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Improved diagnostic testing and malaria treatment practices in Zambia

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Abstract

Context—Improving the accuracy of malaria diagnosis using rapid diagnostic tests (RDT) has been proposed as an approach for reducing over-treatment of malaria in the current era of widespread implementation of artemisinin-based combination therapy in sub-Saharan Africa.

Objective—To assess the impact of microscopy and RDT use on prescription of antimalarials.

Design, Setting, and Participants—Cross-sectional, cluster sample survey of all sick outpatients seen at a health facility during one working day that included all public and mission health facilities in four sentinel districts in Zambia.

Main Outcome Measures—Proportions of patients undergoing malaria diagnostic procedures and receiving anti-malarial treatment.

Results—17% of the 104 health facilities surveyed had functional microscopy, 63% had RDTs available, and 73% had at least one type of malaria diagnostics. 27.8% of subjects with fever (suspected malaria) seen in health facilities with malaria diagnostics were tested and 44.6% were positive. 58.4% of patients with negative blood smears were prescribed an antimalarial as were 35.5% of those with a negative RDT result. 65.9% of the subjects with fever who did not have diagnostic tests done were also prescribed antimalarials. In facilities with artemether-lumefantrine in stock, this antimalarial was prescribed to a larger proportion of febrile patients with a positive diagnostic test (blood smear 75.0%; RDT 70.4%) than those with a negative diagnostic test (blood smear 30.4%; RDT 26.7%).

Conclusion—Despite efforts to scale up the provision of malaria diagnostics in Zambia they continue to be under-utilized and patients with negative test results frequently receive

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antimalarials. The provision of new tools to reduce the inappropriate use of new expensive antimalarial treatments must be accompanied by a paradigm shift in clinical management of patients without evidence of malaria infection.

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INTRODUCTION

Malaria is characterized by gross over-diagnosis and over-treatment, ranging from 32% to 96% of febrile patients having an antimalarial prescribed without any evidence of peripheral *Plasmodium falciparum* infection depending on the background level of malaria transmission.(1-4) The recent introduction of efficacious but expensive artemisinin-based combination treatments (ACT) for malaria across Africa has prompted a renaissance in improving the accuracy of malaria diagnosis.(1;5;6)

The most widely used approach to confirmatory diagnosis is malaria microscopy. However, this requires an organized health system infrastructure with functioning microscopes used by trained technicians with regular provision of reagents, supervision, and quality control. Because parasite detection is usually performed by someone other than the prescriber, there is a tendency to distrust or ignore the results of microscopy provided by the laboratory as evidenced in Tanzania(3), Zambia(2), and Kenya.(4) To put testing and clinical decisions in the hands of the prescriber or provide diagnostic services in settings where microscopy is not available or cannot be effectively supported, the use of rapid antigen-detection diagnostic tests (RDTs) has been encouraged as a potentially cost-effective approach to accompany the widespread implementation of expensive ACT.(5;7;8)

Despite numerous studies on the sensitivity and specificity of RDT for malaria diagnosis(7;9;10) there have been no formal evaluations of their use under routine, operational conditions. Here we present the results of an operational assessment of how microscopy and RDTs were used in the management of outpatients presenting to health facilities in four Zambian districts in 2006 approximately one year after the introduction of RDTs as a new diagnostic tool to support the introduction of a new ACT, artemether-lumefantrine (AL).

METHODS

Scaling up malaria diagnostics in Zambia

The Government of Zambia was one of the first African countries to replace its first-line antimalarial, chloroquine, with AL in response to rising rates of chloroquine treatment failures.(11) Following the policy decision and securing of finances to implement the drug policy change and procurement of AL from the Global Fund for HIV/AIDS, Tuberculosis and Malaria (GFATM), the nationwide implementation of the new drug policy began late in 2003. The availability of AL, revised national treatment guidelines, wall charts, and in-service training for health workers significantly increased between 2004 and 2006.(12) Early in 2003, it was also decided that, given the high cost of AL, there was a need to improve malaria diagnostics to rationalize the use of AL in peripheral clinics. A malaria diagnosis strategy was developed with the aim of providing malaria microscopy in all health facilities and at least 80% of suspected malaria cases having a parasitological diagnostic test done by 2008.(13)

With financial support from the GFATM, 600,000 immunochromatographic test strips, designed to detect the histidine-rich protein II of *P. falciparum* (Parachek Pf Rapid One Step, Orchid Biomedical Laboratories, Goa, India) were purchased in 2004 and 2005. This RDT has been shown in previous studies to have a sensitivity of 92.3-98.6% and specificity of 95.9-98.8% when compared to microscopy.(14-16) The RDTs were first distributed to

district health facilities by the National Malaria Control Center (NMCC) in the first quarter of 2005 in a staggered manner beginning with 10 target districts and then scaling up to all 72 districts.

In collaboration with Novartis Pharma AG, in September 2004, NMCC staff carried out a week long malaria case management workshop including training in the use and interpretation of RDTs. There were 260 participants including clinical officers, nurses, and environmental health technicians from all 72 districts. Training materials in RDT use were developed from the training workshop and used to perform cascade training throughout the country at 9 provincial workshops and subsequent district-level workshops during the first and second quarters of 2005. Wall charts and pictorial guides that described how to do the rapid test for malaria were developed in English, Bemba, and Nyanja. The pictorial guide demonstrates how to check the RDT expiration date, obtain a blood smear by finger prick, perform the test, and interpret a positive, negative, or invalid result but they do not provide any recommendations on how to respond to a positive or negative result.

Survey design

We undertook a cross-sectional, cluster sample survey with primary sampling units consisting of all functional government and mission health facilities that provide general outpatient care in four sentinel districts of Zambia: a) Chingola, an urban hypo/mesoendemic district in Copperbelt Province; b) Kalomo, a semi-arid mesoendemic district in Southern Province; c) Chipata, a mixed rural and urban meso/hyperendemic district in Eastern Province; and d) Samfya, a rural, swampy, hyperendemic district in Luapula Province. These four districts were purposely selected from the 11 Zambian NMCC sentinel surveillance sites as they represent differing malaria ecologies.

At each health facility data were collected over one working day and a cluster was defined as all sick outpatients seen at a health facility. Patients who presented with burns, trauma, or for the follow-up of chronic conditions such as HIV or tuberculosis were excluded. The survey was carried out between March and May 2006 during the high malaria transmission season. The protocol and consent form were reviewed and approved by the University of Zambia Research Ethics Committee (Federal Wide Assurance Number IRB 00001131) and the Boston University Medical Center Institutional Review Board (H-25346).

Study Procedures

The study team underwent training and concordance testing the week prior to the survey. On the day of the survey, study teams arrived at each facility before the clinic opened. No one at the facility was informed in advance regarding when the assessment would occur. The person in charge of the facility was presented a letter of support from the Central Board of Health specifying the purpose and nature of the survey.

In health facilities with laboratories, the RDT was performed by a lab technician. In those facilities that had no laboratory, the health care worker performed the RDTs and prescribed antimalarial treatment to the patient based on the test results. After completing the clinical evaluation including diagnostic testing and receiving antimalarial treatment, if prescribed, the patients or caretakers of sick children were approached when they were ready to leave the facility at the end of the clinic visit and asked if they would be willing to be interviewed. After obtaining written informed consent from potential participants, interviewers collected information about basic demographic characteristics of the patients; presenting complaints including history of fever; the assessment by the health worker; and drug dispensing practices undertaken during the facility visit. Information was also collected from patient-held records about diagnostic procedures requested, results reported, and medications

administered or prescribed. At the end of the exit interview, participants were weighed and had their axillary temperatures taken. Health center records other than the patient-held records were not used to collect any of the patient-specific diagnostic or treatment data. However, each facility was assessed to provide information on the availability of antimalarial drugs, microscopy, and RDTs for malaria.

Data Analysis

Data were double-entered into Microsoft Access 2000 (Microsoft Inc., Redmond, Washington) by independent data entry clerks and completed data files compared for errors. Analysis was performed with STATA version 8.0 (StataCorp, College Station, Texas). The analysis reported in this paper was restricted to health facilities with functional microscopy and/or RDTs, and to subjects whose weight and age were recorded. Fever was defined as a history of fever and/or presence of elevated temperature (≥37.5°C). Data are presented as frequencies and proportions with corresponding 95% confidence intervals (CI) adjusted for clustering by health facility.

RESULTS

An equipment survey in the four study districts revealed that only 17% of the 104 health facilities had functional microscopy. 63% of facilities had RDTs available on the day of the survey. Overall 73% of health facilities had at least one type of malaria diagnostics available. We evaluated 1717 patients of all ages with fever seen by 105 health workers at the 76 health facilities that had the capacity to perform a parasitological malaria diagnosis. 276 patients with fever were evaluated at health facilities with microscopy, 1,207 in health facilities with RDTs and 234 in facilities with both.

Malaria blood smears were performed in 27.8% (95% CI, 13.1% - 42.5%) of subjects seen at health facilities that had functional microscopy; rapid tests were used in 22.8% (95% CI, 13.8% - 31.8%) of those seen in facilities that had RDTs available (Table 1). In facilities that had both diagnostic tests available, no subjects had both microscopy and RDTs performed. There was no difference in the use of parasitological diagnostic tests when subjects were stratified by age. In patients who had a blood slide performed 45.4% (95% CI, 27.2% - 63.6%) had a positive smear reported while in those who had RDTs performed, 44.2% (95% CI, 33.4% - 55.0%) were positive. An antimalarial was prescribed to all subjects who had positive microscopy (100%) and nearly all who had positive RDT results (96.6%; 95% CI, 93.2% - 99.9%). In contrast, 58.4% (95% CI, 36.7% - 80.2%) of the patients with negative blood smears were provided antimalarials while 35.5% (95% CI, 16.0% - 55.0%) of those with negative RDT results were treated.

Most patients with fever (1248/1717; 72.6%) did not have any diagnostic procedure performed. Antimalarials were prescribed to 66% of these subjects; about half of this group received AL (Table 2). AL was prescribed more frequently to subjects with positive blood slides or RDTs relative to those who had negative diagnostic tests. We further analyzed those patients presenting with fever to health facilities that had AL in stock and diagnostics available on the day of the survey. At these facilities AL was prescribed to a larger proportion of febrile patients with a positive diagnostic test (blood smear 75.0%; 95% CI, 51.7% - 98.3% and RDT 70.4%; 95% CI, 39.3% - 100.0%) compared to those with a negative diagnostic test (blood smear 30.4%; 95% CI, 8.0% - 52. 9% and RDT 26.7%; 95% CI, 5.7% - 47.7%). The use of AL for patients who did not have any parasitological diagnostic evaluation was 42.1% (95% CI, 32.8% - 51.4%) overall. A similar proportion of patients with negative blood smears were also not provided treatment as those who had no diagnostic procedure performed (28.3%; 95% CI, 1.7% - 55.4% vs. 35.1%; 95% CI, 27.0% - 43.1%, respectively). In contrast, subjects with negative RDT results were about twice as

likely to not receive any antimalarial as those with negative blood slides. However, this difference was not significant.

DISCUSSION

Following Zambia's decision to scale up the provision of new diagnostic tools in concert with improving malaria case-management with new, expensive ACT within a year, 63% of health facilities had RDTs available for use and over 73% of facilities had either RDTs or microscopy available for malaria diagnosis. However only 27% of febrile patients presenting to these facilities had a parasitological diagnostic test performed. When diagnostic tests were performed and reported as negative for *P. falciparum* over 35% of patients were still prescribed an antimalarial. Malaria parasite prevalence rates in the study districts range from 15.6% in Chipata and 18.2% in Chingola, two districts with meso- and hyperendemic malaria, to 40.4% in Samfya, a hyperendemic district.(17) While these data derive from a survey that was carried out in the dry season in 2004, a more recent nationwide survey carried out in the late rainy season showed similar findings with malaria parasite prevalence rates ranging from 8.6% in Southern Province (where Kalomo District is located) to 37.5% in Luapula Province (Samfya District).(18) Given the high specificity of the RDTs used in the study district health centers, the prevalence of malaria in children is not high enough to warrant routinely treating all those with negative malaria diagnostic tests.

Among patients who had no parasitological diagnostic tests performed, 42% were prescribed AL. Although slightly fewer patients with negative microscopy or RDT results were provided with AL in health facilities where this drug was available, AL was nevertheless used in more than a quarter of all patients with negative diagnostic tests including a substantial portion of febrile older children and adults.

RDTs have been proposed as a cost-effective approach to reducing the over-treatment of malaria(5;7;8); however, under current practice in Zambia, their use will not limit the overuse of expensive new treatments. Assuming an estimated cost of US$0.5 per RDT against the recently reduced price per adult treatment course of AL of US$1 per course, for every 1000 febrile patients with negative RDT results, the cost savings would only be $0.33 per patient or $330 per 1000 patients if 27% of patients with negative test results still received AL treatment as suggested by our findings. Given the additional costs associated with training of health care workers in RDT use and interpretation, it does not appear that the way these diagnostics are currently used is cost-effective.

Although the national malaria guidelines in Zambia recommend the use of malaria microscopy whenever possible, they state that the "presence of signs and symptoms of disease with negative blood smear does not preclude the diagnosis of malaria".(19) Similar ambiguous recommendations are also provided in malaria training manuals.(20;21) None of the training materials or national guidelines in Zambia provides specific instructions on how to respond to negative RDT results. Although patients with negative RDT results were less likely to receive antimalarial treatment than those with negative blood smears, this difference was not statistically significant, possibly because the small numbers of patients in these groups resulted in our not having sufficient power to detect a difference. A recent randomized trial that compared the use of malaria microscopy to RDT in Tanzania found that slightly more than half of patients with negative blood smears or negative RDT results were prescribed an antimalarial.(16) In many countries in Africa, there continues to be a clinical dogma that regards blood smear-negative results as "suspected" malaria.(1;4) Our study and the study by Reyburn *et al.*(16) suggest that this clinical dogma is being extended to RDT results as well. Since the malaria parasite prevalence in the study districts is likely to be less than 50% during much of the calendar year, the routine treatment of negative RDT or

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blood smear results is not warranted. In the absence of a paradigm shift away from treatment of patients with negative blood smears towards the appropriate interpretation of RDTs, with specific guidelines on how to investigate fevers if the rapid test is negative, this new diagnostic intervention is unlikely to improve clinical management or result in the anticipated cost-savings from the misuse of expensive ACT in Africa.

Given the widespread scaling up of ACT in sub-Saharan Africa for the management of uncomplicated malaria, there is a clear need to limit the inappropriate use of these expensive new combinations. Given the increasing body of evidence that a substantial proportion of febrile patients do not have malaria, especially in low to moderate transmission zones(16), efforts need to be undertaken to educate health center staff on the rational use of ACTs. This will require strengthening the availability of malaria diagnostics and enhancing quality control measures so that health care providers will have confidence in the malaria test results. As currently structured in Zambia, the RDT training program needs to be restructured such that trainees are provided with clear instructions as to how to respond to a negative test result. Without taking these steps, we may rapidly be confronted with widespread resistance of *P. falciparum* to ACT and the lifespan of these highly effective new therapies will be greatly reduced.

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DHH and RWS participated in the study design, analysis and interpretation of the data, drafting and finalization of the manuscript. DZ and MN coordinated the survey design, trained the survey staff, and contributed to the analysis and drafting of the manuscript. MF performed the statistical analysis for the study with careful guidance from DH. KYA, NS, PC and JS participated in the interpretation of the data and drafting of the manuscript. All authors reviewed and have approved the final version of the manuscript. DHH and MF had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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Table 1

Microscopy and rapid diagnostic test use and results in subjects with fever, stratified by age

	Age < 5 years n (%, 95% CI)*	Age ≥ 5 years n (%, 95% CI)*	Total n (%, 95% CI)*
Malaria microscopy			
Blood slide performed	82/285 (28.8%, 10.6-47.0)	60/225 (26.7%,14.7-38.6)	142/510 (27.8%, 13.1 - 42.5)
Slide result (% positive)	34/81 ** (42.0%, 20.6-63.4) *	30/60 (50%, 32.1-67.9)	64/141 (45.4%, 27.2 - 63.6)
Antimalarial if blood smear positive	34/34 (100.0%)	30/30 (100.0%)	64/64 (100.0%)
Antimalarial if blood smear negative	27/47 (57.4%, 28.3-86.6)	18/30 (60%, 38.9-81.1)	45/77 (58.4%, 36.7 - 80.2)
Rapid diagnostic test			
RDT done	190/846 (22.5%, 13.7-31.2)	138/594 (23.2%, 13.1-33.4)	328/1440 (22.8%, 13.8 - 31.8)
RDT result (% positive)	92/190 (48.4%, 34.8-62.0)	53/138 (38.4%, 23.0-53.8)	145/328 (44.2%, 33.4 - 55.0)
Antimalarial if RDT positive	89/92 (96.7%, 93.0-100.0)	51/53 (96.2%, 91.5-100.0)	140/145 (96.6%, 93.2 - 99.9)
Antimalarial if RDT negative	37/98 (37.8%, 16.6-58.9)	28/85 (32.9%, 12.0-53.9)	65/183 (35.5%, 16.0 - 55.0)

* 95% CI adjusted for clustering by health care facility

** One blood smear result missing.

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Table 2

Antimalarial prescription in all subjects with fever in all health facilities and only those that had artemether-lumefantrine available, grouped by diagnostic test results

Treatment	No diagnostic test performed n (%, 95% CI)*	Slide + n (%, 95% CI)*	Slide - n (%, 95% CI)*	RDT + n (%, 95% CI)*	RDT - n (%, 95% CI)*	Total n (%, 95% CI)*
AL	423 (33.9%, 25.3 - 42.5)	27 (42.2%, 0.0 - 84.7)	14 (18.2%, 0.0 - 36.8)	44 (30.3%, 8.7 - 52.0)	30 (16.4%, 5.5 - 27. 3)	538 (31.3%, 23.6 - 39.0)
SP	369 (29.6%, 21.6 - 37.6)	26 (40.6%, 0.0 - 83.9)	27 (35.1%, 21.3 - 48.8)	84 (57.9%, 38.6 -77.3)	31 (16.9%, 4.8 - 29.0)	537 (31.3%, 24.3 - 38.2)
Quinine	31 (2.5%, 1.3 - 3.7)	11 (17.2%, 3.4 - 30.9)	4 (5.2%, 0.0 - 10.4)	12 (8.3%, 3.0 - 13.6)	4 (2.2%, 0.0 - 4.3)	62 (3.6%, 2.3 - 5.0)
No antimalarial	425 (34.1%, 27.4 - 40.7)	0 (0%)	32 (41.6%, 19.8 - 63.3)	5 (3.4%, 0.1 - 6.8)	118 (64.5%, 45.0 - 84.0)	580 (33.8,; 27.8 - 39.7)
Total N	1248 (100%)	64 (100%)	77 (100%)	145 (100%)	183 (100%)	1717 (100%)
Facilities with AL in stock						
AL	400 (42.1%; 32.8 - 51.4)	27 (75.0%; 51.7 - 98.3)	14 (30.4%; 8.0 - 52. 9)	38 (70.4%; 39.3 - 100.0)	28 (26.7%; 5.7 - 47.7)	507 (42.6%; 34.0 - 51.2)
SP	194 (20.4%; 13.7 - 27.1)	5 (13.9%; 0.0 - 36.2)	17 (37%; 15.0 - 59.0)	13 (24.1%; 0.0 - 49.3)	11 (10.5%; 0.0 - 23.7)	240 (20.2%; 14.0 - 26.3)
Quinine	23 (2.4%; 1.0 - 3.8)	4 (11.1%; 0.0 - 23.4)	2 (4.3%; 0.0 - 11.3)	1 (1.9%; 0.0 - 6.3)	2 (1.9%; 0.0 - 4.6)	32 (2.7%; 1.5 - 4.0)
No antimalarial	333 (35.1%; 27.0 - 43.1)	0 (0.0%)	13 (28.3%; 1.7 - 55.4)	2 (3.7%; 0.0 - 9.7)	64 (61%; 29.0 - 93.0)	412 (34.6%; 26.7 - 42.4)
Total N	950 (100%)	36 (100%)	46 (100%)	54 (100%)	105 (100%)	1191 (100%)

AL = artemether-lumefantrine

SP = sulfadoxine-pyrimethamine

*CI adjusted for clustering by health care facility