contents have gone bad. You must RETEST this patient.

ONE Line = NEGATIVE
P. falciparum antigen is absent. Only the procedural control line appears. This patient DOES NOT HAVE *P. falciparum* malaria.

Procedural Control Line

TWO Lines = POSITIVE
P. falciparum antigen is present. Both the procedural control line and the test line appear. This patient HAS *P. falciparum* malaria.

Test Line

16. Safely throw away the test strip, the tube, and the lancet in a safe container, after recording results.

Developed by:
Program for Appropriate Technology in Health (PATH)
Address
Address
USA
Phone/fax
Email

PATH Revised Product Insert (August 15, 1998)

Conclusions and Recommendations

The results of this study indicate that quality design research can lead to significant improvements in the way a new product is used. Furthermore, providers can offer valuable suggestions about how to change product design, packaging, and specifications that could sustain high performance. With regard to the new malaria diagnostic tests, this study found that even trained providers felt the need to look at the instructions to remind them of certain steps. If instructions are unclear, supervision is erratic, and a product is difficult to manipulate, even trained providers will not use it effectively. On the other hand, if instructions are clear and comprehensive, little training is necessary.

The study also found that strategies to increase trust in MRDTs may be necessary. In regions where malaria is prevalent and the consequences of failing to treat malaria can be grave, it may be advisable to initially recommend that providers perform a repeat test when the result is negative if they feel strongly that the patient has malaria. If the repeat test is also negative, the provider should then seek an alternate diagnosis. The providers have become so accustomed to clinical diagnosis of malaria that they may need to be reminded of the potential savings and reductions in suffering that come from more rational drug use.

After completing the study, QAP provided the two manufacturers of the MRDTs with the results from this research to improve their products before final introduction. PATH transferred their MRDT technology to two private sector companies for production and distribution. It is hoped that these companies will incorporate these changes into their instructional inserts and product formats (See Table 5). The results of the study have also been provided to the Malawi MOH to assist it in planning for possible introduction of MRDTs. A remaining challenge is to build local capacity and to foster high level commitment to conduct quality design research before introducing any new product or service.

Table 5

Product and Packaging Redesign Recommendations

PATH should:

- Change box from side opening to top opening to make it easier to open
- Make the stand more durable
- Put the expiration date, name of test, and product contents on box top
- Replace foil pouches and clip with a recloseable tube
- Enlarge the test strip area where the ID or name should be written
- Label the buffers with letters for easier identification (and change instructions accordingly)
- Include lancets and a timer
- Include a pocket-size Malaria Patient Logbook so that providers can track which patients have been given the MRDT

FLOW should:

- Eliminate the need for refrigeration
- Put an arrow on its test strip clearly indicating which end is down and should be put into the test well
- Enlarge the test strip area where the ID or name should be written
- Enlarge the test wells and consider putting them in sets of two so that test process is easier to follow
- Put the expiration date, name of test, and product contents on box top
- Enlarge the test strip tube or put fewer strips in a tube so that they come out more easily
- Add a line to the pipette indicating 10 ml
- Make the pipette larger and softer so that it is easier to draw blood
- Include lancets and a timer
- Include a pocket-size Malaria Patient Logbook so that providers can track which patients have been given the MRDT