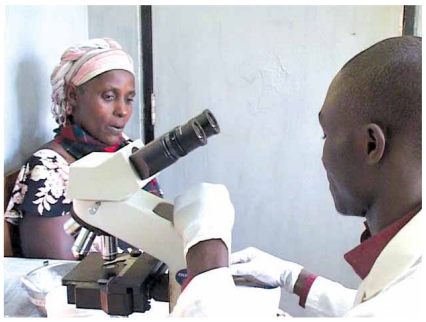
Republic of Kenya

Monitoring Outpatient Malaria Case Management Under the 2010 Diagnostic and Treatment Policy in Kenya

- Baseline Results -



Division of Malaria Control
Ministry of Public Health & Sanitation
June 2010

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TABLE OF CONTENTS

ACKNOWLEDGMENTS iii
ACRONYMS AND ABBREVIATIONS iv
EXECUTIVE SUMMARY v

1. INTRODUCTION AND JUSTIFICATION 1

1.1. International context and challenges 1
1.2. Kenyan context and challenges 2004-2009 1
1.3. The new era - Kenyan context 2009-2017 3

2. OBJECTIVES 5

2.1. General objective 5
2.2. Specific objectives 5

3. METHODS 6

3.1. Indicators 6
3.2. Study design and sample size 6
3.3. Sampling 7
3.4. Survey personnel and training 9
3.5. Data collection 9
3.6. Statistical analysis and approaches 11
3.7. Ethical approval 11

4. RESULTS 12

4.1. Sample Description 12
4.2. Health systems support 13

4.2.1. Availability of basic equipment and malaria diagnostics on survey days 14
4.2.2. Retrospective absence of diagnostic services 15
4.2.3. Availability of antimalarial drugs on survey days 15
4.2.4. Retrospective stock-out of antimalarial drugs 17
4.2.5. Availability and completeness of antimalarial drug management records 18
4.2.6. Frequency and quantity of AL received by health facilities 18
4.2.7. Availability of case management wall charts and guidelines 19
4.2.8. Exposure to in-service training 20
4.2.9. Characteristics of health workers performing consultations on survey day 21
4.2.10. Knowledge about treatment policy for uncomplicated malaria 22
4.2.11. Knowledge about use of malaria tests 23
4.2.12. Health workers perceptions of malaria risk at their facilities 23
4.2.13. Knowledge about interpretation of negative malaria test results 24

4.3. Malaria case management..... 24

4.3.1. Main patients' characteristics 25
4.3.2. Basic assessment practices..... 26
4.3.3. Baseline performance of the new diagnostic and treatment policy..... 26
4.3.4. Health workers adherence to the new diagnostic and treatment policy..... 28
4.4.5. Treatment practices stratified by type and result of routine malaria testing..... 30
4.4.6. Correctness of AL dosing..... 31
4.4.7. Dispensing and counseling practices..... 31

5. DISCUSSION..... 34

5.1. Availability of antimalarial drugs..... 34
5.2. Availability of diagnostics..... 35
5.3. Exposure to in-service training, guidelines, wall charts and supervision..... 36
5.4. Case management practices..... 38

6. CONCLUSIONS AND RECOMMENDATIONS..... 42

6.1. Availability of AL, other antimalarials and antimalarial drug management..... 42
6.2. Availability of parasite-based diagnosis and quality control..... 43
6.3. Coverage with guidelines, job-aids, in-service training and supervision..... 44
6.4. Case management practices..... 44

7. REFERENCES..... 46

8. ANNEXES..... 47

Annex 1: Summary of key health systems support M&E indicators..... 47
Annex 2: Summary of key malaria case management M&E indicators..... 48
Annex 3: AL monitoring data – time trends in the availability of non-expired AL..... 49

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ACRONYMS AND ABBREVIATIONS

AB	Antibiotic
ACT	Atemisinin-based Combination Therapy
AL	Artemether-lumefantrine
AM	Antimalarial
AQ	Amodiaquine
AS	Artesunate
BS	Blood slide
CI	Confidence interval
DCAH	Division of Child and Adolescent Health
DHA	Dehydroartemisinin
DHMT	District Health Management Team
DLT	District Laboratory Technologist
DOMC	Division of Malaria Control
DPF	District Pharmaceutical Facilitator
FBO	Faith-based organization
GOK	Government of Kenya
HF	Health facility
HW	Health worker
IMCI	Integrated Management of Childhood Illnesses
IQR	25%-75% inter-quartile range
KEMSA	Kenya Medical Supply Agency
KEMRI	Kenya Medical Research Institute
KNH	Kenyatta National Hospital
LA	Local authorities
MEDS	Mission for Essential Drug and Supply
M&E	Monitoring and Evaluation
MOH	Ministry of Health
MOMS	Ministry of Medical Services
MOPHS	Ministry of Public Health and Sanitation
MSH	Management Sciences for Health
NGO	Non-government organization
NMS	National Malaria Strategy
NPHL	National Public Health Laboratory
PHMT	Provincial Health Management Team
QN	Quinine
RDT	Rapid Diagnostic Test
Rx	Treatment
SP	Sulfadoxine-pyrimethamine
TOR	Terms of Reference
TWG	Technical Working Group
WHO	World Health Organization

EXECUTIVE SUMMARY

Effective malaria case management based on confirmed parasitological diagnosis and artemisinin-based combination therapy (ACT) is one of the cornerstones of the recently launched National Malaria Strategy (NMS) in Kenya. Prior to the large scale implementation activities aiming at universal availability of ACTs and diagnostics, universal coverage of health facilities and health workers with health systems support activities and universal health worker's adherence to the new malaria case management guidelines, the baseline survey was undertaken at public health facilities nationwide. This report presents results of the first survey planned as a biannual monitoring exercise aiming to timely inform national policy makers, and donor organizations, on the case management progress of the new NMS.

The main objectives of the survey were assessment of the availability of malaria case management commodities and the quality of outpatient case management practices in accordance with new national guidelines for uncomplicated malaria recommending parasitological testing of febrile patients, treatment of only test positive results with a recommended ACT - artemether-lumefantrine (AL), and the provision of dispensing and counseling tasks for patients treated with AL.

The survey was undertaken between 18 January and 12 February 2010 at 174 randomly sampled health facilities nationwide. At each facility data were collected over one survey day and included range of quality of care methods. Following the physical survey, the monthly availability of antimalarial drugs was monitored by phone calls made to the same facilities. To reflect guidelines criteria for malaria testing and AL treatment, the analysis was restricted to febrile, non-pregnant patients weighing 5 kg and above, presenting for an initial outpatient visit without being referred or admitted for hospitalization. The primary outcome was a composite performance indicator including all of the following criteria: 1) patient tested for malaria, 2) if positive test result treated with AL, and 3) if negative test result not treated for malaria. The secondary indicators reflected individual components of the case management including testing, treatment, dispensing and counseling in various patients' subgroups. To reflect baseline performance of the new case management policy practices are first analyzed at all health facilities regardless of the availability of the case management commodities. Then to assess health workers adherence the same analysis was restricted to the facilities where AL and diagnostics were in stock. Finally, the analytical approach and results presentation reflected the main objective of the study, i.e. to provide national level data for which the study was sufficiently powered to obtain information with desired precision.

Of 174 assessed facilities, any non-expired AL packs were in stock on survey day at 94% of facilities. By the end of April the availability of any AL pack decreased to 84%. The simultaneous availability of all four AL packs showed the similar trend – decrease from 65% in January/February to 44% by the end of April. In three months prior to the physical survey 27% of facilities were found to

have 7 or more days of complete AL stock-out. When AL stock outs occurred at these facilities, the median number of stock-out days was 35 or 38% of the time. Only 3% of facilities were found with any packs of expired AL. Although the frequency of supplies generally matched the planned supply intervals, facilities ordering AL have often received different quantities in comparisons with their orders - most commonly lower quantities. Despite more than 80% of facilities having various drug inventory materials, they were often incomplete. On survey days, malaria microscopy was provided at 51% of all facilities, notably at 41% of government facilities. Of facilities providing microscopy, 9% had this service absent in past 3 months in duration of 7 days or more. Only 10% of facilities had any RDTs in stock, and they were uncommon even in districts targeted in the past with RDT supply. Less than 10% of facilities providing parasite based diagnosis had received any visit in the past 3 months that included quality control of microscopy or RDT use.

Health facilities and health workers were variably covered with guidelines, job aids, in-service training and supervision. More than two thirds (70%) of facilities had malaria guidelines while various malaria case management wall charts were exposed at 37-45% of facilities. Of 572 health workers routinely performing outpatient consultations, 40% were trained on ACT case management, 27% on RDTs and 20% on IMCI. Furthermore, in past 3 years 48% of laboratory personnel attended in-service training on malaria microscopy, 42% were trained on RDTs and 37% of health workers dispensing drugs were trained on drug management. Formally non-qualified staffs such as community health workers do dispense antimalarial drugs (19%) and perform consultations (5%); however they have not been exposed to in-service training activities. Only 18% of 224 health workers who performed consultations on survey day had received at least one supervisory visit in past 3 months that included any activity related to malaria case management. Finally, although all health systems support activities undertaken in past 3 years are still relevant for various aspects of malaria case management, they were based on presumptive treatment of febrile children below 5 years of age.

At 174 assessed facilities case management practices were evaluated for 2,405 febrile patients, of which 1,239 patients were evaluated at 90 facilities with available diagnostics and AL. Baseline practices prior to the implementation of the new case management policy showed that at all study facilities only 16% of febrile patients (12% of children below 5 years of age and 19% of patients 5 years and older) are currently managed according to the composite performance indicator and 28% (19% of children and 36% of 5 years and older) at facilities where diagnostics and AL are available. At facilities with malaria diagnostics and AL in stock, the major contributors to discordant practices in comparison with the new guidelines are low testing rates (43%), common antimalarial treatments for test negative patients (53%) and non-recommended treatments for test positive patients (17%), the majority being combination of quinine and AL. While at these facilities 51% of febrile older children and adults were tested it was interesting to observe that 33% of febrile children were also tested, the practice in line with the new policy however at variance with prior presumptive recommendations.

Despite only 34 patients with RDT performed, the striking difference was observed between routine microscopy and RDT positivity rates. Among patients having undergone routine malaria microscopy, the slide positivity rate was 55% while none of the patients who had RDT performed had positive test result. Yet, nearly all (99%) blood slide positive patients were treated for malaria, nearly half (49%) of blood slide negative patients were also treated, and as high as 74% of RDT negative patients.

Finally, the performance of AL dosing, dispensing and counseling tasks was variable but rather high for most of the indicators - 89% of patients had correct weight-specific dose prescribed, 96% were advised how to take drugs at home, 76% were advised to take second dose after 8 hours, 70% were told to take drugs after the meal, 80% were told to complete all AL doses and 51% were weighed before prescribing AL, more commonly in children below 5 years of age (60%). However, only 32% of patients received the first AL dose at the facility and advice on what to do in case of vomiting was provided for only 6% of patients.

The findings of this national survey reveal that most of the key indicators measured in this study are well below the 2013 targets aiming at 100% coverage with the case management input and process indicators. However these findings should be primarily viewed as the baseline information identifying major gaps prior to the forthcoming implementation activities under the new National Malaria Strategy. Yet, in addition to providing baseline information, the findings highlight a series of lessons learned during the past policy implementations that should inform the future case management activities to improve upon the quality of the implementation process. The following key recommendations are summarized below, while more detailed recommendations and specific action points are provided in the section 6.

- The nationwide rollout plan for the implementation of parasite based diagnosis in line with the new case management policy should be urgently developed and implemented not only to improve the quality of care but also to minimize current stock out problems.
- The focus of drug management activities should be at two levels: 1) health facility/district level - strengthening of existing logistic management information systems capable to raise timely stock-out warnings to enable peripheral drug redistribution and 2) national level – timely procurement of AL to ensure sufficient national stocks to enable that quantity of AL distributed can match AL orders and meet AL needs at health facilities.
- To increase coverage with malaria diagnostics in reasonable time, RDT deployment should be prioritized to health facilities without malaria microscopy – an urgent RDT quantification exercise needs to be undertaken according to geographical and level of care roll-out plan.
- Quality control and assurance system for malaria microscopy and RDTs supported by field supervision and monitoring should be urgently implemented in line with the national policy guidelines for parasitological diagnosis of malaria.
- The future malaria in-service trainings, including structured on-job training for formally

non-qualified health workers, should be aligned with the large scale deployment of malaria diagnostic services and supported with distribution of revised malaria and IMCI case management guidelines and wall charts.

- Routine supervisory activities at district level need to be quantitatively increased and qualitatively improved in line with already existent malaria supervisory manuals.
- The following malaria specific case management messages should be emphasized during the in-service trainings and reinforced during the supervisory visits: 1) all febrile patients should be tested, 2) test positive patients should not be treated with combined AL and quinine treatment but only with AL, 3) test negative patients should not be treated for malaria, 4) weighing of all patients, and in particular children, should be systematically performed, 5) the first AL dose should be administered at facilities even in the absence of food, and 6) patients and caretakers should be advised to return for replacement dose to complete full treatment course in case of vomiting.
- To facilitate health workers' and caretakers' administration of AL to children, dispersible tablets of AL should be procured and distributed to health facilities.
- Prior to the large scale introduction of parasite based diagnosis integrated clinical guidelines to support management of non-malaria febrile patients across all age groups should be developed in consultative process with other integrated and disease specific programmes and implemented as part of the roll out process.

1. INTRODUCTION AND JUSTIFICATION

1.1. International context and challenges

Effective case management based on confirmed parasitological diagnosis and artemisinin-based combination therapy (ACT) is a cornerstone for the reduction of the malaria burden across the African continent (WHO 2010). By 2009, all 42 African malaria endemic countries had changed their policies to support ACT use for uncomplicated malaria. Furthermore, 20 countries had adopted policies promoting all-age group parasitological diagnosis using malaria microscopy and rapid diagnostic tests (RDTs) (WHO 2009). Policies in other African countries are under the revision to support parasitological diagnosis. These changes in malaria case management policy represent some of the most significant public health developments in malaria control for decades.

Unfortunately, changing policy and funding drugs and diagnostics procurement, whilst important, will not in themselves ensure correct delivery of ACTs and use of diagnostics according to minimum case management standards specified in national guidelines. The implementation of effective case management may face a number of challenges, of which universal and continuous supply of these commodities to health facilities (Kangwana et al. 2009) and sub-optimal practices are of particular concern (Whitty et al. 2008). Across most African countries routine information on the availability of malaria case management commodities and the quality of their use in the clinical practice is commonly absent; when available it is often incomplete and of poor quality. However, some data collected periodically in localized areas by various research groups suggested that ACTs and malaria diagnostics are frequently out of stock; where diagnostics exist, febrile patients are rarely tested; and if tested, negative results still result in the prescription of antimalarials. Furthermore, the use of non-recommended antimalarials is often reported and the performance of patients' counseling and drug dispensing tasks is rarely optimal. Failure to ensure the delivery of basic commodities and minimum standards of case management severely compromises the cost-benefit of new malaria case management strategies (Lubell et al. 2008).

1.2. Kenyan context and challenges 2004-2009

In 2004, Kenya changed first-line treatment policy for uncomplicated malaria from sulfadoxine-pyrimethamine (SP) to a specific ACT, artemether-lumefantrine (AL) (Amin et al. 2007). AL was recommended for patients weighing 5kg and above, quinine for children below 5kg and pregnant women, SP was reserved only for intermittent preventive treatment in pregnancy (IPTp), and amodiaquine, a prior second-line option, was no longer recommended for the treatment of malaria. Alongside the change of treatment policy, diagnostic policy was streamlined to recommend presumptive treatment of fevers in children below 5 years of age across the country (apart from low risk areas of Nairobi and Central Provinces) and, wherever available, the use of malaria diagnostics (microscopy or

RDT) and subsequent treatment of only test positive cases with AL was recommended for febrile patients above 5 years of age (MOH 2008).

Between 2006 and 2009, the Kenyan Ministry of Health (MOH) has been implementing and strengthening the new treatment policy countrywide. The key programmatic activities of the implementation process relevant for health facility and health worker's ability to deliver new policy included the following components. First, national malaria guidelines for health workers were revised to reflect new case management policy. Second, AL was procured and supplied together with essential drugs directly from the national level to the health facilities either by the Kenya Medical Supply Agency (KEMSA) serving government facilities or by the Mission for Essential Drug and Supply (MEDS) serving faith based facilities. All hospitals have been ordering AL quantities based on consumption ("pull-system") while the lower level health centres and dispensaries, with the exception of two provinces that entirely function on the "pull-system", have been receiving predetermined quantities of AL every three months ("push-system"). Third, in-service training inclusive of malaria case management and pharmaceutical management was provided to health workers countrywide in two rounds during 2006 and 2008. The trainings were organized as three-day workshops with approximately 30 participants per training course. The teaching modalities included lectures and theoretical case scenarios. Fourth, three wall charts of relevance for the management of uncomplicated malaria were developed to serve as job-aids. These charts, together with new guidelines, were delivered to health workers during the in-service training sessions. Finally, although most health workers were trained on the use of RDTs during the in-service case management training, only limited quantities of RDTs were procured and supplied to 28 target districts belonging to epidemic prone areas.

Between 2006 and 2008, data collected at various time periods in four Kenyan districts (Zurovac et al. 2008; Njogu et al. 2008; Kangwana et al. 2009) suggested that 5-26% of government facilities had stock-outs of all four AL weight-specific treatment packs, 39-75% were out of stock of at least one AL pack, 47% of front line health workers had received in-service training, 59% had access to the new guidelines and only 18% had received supervisory visit that included appropriate use of AL. Consequently, initial evaluations at patient level undertaken in the same districts during the early implementation phase in 2006 suggested that of all children who needed AL treatment according to guidelines only 26% had it prescribed, however when AL was prescribed, 92% of children were prescribed correct weight specific dose. The only AL counseling and dispensing task provided to the majority of caretakers was advise on dosing (97%), while tasks such as administration of the first dose of AL at facility, and provision of advice to take AL after a meal and what to do in case of vomiting were provided for only 7-37% of children. Importantly, at facilities with available diagnostics, only 43% of febrile patients above 5 years of age, for whom malaria testing at a time of evaluation was recommended by national guidelines, did undergo

parasitological evaluation, and as high as 61% of patients in this age group with negative test result were prescribed at least one antimalarial drug, despite the national guidelines unambiguously discouraging this practice.

Furthermore, assessments of pharmaceutical managements of malaria medicines undertaken respectively in six and ten districts in 2008 and 2009 (Shieshia et al. 2009; 2010) have suggested common interruptions of AL availability at facility level. Finally, programmatic case management supervisory visits carried out by the MOH have also suggested that clinical practices were often in discordance with national guidelines.

1.3. The new era - Kenyan context 2009-2017

Recognizing case management limitations observed in prior years and in line with declining malaria transmission in the country (O'Meara et al. 2008; Okiro et al. 2008), the new National Malaria Strategy (NMS) 2009-2017 launched in November 2009, specified important programmatic directions to improve availability of ACTs, malaria diagnostics, and quality of case management as well as to implement new malaria diagnostic policy recommending malaria microscopy or RDTs for all febrile patients across all age groups, areas of malaria endemicity and the levels of health care countrywide (MOPHS 2009a).

The key activities planned for this period include strengthening of procurement and supply management of ACTs, improving quality and quantity of microscopy services, large scale introduction of RDTs to peripheral health facilities, revision and dissemination of malaria case management guidelines and support job aids, in-service training for front-line health workers on revised case management guidelines, and importantly, strengthening of supervisory malaria case management activities through provincial and district malaria focal persons.

Alongside the NMS, the new national Malaria Monitoring and Evaluation (M&E) Plan 2009-2017 has also been developed and it has specified that, by 2013, 100% of all facilities should have ACTs and malaria diagnostics and 100% of fever cases who present to health workers should receive parasitological diagnosis and effective treatment (MOPHS 2009b). The M&E plan also specifies the following key indicators to be monitored at the facility level:

- Proportion of HFs having ACTs/RDTs in stock on survey day (for each ACT weight band)
- Proportion of HFs having no stock-out of ACTs/RDTs for 7 consecutive days in past 3 months (for each ACT weight band)
- Proportion of HFs providing malaria diagnostic services (RDT or microscopy)
- Proportion of patients with fever presenting to HF who are tested for malaria with RDT or microscopy (<5 years and >5 years of age)
- Proportion of patients with fever presenting to HF who are tested and treated in accordance with national malaria guidelines (tested for malaria AND test positive prescribed ACT or test

negative not prescribed an antimalarial) (<5 years and >5 years of age)

- Proportion of patients presenting to HF with fever and ACT prescribed who had counseling and ACT dispensing tasks performed according to national guidelines (<5 years and >5 years of age)

Furthermore, it has been widely recognized by the MOPHS's Division of Malaria Control (DOMC) that prior facility based evaluations undertaken only periodically on limited geographical scale in nationally non-representative districts are not anymore adequate to timely monitor progress towards the national targets established as part of the NMS. Beside the equally important activities focusing on integrated strengthening of the currently weak routine Health Management Information Systems and supervisory activities at district and facility level, relatively simple and inexpensive but methodologically rigorous and nationally representative monitoring surveys undertaken on biannual basis are deemed critical to timely inform national policy makers, and donor organizations, on the progress of the new NMS.

In this report, we present results of the first facility survey providing baseline data on the availability of commodities, and the malaria case management practices prior to the nationwide rollout of the large-scale implementation activities under the new National Malaria Strategy.

2. OBJECTIVES

Objectives presented in this section refer to overall study objectives aiming to monitor temporal changes between different surveys over the next three years as well as to individual surveys reporting level estimates as presented in this report.

2.1. General objective

- To monitor progress in achieving NMS targets in the availability of malaria case management commodities and the quality of outpatient malaria case management practices at public health facilities.

2.2. Specific objectives

- To determine the levels and trends in the national availability of recommended and non-recommended antimalarials and malaria diagnostics in public health facilities.
- To determine the levels and trends in health workers' adherence to outpatient guidelines for malaria diagnosis, treatment, counseling, and drug dispensing for patients below and above 5 years of age in public health facilities nationwide.

3. METHODS

3.1. Indicators

The rationale for the selection of key indicators was based on those ones specified in the new national Malaria M&E Plan 2009-2017, those representing key deficiencies detected in past which can compromise the success of ACT and diagnostics based case management policy, and importantly those ones that are simple to collect over short period using only facility assessment tools, health worker interviews and outpatient exit interviews.

Definitions of primary indicators at health facility level refer to the proportions of facilities with recommended, non-expired AL and malaria diagnostics in stock on the survey day and in the 3 months prior to the survey. With regard to the indicators at patient level referring to the management of uncomplicated malaria during initials visits, the critical basic standard under the new diagnostic and ACT policy, and therefore incorporated in our primary indicator, specifies that all febrile outpatients should be tested for malaria and patients with positive test result weighing 5 kg and above should be treated with AL while patients with negative test result should not receive an antimalarial treatment (MOPHS 2010). Secondary indicators at this level address individual components of the case management including testing, treatment, dispensing and counseling in various patients' subgroups (test positive, test negative, no test performed, having AL prescribed and having AL dispensed). The list of key health systems support and case management indicators is presented in the Annex 1-3.

3.2. Study design and sample size

The study design was cross-sectional health facility survey in public health facilities, undertaken as the first survey in a series of 6 biannual surveys between 2010 and 2012, measuring the levels and temporal changes in key indicators on a) availability of malaria case management commodities and b) quality of outpatient malaria case management practices in accordance with national guidelines. Beside the importance of monitoring the private sector in the quality of service delivery - which will be addressed through other initiatives - the first priority of the MOPHS is to ensure availability of commodities and recommended case management practices at public health facilities, therefore these facilities present focus of these evaluations.

The sample size was calculated to detect statistically significant difference of at least 15 percentage points between any two survey points during the monitoring period. For the measurements of case management adherence at the health worker-patient level, the sample size was adjusted to take into consideration clustering effect at the health facility level and the likelihood of practices at facilities with unavailable case management

commodities. The formula used for the sample size calculation was as follows:

$$n = \frac{\mathbf{deff\ x}\ [Z_{1-\alpha}\sqrt{2P\ (1-P)} + Z_{1-\beta}\sqrt{P1(1-P1) + P2(1-P2)}]^2}{(P2-P1)^2}$$

where

Z1-$\alpha\alpha$ = 1.96 (5% significance) is standard value for type I error

Z1-$\beta\beta$ = 0.84 (80% power) is standard value for type II error

P1 = the value of key outcome at time 1

P2 = the value of key outcome at time 2

P = (P1 + P2)/2

deff = design effect

Therefore, in order to detect 15% difference in primary case management indicator (from conservative estimates of 50% to 65%) with the level of confidence of 5%, power of 80%, design effect of 2, and assumption that 50% of facilities will not have ACTs and malaria diagnostics in stock, the estimated sample size was 680 patients in each age group (below and above 5 years of age) during the each survey. We assumed that on average a minimum of 4 eligible patients will be recruited in each age group at each facility over one survey day, resulting in the minimum required number of surveyed facilities of 170 (680/4). Since health facilities are selected using stratified simple random sampling, the indicators at facility level were not subjected to the cluster effect and the sample of 170 facilities was considered sufficient to detect the difference of 15% with the same power (80%) and level of confidence (5%) as for the measurements of adherence indicators at the health worker-patient level. For level estimates from individual surveys, including the survey results reported in this document, these patient and facility samples were estimated to be sufficient to obtain the 95% confidence intervals of ± 7.5% around an observed frequency of 50%.

3.3. Sampling

A national representativeness was assured drawing a stratified random sample from the universe of public health facilities and taking into consideration within-country distribution of facilities and administrative boundaries, type of facilities and their ownership. The latest data showed that there are 6,094 public health facilities in Kenya (Noor et al. 2009). From this universe the following facilities not relevant for our study were excluded: 1) facilities from Nairobi province due to absence of malaria transmission and requiring special studies to evaluate malaria case management, 2) tertiary hospitals since serving mainly as referral facilities, and 3) facilities run by other than MOH and local authorities (LA) because they provide services to special patient groups such as military or prisoners. Therefore our final

sampling frame consisted of 5,233 health facilities, of which 3,706 (70.8%) belonged to the MOH, 43 (0.8%) to the LA, 1,403 (26.8%) to the faith-based organizations (FBO) and 81 (1.6%) to secular non-governmental organizations (NGO). With regard to the type of facility, 4,011 (76.7%) are dispensaries, 925 (17.7%) health centres and 297 (5.7%) are hospitals.

For the purpose of sampling, facilities belonging to the faith-based and non-governmental organizations were classified into one category. Similarly, MOH and LA owned facilities were grouped into one Government of Kenya (GoK) category as well as smaller facilities such as dispensaries and health centres which also represented one category. Therefore, to ensure national representativeness taking into consideration administrative boundaries, type and ownership of facilities 28 strata were formed. From each stratum a simple random sample proportional to the number of facilities in the stratum was drawn. This sampling strategy was selected to minimize any misrepresentation of strata that might have occurred by chance if a simple non-stratified sample would have been drawn.

Table 1: Stratified random sampling process

Strata			Sampling Frame	Sampling Fraction (%)[a]	Proportional Sample Size (%)[b]	Effective Sample Size
Province	**Type**	**Ownership**				
Central	Hospital	GoK	16	0.31	0.53	1
		NGO/FBO	21	0.40	0.68	1
	Smaller HF	GoK	417	8.00	13.60	14
		NGO/FBO	225	4.30	7.31	7
Coast	Hospital	GoK	15	0.29	0.49	1
		NGO/FBO	4	0.08	0.14	1[c]
	Smaller HF	GoK	308	5.89	10.01	10
		NGO/FBO	99	1.89	3.21	3
Eastern	Hospital	GoK	32	0.61	1.04	1
		NGO/FBO	29	0.55	0.94	1
	Smaller HF	GoK	658	12.57	21.37	21
		NGO/FBO	301	5.75	9.78	10
North Eastern	Hospital	GoK	12	0.23	0.40	1[c]
		NGO/FBO	4	0.08	0.14	1[c]
	Smaller HF	GoK	136	2.60	4.42	4
		NGO/FBO	22	0.42	0.71	1
Nyanza	Hospital	GoK	42	0.80	1.36	1
		NGO/FBO	22	0.42	0.71	1
	Smaller HF	GoK	607	11.60	19.72	20
		NGO/FBO	177	3.38	5.75	6
Rift Valley	Hospital	GoK	48	0.92	1.56	2
		NGO/FBO	21	0.40	0.68	1
	Smaller HF	GoK	1154	22.05	37.49	38
		NGO/FBO	449	8.58	14.59	15
Western	Hospital	GoK	22	0.42	0.71	1
		NGO/FBO	9	0.17	0.29	1[c]
	Smaller HF	GoK	282	5.39	9.16	9
		NGO/FBO	101	1.93	3.28	3
Total			**5,233**	**100%**	**170**	**176[c]**

[a] Calculated as percentage for each stratum as (Sampling Frame/total number of 5,233 facilities)*100
[b] Calculated as percentage for each stratum as (Sampling Fraction*Sample Size of 170 facilities)/100
[c] The effective sample size contains 6 additional facilities because rounding to zero was avoided in 6 strata.

3.4. Survey personnel and training

The health facility survey was conducted with ten teams each composed of three data collectors. In each team one senior nurse or pharmaceutical technologist with prior experience in health facility surveys acted as a team leader and performed health facility assessment and interviews with health workers. The other two team members were student nurses who carried out exit interviews with outpatients.

The training of data collectors was undertaken over five days at the health facility in Nairobi. The training was carried out by three trainers for 30 trainees, all trainers being investigators on this study and with extensive experience in undertaking health facility surveys. The training consisted of the general introduction on the purpose and the nature of the survey, instruction and practice of performing health facility assessment, interviewing caretakers, adult patients and health workers, collecting data from patient-held records and taking informed consent. Throughout the training role plays with patients and health workers were carried out. The concordance testing was undertaken until agreement of practice of data collectors in comparison with trainers for each data collection tool was greater than 95%. On the last day of the training, a full field trial of the study procedures was conducted in health facilities that were not included in the survey.

3.5. Data collection

Each survey team was allocated one of 10 different geographic areas countrywide and in average 17 health facilities. At each of the survey facilities data on the availability of key malaria commodities and malaria case management practices were collected over one survey day. On the survey day, survey teams arrived at the facility before the official opening time and stayed until the official closing time or until the time when the night shift would take over duties in facilities opened 24 hours. Each survey team carried with them a letter from the DOMC specifying the purpose and nature of the survey. The facilities were not informed in advance about the surveyors' visits. During the introduction it was explained to in-charges and health workers that the aim of data collection is to monitor availability of malaria case management commodities, health worker's exposure to case management interventions and routine case management practices for the DOMC's M&E purposes. It was emphasized that the data collection exercise is not part of the DHMT supervisory visits, that an individual's performance is not being judged and that the aim is not to highlight or punish an individual's performance.

Data were collected using three methods. First, all patients presenting to the outpatient departments underwent rapid screening when they were ready to leave the facility. The screening included determination of patient's referral or admission status, history of fever,

weight status above 5kg, likelihood of pregnancy, and whether the visit was an initial or follow up. Upon obtaining written informed consent from adult patients or caretakers of legally underage children, non-referred and non-pregnant patients presenting for an initial visit with fever weighing 5kg and above were interviewed during which information was collected from patient-held cards about routine malaria diagnostics requested, results reported and medications prescribed. During the interviews detailed information was also collected about patients' age, weight, sex, temperature, duration of fever, main complaints, prior use of antimalarial drugs, and the basic assessment, drug dispensing and counseling tasks performed during the facility visit.

Second, each facility was assessed to determine the survey day availability of expired and non-expired, recommended and not recommended antimalarial drugs, RDTs, antibiotics, and functional malaria microscopy service. The stock out duration of recommended antimalarials and RDTs in the past 3 months was also determined as well as absence of functional microscopy in the same period. Finally, the availability of weighing scales, case management guidelines, wall charts, medicine inventory materials and health workers exposure to malaria case management and drug management training was also established. The facility assessment data were collected using combination of methods including direct observations, review of medicine inventory materials and interviewing in-charges of facilities or outpatient and laboratory departments of larger facilities where appropriate.

Third, at the end of the working day all health workers who attended recruited patients on the survey day were interviewed to collect information on their demographics, pre-service training, access to guidelines, and retrospective exposure to in-service training and supervision. During the interviews information was also collected on health workers knowledge of malaria case management policies. Informed written consent was obtained for all health workers.

At the end of the survey day and before leaving the facility, the team leader reviewed all data forms for blanks, inconsistencies and illegible writing, and provided confidential and constructive feedback to the facility's in-charge and health workers.

Finally, following the completion of the health facility survey, monthly phone calls are being made by the same data collectors who did physical survey. The phone calls are made in the first week of each calendar month to each of the surveyed facility to track specifically availability of ACTs and recommended antimalarials on the day of the call. These complementary data are important to ensure 6 months continuity of data on the key drug commodities in a facility-level recording system where long-term retrospective data may be difficult to obtain. In addition to the findings of the physical survey this report presents 3 follow up rounds of the phone call collected data.

3.6. Statistical analysis and approaches

Data entry and management was undertaken using Access (Microsoft, USA), through customised data entry screens with in-built range and consistency checks. All forms were entered twice by independent data entry clerks and data files were compared for errors using a verification programme and referring to original questionnaires. The analysis was performed using STATA, version 11 (StataCorp, College Station, Texas). Descriptive statistics formed the basis of analysis through frequencies, means, and confidence intervals, and medians and inter-quartile ranges for non-normally distributed data. The analytical approach reflected the main objective of the study, i.e. to provide national level data for which the study was sufficiently powered to obtain information with desired precision.

The primary objective of the case management analysis was to compare the current practices with the new national malaria case management guidelines reflecting the new policy and recommending that across all age groups 1) "*all patients with fever or history of fever should be tested for malaria and only patients who test positive should be treated for malaria*" and that 2) *"the recommended first line treatment for uncomplicated malaria in Kenya is artemether-lumefantrine"* (MOPHS 2010).

The analysis was performed at three levels. First, to assess the baseline performance of the new case management policy practices are analyzed at all health facilities regardless of the availability of case management commodities. Second, to assess health workers adherence to the guidelines the same analysis was restricted to the facilities where AL and diagnostics were in stock on the day of the survey. Third, at facilities with available AL, the quality of AL dosage prescriptions, and the quality of dispensing and counseling practices was respectively restricted to patients who had AL prescribed and to those who had both, AL prescribed and dispensed at facility. Finally, all results were stratified for children below 5 years of age where old guidelines were recommending presumptive antimalarial treatment and for patients 5 years and older where recommendations based on confirmed diagnosis remained unchanged. This stratification allowed contextualization of the findings, lessons learned from the prior policy implementations and still valid interest in age specific comparisons under the new policy. The precisions of proportions for all case management indicators were adjusted for clustering at the health facility level.

3.7. Ethical approval

The ethical approval for this study was provided by the Kenyatta National Hospital/ University of Nairobi-Ethics & Research Committee (reference number KNH-ERC/A/383)

4. RESULTS

4.1. Sample description

The survey was undertaken between 18 January and 12 February 2010 at 174 health facilities. Two facilities, both located in Turkana District, were not assessed due to lack of time to complete survey in this area of Kenya. From the initial list of facilities 21 were replaced by the nearest facility of the same ownership and the level of care. The reasons for replacement were the following: 11 were not operational either permanently or temporarily, 4 facilities could not be found by the survey teams, 3 existed but were not yet opened, 2 could not be physically accessed and 1 facility refused to participate. Furthermore, as reported by the in-charges 20 facilities changed the level of care status compared to the initial list – 16 facilities were upgraded and 4 facilities were downgraded. Finally, 4 facilities changed ownership status from the FBO to the MOH. Overall, the final sample of assessed facilities reflected well administrative and ownership distribution of all facilities nationwide, with minor shift with the respect to the level of care. This was mainly due to the upgraded status of some facilities resulting in 6.6% less dispensaries and 5.8% more hospitals assessed than represented nationwide (Table 2).

Table 2: Proportional distribution of sampled facilities compared to the national distribution

Stratification	National distribution N=5,233		Sampled facilities N=174	
	n	%	n	%
Province				
Central	679	13.0	23	13.2
Coast	426	8.1	15	8.6
Eastern	1,020	19.5	33	19.0
North Eastern	174	3.3	7	4.0
Nyanza	848	16.2	28	16.1
Rift Valley	1,672	32.0	54	31.0
Western	414	7.9	14	8.1
Level of care				
Dispensary	4,011	76.7	122	70.1
Health Centre	925	17.7	32	18.4
Hospital	297	5.7	20	11.5
Ownership				
GoK	3,749	71.6	127	73.0
Faith-based	1,403	26.8	45	25.9
NGO	81	1.6	2	1.2

Health worker interviews were undertaken with all 224 health workers who saw recruited patients on survey days at 173 health facilities. At one facility no consultations took place during the survey day. Overall, 3,450 outpatients were screened on the exit. Of 3,450 screened outpatients, the practices were evaluated for 2,409 non-pregnant febrile patients weighing 5kg and above and presenting for an initial outpatient visit. The remaining 1,041 patients were patients referred or admitted for hospitalization (48), pregnant women

(55), follow up visits (335), weighing less than 5 kg (29) and presenting without history of fever (753). Of 2,409 patients, 4 had incomplete data preventing analysis of the practices. Therefore our analysis evaluating baseline performance of the new case management policy included 2,405 patients of which 1,070 (44.5%) were below 5 years of age and 1,335 (55.5%) were 5 years and older. At 90 (51.7%) facilities malaria diagnostics and AL were available on the survey day. At these facilities, health workers' adherence to the new policy was evaluated for 1,239 patients, of which 591 (47.7%) patients were below 5 years of age and 648 (52.3%) were 5 years and older.

The Table 3 presents number of assessed facilities, interviewed health workers and evaluated outpatient consultations for recruited patients stratified by province, level of care and ownership of health facilities. If not specified otherwise, the results in further text of this report present the national figures reflecting the main objective of the study for which this study was sufficiently powered to provide all indicators with desired precision.

Table 3: Number of health facilities assessed, health worker interviews performed and outpatient consultations assessed at all facilities and facilities with diagnostics and AL in stock - stratified by province, level of care and facility ownership

Stratification	HFs assessed	HWs interviewed	Outpatient consultations at all HFs		Outpatient consultations at HFs with diagnostics and AL in stock[a]	
			<5 years	≥5 years	<5 years	≥5 years
Province						
Central	23	31	108	127	51	73
Coast	15	22	168	180	122	114
Eastern	33	40	254	404	75	111
North Eastern	7	11	27	51	2	6
Nyanza	28	32	211	240	146	154
Rift Valley	54	71	160	215	92	106
Western	14	17	142	118	103	84
Level of care						
Dispensary	122	142	678	919	273	329
Health Centre	32	40	237	281	189	222
Hospital	20	43	155	135	129	97
Ownership						
GoK	127	159	866	1,058	441	447
FBO	45	64	197	271	150	201
NGO	2	2	7	6	0	0

[a] These facilities represent subset of all surveyed health facilities

4.2. Health systems support

The results presented in this section include health facility and health worker characteristics considered important for the performance of adequate malaria case management.

4.2.1. Availability of basic equipment and malaria diagnostics on survey days

Four different types of functional weighing scales were found at health facilities and the majority of surveyed facilities had each type of weighing scale (Table 4). At least one type of weighing scale was universally available at all 174 facilities. Only 3 (1.7%) health facilities operated without availability of any potable water. At least one functional thermometer was present at the large majority of facilities (90.8%).

On survey day 55.2% of all health facilities had capacity for parasitological diagnosis of malaria either using microscopy or non-expired RDTs (Table 4). Malaria microscopy service was provided at half of the facilities (50.6%), less commonly at GoK (40.9%; 95% CI: 32.3-49.6) than in FBO/NGO facilities (76.6%; 95% CI: 64.0-89.2). Microscopy was largely available within hospitals (19/20; 95.0%) and health centres (25/32; 78.1%) however this service was also found at 22.5% (95% CI: 13.6-31.3) of GoK dispensaries. Of 88 facilities with microscopy, only 8 (9.1%) received supervisory visit in past 3 months that included quality control of malaria microscopy.

Prior to this survey malaria RDTs procured by the government were supplied to only 28 districts in epidemic prone areas in overall quantity of 200,000 tests. Therefore, it was not surprising that any RDTs were found at only 10.3% of all 174 surveyed facilities, at only 10 of 28 facilities (35.7%) in RDT supplied districts and at only 8 of 146 facilities (5.5%) at districts which were not targeted with RDT supply. However, it was interesting to observe that of 18 facilities where RDTs were found across the country, the expired tests were present at 6 facilities. Only one of these 18 facilities received supervisory visit on RDT use in 3 months prior to the survey.

Table 4: Availability of basic equipment and malaria diagnostics

N=174	n	%	95% CI
Availability of weighing scales			
Salter hanging scale	101	58.1	50.6-65.5
Infant scale	146	83.9	78.4-89.4
Bathroom scale	132	75.9	69.4-82.3
Balance scale	88	50.6	43.1-58.1
Availability of functional thermometer	158	90.8	86.5-95.1
Availability of malaria diagnostics			
Functional microscopy	88	50.6	43.1-58.1
Any malaria RDT (non-expired or expired)	18	10.3	5.7-14.9
Non-expired malaria RDT	13	7.5	3.5-11.4
Expired malaria RDTs	6	3.5	0.7-6.2
Any functional diagnostics (microscopy or non expired RDT)	96	55.2	47.7-62.6

4.2.2. Retrospective absence of diagnostic services

Data on retrospective availability of malaria diagnostic services were collected for 3 months period between 01 October and 31 December 2009. The new malaria policy recommends universal parasitological diagnosis, using either malaria microscopy or RDTs. Therefore, of all 174 facilities, malaria diagnostic service (both RDTs and microscopy) was not present for at least 7 consecutive days at 46.6% of facilities.

Of 88 facilities who had functional microscopy on survey day, this service was not provided for at least 7 consecutive days in past 3 months at 8 facilities (9.1%; 95% CI: 3.0-15.2). At these 8 facilities the median number of days without microscopy service was 20 [IQR: 16–53] or 22% of the study time. Of 18 facilities which had RDTs in stock on survey day, the test was out of stock for at least 7 consecutive days in past 3 months at 11 facilities (61.1%; 95% CI: 36.2-86.1).

4.2.3. Availability of antimalarial drugs on survey days

Availability of antimalarial drugs was assessed at all health facilities during the physical survey in January/February and thereafter these data were collected by phone interviews in the first week of March, the first week of April and the last week of April. Two rounds of data collection in April are exceptional due to rescheduling of this activity to the last week of month to comply with existing phone call activities at KEMSA taking place in this week of the calendar month.

It should be noted that the physical survey was done shortly after the nationwide drug distribution that took place at the beginning of January 2010 when drugs were delivered from the national level directly to the peripheral facilities. The next round of nationwide drug distribution took place at the beginning of April, however, this time the drugs were exceptionally delivered only to district headquarters from where their further distribution to peripheral facilities was to be organized.

As expected, given the timing of the survey in relation to drug distribution cycles, the availability of non-expired antimalarials was relatively high during the physical survey in January/February. For further understanding it should be noted that each tablet of AL is of the same strength, however to facilitate patients' adherence to the treatment, AL is delivered in four different weight-specific packages (6, 12, 18 and 24 tablets), each one with specific pictorial descriptions on appropriate AL use. In absence of particular AL pack the treatment with AL is still possible but subject to dispensing improvisations either by cutting or combing different packs. Therefore our physical survey found that any tablet packs of AL were in stock at 94.3% of facilities and the availability of various packs was

fairly similar ranging from 79.3% for 18 pack to 86.2% for 24 pack. All four AL packs were in stock at 64.9% of facilities. With respect to other antimalarials, the large majority (88.5%) of facilities stocked SP tablets while quinine tablets and quinine injections were less commonly present (69.0% and 77.6% respectively).

However, the availability of AL in subsequent monthly assessments showed downward trend. By beginning of April 2010, the presence of any AL pack in stock dropped from 94.3% to 81.6%, availability of all four AL packs dropped from 64.9% to 41.1% and the same downward trend has been observed for all weight-specific AL packs. By the end of April 2010 the downward trend in AL stock outs has stopped and some minor improvement in the AL availability was observed. This pattern is likely reflection of some, but not yet all facilities, accessing AL supplies delivered up to the district headquarters at the beginning of April. Although somewhat less pronounced, by April 2010 the similar trend was observed for other antimalarials. Table 5 presents data on the availability of recommended non-expired antimalarials and Figure 1 presents AL availability trend data in graphical format.

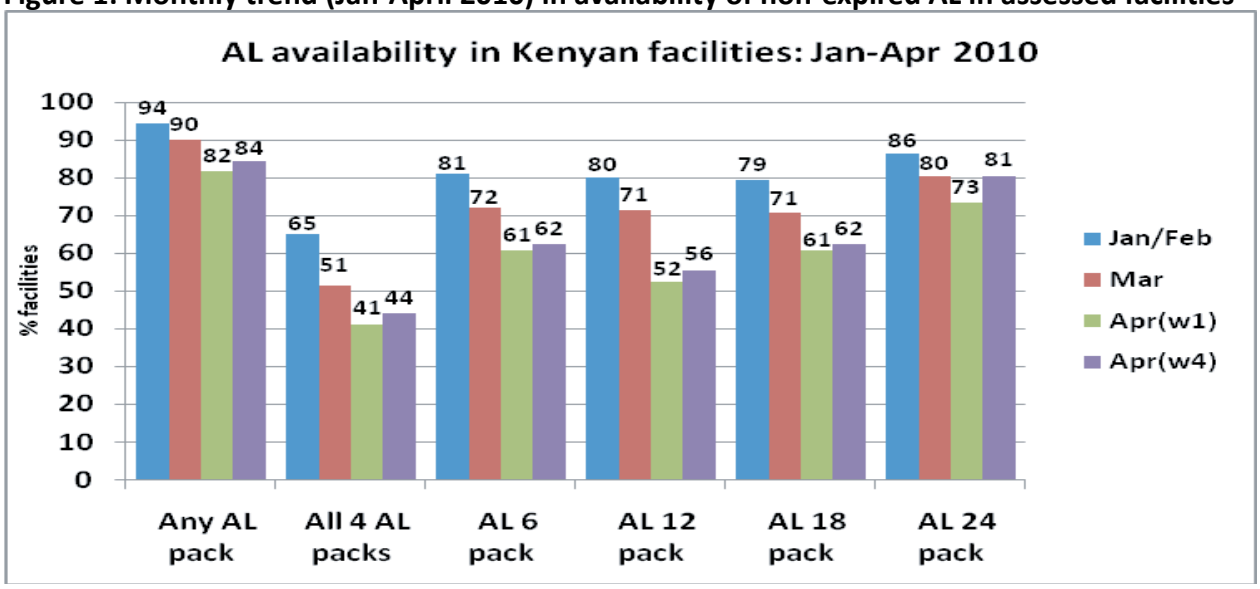
With regard to expired antimalarial drugs, these drugs were rarely present. During the physical survey any expired AL pack was found at only 5 (2.9%) facilities, while expired SP tablets, quinine tablets and quinine injections were found at only 2 (1.2%), 2 (1.2%), and 6 (3.5%) facilities respectively. For antimalarial drugs other than AL, the information on expired drugs was not recorded at one facility during the physical survey.

Surprisingly, physical stock assessments revealed that 23.6% (95% CI: 17.2-29.9) of facilities still stocked non-expired amodiaquine, an antimalarial drug whose supply was discontinued in 2007. Beside amodiaquine, only 8 (4.6%) facilities stocked any other non-recommended antimalarial – most commonly quinine syrup (4 facilities) and only one facility had artemisinin monotherapy (dehydroartemisinin) in the stock.

Table 5: Facilities with recommended, non-expired antimalarial drugs in stock

	Jan/Feb 2010 N=174			March 2010 N=168			April 2010 (week 1) N=168			April 2010 (week 4) N=164		
	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI
Any AL pack	164	94.3	90.8-97.7	151	89.9	85.3-94.5	137	81.6	75.6-87.5	138	84.2	78.5-89.8
All AL packs	113	64.9	57.8-72.1	86	51.2	43.6-58.8	69	41.1	33.6-48.6	72	43.9	36.2-51.6
AL 6 pack	141	81.0	75.2-86.9	121	72.0	65.2-78.9	102	60.7	53.3-68.2	102	62.2	54.7-69.7
AL 12 pack	139	79.9	73.9-85.9	120	71.4	64.5-78.3	88	52.4	44.8-60.0	91	55.5	47.8-63.2
AL 18 pack	138	79.3	73.2-85.4	119	70.8	63.9-77.8	102	60.7	53.3-68.2	102	62.2	54.7-69.7
AL 24 pack	150	86.2	81.0-91.4	135	80.4	74.3-86.4	123	73.2	66.4-80.0	132	80.5	74.4-86.6
SP tablets	154	88.5	83.7-93.3	140	83.3	77.6-89.0	142	84.5	79.0-90.0	150	91.5	87.1-95.8
QN tablets	120	69.0	62.0-75.9	103	61.3	53.9-68.8	120	71.4	64.5-78.3	110	67.1	59.8-74.3
QN injections	135	77.6	71.3-83.8	110	65.5	58.2-72.7	110	65.5	58.2-72.7	102	62.2	54.7-69.7

Figure 1: Monthly trend (Jan-April 2010) in availability of non-expired AL in assessed facilities



4.2.4. Retrospective stock-out of antimalarial drugs

Retrospective stock-out data of recommended antimalarials were collected for period between 01 October and 31 December 2009. In accordance with international standards the stock out duration of at least 7 consecutive days over 3 months period was used as the criterion for the stock out presence. At 144 facilities, the presence of antimalarial stock-out was established from the facility records using triangulation of sources including stock cards, AL dispenser books and health facility monthly summary forms for antimalarial drugs. At 29 facilities this information could not be obtained from the records and at these facilities the information was determined by asking the health workers. At one facility, apart for SP tablets, no information could be obtained from any of the sources.

The stock-outs of AL in this period were common: 59.5% of facilities experienced stock-out of at least one of the four AL tablet packs; between 37.6% and 52.0% reported stock-outs for specific AL packs; and 27.2% of facilities were found to have simultaneous stock-out of all four AL packs (Table 6). At these facilities the median number of stock-out days without any AL was 35 [IQR: 25–31] or 38% of the study time. During the same retrospective period, SP tablets, quinine tablets and quinine injections were less commonly out of stock (14.4%, 25.4%, and 20.8% respectively), however when these drugs were out of stock the stock durations were substantial, ranging per drug between 54.3% and 63.0% of the time.

Table 6: Retrospective antimalarial stock-outs and their durations – October-December 2009

	Stock out of at least 7 consecutive days in past 3 months			Number of stock out days[a]		
N=174	n	%	95% CI	Median	IQR	% time
All AL packs[b]	47	27.2	20.5-33.9	35	25-51	38.0
AL 6 pack	65	37.6	30.3-44.9	41	25-66	44.6
AL 12 pack	76	43.9	36.5-51.4	55	27-79	59.8
AL 18 pack	90	52.0	44.5-59.5	59	30-83	64.1
AL 24 pack	68	39.3	32.0-46.6	46	29-70	50.0
Any AL pack	103	59.5	52.2-66.9	na	na	na
SP tablets	25	14.4	9.1-19.6	50	26-92	54.3
Quinine tablets[b]	44	25.4	18.9-32.0	61	33-92	66.3
Quinine injections[b]	36	20.8	14.7-26.9	58	28-92	63.0

[a] Denominators include facilities with reported stock out in past 3 months for which complete 3 months retrospective stock-out data were available: N (all AL packs) = 45; N (6-tablet pack) = 61; N (12-tablet pack) = 69; N (18-tablet pack) = 80; N (24-tablet pack) = 65.
[b] Denominator does not include one facility where information was not available from any of the sources

4.2.5. Availability and completeness of antimalarial drug management records

Of 174 health facilities surveyed, the availability of inventory materials was relatively high - 86.2% of facilities had stock cards (original or improvised), 89.7% had AL dispenser book and at 81.5% of facilities monthly summary forms for antimalarial drugs were found. However, only 44.8% and 66.6% of facilities had respectively stock cards and AL dispenser book updated for the last one month. Although present at 81.5% of facilities, the monthly summary forms for the past 3 months were completed in only 65.9% of facilities (Table 7).

Table 7: Availability and quality of antimalarial drug management records

N=174	**n**	**%**	**95% CI**
Stock cards available	**150**	**86.2**	**81.0-91.4**
Stock cards updated for the last one month	**78**	**44.8**	**37.4-52.3**
AL dispenser book available	**156**	**89.7**	**85.1-94.2**
AL dispenser book updated for the last one month	**116**	**66.7**	**59.6-73.7**
Monthly summary form for malaria medicines available[a]	**141**	**81.5**	**75.2-86.9**
Monthly summary form completed in the past 3 months[a]	**114**	**65.9**	**58.8-73.0**

[a] Denominator does not include one facility with missing value

4.2.6. Frequency and quantity of AL received by health facilities

Of 174 surveyed facilities, 152 (87.4%) are supplied directly from the national level by KEMSA, 19 (10.9%) by MEDS, and 11 (6.3%) facilities use other supply channels such as collection of drugs from district hospital (5), local procurement (4) and NGO supplies (2). Seven (4.0%) facilities are regularly supplied from more than one source. Of all facilities 108 (62.1%) function on "push" system receiving fixed quantities of drugs and 66 (37.9%) on "pull" system ordering drug quantities. Information on dates of the last two AL

deliveries was available for 105 facilities functioning on "push" system and 52 facilities on "pull" system. Overall, the median number of weeks between last two AL deliveries was higher for facilities on "push" system (15 weeks [IQR: 13-17]) than for facilities functioning on "pull" system (9 weeks [IQR: 4-14]). Quantities of AL received were compared with quantities of AL ordered among health facilities functioning on "pull" system for which this information was available (Table 8). While deliveries of different AL packs rarely matched the quantities ordered by facilities (pack range: 23.1-30.8%), it was worrying to observe that facilities commonly received lower quantities than what they ordered. In particular this was observed for AL 12, AL 18 and AL 24 packs.

Table 8: Quantities of AL ordered and received among facilities functioning on "pull" system

	Received as ordered		Received less than ordered[a]		Received more than ordered[a]	
	n	%	n	%	n	%
AL 6 pack (N=52)	16	30.8	19	36.5	17	32.7
AL 12 pack (N=51)	13	25.5	33	64.7	5	9.8
AL 18 pack (N=51)	12	23.5	32	62.8	7	13.7
Al 24 pack (N=52)	12	23.1	27	51.9	13	25.0

[a] Discrepancies higher than 5% were used to categorize AL deliveries as less or more than ordered

4.2.7. Availability of case management wall charts and guidelines

The national malaria guideline for health workers and three malaria case management wall charts important for outpatient management were developed by the DOMC and distributed nationwide between 2006 and 2009. Of 174 facilities surveyed, 69.5% had malaria guidelines and 36.8-44.8% had wall charts exposed on their walls (Table 9). It should be noted that the chart recommending AL dosing and dispensing procedures remains relevant for the new case management policy, however the national guidelines and wall charts recommending presumptive fever management in children below 5 years and parasitological diagnosis in patients 5 years and older reflect old diagnostic policy. Therefore, prior to dissemination of revised guidelines and wall charts recommending parasitological diagnosis across all age groups, careful interpretation of these results is required.

Table 9: Availability of case management wall charts and guidelines

N=174	n	%	95% CI
Wall charts exposed			
AL dosing and dispensing chart	64	36.8	29.5-44.0
Algorithm for fever management in children under 5 years	78	44.8	37.4-52.3
Outpatient algorithm for older children and adults	69	39.7	32.3-47.0
Availability of guidelines			
Malaria case management guideline	121	69.5	62.6-76.4

4.2.8. Exposure to in-service training

At 174 surveyed facilities, 592 health workers were reported to routinely perform outpatient consultations. Of these health workers, nurses represent 69.8%, clinical officers 23.1%, doctors 2.4% and various formally non-qualified clinical cadres 4.7% of health workers. Of all health workers, 40.0% attended in service training on malaria ACT case management, 27.2% attended training on the use of RDTs and 19.8% were trained on IMCI. Although it was not universally applied, it should be noted that despite the geographically limited deployment of RDTs, an effort has been made that malaria case management trainings undertaken nationwide between 2006 and 2009 include an RDT component. Among different health worker cadres, malaria case management and RDT training coverage is the highest among the nurses (45.8% and 33.4% respectively) while, as expected, formally non qualified cadres are rarely included in in-service trainings (Table 10). As highlighted in the previous section, the similar caution in interpretation of these results is required since these trainings were based on the presumptive treatment of children below 5 years of age.

Table 10: Health workers exposure to case management in-service trainings stratified by cadre

	Trained on ACT case management		Trained on RDTs		Trained on IMCI	
	n	%	n	%	n	%
All outpatient clinicians (N=592)	237	40.0	161	27.2	117	19.8
Doctors (N=14)	5	35.7	1	7.1	2	14.3
Clinical officers (N=137)	41	29.9	21	15.3	30	21.9
Nurses (N=413)	189	45.8	138	33.4	85	20.6
Clinically non-qualified staff (N=28)[a]	2	7.1	1	3.6	0	0

[a] This category includes 14 CHWs, 8 support staff, 3 nurse aids, 2 patient attendants, 1 laboratory technician and 1 pharmaceutical technician

Furthermore, total of 172 laboratory personnel were reported to routinely perform malaria testing. Of these health workers, 82 (47.7%) attended in-service malaria microscopy training since 2006 and 72 (41.9%) were trained on the use of RDTs. Finally, at 174 health facilities, 528 health workers were reported to routinely dispense antimalarial drugs to patients. Of these health workers, nurses represent 66.3%, pharmacists (technologists and technicians) 12.5%, community health workers 8.3%, support staff 6.4%, nurse aids 2.3%, clinical officers 2.3%, and various other cadres 1.9% of health workers. Of all health workers, 36.9% attended in service training on antimalarial drug management. Similar to the pattern observed under case management training, higher level cadres such as nurses and pharmacists were more commonly trained compared to lower and formally non-qualified cadres (Table 11).

Table 11: Health workers exposure to drug management trainings stratified by cadre

	Trained on antimalarial drug management	
	n	%
All staff dispensing antimalarial drugs (N=528)	195	36.9
Nurses (N=350)	149	42.6
Pharmacists (N=66)	36	54.5
Community health workers (N=44)	0	0
Support staff (N=34)	1	2.9
Nurse aids (N=12)	1	8.3
Clinical officers (N=12)	7	58.3
Other cadres (N=10)[a]	1	10.0

[a] This category includes 4 patient attendants, 3 clerks, 2 laboratory technicians and 1 volunteer.

4.2.9. Characteristics of health workers who performed consultations on survey days

Of 224 health workers who performed outpatient consultations on survey days, 118 (52.7%) were female, 104 (46.4%) were in-charges of health facilities and health worker's mean age was 37 years. The majority were nurses (141; 63.0%); 70 (31.3%) were clinical officers; only 2 (0.9%) were doctors and further 11 (4.9%) health workers were without formal clinical training. These included community health workers (5), support staff (3), nurse aids (1), patient attendants (1) and pharmaceutical technicians (1). The majority of health workers (125; 55.8%) were trained on malaria ACT case management, half of them on RDT use (111; 49.6%) and only 51 (22.8%) were trained on IMCI. Nearly two-thirds of health workers (145; 64.7%) reported having access to malaria case management guidelines.

Importantly, less than half (41.5%) of health workers received at least one supervisory visit in 3 months prior to the survey, and only 17.9% received a supervisory visit that included any activity related to malaria case management (Table 12). Of 40 health workers who reported malaria case management supervisory visit, 31 (77.5%) reported one visit, 6 (15.0%) two visits, and 3 (7.5%) health workers reported more than two visits. These 40 health workers also reported that the following components of the supervisory visits were variously present: review of malaria records and registers (82.5%), discussion about malaria case management (67.5%), observation outpatient consultations (37.5%), and provision of feedback, either in oral or written format (45.0%).

Although statistically significant differences could not be demonstrated, health workers working in lower level facilities seem to be more commonly supervised on malaria case management (22.7% at dispensaries vs 15% at health centres vs 4.7% in hospitals). No significant difference was observed for the same indicator between GoK (18.9%) and FBO/NGO (15.4%) facilities.

Table 12: Health worker's exposure to supervisory visits in 3 months prior to the survey

N=224	n	%	95% CI
Had any supervisory visit	93	41.5	35.0-48.0
Had supervisory visit including malaria case management activity	40	17.9	12.9-22.9

4.2.10. Knowledge about treatment policy for uncomplicated malaria

Nearly all health workers (223/224) responded that that the recommended treatment policy for uncomplicated malaria in patients weighing 5 kg and above is AL. The only health worker reporting quinine was a community health worker. Health workers responded less commonly that the quinine is recommended treatment for children weighing less than 5 kg (71.4%), in the first trimester of the pregnancy (67.4%) and in the second and the third trimester of pregnancy (29.9%). However, it should be noted that while the current treatment policy for uncomplicated malaria recommends quinine throughout the pregnancy, it also allows use of AL in the second and the third trimester as well as its use in the first trimester where quinine is not available. The combined response rates referring to recommended use of SP or amodiaquine in the first trimester of pregnancy (16.0%), the second and the third trimester (10.0%) as well as in children weighing less than 5 kg (17.0%) were of concern. Compared to the trained health workers, these responses were more common among health workers who did not attend ACT case management training (28.3% vs 6.4% for the first trimester question, 18.8% vs 5.6% for the second and the third trimesters question and 26.6% vs 9.6% for children below 5kg), and all differences were statistically significant. Table 13 presents all health workers responses on treatment policy questions for various patients groups with uncomplicated malaria.

Table 13: Knowledge about antimalarial treatment policy for uncomplicated malaria

N=224	n	%	95% CI
For patients 5 kg and above			
Artemether-lumefantrine	223	99.6	98.7-100
Quinine	1	0.4	0-1.3
For children less than 5 kg			
Quinine	160	71.4	65.5-77.4
Artemether-lumefantrine	24	10.7	6.6-14.8
Amodiaquine	21	9.4	5.5-13.2
SP	17	7.6	4.1-11.1
Other[a]	2	0.9	0-2.1
For pregnant women in first trimester			
Quinine	151	67.4	61.2-73.6
Artemether-lumefantrine	37	16.5	11.6-21.4
SP	33	14.7	10.1-19.4
Amodiaquine	3	1.3	0-2.9
For pregnant women in second and third trimester			
Artemether-lumefantrine	132	58.9	52.4-65.4
Quinine	67	29.9	23.9-36.0
SP	22	9.8	5.9-13.7
Amodiaquine	3	1.1	0-2.9

[a] This category includes following responses: dehydroartemisinine (1) and "no antimalarial recommended" (1)

4.2.11. Health workers knowledge about use of malaria tests

Health workers were asked if national policy recommends malaria testing for all febrile patients presenting for an initial non-severe outpatient visit at facilities where microscopy or RDTs are available (Table 14). Since the new diagnostic policy was not yet implemented and health workers had been trained only on the old policy, it could have been expected that the pattern of responses would more prominently reflect an old age-specific policy recommending presumptive treatment in children below 5 years and testing for patients 5 years and older. However, somewhat surprising pattern of responses was revealed. As high as 50.5% of health workers reported that in high risk areas all febrile children below 5 years of age should be tested, while 60.3%, 77.2% and 66.1% of health workers reported that testing is respectively recommended in children below 5 years in low risk areas, in patients 5 years and older in high risk area and in patients 5 years and older in low risk areas. Interestingly, of 17 health workers interviewed at facilities in Western province, where malaria transmission is uniformly high, and indeed the highest in the country, 8 (47.1%) reported that malaria testing is recommended in febrile children below 5 years of age.

Table 14: Health workers providing positive response about use of malaria testing

N=224	n	%	95% CI
Responses for children below 5 years of age[a]			
In high malaria risk area all febrile children should be tested	113	50.5	43.8-57.0
In low malaria risk area all febrile children should be tested	135	60.3	53.8-66.7
Responses for patients 5 years and older[b]			
In high malaria risk area all febrile patients should be tested	173	77.2	71.7-82.8
In low malaria risk area all febrile patients should be tested	148	66.1	59.8-72.3

[a] "Does not know" response provided by 2 (0.9%) health workers in high risk area and 9 (4.0%) in low risk area

[b] "Does not know" response provided by 3 (1.3%) health workers in high risk area and 10 (4.5%) in low risk area

4.2.12. Health workers perceptions of malaria risk at their facilities

When health workers were asked their opinion how they would classify their working area in terms of malaria risk, 6 of 31 health workers (19.4%) from Central Province surprisingly responded their area to be of high malaria risk. In other parts of Kenya, which have higher or lower intensity of malaria transmission but were all classified for the case management purposes by national guidelines as high malaria risk area, 80.7% of health workers responded that their areas are of high malaria risk. Finally, of 17 health workers interviewed in the Western Province, which is the only province belonging uniformly to the high malaria risk area by both transmission and case management recommendation criteria, all 17 (100%) health workers considered their area to be high risk area.

4.2.13. Health workers knowledge about interpretation of negative malaria test results

Health workers were asked if the national diagnostic policy recommends that most febrile patients presenting for an initial, non-severe outpatient visit and having negative malaria test should be still treated for malaria (Table 15). Interestingly, for patients 5 years and older, and in discordance with all policies, 37.1% and 31.3% of health workers responded that patients with respectively negative RDT and negative blood slide should be still treated for malaria. Although diagnostic testing was not recommended by old policy in children below 5 years of age and therefore no recommendations on test interpretation was explicitly provided, it was striking to observe that respectively 75.5% and 64.3% of health workers responded that RDT negative and blood slide negative children should be still treated for malaria.

Table 15: Health workers providing positive response about treating test negative patients

N=224	n	%	95% CI
Responses for children below 5 years of age[a]			
Most children with negative RDT should be treated for malaria	169	75.5	69.8-81.1
Most children with negative BS should be treated for malaria	144	64.3	58.0-70.6
Responses for patients 5 years and older[b]			
Most patients with negative RDT should be treated for malaria	83	37.1	30.1-43.4
Most patients with negative BS should be treated for malaria	70	31.3	25.1-37.4

[a] "Does not know" response provided by 10 (4.5%) health workers for RDT and 7 (3.1%) for blood slide results

[b] "Does not know" response provided by15 (6.7%) health workers for RDT and 10 (4.5%) for blood slide results

4.3. Malaria case management

This section presents results on the case management practices for febrile, non-pregnant patients weighing 5 kg and above, presenting for an initial outpatient visit without being referred or admitted for hospitalization. The presentation of the results followed the multi-level analytic approach of the study. First, to assess the baseline performance of the new case management policy the results are presented from all health facilities regardless of the availability of case management commodities. Second, to assess health workers adherence to the new guidelines the same results were restricted to the facilities where AL and diagnostics were in stock on the day of the survey. Third, at facilities with available AL, the quality of ACT dosage prescriptions, and the quality of dispensing and counseling practices was respectively restricted to patients who had ACTs prescribed and to those who had both, ACTs prescribed and dispensed at facility. Finally, to allow contextualization of the findings, lessons learned from the prior policy implementations and still valid interest in age specific comparisons under the new policy, all results were stratified for children below 5 years of age where old guidelines were recommending presumptive antimalarial treatment and for patients 5 years and older where recommendations based on confirmed diagnosis remained unchanged.

4.3.1. Main patients' characteristics

Of 2,405 recruited patients, 1,070 (44.5%) were below 5 years of age and 1,335 (55.5%) were 5 years and older. 56.1% of patients were female, more represented among patients 5 years and older (61.9%) than in children below 5 years of age (49.1%). The mean age of patients was 15 years. With the respect to the weight based recommendations of the first line treatment policy, the most common weight category included patients weighing 5-14 kg (41%), followed by those weighing 35kg and above (37.0%), 15-24 kg (17.1%) and 25-34kg (5.0%). Only one-third of the patients (32.6%) reported to the facility within two days of the sickness, more children below 5 years (38.4%) than patients 5 years and older (28.0%). Worryingly, 11.2% of children and 20.8% of patients 5 years and older reported to the facility 7 days or more after the beginning of the febrile illness. All patients reported fever during the present illness, however fever alone, or in combination with other symptoms, was reported as the main complaint during the facility visit for 79.6% of patients, more commonly among children below 5 years of age (88.5%) than in patients 5 years and older (72.4%). Only 26.3% of patients had axillary temperature ≥37.5ºC, more commonly children below 5 years of age (35.2%). Similarly across both age groups, only 5.0% of patients had taken any antimalarial drug prior to the facility visit, only 1.9% had taken AL, and only 11 (0.5%) patients had taken complete course of AL (Table 16).

Table 16: Main characteristics of febrile patients across age groups

	<5 years N=1,070			5 years and older N=1,335			All age groups N=2,405		
	n	%	95% CI	n	%	95% CI	n	%	95% CI
Female	524	49.0	45.9-52.1	826	61.9	58.9-64.8	1,350	56.1	54.0-58.3
Age									
<1 year	289	27.0	24.0-30.0	na	na	na	289	12.0	10.4-13.7
1-4 years	781	73.0	70.0-76.0	na	na	na	781	32.5	30.2-34.7
5-14 years	na	na	na	508	38.1	34.8-41.3	508	21.1	19.2-23.0
≥15 years	na	na	na	827	62.0	59.3-64.6	827	34.4	32.5-36.3
Weight									
5-14 kg	936	87.5	84.8-90.1	49	3.7	2.5-4.8	985	41.0	38.2-43.7
15-24 kg	133	12.4	9.9-15.0	278	20.8	18.5-23.1	411	17.1	15.4-18.8
25-34 kg	1	0.1	0-2.8	118	8.8	7.2-10.5	119	5.0	4.1-5.8
≥35 kg	0	na	na	890	66.7	63.6-69.8	890	37.0	34.2-39.8
Duration of illness									
1-2 days	411	38.4	35.1-41.8	374	28.0	25.0-31.0	785	32.6	30.2-35.1
3-4 days	461	43.1	39.9-46.2	524	39.3	36.2-42.3	985	41.0	38.4-43.5
5-6 days	78	7.3	5.3-9.3	158	11.8	9.8-13.9	236	9.8	8.1-11.5
≥7 days	120	11.2	9.1-13.3	278	20.8	18.4-23.2	398	16.6	14.7-18.4
Temperature ≥37.5ºC	376	35.2	31.3-39.1	255	19.1	16.3-21.9	631[a]	26.3	23.5-29.0
Fever main complaint	947	88.5	85.5-91.5	967	72.4	67.8-77.0	1,914	79.6	76.2-83.0
Prior use of any AM	55	5.1	3.6-6.7	64	4.8	3.4-6.1	119	5.0	3.8-6.1
Prior use of AL	15	1.4	0.6-2.2	30	2.3	1.4-3.1	45	1.9	1.2-2.5
Prior use of full AL dose	3	0.3	0-0.6	8	0.6	0.2-1.0	11	0.5	0.2-0.7

[a] Denominator does not include 4 patients with missing values (2 children <5 years and 2 patients ≥5 years)

4.3.2. Basic assessment practices

The information if routine health workers determined patients' age, weight, temperature and prior use of antimalarials was obtained from the patient cards, or in absence of the information, upon direct questioning of caretakers or adult patients. Overall, health workers determined only age for the majority (87.1%) of the patients. The weight and temperature was taken for 43.2% and 30.3% of patients respectively, more commonly for children below 5 years of age than for patients 5 years and older. Health workers asked 44.0% of patients about prior use of antimalarial drug, equally across both age groups. Table 17 present basic assessment practices for febrile patients across age groups.

Table 17: Assessment practices among febrile patients across age groups

	<5 years			5 years and older			All age groups		
	N=1,070			N=1,335			N=2,405		
	n	%	95% CI	n	%	95% CI	n	%	95% CI
Age determined	953	89.1	85.7-92.4	1,142	85.5	81.9-89.2	2,095	87.1	83.9-90.3
Weight measured	574	53.6	46.9-60.4	466	34.9	28.8-41.0	1,040	43.2	37.5-48.9
Temperature measured	441	41.2	34.2-48.3	287	21.5	16.8-26.2	728	30.3	25.2-35.3
Prior use of AM asked	468	43.7	38.3-49.2	590	44.2	39.4-44.0	1,058	44.0	39.5-48.5

4.3.3. Baseline performance of the new diagnostic and treatment policy

The new national case management guidelines recommend that 1) "*all patients with fever or history of fever should be tested for malaria and only patients who test positive should be treated for malaria*" and 2) *"the recommended first line treatment for uncomplicated malaria in Kenya is artemether-lumefantrine"* (MOPHS 2010). We considered composite case management performance in accordance with national guidelines if the following three criteria were met: 1) febrile patient was tested for malaria; 2) if positive test result was reported patient was treated with AL, and 3) if negative test result was reported patient was not treated for malaria. Overall, at all study facilities only 15.7% of febrile patients are currently managed according to guidelines stipulated as part of the new case management policy, more commonly patients 5 years and older (18.9%) than children below 5 years of age (11.8%), however, the difference was not statistically significant (Table 18).

The major reason for this deficiency is very low testing rate - only 23.9% of febrile patients are tested without statistically significant difference between age groups. Stratified analysis by test result provides further explanation for low rate of the composite performance. Among routinely reported test positive patients 82.7% are treated in accordance with the national policy (AL), while the most common non-recommended treatments included combined treatment of AL and quinine (10.2%), and quinine alone (4.0%). The practice of combining AL with quinine or prescribing quinine alone was particularly common in children below

5 years of age (23.3%). Notably, it was reassuring to observe that discontinued non-ACT monotherapies were not anymore prescribed for test positive patients – only 3 (1.0%) patients were treated with SP and none of the patients were prescribed amodiaquine. Finally, despite nearly universal prescription of antimalarial drug for test positive patients (99.3%), 62.0% were also treated with an antibiotic, more commonly in children below 5 years of age (75.8%) than in patients 5 years and older (55.1%) (Table 18).

In the second subset of patients with negative test result, it was surprising to observe that 52.1% were treated for malaria, 56.7% of children below 5 years of age and 48.8% of patients 5 years and older, however without statistically significant difference between age groups (table 18). In this group of patients AL remained the most commonly prescribed antimalarial drug (34.6%), and in contrast with the test positive patients 11.4% of patients were treated with SP and combined prescriptions of AL and quinine or quinine alone were less common (2.9% and 1.8% respectively). As high as 85.4% of patients with negative test result were treated with an antibiotic, the practice being common in both age groups (Table 18). Finally, of 239 patients who had negative malaria test result and antibiotic prescribed, 116 (48.5%) were still treated for malaria, 53.7% of children and 44.3% of patients 5 years and older.

In the last subset of febrile patients who did not have test done and therefore were not managed according to the new national guidelines, 67.8% of patients were treated for malaria, 76.0% with antibiotics and AL was the most common antimalarial treatment option (59.8%) without difference between age groups (Table 18).

Table 18: Baseline performance of the new case management policy - diagnostic and treatment practices for febrile patients presenting to all 173 health facilities regardless of the availability of commodities

	<5 years			5 years and older			All age groups		
	N=1,070			N=1,335			N=2,405		
	n	%	95% CI	n	%	95% CI	n	%	95% CI
Composite performance	126	11.8	8.3-15.3	252	18.9	14.1-23.6	378	15.7	12.0-19.4
Malaria test performed	219	20.5	15.2-25.7	356	26.7	20.5-32.8	575	23.9	18.9-28.9
Rx practice among test positives	N=99			N=196			N=295		
AL	74	74.8	61.9-87.6	170	86.7	80.2-93.3	244	82.7	75.8-89.6
AL+QN	17	17.2	5.8-28.5	13	6.6	2.2-11.0	30	10.2	4.8-15.6
QN	6	6.1	1.3-10.8	6	3.1	0.2-5.9	12	4.1	1.5-6.6
Other AM[a]	2	2.0	0-4.8	5	2.6	0.3-4.8	7	2.4	0.6-4.1
No AM prescribed	0	0	na	2	1.0	0-2.5	2	0.7	0-1.7
AB prescribed	75	75.8	65.9-85.7	108	55.1	44.9-65.3	183	62.0	53.6-70.4
Rx practice among test negatives	N=120			N=160			N=280		
AL	48	40.0	27.8-52.2	49	30.6	20.1-41.1	97	34.6	25.2-44.1
SP	9	7.5	0-15.7	23	14.4	5.5-23.2	32	11.4	3.8-19.1
AL+QN	6	5.0	0.1-9.9	2	1.3	0-3.7	8	2.9	0-6.0
QN	3	2.5	0-5.5	2	1.3	0-3.1	5	1.8	0.1-3.4
Other AM[b]	2	1.7	0-4.0	2	1.3	0-3.0	4	1.4	0-2.8
No AM prescribed	52	43.3	32.0-54.6	82	51.3	41.1-61.4	134	47.9	38.7-57.0
Any AM prescribed	68	56.7	45.4-68.0	78	48.8	38.6-58.9	146	52.1	43.0-61.3
AB prescribed	108	90.0	83.1-96.9	131	81.9	75.8-87.9	239	85.4	80.0-90.7
Rx practice when test not done	N=851			N=979			N=1,830		
AL	518	60.9	54.7-67.0	576	58.8	52.2-65.4	1,094	59.8	54.3-65.3
AL+QN	38	4.5	1.6-7.3	36	3.7	1.5-5.9	56	3.1	1.4-4.7
SP	17	2.0	0.3-3.6	18	1.8	0.5-3.1	53	2.9	1.2-4.6
QN	19	2.2	0.8-3.7	10	1.0	0-1.8	29	1.6	0.8-2.4
Other AM[c]	5	0.6	0-1.1	4	0.4	0-0.8	9	0.5	0.2-8.1
No AM prescribed	254	29.9	24.2-35.5	335	34.2	27.9-40.6	589	32.2	26.9-37.4
Any AM prescribed	597	70.2	64.5-75.8	644	65.8	59.4-72.1	1,241	67.8	62.6-73.1
AB prescribed	673	79.1	74.1-84.1	717	73.2	69.2-72.3	1,390	76.0	72.6-79.3

[a] Other antimalarial treatments include SP (3), AS+AQ (2), QN+SP (1) and DHA (1)
[b] Other antimalarial treatment include AQ (3) and AS+AQ (1).
[c] Other antimalarial treatments include AQ (5), QN+SP (1), QN+AQ (1), AL+SP (1) and DHA (1).

4.3.4. Health workers adherence to the new diagnostic and treatment policy

While previous section reported results from all health facilities regardless of the availability of case management commodities, in this section we evaluated health workers case management practices only at facilities where, both diagnostics and AL were in stock during the survey (Table 19). Of 173 facilities where outpatient consultations took place, malaria diagnostic services (either microscopy or RDTs) and any AL pack were in stock at 90 facilities. At these facilities, the performance of the same composite case management indicator increased from 15.7% reported at all facilities to 28.1%, and interestingly it was not higher than 36.1% in patients 5 years and older where testing of febrile patients has been recommended policy.

Compared to the results presented from all facilities, there was an increase in testing rates from 23.9% to 42.5%, but not beyond 50.8% even in patients 5 years and older. Interestingly, in discordance with the old policy promoting presumptive treatment, 33.3% of febrile children below 5 years of age were tested for malaria. Since only 5.7% of facilities did not

have any AL in stock, the treatment practices for test positive, test negative and patients without test performed largely mirrored the overall and age-specific pattern reported at all facilities, with only minor and non-significant increase in AL prescriptions across all categories. In summary, at these facilities 83.3% of test positive patients were treated with AL, 52.8% of test negative patients were treated for malaria, as well as 63.7% of patients without test performed.

Of interest, the rates of febrile patients 5 years and older seen by health workers who attended malaria case management training were nearly equally to those seen by untrained health workers (51.8%; 95% CI: 41.9-61.8 vs 49.3%; 95% CI: 36.8-61.7). At the same time, febrile children below 5 years of age seen by trained health workers were somewhat less commonly tested than the same children seen by untrained health workers (31.4%; 95% CI: 20.6-42.2 vs 36.4%; 95% CI: 23.7-49.1). While this pattern in children may suggest some effect of the training providing presumptive treatment recommendations under the old policy, the differences demonstrated between trained and untrained health workers were, however, minor and statistically non significant.

Finally, in patients 5 years and older no difference was observed between test negative patients treated for malaria who are seen by trained health workers and the same patients seen by untrained health workers (48.6%; 95% CI: 30.1-67.1 vs 50.0%; 95% CI: 37.0-63.0). Although the sample size was small and statistically significant differences could not be demonstrated, it was observed that test negative children below 5 years of age seen by trained health workers were somewhat more commonly treated for malaria (60.7%; 95% CI: 44.7-76.6) than the same children seen by untrained health workers (53.5%; 95% CI: 30.7-76.3). In the same patient group, an interesting pattern was observed with respect to IMCI training. Children seen by IMCI trained health workers, who were in addition to test negative result prescribed an antibiotic, were more commonly treated for malaria than those seen by non-IMCI trained health workers (76.7%; 95% CI: 54.1-99.2 vs 44.4%; 95% CI: 26.8-62.1).

Table 19: Health workers adherence to guidelines - diagnostic and treatment practices for febrile patients presenting to 90 facilities where malaria diagnostic services were available and AL was in stock

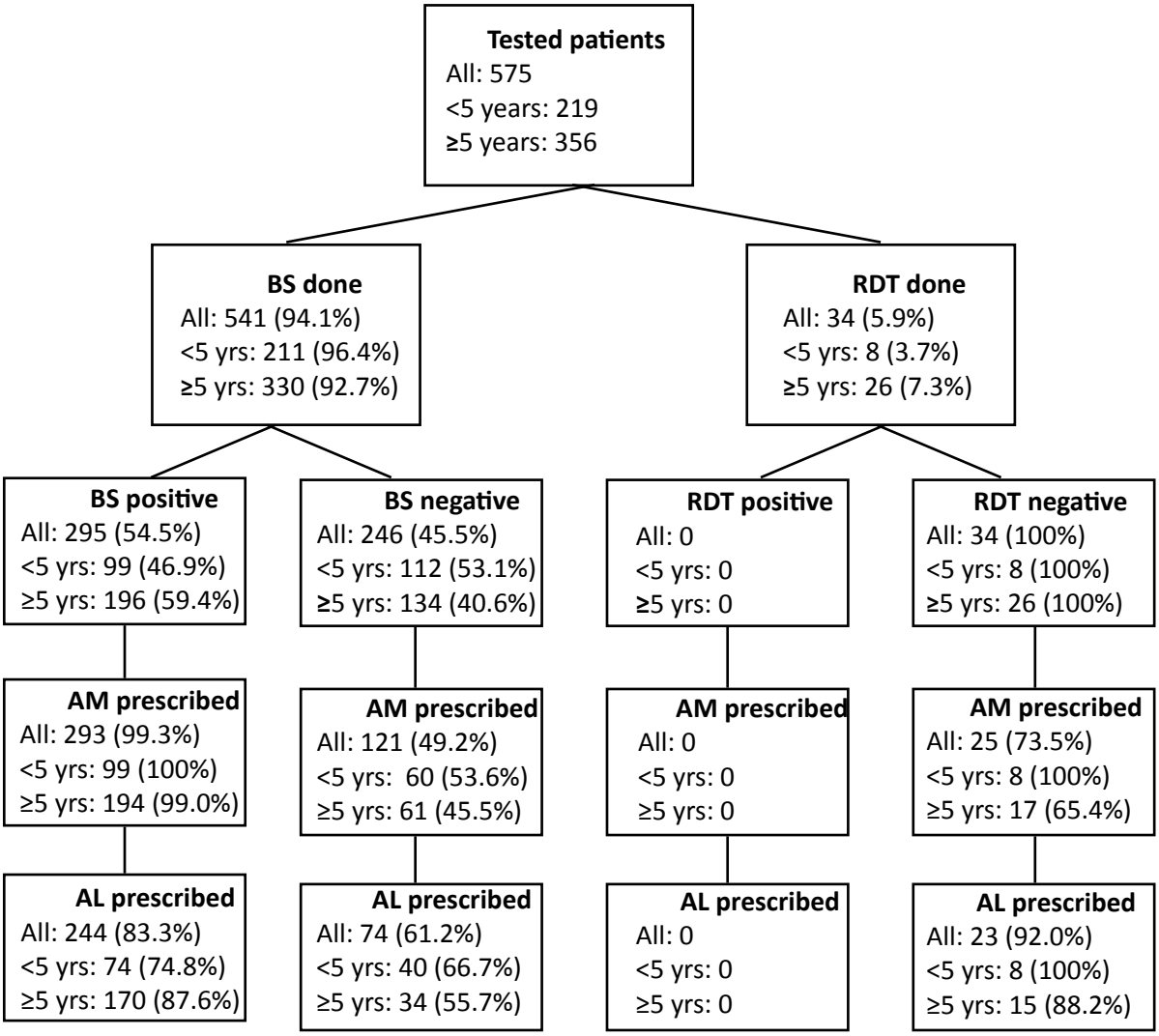
	<5 years			5 years and older			All age groups		
	N=591			N=648			N=1,239		
	n	%	95% CI	n	%	95% CI	n	%	95% CI
Composite performance	114	19.3	13.4-25.2	234	36.1	29.3-42.9	348	28.1	22.6-33.6
Malaria test performed	197	33.3	25.1-41.5	329	50.8	42.9-58.6	526	42.5	35.9-49.0
Rx practice among test positives	N=93			N=183			N=276		
AL	70	75.3	61.7-88.8	160	87.4	80.8-94.1	230	83.3	76.1-90.5
AL+QN	17	18.3	6.3-30.3	12	6.6	12.0-11.2	29	10.5	4.8-16.2
QN	5	5.4	0.8-10.0	6	3.3	0.2-6.4	11	4.0	1.4-6.6
Other AM[a]	1	1.1	0-3.3	3	1.6	0-3.5	4	1.5	0-2.9
No AM prescribed	0	0	na	2	1.1	0-2.7	2	0.7	0-1.8
AB prescribed	72	77.4	67.4-87.5	104	56.8	46.5-67.2	176	63.8	55.3-72.2
Rx practice among test negatives	N=104			N=146			N=250		
AL	43	41.4	28.0-54.7	46	31.5	20.4-42.6	89	35.6	25.6-45.6
AL+QN	6	5.8	0.3-11.3	2	1.4	0-4.1	8	3.2	0-6.7
SP	6	5.8	0-13.7	21	14.4	4.8-24.0	27	10.8	2.6-19.0
QN	3	2.9	0-6.4	2	1.4	0-3.4	5	2.0	0.2-3.8
AQ	2	1.9	0-4.6	1	0.7	0-2.1	3	1.2	0-2.6
No AM prescribed	44	42.3	29.4-55.2	74	50.7	39.7-61.6	118	47.2	37.0-57.4
Any AM prescribed	60	57.7	44.8-70.6	72	49.3	38.4-60.3	132	52.8	42.6-63.0
AB prescribed	93	89.4	81.5-97.3	119	81.5	74.0-89.0	212	84.8	79.0-90.6
Rx practice when test not done	N=394			N=319			N=713		
AL	229	58.1	47.8-68.5	165	51.7	40.8-62.7	394	55.3	46.7-63.8
AL+QN	22	5.6	0.5-10.7	1	0.3	0-0.9	23	3.2	0.3-6.1
SP	8	2.0	0-4.6	13	4.1	0-8.3	21	3.0	0-6.1
QN	10	2.5	0.3-4.7	1	0.3	0-0.9	11	1.5	0.3-2.8
Other AM[b]	4	1.0	0-2.0	1	0.3	0-0.9	5	0.7	0-1.3
No AM prescribed	121	30.7	21.3-40.1	138	43.3	31.6-55.0	259	36.3	27.8-44.8
Any AM prescribed	273	69.3	59.9-78.7	181	56.7	45.0-68.4	454	63.7	55.2-72.2
AB prescribed	295	74.9	66.3-83.4	232	72.7	66.5-78.9	527	73.9	68.4-79.4

[a] Other antimalarial treatment include SP (2), DHA (1) and QN+SP (1).
[b] Other antimalarial treatment include AQ (4) and DHA (1).

4.3.5. Treatment practices stratified by type and result of routine malaria testing

Of 575 patients who were tested for malaria, the large majority (94.1%) had microscopy performed and only 5.9% had RDT done. Among patients who had blood slide done, the routine test positivity rate across all age groups was 54.5% (95% CI: 50.3-58.7), significantly higher in patients 5 years and older (59.4%; 95% CI: 54.1-64.7) than in children below 5 years of age (46.9%; 40.1-53.7). However, of 34 patients who had RDT performed at 4 facilities none of them had positive RDT result. Nearly all (99.3%) of blood slide positive patients were treated for malaria, nearly half of blood slide negative patients were also treated (49.2%), yet as high as 73.5% of RDT negative patients. Although the sample size in RDT tested group was small for statistically significant comparisons, it was striking to observe that of 8 test negative children below 5 years of age all of them were treated for malaria and of 26 RDT negative patients 5 years and older 17 (65.4%) were treated for malaria. Among 25 RDT negative patients treated for malaria 23 (92%; 95% CI: 80.6-100) were treated with AL, compared to 61.2% (95% CI: 52.3-70.0) of patients with negative blood slide who were treated for malaria (Figure 1).

Figure 1: Treatment practices stratified by blood slide (BS) and RDT results with respect to the age and treatment with an antimalarial (AM) drug



4.3.6. Correctness of AL dosing

The correctness of AL dosage prescriptions was assessed in accordance with dosage recommendations for four weight-specific AL categories and was classified into three categories: 1) recommended (one tablet twice a day over three days for a 5–14 kg patient; two tablets twice a day over three days for a 15–24 kg patient; three tablets twice a day over three days for a 25–34 kg patient; and four tablets twice a day over three days for a patient 35 kg and above), 2) overdosed, and 3) underdosed prescriptions.

Of 1,328 patients who had AL prescribed and for whom dosage prescriptions were complete (107 had missing information), 89.2% were prescribed recommended AL weight-specific dosage while overdose and underdose prescriptions were relatively rare (7.2% and 3.7% respectively). High rates of recommended dosage prescriptions were observed in both age groups without statistically significant difference (Table 20). However, in separate analysis

stratified by AL weight categories, it has been observed that recommended dosing was significantly higher in weight groups 5-14kg (93.8%) and in patients weighing 35kg or more (94.8%) compared to patients weighing 15-24kg (73.0%) and 25-34kg (72.2%).

Table 20: Correctness of weight-specific AL dosing for patients who had AL prescribed

	<5 years N=591			5 years and older N=737			All age groups N=1,328[a]		
	n	%	95% CI	n	%	95% CI	n	%	95% CI
Recommended dose	524	88.7	85.6-91.7	660	89.6	87.1-92.0	1,184	89.2	87.1-91.3
Underdose	46	7.8	5.4-10.1	49	6.7	4.5-8.8	95	7.2	5.5-8.8
Overdose	21	3.6	1.7-5.4	28	3.8	2.4-5.2	49	3.7	2.4-5.0

[a] Denominator does not include 107 incomplete AL prescriptions

4.3.7. Dispensing and counseling practices

The quality of AL dispensing and counseling was evaluated based on the tasks specified in national malaria guidelines, malaria case management training manuals and AL dispensing wall charts. Of 1,435 patients who had AL prescribed, 1,408 (98.1%) had AL dispensed at the facility, equally high in children below 5 years of age (98.4%) and in patients 5 years and older (97.9). Of 1,408 patients who had AL dispensed at the health facility, the following dispensing and counseling tasks were performed for the majority of the patients: 51.8% had weight measured, 96.2% had dosage explained, 76.0% were advised to take second dose after 8 hours, 66.9% were told to take drugs after the meal and 80.3% were told to complete all AL doses. However, only 32.1% of patients received the first AL dose at the facility and advice on what to do in case of vomiting was provided for only 6.3% of patients. Interestingly apart from measuring the weight which health workers more commonly performed for children below 5 years of age (60.0%) than in patients 5 years and older (45.1%) there was no significant difference between age groups in the performance of any other dispensing and counseling tasks (Table 21).

Table 21: Dispensing and counseling practices among patients who had AL dispensed

	<5 years N=630			5 years and older N=778			All age groups N=1,408		
Weight measured	378	60.0	52.4-67.6	351	45.1	37.5-52.7	729	51.8	45.3-58.3
First dose given at facility	225	35.7	26.0-45.4	227	29.2	19.6-38.8	452	32.1	23.2-41.0
Dosage explained	606	96.2	94.5-97.8	748	96.1	94.8-97.5	1,354	96.2	94.9-97.4
Told to take 2nd dose after 8 hrs	483	76.7	70.6-82.8	587	75.5	68.5-82.4	1,070	76.0	70.0-82.0
Told to take drugs after the meal	414	65.7	59.8-71.6	528	67.9	62.8-73.0	942	66.9	62.2-71.6
Told what to do in case of vomiting	49	7.8	4.1-11.4	39	5.0	2.4-7.6	88	6.3	3.5-9.0
Told to complete all doses	488	77.5	73.3-81.6	643	82.7	79.6-85.7	1,131	80.3	77.4-83.3

Finally, the adequacy of dispensed AL packs across AL weight categories was evaluated for those patients who had recommended dose of AL prescribed and dispensed. The results of the same practices are also presented for the patients at the facilities where a weight-

specific AL pack was in stock. The results revealed that the majority (82.1%) of patients had received a single adequate AL pack for their weight category, the most commonly patients weighing 35kg and more (91.0%), and the least commonly children weighing 5-14kg (75.2%). In this lowest weight category 24.3% of children received AL packs of higher weight category but cut in a way to contain recommended 6 tablets. Furthermore, in heavier weight groups the practices also included combining one or more original AL packs to dispense recommended number of tablets. For example, in weight category 5-14kg, 10.7% of patients received two AL 6-packs to contain in total recommended number of 12 tablets. Taking out tablets out of AL packs and dispensing to patients was very rare and only 4 patients received such loose AL tablets. As shown in Table 22 at facilities where weight specific AL pack was in stock these coping mechanisms were nearly universally absent.

Table 22: Adequacy of AL dispensed packs among patients who had weight based recommended dose of AL prescribed and dispensed

All health facilities	5-14 kg N=499		15-24 kg N=159		25-34 kg N=56		≥35kg N=445		All weight groups N=1,159	
	n	%	n	%	n	%	n	%	n	%
Adequate AL pack	375	75.2	127	79.9	44	78.6	405	91.0	951	82.1
Combined AL packs	0	0	17	10.7	5	8.9	24	5.4	46	4.0
Cut AL packs	121	24.3	16	10.1	6	10.7	16	3.6	159	13.7
Loose AL tablets	3	0.6	0	0	1	1.8	0	0	4	0.4
Facilities with weight-specific AL pack in stock	N=381		N=134		N=43		N=407		N=714	
Adequate AL pack	375	98.4	124	92.5	41	95.4	402	98.8	699	97.9
Combined AL packs	0	0	4	3.0	1	2.3	1	0.3	6	0.8
Cut AL packs	5	1.3	6	4.5	0	0	4	1.0	7	1.0
Loose AL tablets	1	0.3	0	0	1	2.3	0	0	2	0.3

5. DISCUSSION

The main objective of this report is to provide national baseline data focusing on the availability of antimalarial drugs, malaria diagnostics and malaria case management practices prior to the nationwide rollout of the large scale implementation activities under the new National Malaria Strategy (NMS). The major case management shift of the new NMS recommends universal diagnostic testing across all age groups, however, it should be noted that AL treatment policy has been recommended under both policies, that malaria microscopy and RDTs have already been present in the country on some scale and that diagnostic testing and adherence to test results has already been recommended policy in febrile patients 5 years and older. Therefore, in addition to providing baseline information for the new NMS, these results highlight lessons learned during the prior implementation process that should inform the forthcoming case management activities. In this section the main findings are discussed with the reference to the four critical aspects of this evaluation. They refer to 1) availability of antimalarial drugs, 2) availability of malaria diagnostics, 3) exposure to in-service training, guidelines, wall charts and supervision, and 4) case management practices.

5.1. Availability of antimalarial drugs

Universal and continuous availability of non-expired AL, as well as the absence of expired drugs, is the crucial prerequisite for the implementation of any case management policy at public health facilities. The findings of this study show that expired AL at Kenyan facilities presents a negligible problem – only 2.9% were found with any expired AL pack.

The availability of non-expired AL is of greater concern. The minimal standard, which compromises the optimal management, but however allows improvised case management to take place, requires that at least one AL pack is universally and continuously available at all health facilities. Our findings show that, between October and December 2009, 27.2% of facilities experienced at least 7 days of simultaneous stock out of all four AL packs, that the stock out of all four AL packs was rare (5.7%) during the survey undertaken in January/ February 2010 - which notably took place shortly after the nationwide drug distribution in January - and that in the absence of distributions in February and March, the proportion of facilities without any AL in stock increased to 18.4% by the beginning of April 2010. Following the nationwide drug distribution at the beginning of April - which was this time exceptionally undertaken only to the district headquarters - the downward trend in AL stock outs was stopped, however the improvements measured at the end of April were minor and 15.8% of facilities were still without any AL in stock. The presence of stock-outs three weeks after AL delivery was likely the reflection of slow access of peripheral facilities to the stocks at district level.

Furthermore, when AL stocks at facilities were completely depleted, the facilities remained in this status for the median of 35 days or 38% of the retrospective three months evaluation period. While retrospective stock outs of SP and quinine were generally less common, when they occurred the facilities remained in this status for longer period (54-64% of the time). Moreover, the findings from facilities supplied by "pull" system suggested that facilities have frequently received lower quantities of AL packs compared to the ordered quantities. Yet, the frequency of supplies - when these are delivered directly from the national level to the health facilities as part of the usual drug supply logistics - generally matched the planned supply intervals. Finally, despite the three quarters of facilities having drug inventory materials the poor recording and reporting was widespread resulting in further compromising of the adequate supply chain.

Therefore, these findings suggest that under the current case management practices the quantities of AL supplied are not optimal resulting in stock outs which steadily increase following the elapse of the distribution cycle. In the drug supply system such as Kenyan which is largely dependent on the supplies dispatched from the national level directly to the facilities, the natural reflex in the past was to re-quantify national AL needs, increase amounts of the drug procured (subject to donor funding) and therefore potentially increase amounts of AL distributed to health facilities nationwide. However, the future strengthening of the drug supply chain must be viewed in the context of the new case management policy where implementation of rational use of antimalarial drugs based on universal deployment of malaria diagnostics should be an utmost priority. In this context, more importantly than mechanical increase in AL procurement and distribution, the priority for drug management activities should be strengthening of the facility and district level logistic management information systems including not only antimalarial drugs but also malaria diagnostics. The focus of these activities should be proper recording and reporting able to raise timely stock-out warnings to allow redistribution of commodities between peripheral facilities facing stock-outs and those where sufficient quantities of drugs and diagnostics are available. Finally, the drug and case management improvement activities at the facility and district level must be accompanied with timely procurement of planned quantities of AL at national level to ensure the central minimum stock levels for each of AL packs – the aspect not evaluated in this study but repeatedly highlighted as persistent problem in Kenya inevitably affecting stock outs at facility level (DOMC 2009a; 2009b; Kangwana et al. 2009).

5.2. Availability of malaria diagnostics

The universal and continuous availability of malaria diagnostic services is critical prerequisite for implementation of the new case management policy recommending universal testing of febrile patients. The findings of this survey show that malaria microscopy service was

provided at half of the facilities (50.6%), notably at 40.9% of GoK health facilities. This service was also provided at 22.5% of GoK dispensaries - likely as the result of community funded laboratories supplied with basic equipment and staffed with a single laboratory technician under the facility cost sharing arrangements. Importantly, at 9.1% of facilities providing malaria microscopy this service was absent for at least 7 consecutive days in past 3 months and at these facilities the median number of days without this service was 20 or 22% of the time.

As expected prior to nationwide implementation, the RDT availability was low – only 10.3% had RDTs in stock. Although the sample size was small and results should be cautiously interpreted it was however surprising that only 35.7% of facilities had any RDT in stock in districts which have been receiving RDT supplies, that at facilities with RDT in stock 61.3% experienced stock outs for at least 7 consecutive days in past 3 months, and that at the same facilities expired tests are found in one-third of the facilities. These finding suggest that most facilities nationwide have never been exposed to RDTs, facilities in areas targeted for RDT supply have been receiving irregular and insufficient supplies, but also that at some facilities RDTs have been used in the past and ran out of the stock while in others they have not been used as malaria diagnostic tool what resulted in their expiry.

Overall, from the baseline perspective important for the evaluation of the new case management policy, malaria diagnostic service (both RDTs and microscopy) were not present for at least 7 consecutive days in 3 months prior to the survey at 46.6% of facilities. To bridge this gap, given the complexity of the implementation and its maintenance, the expansion of malaria microscopy beyond the facilities where this service already exists should not be the priority. At facilities with existent microcopy the quality assurance of this service is the utmost priority. To increase the coverage of health facilities with malaria diagnostic services in reasonable time the focus of the forthcoming interventions should include sufficient procurement and supply of RDTs accompanied with appropriate quality assurance and case management support activities to those facilities where malaria microscopy service is currently not available. Yet, RDTs can be introduced at some facilities with laboratories to complement microscopy if this service is not available at certain times or days and where staff shortages limit feasibility of microscopy to screen febrile patients.

5.3. Exposure to in-service training, guidelines, wall charts and supervision

The provision of ACTs and diagnostics requires a package of health systems support activities necessary to implement, reinforce and maintain case management practices up to the standards defined in national guidelines. These activities include provision of in-service training, job aids and importantly, supervisory activities. The findings of this survey revealed that less than half of all health workers who routinely perform various case management duties at health facilities have attended case management related in-

service trainings. In summary, 40.1% of outpatient clinicians were trained on ACT case management, 27.2% on RDTs and only 19.8% on IMCI. Furthermore, 47.7% of laboratory personnel attended in-service training on malaria microscopy, 41.9% on RDTs and 36.9% of health workers dispensing drugs were trained on drug management. Notably, formally non-qualified cadres do perform outpatient consultations and dispense antimalarial drugs; however these cadres are not included in in-service trainings. This finding is of particular importance for drug management trainings where of all health workers dispensing drugs 18.9% are non-qualified cadres, yet only 3.0% of these were trained on drug management. Finally, the presence of job aids was variably present at facilities - while more than two thirds (69.5%) had national malaria guidelines, various wall charts were exposed at 36.8-44.8% of facilities.

An important component of health systems support activities needed to reinforce and maintain outpatient case management practices is health worker's supportive supervision. This routine activity in the Kenyan system should take place at least once every three months. This survey revealed that this programmatic component was quantitatively and qualitatively deficient. In summary, 41.5% of clinicians had received any supervisory visit in 3 months prior to the survey, and only 17.9% received a visit that included any activity related to malaria case management. When these visits however took place 37.5% and 45.0% of health workers were respectively observed performing outpatient consultations and were provided feedback.

In summary, there is an important gap in the health workers and health facility coverage with the in-service training, job aids and in particular with malaria related supervisory activities. Moreover, it should be noted that although all health systems support activities undertaken in past 3 years are still relevant for many aspects of malaria case management, they were not based on recommendations promoting testing of febrile children below 5 years of age but on presumptive treatment. Since this represents the major shift of the new policy, and a substantial behavioural change is still required in many other unchanged aspects of case management practices (even among exposed health workers), the future interventions, and in particular in-service training, should target health workers without distinction based on the prior exposure. Finally, to ensure high coverage of trained health workers and reach formally non-qualified health workers the most suitable solution should include extension of formal in-service training to on-job training activities that could be performed during the supervisory visits. However, these activities should be done in structured manner, the current curriculum should be shortened to one day, and the component of observed clinical practice should be introduced. This exercise can also provide an opportunity to revisit practices of previously trained health workers. However, prior to implementation of this activity the guidance from the DOMC should be sought in revising training materials, securing additional funds and providing evaluation of the effectiveness of this intervention.

5.4. Case management practices

Our findings revealed that at all study facilities only 15.7% of febrile patients are currently managed according to the new guidelines which was measured in our study as the composite performance indicator including all of the following criteria: 1) patient tested for malaria, 2) if positive test result treated with AL, and 3) if negative test result not treated for malaria. While the low performance rate at these facilities can be explained by the absence of diagnostics and AL in nearly half of the facilities, at the facilities with available diagnostic services and AL, the performance of the same indicator increased only to 28.1%. While it could be further explained that the policy of all age groups testing has not yet been implemented at these facilities, it was striking to observe that at the same facilities the indicator still remained low for patients 5 years and older (36.1%) where malaria testing, AL treatment and adherence to test results have been promoted since 2006.

There are three levels of discordance contributing to the non-adherent case management practices and poor performance of the composite indicator. First, the major one is low testing rate – only 23.9% and 42.5% of all febrile patients are respectively tested at all facilities and at those with available commodities. Interestingly, at the latter facilities half (50.8%) of febrile patients 5 years and older are tested but also one-third (33.3%) of children below 5 years of age, the practice in line with the new policy but at variance with the old policy. Second, more than half (52.8%) of test negative patients are still treated with an antimalarial drug similarly across both age groups. Although this group currently represents only 11.6% of all febrile patients, if this practice is not minimized, the future increase in testing rates would severely compromise current case management policy. Finally, the lowest discordance was found in patients group having positive test result where 83.3% of patients were treated with AL as recommended by the guidelines and notably the majority (10.5%) of non-adherent treatments included combination of AL and quinine while the rates of prescribed non-ACT monotherapies such as SP and amodiaquine were very low.

The striking findings were revealed on the routine test results and their interpretation stratified by type of testing. Among patients having undergone malaria microscopy, the slide positivity rate was 54.5% while none of the patients who had RDT performed had positive test result. Yet, nearly all blood slide positive patients were treated for malaria, nearly half of blood slide negative patients were also treated (49.2%), and as high as 73.5% of RDT negative patients. Although somewhat higher, these practice patterns for test negative patients were also suggested from the responses obtained from health workers during the interviews. Even if these routine test results were not reported on the same patients the size of the gap in the positivity rates between microscopy and RDTs may be indicative of several patterns: either routine malaria microscopy reports are largely false positive, or the

quality of RDTs is compromised resulting in false negative reports, or the quality of both diagnostic services is inaccurate. Given that less than 10% of facilities providing microscopy and RDTs have received any quality assurance visits in past 3 months none of the above explanations can be excluded.

With the respect to the testing and training exposure, the effect of ACT case management training on the age specific testing rates was nearly non-existent – not exceeding 5% in both age groups. Similarly, there was no effect of the training on the prescribing of antimalarial treatment for test negative patients 5 years and older, and although the sample size was small, it appeared that test negative children below 5 years of age seen by trained health workers were somewhat more commonly treated for malaria (60.7%) than the same children seen by untrained health workers (53.5%). The last finding is probably an important "side-effect" of the presumptive policy reinforced through the trained health workers in this age group where presumptive treatment but not testing was recommended. Overall, the effects of the prior malaria training on test use and test interpretation according to guidelines was generally minor or non-existent.

In summary, despite the prior different recommendations for patients below and above 5 years of age, malaria testing practices and treatments for test negative patients were not substantially different between two age groups, and exposure to training was unlikely to be a determining factor. Several possible explanations from clinical perspective deserve attention. Health workers might disregard guidelines recommending testing of all fevers based on believes that they can reliably rule out malaria based on their clinical skills. While this view might be true, the practice showing that as high as 63.7% of patients without test performed are still treated for malaria would not concord with this perception. With respect to guidelines, the past studies have repeatedly shown low sensitivity of various clinical signs and symptoms to detect malaria in febrile patients across all age groups and areas of endemicity and the universal conclusion was that parasitological diagnosis in febrile patients is the only reliable solution to confirm or rule out malaria. Pending further evidence-based clinical algorithms, testing of all febrile patients with subsequent treatment of all positive test results and withholding treatment for test negative results should be promoted practice not only to decrease levels of overdiagnosis but also to detect true malaria cases across all age groups, which are increasingly vulnerable to severe malaria and death with the decline of malaria transmission. This aspect becomes even more important in the context of establishing accurate surveillance data and future shifts from control to malaria elimination activities.

Would inclusion of integrated clinical algorithms in malaria guidelines and malaria training programmes decrease high rates of unnecessary malaria treatments for test negative febrile patients? Theoretically yes, however with regard to children below 5 years of age,

the practices observed in this study with regard to IMCI trained health workers question this hypothesis. Although the IMCI was recommending presumptive treatment of children, it can be hypothesized that if IMCI trained health worker disregarded IMCI, tested for malaria and prescribed an antibiotic then test negative children seen by IMCI trained health workers who were equipped with integrated case management skills would be less commonly treated for malaria. However, we observed an opposite pattern - test negative children seen by IMCI trained health workers, who moreover prescribed an antibiotic for these children, were more commonly treated with an antimalarial drug than those seen by non-IMCI trained health workers (76.7% vs 44.4%).

As a related issue, three-quarters (75.3%) of all febrile outpatients were prescribed antibiotics, the proportion as high as 85.4% in test negative patients. While it could be argued that patients or health workers view prescriptions of medications as an indicator of good quality of care, the change of currently irrational practice of prescribing antimalarial drugs for test negative patients would not substantially interfere with this perception. In most cases, the main difference to the current practices would be only an omission of antimalarial treatment from the existing polypharmacy prescriptions. Having said this, the provision and the in-service training on integrated clinical algorithms is still an important component to increase capacities of health workers to manage appropriately non malaria febrile patients, potentially improve general quality of care and ideally it should also be promoted as part of malaria control activities in collaboration with other disease programmes. An opportunity for this should be forthcoming large scale implementation of RDTs. With respect to other programmes such as IMCI they should do urgent amendments to incorporate malaria testing and adherence to test negative results into guidelines and in-service training programmes.

Finally, adequate AL dosing, dispensing and counseling practices deserve attention. The performance of these tasks, as they should be provided as part of good clinical practice, is important to ensure high rates of patients' adherence and treatment success. In this study we found rather high performance for most of the tasks: 89.2% of patients received correct weight-specific dose, nearly all (98.2%) had AL dispensed, as high as 96.2% were advised how to take drugs at home, 76.0% were advised to take second dose after 8 hours, 66.9% were told to take drugs after the meal, 80.3% were told to complete all AL doses and 51.3% were weighed before prescribing AL, more commonly in children below 5 years of age (60.0%). Furthermore, 82.1% of patients were dispensed a single recommended AL pack for their weight category. However, less than one-third (32.1%) of patients received the first AL dose at the facility and advice on what to do in case of vomiting was provided for only 6.3% of patients. The reasons explaining poor performance of the last two tasks may include health workers misperceptions on administration of the first AL dose in the absence of food at facility, potentially burdensome procedure of crushing AL tablets for

small children at busy facilities and unclear dispensing recommendations with regard to the provision of replacement dose in case of vomiting. Given that potable water from at least one source was available at nearly all facilities, this should not present an excuse for not dispensing the first dose. Finally, it could be expected that the administration of the first AL dose in children will be facilitated with the arrival of dispersible AL tablets.

6. CONCLUSIONS AND RECOMMENDATIONS

The findings of this national survey reveal that most of the key indicators measured in this study are well below the 2013 optimistic targets aiming at universal availability of malaria case management commodities, universal coverage of health facilities and health workers with malaria related health systems support activities and universal health worker's adherence to national outpatient guidelines for malaria diagnosis, treatment, counseling, and drug dispensing (Annex 1-3). These findings should be primarily viewed as the baseline information identifying major gaps prior to the forthcoming implementation activities under the new National Malaria Strategy. In addition to providing baseline information for the new NMS, the findings highlight a series of lessons learned during the past policy implementation that should inform the future case management activities to improve upon the quality of the implementation process. Therefore, in the following sections the key conclusions and recommendations that can be drawn from the findings of this survey are summarized around four critical domains that were focus of this survey and should present areas for the future actions.

6.1. Availability of AL, other antimalarials and antimalarial drug management

Conclusions:

1. The presence of expired antimalarial drugs at facilities is nearly non-existent

2. Stock-outs of AL are common and when they take place facilities remain in this status for a substantial period

3. Despite the majority of facilities having antimalarial drug inventory materials there is suboptimal recording and reporting

Recommendations:

- The change of CM practices based on malaria diagnostics and rational drug use should be urgently implemented not only to improve the quality of care but also to minimize current stock out problems.

  Action: DOMC with the support of Case Management TWG should develop a comprehensive nationwide plan for the implementation of parasite-based diagnosis and treatment.

- The office of the DPF should be strengthened to undertake pharmaceutical monitoring and supervision including redistribution of AM drugs between facilities.

  Action: Department of Pharmacy should appoint DPFs in all districts, provide them with specific TORS and facilitate them to undertake the required activities.

- Timely procurement of AL is required to ensure sufficient stocks of all AL packs at health facilities

  Action: DOMC with the support of Case Management TWG (Drug Management Subcommittee) and the Procuring agency should monitor and evaluate the procurement process and enforce contract management.

6.2. Availability of parasite-based diagnosis and quality control

Conclusions:

1. Parasite-based diagnosis is currently not provided in nearly half of the facilities, and when available it is largely provided through malaria microscopy.

2. Despite the small sample size of routinely performed RDTs, the difference in the positivity rates between malaria microscopy (55%) and RDTs (0%) question the accuracy of routine diagnostic services.

3. At facilities with diagnostic services supervisory activities ensuring QC of malaria microscopy and RDT use are nearly non-existent.

Recommendations:

- Malaria microscopy should be strengthened at facilities where this service already exists.

  Action: DOMC and NPHL to communicate the recommendation to PHMTs, DHMTs, malaria focal persons and DLTs.

- Malaria RDTs should be procured in sufficient quantities to screen fevers at HFs where microscopy is not available and can complement microscopy where staff shortages limit feasibility of the service.

  Action: DOMC with the support of Case Management TWG to undertake RDT quantification exercise to estimate needs according to geographical and level of care roll-out plan for the large scale introduction of RDTs.

- QC and QA systems for malaria microscopy and RDTs supported by supervision and monitoring should be urgently implemented in line with national policy guidelines for parasitological diagnosis of malaria.

  Action: DOMC and NPHL to develop implementation plan for the quality control and assurance of malaria microscopy and RDTs as part of the national roll-out plan for the implementation of parasite-based diagnosis.

6.3. Coverage with guidelines, job-aids, in-service training and supervision

Conclusions:

1. There is a gap in HF and HW coverage with in-service training, job aids and in particular with malaria supervisory activities. In addition, they are currently based on old diagnostic policy
2. CHWs and other formally non-qualified staff do perform outpatient consultations and dispense AM drugs; however they are currently not covered with the in-service trainings

Recommendations:

- The future malaria case management in-service trainings should be aligned with the universal and continuous availability of malaria diagnostic services and should target all health workers without distinction based on the prior exposure to the training.

  Action: DOMC with the support of Case Management TWG to develop training plan for health workers as part of the national roll-out of the parasite-based diagnosis.

- Supervisory activities at district level that include malaria case management component need to be quantitatively increased and qualitatively improved in line with supervisory manuals.

  Action: DHMTs with the support of DOMC to strengthen supervision according to the newly developed malaria supervision manual.

- Formally non-qualified staff should receive structured, on-job training on malaria drug and case management

  Action: DOMC with the support of Case Management TWG should develop a training manual and roll-out plan.

- The revised versions of the national malaria case management guidelines, IMCI guidelines, case management wall charts and other job aids should be disseminated to the health facilities and health workers during the in-service trainings.

  Action: DOMC and DCAH to disseminate revised guidelines and job aids.

6.4 Case management practices

Conclusions:

1. Baseline practices prior to the implementation of the new case management policy show that 16% of febrile patients (12% of children and 19% of 5 years and older) at all study facilities are currently managed according to the new guidelines and 28% (19%

of children and 36% of 5 years and older) at facilities where diagnostics and AL are available.

2. At facilities with available diagnostics and AL, the major contributors to the discordant practices in comparison with the new guidelines are low testing rates (43%), common antimalarial treatments for test negative patients (53%) and non-recommended treatments for test positive patients (17%), the majority being combination of quinine and AL.

3. The effects of the prior in-service malaria case management trainings on the test use and test interpretation in comparison with guidelines was minor or non-existent.

4. The performance of the majority AL dosing, dispensing and counseling tasks is rather high, however, the following tasks are not yet optimal: weighing of patients, administration of the first AL dose at the facility and provision of advice on what to do in case of vomiting.

Recommendations:

1. Alongside the implementation of parasite based diagnosis the following case management messages should be emphasized during the in-service trainings and reinforced during the supervisory visits: 1) all febrile patients should be tested, 2) test positive patients should not be treated with combined AL and quinine treatment but only with AL, 3) test negative patients should not be treated for malaria, 4) weighing of all patients, and in particular children, should be systematically performed, 5) the first AL dose should be administered at facilities even in the absence of food, and 6) patients and caretakers should be advised to return for replacement dose to complete full treatment course in case of vomiting.

   Action point: DOMC through DHMTs, malaria focal persons and in-service training partners to emphasize these guidelines messages through the training and supervision.

2. To facilitate health workers' and caretakers' administration of AL to children, pediatric formulations should be procured and distributed to health facilities.

   Action point: DOMC to advise national procurement agencies what pediatric AL formulation is an optimal national standard for malaria treatment.

3. Clinical guidelines to support health workers in management of non malaria febrile patients should be developed and implemented

   Action point: MOPHS and MOMS to develop guidelines in collaboration with DOMC, DCAH and other disease specific programs

7. REFERENCES

Amin AA et al. (2007). *The challenges of changing national malaria drug policy to artemisinin-based combinations in Kenya. Malar J,* **6:** 72.

Kangwana BB et al. (2009). *Malaria drug shortages in Kenya: A major failure to provide access to effective treatment. Am J Trop Med Hyg,* **80:** 737-738.

Lubell YH et al. (2008). *The impact of response to the results of diagnostic tests for malaria: cost-benefit analysis. BMJ,* **336:** 202–205.

MOH (2008). *National Guidelines for Diagnosis, Treatment and Prevention of Malaria for Health Workers.* Ministry of Health, Division of Malaria Control, Nairobi.

DOMC (2009a). *Kenya Artemether-lumefantrine Stock Situation Analysis* (end April 2009). Drug Management Subcommittee, Division of Malaria Control, Nairobi.

DOMC (2009b). *Kenya Artemether-lumefantrine Stock Situation Analysis* (end September 2009). Drug Management Subcommittee, Division of Malaria Control, Nairobi.

MOPHS (2009a). *National Malaria Strategy 2009-2017.* Ministry of Public Health and Sanitation, Division of Malaria Control, Nairobi.

MOPHS (2009b). *Kenya Malaria Monitoring and Evaluation Plan 2009-2017.* Ministry of Public Health and Sanitation, Division of Malaria Control, Nairobi.

MOPHS (2010). *National Guidelines for Diagnosis, Treatment and Prevention of Malaria for Health Workers.* Ministry of Public Health and Sanitation, Division of Malaria Control, Nairobi.

Njogu J et al. (2008). *Health facility and health worker readiness to deliver new national treatment policy for malaria in Kenya.* East Afr Med J, **85**: 213–221.

Noor et al. (2009). *A spatial national health facility database for public health sector planning in Kenya in 2008.* Malaria J, 8:13.

O'Meara et al. (2008). *Effect of a fall in malaria transmission on morbidity and mortality in Kilifi, Kenya. Lancet,* 372: 1555-1562.

Okiro et al. (2009). *Malaria paediatric hospitalization between 1998 and 2008 across Kenya.* BMC Med, 9: 70:75.

Shieshia M et al. (2009).*Pharmaceutical Management of Malaria Medicines Survey in Kenya*. Management Sciences for Health.

Shieshia M et al. (2010). *An Assessment of Pharmaceutical Management of Malaria Medicines in Kenya.* Management Sciences for Health.

Whitty CJM et al. (2008). *Deployment of ACT antimalarials for treatment of malaria: challenges and opportunities. Malaria J,* 7 (Suppl 1): S7.

WHO (2009). *World Malaria Report 2009.* World Health Organization, Geneva.

WHO (2010). *Guidelines for the Treatment of Malaria.* World Health Organization, Geneva.

Zurovac D et al. (2008). Translation of artemether-lumefantrine treatment policy into paediatric clinical practice: an early experience from Kenya. Trop Med Int Health, **13:** 99-107.

Annex 1: Summary of key health systems support M&E indicators

Health systems support M&E indicators	2010 Rd 1	2010 Rd2	2011 Rd 3	2011 Rd 4	2012 Rd 5	2012 Rd 6	Target 2013
% of facilities with stock out of AL for 7 or more consecutive days in past 3 months							
All AL packs	**27.2**						**0**
AL 6 pack	**37.6**						**0**
AL 12 pack	**43.9**						**0**
AL 18 pack	**52.0**						**0**
AL 24 pack	**39.3**						**0**
Any AL pack	**59.5**						**0**
% of facilities with stock out of recommended antimalarials for 7 or more consecutive days in past 3 months							
SP tablets	**14.4**						**0**
Quinine tablets	**25.4**						**0**
Quinine injections	**20.8**						**0**
% of facilities without any malaria diagnostic support (RDT or microscopy) for 7 or more consecutive days in past 3 months	**46.6**						**0**
% of facilities having national malaria case management guideline	**69.5[a]**						**100**
% of health workers who were trained on:							
Malaria case management	**40.0[a]**						**100**
Use of RDTs	**27.2[a]**						**100**
Drug management	**36.3**						**100**
% of health workers who had at least one supervisory visit in past 3 months that included observation of malaria case management	**15.5**						**100**
% of facilities which had at least one visit in past 3 months that included quality control of malaria microscopy[b]	**9.1**						**100**
% of facilities which had at least one visit in past 3 months that included use of malaria RDTs[b]	**5.6**						**100**

[a] Guidelines and training undertaken under case management policy recommending presumptive treatment in children below 5 years of age
[b] The indicator includes only facilities which provide these services on survey days

Annex 2: Summary of key malaria case management M&E indicators

Malaria case management M&E indicators	2010 Rd 1	2010 Rd2	2011 Rd 3	2011 Rd 4	2012 Rd 5	2012 Rd 6	Target 2013
Indicators showing overall performance of the new case management policy - all facilities regardless the availability of the commodities							
% of febrile patients who are managed according to national guidelines (tested for malaria AND only positive test results are treated with AL)	**15.7 ($11.8_{<5}$, $18.9_{\geq 5}$)**						**100**
% of febrile patients who are tested with RDT or microscopy	**23.9 ($20.5_{<5}$, $26.7_{\geq 5}$)**						**100**
% of febrile patients with positive test result who are treated with AL	**82.7 ($74.8_{<5}$, $86.7_{\geq 5}$)**						**100**
% of febrile patients with negative test result who are not treated for malaria	**47.9 ($43.3_{<5}$, $51.3_{\geq 5}$)**						**100**
Indicators showing health workers adherence to guidelines – facilities where malaria diagnostics and AL are available							
% of febrile patients who are managed in accordance with national guidelines (tested for malaria AND only positive test results treated with AL)	**28.1 ($19.3_{<5}$, $36.1_{\geq 5}$)**						**100**
% of febrile patients who are tested with RDT or microscopy	**42.5 ($33.3_{<5}$, $50.8_{\geq 5}$)**						**100**
% of febrile patients with positive test result who are treated with AL	**83.3 ($75.3_{<5}$, $87.4_{\geq 5}$)**						**100**
% of febrile patients with negative test result who are not treated for malaria	**47.2 ($42.3_{<5}$, $50.7_{\geq 5}$)**						**100**
Indicators showing quality of AL prescribing, dispensing and counseling – febrile patients with AL prescribed and dispensed							
% of patients with AL prescribed in recommended weight-specific dose	**89.2 ($88.7_{<5}$, $89.6_{\geq 5}$)**						**100**
% of patients with AL dispensed who had weight measured	**51.8 ($60.0_{<5}$, $45.1_{\geq 5}$)**						**100**
% of patients with AL dispensed who had first dose given at facility	**32.1 ($35.7_{<5}$, $29.2_{\geq 5}$)**						**100**
% of patients with AL dispensed who were explained on dosing at home	**96.2 ($96.2_{<5}$, $96.1_{\geq 5}$)**						**100**
% of patients with AL dispensed who were advised what to do if vomiting occurs	**6.3 ($7.8_{<5}$, $5.0_{\geq 5}$)**						**100**

Annex 3: AL monitoring data – time trends in the availability of non-expired AL

% facilities with AL in stock		Jan[a]	Feb	Mar	Apr	May[b]	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Any AL pack	2010	**94.3**		**89.9**	**81.6**	**84.2**							
	2011												
	2012												
AL 6 pack	2010	**81.0**		**72.0**	**60.7**	**62.2**							
	2011												
	2012												
AL 12 pack	2010	**79.9**		**71.4**	**52.4**	**55.5**							
	2011												
	2012												
AL 18 pack	2010	**79.3**		**70.8**	**60.7**	**62.2**							
	2011												
	2012												
AL 24 pack	2010	**86.2**		**80.4**	**73.2**	**80.5**							
	2011												
	2012												
All AL packs	2010	**64.9**		**51.2**	**41.1**	**43.9**							
	2011												
	2012												

[a] Data in 2010 collected from 18 January – 12 February

[b] Data in 2010 collected in the last week of April

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