

Original

## Factors Associated With Prescribers' Use of Malaria Rapid Diagnostic Tests and Adherence to Test Results in Areas of Unstable Malaria Transmission in Madagascar

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Despite increasing availability of malaria rapid diagnostic tests (RDTs), presumptive diagnosis of malaria are common in malaria endemic countries and many health workers prescribe antimalarial drugs despite negative test results. This study aims to determine individual and health facility factors predicting prescribers' use of RDT and adherence to test results. We conducted a cross-sectional survey using a questionnaire among prescribers working in 31 primary health centers located in a semi-arid region of the South-West Region of Madagascar in 2009. The questionnaire addressed prescribers' individual characteristics, prescribers' perception on RDT, and health facility characteristics. Factors associated with RDT use and adherence were determined by multiple logistic regression. Among 77 respondents, 21 (27.3%) used RDT for all febrile patients and 14 (18.2%) did not prescribe antimalarial drugs whenever RDT results were negative, conforming to national policy on malaria. Principal prescribers were likely to use RDT than secondary prescribers. For higher adherence to RDT negative results, two determinant factors were identified: working position as principal prescribers and higher monitoring frequency. In the study setting neither use of RDT nor adherence to RDT results was adequate. For effective use of RDT, improvement of monitoring frequency is needed with a focus on secondary prescribers.

**Key Words:** malaria, rapid diagnostic test, prescription behavior, guideline implementation, madagascar

### Introduction

Reduction of malaria morbidity and mortality is a global health issue and one of the targets of the United Nations' Millennium Development Goals. Accurate parasitological diagnosis is essential for prompt and effective management, one of the main components of malaria control strategy as well as reliable surveillance of malaria. Until recently, however, diagnosis of all febrile patients as malaria followed by presumptive treatment with antimalarial drugs was widely practiced in most malaria endemic countries with limited laboratory facilities. This resulted in malaria over-diagnosis and over-treatment due to low specificity of clinical diagno-

sis<sup>1)</sup>. Resistance of *Plasmodium falciparum* to commonly used antimalarial drugs such as chloroquine and sulphadoxine-pyrimethamine has been increasing and thus artemisinin-based combination therapy (ACT) has been adopted in nearly all Sub-Saharan African countries following World Health Organization (WHO) recommendation<sup>2)</sup>. ACT is much more expansive than previous drugs and consequently over-treatment of ACT has a great impact on cost-effectiveness. The WHO<sup>3)</sup> now recommends accurate parasite-based diagnosis for all patients suspected of malaria infection for its cost-effectiveness as well as improvement of clinical management of non-malaria febrile illness. More-

over, the accurate parasite-based diagnosis reduces the risk of adverse drug reactions and unnecessary drug pressure to malaria parasite.

In many malaria endemic countries, parasitological diagnosis with microscopy is feasible in only a few hospitals having adequate human and material resources. Meanwhile, the rapid diagnosis test (RDT) using the immunochromatographic method with high sensitivity ( $\geq 95\%$ ) has become commercially available since the early 2000s. RDT is the only tool which enables accurate diagnosis in many malaria endemic areas without laboratory facilities and thus intervention studies were widely conducted to assess the effectiveness of RDT compared with that of previous diagnoses. However, several studies have proven that a considerable proportion of health workers prescribed antimalarial drugs even when RDT test results were negative<sup>4-6</sup>. Health workers' response to RDT test results as well as malaria transmission level has a great impact on the total medical cost. In low and moderate levels of malaria transmission, prescribers' adherence to RDT results is a key determinant to the cost-effectiveness of RDT<sup>7</sup>.

A recent qualitative study proposed the importance of patient-health worker/peer interactions in adherence to RDT test results in an intervention context of RDT deployment<sup>8</sup>. However, which factors determine health workers' behavior related to RDT in routine health care situations is yet to be clarified. Thus, we investigated the behavior of health workers including the use of RDT, adherence to test results, and their associations to individual and health facility characteristics by using the quantitative method.

## Methods

### Deployment of RDT and ACT in Madagascar

In April 2000, like many other African countries, Madagascar ratified the declaration of Abuja action plan related to the Roll Back Malaria initiative. The current national policy against malaria was published in 2005<sup>9</sup>. Since then, RDT and ACTs were gradually rolled out in primary health centers over the country. CareStart Malaria HRP2/pLDH Combo (Access Bio, Inc. New Jersey, USA) was ex-

clusively used as a RDT in Madagascar (sensitivity: 95% at a low parasite density (200 parasites/ $\mu\text{l}$ ), 100% at a higher parasite density (2,000 or 5,000 parasites/ $\mu\text{l}$ ); specificity: 99% at a low parasite density, 100% at a higher parasite density).

According to national policy, the diagnostic approach varies according to the health care structures (community, primary health center, and reference hospital) and the pattern of malaria epidemiology (stable and unstable). Malaria transmission is frequent and perennial along the east and the west coasts of Madagascar. In these areas, adult people develop acquired immunity against malaria and most infection is asymptomatic. However, small children and pregnant women remain vulnerable to this disease due to insufficient immunity. This situation is determined as stable transmission. In contrast, malaria transmission is low, seasonal or epidemic in the central highland and the sub-desert area of the south part of Madagascar. Full protective immunity against malaria is not acquired among inhabitants in these areas and it is possible for people of all ages to have symptomatic infection. The situation is termed unstable transmission. In areas of stable malaria transmission, the national policy in Madagascar recommends clinical diagnosis, which can be based on symptoms, rather than parasite-based diagnosis in children under the age of 5. Meanwhile, in areas of unstable transmission, parasite-based diagnosis is used for the diagnosis of malaria infection using RDT or microscopy at all ages in primary health centers and hospitals.

Combination of artemisinin and amodiaquine is the first line treatment in Madagascar; artemisinin-lumefantrine is indicated in case of treatment failure. Quinine-tetracycline or quinine-doxycycline combinations can be used when artemisinin-lumefantrine is not available. Chloroquine was withdrawn gradually from public primary health centers and use of sulfadoxine-pyrimethamine has been restricted to the intermittent preventive treatment in pregnant women. However, outside governmental health care structures, such as private pharmacies, local shops, and private donations have been beyond control. Chloroquine, sulfadoxine-pyrimeth-

thamine, and other brands of Artemisinin-based combination drugs were easily available through these nongovernmental channels in the study period.

### **Study area and participants**

This study was conducted at primary health centers in Toliara, the capital of Atsimo-Andrefana Region, Madagascar. This region was semi-arid and malaria transmission was low and seasonal, sometimes inexistent for some years<sup>10</sup>. Primary health centers, the smallest health structure held by qualified health workers (medical doctors, nurses, or midwives) in Madagascar, received only outpatients and those who needed hospitalization were referred to district hospitals. We selected all primary health centers ( $n = 32$ ) located within 4 hours drive from Toliara central town, which were classified as health facilities within urban ( $n = 20$ ) or rural ( $n = 12$ ) catchment areas. Twenty one primary health centers were run by government, and all ( $n = 11$ ) private health centers were located in the urban area.

Among 83 prescribers working in the selected 32 primary health centers, 77 (92.8%) in 31 primary health centers participated in the survey. Six were unable to participate because of professional duties in other places, sudden illnesses, and unexpected family obligations. Generally, each primary health center had 1 principal prescriber (doctor or head of primary health center) with 1 or 2 secondary prescribers (nurses or midwives). Secondary prescribers were assumed to temporarily take on the role of principal prescriber in case of absence. Prescribers generally decided to use RDT, practiced RDT, and evaluated RDT results because there were no laboratory technicians in the primary health centers.

Regional malaria supervisors have performed monitoring of health workers' activities since introduction of RDT. They monitored availability of RDT, availability of ACT, number of RDT positive cases and number of malaria cases at each primary health center. Recommendations related to RDT usage were also given to health workers.

### **Study design and data collection**

A cross-sectional survey was carried out in October-November 2009 at the beginning of the

rainy season. A structured questionnaire was developed in French, partly referring to previous published guidelines of clinical practice implementation<sup>11,12</sup>. The primary investigator (HDR) and 4 trained field assistants interviewed prescribers using the questionnaire and collected two dependent variables. The first dependent variable was whether or not prescribers used RDT for febrile patients. We defined "RDT use" as "Choice to use RDT for patients with fever or history of fever regardless of patient symptoms or characteristics". The second dependent variable was whether or not prescribers adhered to RDT results. "RDT adherence" was defined as "No antimalarial prescription in response to RDT negative results".

Explanatory variables in the questionnaire fell into the following categories: (1) individual background characteristics: age, sex, qualification, position at the primary health center, receiving training on RDT before its introduction; (2) individual perception of RDT: reliability, workload, time spent; and (3) health facility background characteristics: type of primary health center, location of primary health center, availability of RDT, availability of Artemisinin-based combination therapy (ACT), availability of the book on National Malaria Policy Program, and frequency of monitoring by regional malaria program staff.

### **Statistical analysis**

All survey data were coded then double-checked by the authors to ensure accuracy. We used JMP 8.0.1 software and SAS 9.1 software from SAS Institute Inc., NC, USA, for the analysis. In order to identify determinants of prescribers' use of RDT and their adherence to RDT test results, logistic regression analysis were run with 14 explanatory variables for RDT use (age, sex, qualification, position, training, RDT reliability, workload of RDT performance, RDT time spent, health center type, health center location, availability of National Policy Book, RDT availability, ACT availability, monitoring frequency) and 10 explanatory variables for prescribers' adherence to RDT results (age, sex, qualification, position, training, RDT reliability, health center type, health center location, availability of National

Policy Book, monitoring frequency).

We started with a univariate analysis to calculate the independent effect of each factor on the two dependent variables. We reported these individual effects as crude odds-ratio (OR) shown with their respective 95% confidence interval (95% CI). Multivariate logistic regression analysis was then performed. All variables were introduced together and a forward stepwise selection method proceeded. A *p* value of 0.3 was fixed for a variable to enter the model. This procedure was followed by a backward stepwise selection. A *p* value of 0.05 was fixed for a variable to stay in the final model. We reported the final effects of the explanatory variable retained in the final model as adjusted odds-ratios (AOR) with their 95% CI.

#### **Ethical approval**

This study was performed under a protocol approved by the Regional Representative of the Ministry of Health in Toliara, Madagascar and the Ethical Review Committee of Tokyo Women's Medical University, Japan. Informed consent was obtained from all participants.

### **Results**

#### **RDT use and adherence**

Only 27.3% (21/77) of prescribers responded that they utilized RDT for febrile patients regardless of patients' symptoms or characteristics. In cases where RDT was negative, 24.7% (19/77) prescribed ACT and more than half (57.1%, 44/77) prescribed antimalarial drugs other than ACT. Consequently 18.2% (14/77) of prescribers adhered to RDT negative results.

#### **Demographic characteristics and perceptions of prescribers**

The characteristics of the prescribers are summarized in Table 1. Prescribers' age ranged from 25 to 69 years [median = 44.0, 25-75% quantile = 32.5-51.5]. Although all medical doctors were principal prescribers, only 19.1% (8/42) of nurses and midwives were principal prescribers. The majority of prescribers worked in public health centers (71.4%), in urban areas (79.2%), with constant availability of RDT (81.8%), or with constant availability of ACT (66.2%). In contrast, only 19.5% of prescribers re-

ceived training before introduction of RDT, and less than half had an opportunity to receive frequent (once or more every 3 months) monitoring (42.9%) or an opportunity to utilize the National Health Policy Book (44.2%). The majority of prescribers considered RDT practice as part of normal operational conditions (71.4%), RDT practice as adequate time spent (68.8%), but only 44.1% felt that RDT was reliable.

#### **Factors associated with RDT use**

Univariate analysis showed that medical doctors (OR = 8.97 vs. nurse/midwife, *p* < 0.001) and principal prescribers (OR = 12.67 vs. secondary prescribers, *p* = 0.001) were associated with RDT use for all febrile patients (Table 2). Prescribers who considered RDT practice as part of normal operational conditions were likely to use RDT for all febrile patients than those who considered RDT practice to be additional work ( $\chi^2 = 7.80$ , *p* = 0.005) but the odds ratio could not be calculated because there was no prescriber (0/15) who used RDT for all febrile patients and considered RDT practice to be additional work. All variables related to health facility characteristics were not significantly associated with RDT use. In multivariate analysis, only one variable, position (principal prescriber vs. secondary prescriber), was selected for the final model (Table 2).

#### **Factors associated with adherence to RDT results**

None of the 10 variables were significantly associated with adherence to RDT results in univariate analysis. However, multivariate analysis showed that two variables (position of prescriber and monitoring frequency) were associated with adherence to RDT results (Table 3). The principal prescriber was more likely to adhere to RDT results than the secondary prescriber (OR = 0.03, *p* = 0.020). Monitoring frequency was also positively associated with adherence to test results (once or more every 3 months vs. less than once every 3 months, OR = 3.82, *p* = 0.048).

### **Discussion**

This is the first quantitative study to explore determinants of the behavior of prescribers in relation to RDT. More than 80% of prescribers declared not

**Table 1** Characteristics of prescribers

	Number	%	Median	25-75% quantile
Individual characteristics				
Age			44.0	32.5-51.5
Sex				
Female	45	58.4		
Male	32	41.6		
Qualification				
Nurse or midwife	42	54.5		
Medical doctor	35	45.5		
Position				
Secondary prescriber	34	44.2		
Principal prescriber	43	55.8		
Training				
No	62	80.5		
Yes	15	19.5		
Individual perception				
RDT reliability				
Reliable	34	44.1		
No idea	20	26.0		
Not reliable	23	29.9		
Workload of RDT				
Additional workload	15	20.8		
Normal activity	57	79.2		
Time spent of RDT				
Long or very long	24	31.2		
Adequate	53	68.8		
Health facility characteristics				
Health center type				
Private	22	28.6		
Public	55	71.4		
Location				
Rural	16	20.8		
Urban	61	79.2		
RDT availability				
Not available	0	0.0		
Some shortages	14	18.2		
Always available	63	81.8		
ACT availability				
Not available	0	0.0		
Some shortages	26	33.8		
Always available	51	66.2		
Availability of National Policy Book				
Not available	43	55.8		
Available	34	44.2		
Monitoring frequency				
No monitoring	0	0.0		
Less than once every 3 months	44	57.1		
Once or more every 3 months	33	42.9		

fully adhering to RDT negative results. Different studies reported the same findings in Africa and drew attention on potentially negative consequences of this attitude such as over-diagnosis, over-treatment and under-diagnosis<sup>(5)(13)(14)</sup>.

Our study showed that more frequent monitor-

ing of health facilities was associated with higher adherence to RDT results. Monitoring by supervisors was known to be one effective way to improve the effectiveness of guideline implementation<sup>(15)(16)</sup>. Principal prescribers were also associated with higher adherence to RDT results. In our study set-

**Table 2** Factors associated with RDT use for febrile patients

	UNIVARIATE			MULTIVARIATE		
	OR	95% CI	p value	AOR	95% CI	p value
Individual characteristics						
Age	0.98	(0.93-1.03)	0.423			
Sex						
Female	1	-				
Male	2.4	(0.87-6.85)	0.093			
Qualification						
Nurse or midwife	1	-				
Medical doctor	8.97	(2.85-34.78)	<0.001			
Position						
Secondary prescriber	1	-		1	-	
Principal prescriber	12.67	(3.26-84.42)	0.001	12.67	(3.26-84.42)	0.001
Training						
No	1	-				
Yes	1.41	(0.40-4.72)	0.558			
Individual perception						
RDT reliability						
Not reliable	1	-				
RDT is reliable or no idea	0.59	(0.21-1.76)	0.337			
Workload of RDT*						
Additional workload	1	-				
Normal activity	-	-	0.005			
Time spent of RDT						
Long or very long	1	-				
Adequate	0.65	(0.23-1.91)	0.423			
Health facility characteristics						
Health center type						
Private	1	-				
Public	0.54	(0.19-1.61)	0.261			
Location						
Rural	1	-				
Urban	1.16	(0.35-4.59)	0.819			
RDT availability						
Some shortages	1	-				
Always available	0.92	(0.27-3.72)	0.904			
ACT availability						
Some shortages	1	-				
Always available	1.03	(0.36-3.10)	0.961			
Availability of National Policy Book						
Not available	1	-				
Available	0.71	(0.25-1.96)	0.513			
Monitoring frequency						
Less than once every 3 months	1	-				
Once or more every 3 months	0.76	(0.26-2.10)	0.606			

\*p value was calculated by Chi-square test.

ting, hierarchical positions of principal prescriber were mostly held by heads of health centers, thus their chance to meet supervisors is greater than those of secondary prescribers. This implies that they have more opportunities for discussion with supervisors about RDT effectiveness and sensibility than secondary prescribers. Eventually, they may receive more direct requests, reprimands or praise

from supervisors than secondary prescribers, resulting in a higher adherence to RDT results. More than half of prescribers claimed to choose conventional antimalarial drugs other than ACTs, such as chloroquine, quinine, and sulfadoxine-pyrimethamine in RDT negative cases. In Madagascar, *Plasmodium falciparum* parasites resistant to different antimalarial drugs have already been identified and

**Table 3** Factors associated with RDT adherence

	UNIVARIATE			MULTIVARIATE		
	OR	95% CI	p value	AOR	95% CI	p value
Individual characteristics						
Age	0.96	(0.90-1.02)	0.181			
Sex						
Female	1	-				
Male	1.07	(0.32-3.44)	0.913			
Qualification						
Nurse/or midwife	1	-				
Medical doctor	1.78	(0.55-5.98)	0.335			
Position						
Secondary prescriber	1	-		1	-	
Principal prescriber	3.55	(1.00-16.82)	0.070	6.03	(1.48-32.65)	0.020
Training						
No	1	-				
Yes	1.89	(0.45-6.89)	0.348			
Individual perception						
RDT reliability						
Not reliable	1	-				
RDT is reliable or no idea	3.00	(0.73-20.42)	0.175			
Health facility characteristics						
Health center type						
Private	1	-				
Public	1.00	(0.29-4.01)	1.000			
Location						
Rural	1	-				
Urban	0.95	(0.25-4.66)	0.947			
Availability of National Policy Book						
Not available	1	-				
Available	1.33	(0.41-4.34)	0.627			
Monitoring frequency						
Less than once every 3 months	1	-		1	-	
Once or more every 3 months	2.03	(0.63-6.84)	0.238	3.82	(1.04-15.43)	0.049

their prevalence has been increasing<sup>17)(18)</sup>. We consider that continuous usage of these antimalarial drugs can maintain the selecting pressure to parasites population, which will further increase the resistance to these conventional antimalarial drugs in Madagascar. In contrast, previous studies have recently shown that abandoning chloroquine have returned its efficacy in Malawi and Kenya<sup>19)(20)</sup>. Thus, correction of unnecessary usage of conventional antimalarial drugs, especially chloroquine, may decrease the level of resistance in our study area.

Despite RDT negative results, 24% of prescribers used nongovernmental ACTs. Nongovernmental ACTs are widely available in private pharmacies, local shops, and donor agencies in Madagascar. Concurrently, some statements in the national policy may not be sufficiently explicit for prescribers on

the criteria for ACT use, and prescribers may think that the recommendation, "ACTs for RDT positive only" pertains only to governmental ACTs, and not to other ACTs sold through nongovernmental channels.

More importantly, no clear instructions for the diagnosis and treatment for RDT negative results were given in the national policy of Madagascar. This may have caused the situation in which health workers prescribed nongovernmental ACTs or other antimalarial drugs other than ACTs in RDT negative cases. Ambiguities in malaria national policy for diagnosis and treatment for negative test results is not unique to Madagascar, and similar issues have been reported in Angola and Kenya<sup>13)(21)</sup>. In the latest WHO guidelines for the treatment of malaria, health workers were given exceptional per-

mission to use antimalarial drugs for negative test cases with severe symptoms considering the possible small risk of false negative tests<sup>3)</sup>. In contrast, some researchers insist that all negative cases should be treated as non-malaria diseases to avoid ambiguity<sup>22)</sup>. Without specific guidance, health workers may justify ignoring negative test results. Continuous evaluation on prescribing behaviors of health workers and update of national policy are needed to achieve accurate diagnosis and proper treatment in routine clinical practice.

Our results also showed that only 27% used RDT for all fever cases in accordance with the national policy. This under-use of testing is similar to results reported from Angola<sup>13)</sup> and Tanzania<sup>14)</sup>. Previous studies suggested that environmental factors such as lower workload of health workers and patient symptoms (higher temperature, vomiting and headache) were associated with testing. In contrast, an individual factor, to be principal prescriber, showed a significant association with adequate use of RDT in this study. Lack of opportunity to enforce new guidelines was previously identified as a barrier for guideline implementation<sup>11)</sup>. Therefore, we speculate that secondary prescribers who examine relatively fewer patients than principle prescribers tend to diagnose presumptively without using RDT.

This study showed that the monitoring frequency as well as the hierarchical position of the prescriber was related to the behavior of the prescribers toward RDT. The most significant way to improve prescribers' adherence to RDT results is monitoring. Visiting primary health centers to monitor RDT implementation of health workers is already a part of the routine work of malaria program supervisors, however, this needs to be strengthened with more focus on secondary prescribers who are nurses or midwives. As with many other developing countries, nurses and midwives ensure an important part of consultation activities due to scarce number of physicians in Madagascar. Monitoring can be used as a means to deliver up-to-date information and an opportunity to encourage and increase motivation adhere to RDT results, particularly in secondary prescribers.

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## マダガスカルのマラリア低流行地域における医療従事者のマラリア迅速診断キット使用 および診断結果遵守に関連する因子

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Rakotonand rasana Harimbola David<sup>1,2</sup>・塚原 高広<sup>1</sup>・清水 悟<sup>3</sup>・美田 敏宏<sup>1</sup>・遠藤 弘良<sup>1</sup>

マラリア流行地域では、マラリア迅速診断キット (rapid diagnostic test : RDT) の導入が進んでいるにもかかわらず、いまだ臨床診断が広く行われている。また、RDTの結果が陰性にもかかわらずその結果を遵守せず、多くの医療従事者は抗マラリア薬を処方している。本研究の目的は、適正なRDTの使用およびRDT結果遵守に関連する医療者個人および医療施設因子を決定することである。2009年にマダガスカル国南部の半乾燥地域において、31ヵ所の一次診療所に勤務する処方担当者を対象として質問紙を使用した横断研究を行った。質問項目は、処方担当者の個人特性、処方担当者のRDTに関する認識、医療施設の特性とし、RDT使用およびRDT結果遵守に関連する因子は多重ロジスティック回帰を用いて分析した。対象者77人のうち、政府のマラリア治療指針を遵守して、すべての発熱患者に対してRDTを使用すると回答した者は21人(27.3%)、RDT結果が陰性の場合には抗マラリア薬を使用しないと回答した者は14人(18.2%)であった。主任処方者(医師または診療所長)であることが、適正なRDT使用に関連していた。また、RDT結果遵守には主任処方者であることおよび監督者の訪問による監視頻度が高いことが関連していた。本研究では、RDT使用、RDT結果遵守の両方とも適正にはなされていない。RDTを有効に活用するためには、特に補助的な処方担当者(看護師または助産師)を対象として監督者の訪問による監視頻度を改善していく必要があると考えられる。