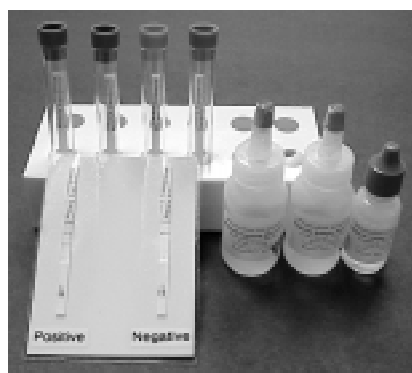


OPERATIONS RESEARCH SUMMARY

Quality Design Improves Malaria Tests in Malawi

Malaria rapid diagnostic tests (MRDTs) have the potential to significantly improve the diagnosis of malaria in developing countries. However, in order for such tests to be effective, the informational inserts and product design of MRDT kits must be clearly understood by the healthcare providers who use them. Using quality design principles, manufacturers of MRDT kits can introduce safe and acceptable products, which can reduce medical errors and save costs.



MRDT kits contain instructional inserts and equipment (e.g., pipettes, buffers) to test blood for malaria parasites.

Background

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 being tested.

MRDTs can significantly improve the diagnosis of malaria. The tests use whole blood, rather than smears, take only about 10 minutes, and give accurate diagnoses. However, MRDTs are not effective unless providers correctly perform all of the procedures, interpret the results accurately, and persuade clients to take appropriate actions based on the results.

Quality design research assesses the usability of a product from the end user or client's viewpoint and identifies ways to change a product and its instructions to reduce error and increase the likelihood of correct use. In 1998, the Quality Assurance Project (QAP) assessed the usability of two MRDTs: PATH's Falciparum Malaria IC Strip Test and OptiMAL® Assay by FLOW, Inc. QAP also tested whether quality design of the products' instructions could improve the ability of providers to follow the steps correctly.

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

Methodology

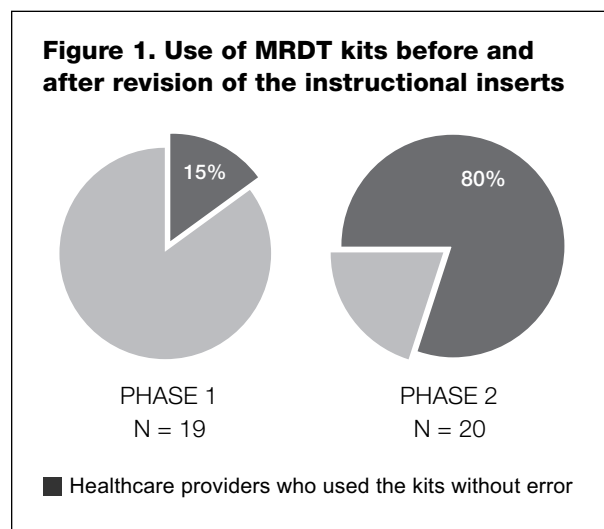
In a two-phase study, a research team assessed the ability of healthcare providers (end users) to follow both tests' instructions. The study included different cadres of health providers at 16 public health facilities and two mobile clinics in Malawi. During both phases, the lead investigator queried providers about ease of use, assessed their ability to use the tests without training, and identified barriers to correct use.

During the first phase, the team introduced both products to 19 providers. Eight received training in using the tests and 11 did not. The research team noted where users seemed to have trouble with the tests and interviewed



them about the products and instructions. The team redesigned the instructions, pretested them, and then redesigned them again.

For the second phase, the team selected a new group of 20 providers and divided them between the two products, making sure that equal proportions of providers from the various cadres were represented. During this phase, none of the providers was given training and the redesigned instructional insert was used.



Results

During the first phase, only about 15 percent of providers were able to use the products without error. Among the eight providers who received training before using the MRDTs, two followed all of the steps correctly; only one in 11 of the untrained providers did. More than half the providers missed more than 20 percent of the steps. Education and experience with malaria diagnostics did not correlate with performance: no cadre performed consistently well with the original instructions.

After the instructions were revised, more than 80 percent of the providers were able to use both products without error (see Figure 1). Both products yielded almost equally good results. There was no significant difference by cadre, and no provider missed more than 20 percent of the steps.

Providers also encountered problems that could not be rectified with improved instructional inserts. Some of these problems—such as difficulty in collecting blood or labeling the specimens—would require redesign of the kits' equipment. Numerous technical problems were observed (e.g., difficulty collecting blood, lack of timing devices and lancets, unclear labels).

Conclusions

This research demonstrated that important performance improvements can be achieved through changes made to instructional inserts. Changing the inserts seems to have been more effective than training providers in product use.

For optimal results, changes should also be made to the equipment in the kits. QAP provided both MRDT manufacturers with recommendations to improve their products before final introduction. The results of the study were also provided to the World Health Organization and Malawi's Ministry of Health.

Though quality design research can lead to significant improvements in the way a new product is used, a remaining challenge is to build local capacity and foster commitment to conduct quality design research before introducing new healthcare products in developing countries.

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This summary is based on the *Operations Research Results* report, "Using quality design to improve malaria diagnostics tests in Malawi," written by Paula Tavrow, Elisa Knebel, and Lynne Cogswell. To order the report, please access our Website: www.qaproject.org, or write to qapdissem@urc-chs.com.