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Laboratory malaria diagnostic capacity in health facilities in five administrative zones of Oromia Regional State, Ethiopia

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Summary

objectives and Methods Quality laboratory services are a requisite to guide rational case management of malaria. Using a pre-tested, standardized assessment tool, we assessed laboratory diagnostic capacity in 69 primary, secondary and tertiary health facilities as well as specialized laboratories in five administrative zones in Oromia Regional State, Ethiopia, during February and March 2009.

RESULTS There was marked variability in laboratory diagnostic capacity among the facilities assessed. Of 69 facilities surveyed, 53 provided both comprehensive malaria laboratory diagnosis and outpatient treatment services, five provided malaria microscopy services (referring elsewhere for treatment), and 11 primary care health posts provided rapid diagnostic testing and outpatient malaria treatment. The facilities' median catchment population was 39 562 and 3581 people for secondary/tertiary and primary health facilities, respectively. Depending on facility type, facilities provided services 24 h a day, had inpatient capacity, and access to water and electricity. Facilities were staffed by general practitioners, health officers, nurses or health extension workers. Of the 58 facilities providing laboratory services, 24% of the 159 laboratory staff had received malaria microscopy training in the year prior to this survey, and 72% of the facilities had at least one functional electric binocular microscope. Facilities had variable levels of equipment, materials and biosafety procedures necessary for laboratory diagnosis of malaria. The mean monthly number of malaria blood films processed at secondary/tertiary facilities was 225, with a mean monthly 56 confirmed parasitologically. In primary facilities, the mean monthly number of clinical malaria cases seen was 75, of which 57 were tested by rapid diagnostic test (RDTs). None of the surveyed laboratory facilities had formal quality assurance/quality control protocols for either microscopy or RDTs.

conclusions This is the first published report on malaria diagnostic capacity in Ethiopia. While our assessment indicated that malaria laboratory diagnosis was available in most facilities surveyed, we observed significant gaps in laboratory services which could significantly impact quality and accessibility of malaria diagnosis, including laboratory infrastructure, equipment, laboratory supplies and human resources.

keywords Malaria, laboratory, diagnosis, health systems, capacity, Ethiopia

Introduction

Malaria is the most frequent cause of outpatient visits, health facility admissions and inpatient deaths in Ethiopia, accounting for 12% of outpatient visits and 10% of admissions in 2007/2008 (Federal Democratic Republic of Ethiopia Ministry of Health 2008). Rainfall and altitude are the major determinants of malaria epidemiology in the country (Ghebreyesus *et al.* 2000; Adhanom *et al.* 2006). Transmission occurs throughout the year in most locations

with two distinctive peaks after the short and long rainy seasons in March–May and July–September, respectively (Graves *et al.* 2009; Peterson *et al.* 2009). Widespread and large-magnitude epidemics occur every 5–8 years (Negash *et al.* 2005; Guthmann *et al.* 2007).

In Ethiopia, health services are provided through a fourtiered system comprising specialized referral hospitals, zonal hospitals, district hospitals and primary health care units (PHCUs), with average catchment populations of about 5 000 000, 1 000 000, 250 000 and 25 000 people, respectively. PHCUs consist of district health centres and community-level health posts. The latter focus on preventive services, providing only limited curative services. In 2007, for a total population of 77 million people, there were 143 hospitals [88 and 55 of which were administered by the Federal Ministry of Health (FMOH) and private sector/non-governmental organizations (NGOs), respectively]; 690 health centres (671 FMOH and 15 private sector/NGOs); 1376 health stations; and 9914 health posts.

Hospitals and health centres are primarily concentrated in urban areas, whereas health posts are usually situated in rural areas. Hospitals have several cadres of health workers, including physicians (training: 6–7 years), nurses (2–3 years), laboratory technicians (2 years) and technologists (4 years). Health centres are usually staffed by at least one health officer or nurse, laboratory technicians, pharmacists or druggists, and midwives. Health posts are staffed by two female health extension workers (HEWs), i.e. high school graduates with 1-year training on a package of 16 health interventions, including malaria.

Most patients with uncomplicated malaria are evaluated and treated at health post and health centre levels. The latter usually has laboratory services providing microscopic examination of blood films, whereas the former relies on malaria rapid diagnostic tests (RDTs). Depending on aetiology, malaria cases are treated with the artemisinin-based combination therapy (ACT), artemether-lumefantrine (AL), for *Plasmodium falciparum* or chloroquine (CQ) for Plasmodium vivax according to national malaria case management guidelines (Federal Democratic Republic of Ethiopia Ministry of Health 2004). Because health centres have inpatient capabilities (albeit limited), they are the first referral point for the health posts for severe malaria cases. Most patients with severe malaria are managed by district and zonal hospitals, where they typically receive systemic quinine therapy. The country's laboratory services are supported by the Ethiopian Health, Nutrition and Research Institute (EHNRI) through a network of twelve regional reference laboratories (RRLs); currently, the support given is basic and focuses mainly on HIV and tuberculosis, and does not include malaria. EHNRI and its satellite RRLs have a broad mandate ranging from

national infectious disease surveillance to public health emergency medicine and, as national reference laboratory, ensuring laboratory services quality control (QC) (EHNRI 2009).

Two large grants from the Global Fund to Fight AIDS, Tuberculosis and Malaria [Round 2 (2002-2008) total budget: \$73 million and Round 5 (2005-2010) total budget: \$140 million], provided funding for Ethiopia to dramatically scale-up malaria prevention and control interventions (Jima & Medhin 2008). This scale-up included the distribution of 12.5 million RDTs and 15.4 million ACT treatment doses to health facilities to increase access and availability of timely malaria diagnosis and effective treatment services (Jima et al. 2010). The initial scale-up of malaria prevention and control efforts in Ethiopia largely focused on the procurement of and access to key malaria commodities, rather than strengthening the support systems (Federal Democratic Republic of Ethiopia Ministry of Health 2006). Currently, no data exist on the reliability of laboratory confirmation of malaria diagnosis in Ethiopia, despite ongoing efforts to strengthen the laboratory quality assurance and quality control (QA/QC) systems. Health workers have variable training in malaria laboratory diagnosis and experience shortages of equipment and supplies that may compromise effective malaria diagnostic and treatment services.

Oromia Regional State is the largest of the 11 regional states of Ethiopia, with a population of 27 million people and covering about one-third of the country's landmass. Because of its malaria burden, Oromia has been the focus state for the US President's Malaria Initiative (PMI; http://www.pmi.gov). The aim of the survey reported here was to (i) comprehensively assess the capacity of selected health facilities within five zones in Oromia, Ethiopia, to perform malaria laboratory diagnosis and (ii) identify laboratory requirements to develop operational programme activities to support quality malaria case management for patients evaluated at these health facilities.

Materials and methods

Study setting and survey

Between February and March 2009, we assessed 69 health facilities within five administrative zones of Oromia, namely Arsi, East Shoa, Jimma, West Arsi and West Hararge (Figure 1). The surveyed facilities included seven hospitals, 45 health centres, three malaria control centres (MCCs), three RRLs and 11 health posts. This representative sample of health facilities was selected following discussions with the Oromia Regional Health Bureau (ORHB) and EHNRI.

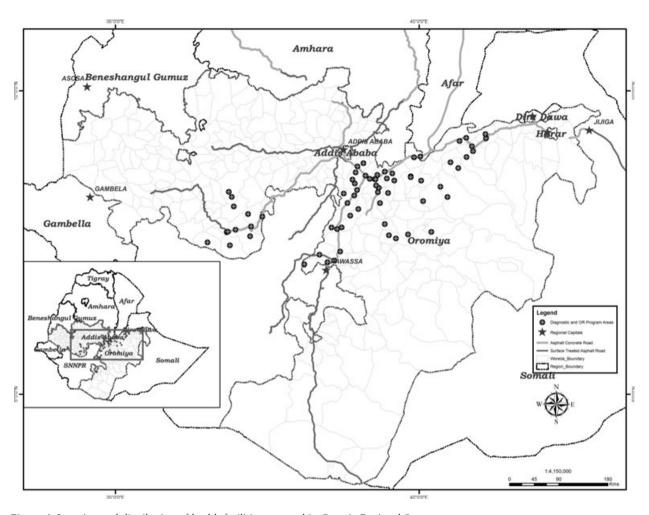


Figure 1 Location and distribution of health facilities surveyed in Oromia Regional State.

We collected facility-based data, using a pre-tested, standardized, structured questionnaire. The questionnaire addressed: (i) general information about the facilities; (ii) information on type of malaria laboratory services, including availability of human resources, essential laboratory and clinical equipment and supplies, QA protocols for malaria laboratory diagnostics, status of biosafety and implementation; and (iii) laboratory data from different health facility registers. Four assessment teams comprising members of the International Center for AIDS Care and Treatment Programs - Columbia University (ICAP-CU), ORHB, the EHNRI, and Oromia RRL, together with Zonal and District Health Office malaria focal persons conducted the assessments. Prior to the survey, the assessment teams received 1 day of orientation on the survey tools and procedures. The survey approach included key informant interviews with facility-based health

professionals, direct observation and review of secondary data.

Data analysis

The data were entered, tabulated and analysed in spss Version 15 (SPSS, Chicago, IL, USA).

Results

Seven hospitals, 45 health centers (HCs) and one MCC provided comprehensive malaria case management and were classified as 'clinical referral centres'. The three RRLs provided laboratory services for QA/QC purposes only, and two MCCs provided laboratory services but referred patients to nearby HCs or hospital clinics for malaria treatment after laboratory diagnosis by microscopy. The

11 primary care health posts are typically in rural settings often without electricity, and these provide malaria treatment based upon RDT test results. Thus, the data below are presented as clinical referral centres (n = 53), laboratories (n = 58) and health posts (n = 11).

Characteristics of health facilities surveyed

The median catchment population of the 53 clinical referral centres was 39 562 people (range: 14 875–2 000 000). Hours of operation were 24 h a day in 46 (87%) of the surveyed facilities and 8 h a day for 5 days a week in the remaining 7. The median number of inpatient beds was six (range 0–400).

Laboratory hours of operation were 24 h a day in 29 (50%) of the 58 surveyed facilities with microscopy laboratory; the remaining laboratories were open for 8 h a day/5 days a week. Electricity was available in 50 (86%) facilities, although 48 (96%) of these reported frequent power interruptions, with 30 (63%) reporting interruptions at least two times per week. Of facilities with access to electricity, 16 (32%) had a functional back-up generator. Of surveyed laboratories, 46 (79%) had ready access to water, with 41 and 5 using tap and well water, respectively. All the facilities reported having a disposal system, using either an incinerator (78%), pit burial (28%) or open field (7%) (Figure 2).

Health posts surveyed provided clinical services to a median 3581 people (range: 1608–41 567), but do not provide microscopy laboratory services. Hours of

operation of health posts were 8 h a day/5 days a week; six (55%) had water access, with four and two using well and pond water, respectively. All had a disposal system, with 10 using pit burial.

Human resources and training

Of the 53 clinical referral service facilities, 6 (11%), 4 (6%), 42 (79%) and 53 (100%) had general practitioners, medical specialists, health officers and nurses, respectively. Clinical manuals, reference books and guidelines for malaria were available in 32 (60%) of surveyed malaria clinics. In four (7%) facilities, health workers had attended training in RDTs in the past year.

A total 159 laboratory staff worked at the 58 microscopy laboratories (mean: 3; range 1–21). All facilities had at least one laboratory professional, with 38 (66%) having at least one laboratory technologist (BSc-level undergraduate training) and 47 (81%) having at least one laboratory technician (diploma-level undergraduate training). Only one laboratory, the RRL in Adama, East Shoa Zone, had laboratory professionals with postgraduate-level training (n = 3). Laboratory cleaners were available in 52 (89%) of the surveyed facilities.

Laboratory staff reported refresher training within the past year for malaria microscopy or RDT diagnosis at 14 (24%) and 2 (3%) of facilities, averaging 5.5 and 5 days duration, respectively; training was provided by the ORHB in collaboration with partner NGOs.



Figure 2 Disposal systems at surveyed facilities: (a) incinerator at health centre; (b) pit disposal system at assessed laboratory; (c) waste disposal system at one of the assessed health posts; (d) waste storage at one of the assessed laboratories.

1452

Staffing at the 11 health posts consisted of two HEW's (n = 8), one HEW (n = 2) and one nurse (n = 1); at each, at least one of these health workers had refresher RDT training within 1 year.

Major and minor clinical and laboratory equipment

Of the surveyed facilities, 46 (79%) had at least one electric binocular microscope and 24 (41%) had 1 daylight binocular microscope; of these, 42 (91%) and 20 (83%) were functional, respectively (Table 1). Among facilities having binocular microscopes, 14 (20%) reported having spare microscope bulbs. We observed slide staining and drying racks in 33 (57%) and 37 (64%) facilities, respectively. Other major and minor laboratory equipment surveyed is summarized in Table 1. As health posts do not provide laboratory services, equipment and supplies are limited to diagnosing malaria cases with RDTs (Table 1).

Consumables, consumable storage and equipment maintenance

Of the surveyed facilities with laboratory services, 16 (28%) and 13 (22%) reported problems maintaining supplies of Giemsa stain and microscope slides, respectively. Reportedly, the Adama and Jima RRLs and the Adama Malaria Control Center that prepare Giemsa stock solutions had problems maintaining adequate supplies and quality of Na₂HPO₄ and KH₂OPPO₄ buffers (necessary to prepare Giemsa) and pH paper. The survey indicated problems with the supply of lancets, immersion oil, lens tissue, lead/grease pencils, alcohol and bleach in 7 (12%), 14 (24%), 45 (78%), 48 (83%), 27 (47%), and 26 (67%) facilities, respectively. During power interruptions, 13 (22%) facilities reported having the capacity to use alternative methods of temperature-controlled storage of consumables, either ice packs (85%) or kerosene refrigerators (15%). We observed labels on laboratory reagent containers in 39 (67%) of these facilities, but clearly recorded laboratory reagent expiry dates in only five (13%) of these facilities. Staff were trained in equipment maintenance in two (3%) of these facilities, and laboratory staff were trained to re-order laboratory consumables (e.g. supply chain management training) in four (7%) of these facilities. None of the facilities surveyed had service contracts with vendors for equipment maintenance.

All of the health posts surveyed had the single-species Paracheck® RDT (Orchid Biomedical Systems, Goa, India) capable of detecting *P. falciparum*, stored at a mean room temperature of 27.2 °C (range 23.0–32.0) at the time of the assessment. In six (54.5%) of the health posts, the RDTs had expired, with the mean number of

expired boxes (note, one box contains 25 RDTs) being 22. None of the HEWs reported being trained in supply management.

Biosafety and operations

We observed laboratory staff wearing protective coats in 46 (82%) laboratory facilities; a further 5 (9%) had protective coats available but did not use them, and 4 (7%) facilities did not have protective coats. We observed use of protective gloves in 29 (50%) laboratory facilities; at 9 (16%) staff did not use available gloves and at 18 (32%) staff did not have gloves. Hand-washing facilities were available for staff in 27 (48%) laboratory facilities surveyed. We observed use of disinfectants and antiseptics in 36 (63%) and 32 (56%) facilities, respectively. Of surveyed laboratory facilities, 46 (84%) were using household waste bins for storing contaminated non-sharp wastes (e.g. used plastic ware, gloves and swabs) (Figure 2), while sharp boxes were used for storing contaminated sharp wastes in 33 (60%) facilities. The primary method of disposal for contaminated sharps, contaminated non-sharps, and blood and blood products was an incinerator in 34 (78%), 42 (76%) and 17 (31%) facilities, respectively. Disposal of contaminated but treated blood and blood products and of chemical/toxic agents was through sinks in 17 (31%) and 20 (36%) facilities, respectively.

At health posts, we observed staff in three (27%) wearing protective gloves when performing RDTs. All biohazardous materials were properly labelled and stored in three (27%) health posts. Of health posts, one (9%) had hand-washing facilities available, eight (73%) used waste bins for storing contaminated non-sharp supplies, and nine (81%) used burning for disposing of contaminated supplies.

Malaria diagnosis

Of 58 facilities reportedly performing malaria microscopy laboratory services, microscopy was actually available at only 51 (88%); reasons for unavailability of microscopic diagnosis included lack of functional microscopes, supplies, or lack of trained staff in microscopy. RDT malaria diagnosis was available in 24 (41%) of 58 malaria microscopy laboratory centres and 19 of these facilities used both microscopy and RDTs for malaria diagnosis.

When available, RDTs were reportedly used in place of microscopy during busy laboratory working conditions when additional microscopy workload would cause excessive delays in clinical management, and when laboratory staff were not available. Haemoglobin estimation

Table I Functional major and minor equipment at surveyed health facilities

	Malaria clinical referral centers <i>n</i> (%)	Laboratories n (%)	Health Posts n (%)
Major equipment			
Microscopes			
Electric	_	42 (72)	_
Daylight	_	20 (35)	_
Monocular	_	2 (3)	_
Centrifuges			
Electric	_	43 (74)	_
Manual	_	18 (31)	_
Microhematocrit centrifuge	_	18 (31)	_
Refrigerators (shared or laboratory only)	_	38 (66)	_
Spectrophotometer/colorimeter	_	6 (10)	_
Hemoglobinometer	_	25 (43)	_
Autoclave	_	15 (26)	_
Automated blood cell analyzer	_	5 (9)	_
pH meter	_	2 (3)	_
pri meter		2 (3)	
Minor equipment			
Otoscope	30 (57)	_	_
Stethoscope	53 (100)	_	_
Blood pressure apparatus	50 (94)	_	_
Thermometer	30 (57)	_	2 (18)
Torch/flashlight	9 (17)	_	_ ` `
Weighing scale			
Adults	53 (100)	_	6 (55)
Infants	49 (92)	_	7 (64)
Laboratory	_ ` ′	13 (22)	_ ` ′
Slide staining rack	_	33 (57)	_
Slide drying rack	_	37 (64)	_
Slide troughs	_	23 (40)	_
Slide box	_	37 (64)	_
Glassware		07 (0.)	
Beakers	_	25 (43)	_
Flasks	_	18 (31)	_
Funnels	_	27 (47)	_
Lancets	_	57 (98)	10 (91)
Pipettes	_	37 (20)	10 (71)
Automated		36 (62)	
	_	36 (62)	2 /10\
Pasteur pipettes	_	- 59 (100)	2 (18)
Sharps container	_	58 (100)	10 (91)
Microscope slides	_	58 (100)	2 (18)
Biohazard container	_	58 (100)	9 (82)
Gloves	_	58 (100)	10 (91)
Timer	_	32 (55)	1 (9)
Cell counters (differential or tally)	_	37 (64)	-
First aid kit	_	35 (60)	
Number of facilities surveyed	53	58	11

was performed in 39 (67%) facilities, with use of colorimetry, hematocrit, and automated analyzer techniques in 27 (69%), 17 (44%) and 4 (10%) of the facilities, respectively.

Malaria blood films were performed in 51 (88%) facilities; 16 (31%) performed both thick and thin blood

films; 34 (67%) performed only thick blood films; and one (2%) facility performed only thin blood films. All surveyed facilities reported using Giemsa staining for thick and thin films, with two facilities using additionally Wright's stain for thin films. Among the 51 facilities where blood films were performed, malaria species

identification was observed in 39 (77%) and reported in 12 (23%) facilities, while malaria parasite quantification was observed in 11 (22%) and reported in 3 (6%) facilities. In all facilities performing malaria parasite quantification, the plus system (World Health Organization 1991) was used.

RDTs for malaria were reportedly used in 16 facilities, but we also observed evidence of RDT use in an additional eight facilities, making a total of 24 facilities. Clinicians reportedly discussed laboratory results with laboratory staff in 28 (52%) of surveyed facilities, with laboratory personnel usually repeating the malaria tests should clinicians disagree with the original laboratory diagnostic test result. Clinicians at 60% and 25% of surveyed facilities reportedly treated febrile patients with negative blood films with ACTs and with CO, respectively. At the 58 microscopy laboratory facilities, a register recorded malaria laboratory results in 52 (90%); laboratory request forms were reportedly used at 32 (55%) facilities but only observed to be completed in 20 of these (63%). Between January and December 2008, the mean monthly number of blood films processed was 225 and the mean monthly number of parasitologically confirmed malaria cases per facility was 56. Of the total 34 536 confirmed cases at all facilities, 17 426 (50%) and 15 240 (44%) were because of P. vivax and P. falciparum, respectively; the remainder were mixed infections.

In assessed health posts, registers or record books for recording malaria RDT test results were available in eight (73%). Between January to December 2008, the mean monthly number of clinical malaria cases seen was 75 per health post, of which a mean 57 (76%) were tested by RDTs.

Quality assurance

None of the surveyed laboratory facilities had formal QA/QC protocols for either microscopy or RDTs. Of 51 facilities performing blood films, 25 (49%) reportedly recycled slides, 24 (47%) discarded used slides and two saved slides for QA purposes. Slides were re-read for internal QC purposes in 10 (20%) facilities, but none of these kept QC records. No health facility reported rereading of slides through external QC. External supervisory visits (done by the ORHB and/or Zonal Health Office) in the last 6 months were reported in 36 (62%) of surveyed facilities, with only 3 (8%) reporting that visits included review of malaria microscopy or RDTs as well as quarterly feedback on staff performance by the supervisor. Standard Operating Procedure (SOPs) for malaria blood film preparation and reading was observed in four (7%) facilities and none had SOPs for use of RDTs. Bench aids

for malaria microscopy were available in eight (14%) facilities; none had bench aids for RDTs.

QA protocols were lacking in all health posts surveyed, but in four health posts, HEW's re-read each other's RDTs for QC. No samples tested by RDT were submitted to a RRL for QC in any form nor were records kept at health posts showing internal QC. External supervision (done by ZHO and DHO) in the last 6 months was reported by all health posts; visits included review of RDTs in seven (64%) health posts, of which 4 received feedback on their performance from the supervisor. None of the health posts had SOPs or bench aids.

Discussion

Following guidance from Global Malaria Action Plan (Roll Back Malaria Partnership 2008) and utilizing the substantial increase in international donor funding support for malaria prevention and control programmes, many countries across sub-Saharan Africa are scaling-up malaria prevention and control interventions, including insecticidetreated nets, indoor residual spraying of households, and provision of early diagnosis and treatment. WHO and GMAP both emphasize that presumptive treatment for malaria should be minimized, and suspected malaria cases in all age groups should be confirmed by laboratory diagnosis (World Health Organization 2009). As the proportion of fevers because of malaria will drop after the scale-up of malaria efforts, it is crucial that only true malaria cases receive antimalarial treatment (Anonymous 2006). Although reliable tools exist to enable accurate malaria diagnosis even at community level (D'Acremont et al. 2009), requirements for diagnosis may be variable for different tiers of the health service delivery system (Long 2009). It is also evident that strengthening malaria diagnosis is fundamental for strengthening the whole of a country's laboratory services (Birx et al. 2009; Nkengasong 2009).

Published, peer-reviewed literature on in-country malaria (and in general laboratory) diagnostic capacity is scant, with data almost exclusively coming from assessment reports available in the grey literature (Kassu & Aseffa 1999; World Health Organization 2003; National Bureau of Statistics Tanzania & Macro International Inc. 2007; National Institute of Statistics Rwanda, Ministry of Health Rwanda, and Macro International Inc. 2007; Ministry of Health Uganda & Macro International Inc. 2008). Unpublished reports on malaria diagnostic capacity from various countries in Africa have been compiled by the PMI-funded Improving Malaria Diagnostics project, from which the questionnaire used for this survey was adapted (J. Carter, personal communication).

While our assessment indicated that malaria laboratory diagnosis, either by microscopy or RDTs, was available in most facilities surveyed (90%), the assessment revealed significant gaps in laboratory services' functions that could impact on quality and accessibility of malaria diagnosis, such as laboratory infrastructure, equipment, laboratory supplies and human resources. Data such as those presented here should help inform planning, budgeting, and developing strategies to strengthen laboratory capacity to diagnose malaria (Ohrt et al. 2007). Clearly, some of the needs and gaps identified are more easily addressed (e.g. supply of gloves) than others (e.g. access to water, electricity, refrigeration) and may require little (e.g. provision of laboratory coats) or more substantial policy and financial support (e.g. availability of staff positions and training).

Findings from this assessment have been used to design and now implement activities to strengthen laboratory capacity for malaria diagnosis in Oromia, using PMI support. For example, facilities with non-functional microscopes have been equipped with microscopes (including microscope repair kits); and all laboratories have been provided with an estimated year's consumption of laboratory reagents and supplies to ensure that blood slide examination is not interrupted. Both clinical and laboratory facility staff are being (re-)trained in malaria diagnostic issues, addressing microscopy, RDTs, laboratory safety and QA/QC. An external quality assessment (EQA) system has been developed (Ethiopian Health and Nutrition Research Institute 2010) and is now being implemented under the leadership of EHNRI and in collaboration with ORHB and ICAP-CU. Moreover, the FMOH's decision in 2009 to change from single-species RDTs capable of detecting P. falciparum to multi-species RDTs capable of detecting both P. falciparum and non-P. falciparum species (Ashton et al. 2010) should improve malaria case management. While lot-testing of RDTs at the WHO RDT Lot Testing Reference Laboratories in Muntinlupa City, Phnom Penh or Addis Ababa is a pre-requisite to distribution, the EQA system in place will be able to monitor the quality of RDTs at field level (Ethiopian Health and Nutrition Research Institute 2010).

Standardized assessments such as ours or the similar Service Provision Assessments (National Bureau of Statistics Tanzania & Macro International Inc. 2007; National Institute of Statistics Rwanda, Ministry of Health Rwanda, and Macro International Inc. 2007; Ministry of Health Uganda & Macro International Inc. 2008) are crucial to define requirements needed to strengthen various aspects of health services delivery, including a country's capacity for malaria laboratory diagnosis. These and other health systems strengthening

efforts are crucial for reducing malaria morbidity and mortality in Ethiopia.

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