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HEALTH FACILITY AND HEALTH WORKER READINESS TO DELIVER NEW NATIONAL TREATMENT POLICY FOR MALARIA IN KENYA

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J. NJOGU, W. AKHWALE, D.H. HAMER and D. ZUROVAC

ABSTRACT

Objective: **To evaluate health facility and health worker readiness to deliver new artemether-lumefantrine (AL) treatment policy for uncomplicated malaria in Kenya.**

Design: **Cross-sectional survey.**

Setting: **Health facilities in four sentinel districts in Kenya.**

Participants: **All government facilities in study districts (n = 211) and all health workers performing outpatient consultations (n = 654).**

Main outcome measures: **Availability of antimalarial drugs on the survey day, stock-outs in past six months, presence of AL wall charts, health worker's exposure to in-service training on AL and access to new national malaria guidelines.**

Results: **The availability of any tablets of AL, sulfadoxine-pyrimethamine and amodiaquine was nearly universal on the survey day. However, only 61% of facilities stocked all four weight-specific packs of AL. In the past six months, 67% of facilities had stock-out of at least one AL tablet pack and 15% were out of stock for all four packs at the same time. Duration of stock-out was substantial for all AL packs (median range: 27-39% of time). During the same period, the stock-outs of sulfadoxine-pyrimethamine and amodiaquine were rare. Only 19% of facilities had all AL wall charts displayed, AL in-service training was provided to 47% of health workers and 59% had access to the new guidelines.**

Conclusion: **Health facility and health worker readiness to implement AL policy is not yet optimal. Continuous supply of all four AL pack sizes and removal of not recommended antimalarials is needed. Further coordinated efforts through the routine programmatic activities are necessary to improve delivery of AL at the point of care.**

INTRODUCTION

In sub-Saharan Africa, treatment with highly efficacious artemisinin-based combination therapies (ACT) is one of the recent, key strategies aiming to address the problem of failing monotherapies and reduce the enormous burden of malaria across the continent (1,2). In Kenya, between 2000 and

2004, the failure rates of recommended sulfadoxine-pyrimethamine (SP) and amodiaquine therapies for uncomplicated malaria increased rapidly (3,4). In 2004, Kenya changed first-line treatment policy from SP to a specific ACT, artemether-lumefantrine (AL) (5). In 2006, the Kenyan Ministry of Health (MoH) implemented the new policy countrywide. The key programmatic activities of the implementation process relevant for health facility and health worker's ability to deliver AL policy included: (i) revision of national malaria case-management guidelines, (ii) provision of in-service training for health workers, (iii) AL supply to the facilities, and (iv) the distribution of guidelines and wall charts to health workers.

In March 2006, the revision process of the previous malaria case-management guidelines was completed (6,7). The diagnosis recommendations in children below five years of age were harmonised with fever algorithms of Integrated Management of Childhood Illnesses (IMCI) guidelines (8) and separate outpatient case-management algorithms were developed for patients five years of age and older (7). The new guidelines recommended AL as first line treatment for uncomplicated malaria for patients weighing 5kg and above, quinine for children below 5kg and pregnant women, SP was reserved only for intermittent preventive treatment in pregnancy (IPT), and amodiaquine was no longer recommended for the treatment of malaria (7).

In-service training of health workers on the new guidelines was organised in a cascade manner, starting at the national level by training 48 provincial trainers in April 2006 who subsequently trained 405 district trainers who, by September 2006, were charged to train 60% of all front-line health workers nationwide. Trainings at each level followed the same curriculum and were organised as a three-day workshop with approximately 30 participants per training course. The teaching modalities included lectures and theoretical case scenarios but did not involve any clinical practice. One training day was devoted to the management of uncomplicated malaria.

Simultaneously it was planned that between June and September 2006 all government facilities were to receive supplies of AL and the process of discontinuing supplies of amodiaquine and substantial rationing of SP was to be initiated (9). Thereafter, all hospitals were supposed to make orders based on AL consumption (pull-system) while the lower level health centres and dispensaries, with the exception of two provinces that entirely function on the pull-system, were supposed to receive a predetermined quantity of AL every three months (push-system).

Finally, wall charts reflecting AL case-management recommendations were developed to serve as job-aids. These charts, together with new guidelines, were to be delivered to health workers either through District Health Management Teams (DHMT) or during the in-service training sessions.

Between October and December 2006, a health facility survey undertaken in four sentinel districts revealed that the coverage of health workers and health facilities with programmatic activities had been variably achieved (10). In addition, the implementation of some activities delayed and that short interval between rolling out the AL drug supply and timing of the survey did not allow for evaluation of the stability of the AL supply chain and estimates of stock-out durations.

In 2007, six months after the initial survey, a repeat survey was undertaken in the same districts to evaluate health facility and health workers readiness to deliver AL policy following completion of all implementation activities. Here, we describe how effectively the Kenyan MoH did in attaining its implementation goals and discuss what additional programmatic activities may be required in the future to improve upon the current coverage.

MATERIALS AND METHODS

Study districts: The study was undertaken in four sentinel districts identified by the MoH's Division of Malaria Control (DOMC) for routine monitoring and evaluation of malaria control activities in the country. These districts were purposely selected to represent different malaria ecologies in Kenya. They included: Kwale, a coastal area on the Indian Ocean with moderate to high transmission; Bondo, on the shores of Lake Victoria with perennial high malaria transmission; greater Kisii (comprised of Kisii Central and Gucha districts) located in a highland area with seasonal transmission; and Makueni, a semi-arid area with acutely-low seasonal transmission.

Study design and data collection: A cross-sectional health facility survey was conducted at all government health facilities in the four districts between 1st May

and 15th June 2007. Data were collected by four survey teams, each comprised of two nurses. Data collection included health facility assessments and health worker interviews. Prior to the data collection, training and concordance testing was undertaken over four days until the agreement of practice results between nurses and trainers was greater than 90%. Two survey coordinators supervised field work and one day was spent at each facility.

After verbal informed consent was obtained from the in-charges of health facilities and health workers data were collected using two methods. First, a health facility assessment was undertaken to collect retrospective information on the timing and the quantity of AL receipts since the first delivery to the facility, availability of AL on the survey day and duration of stock-out period during six months prior to the survey. Availability and stock-outs were also assessed for SP, amodiaquine and quinine. The presence of malaria microscopy, rapid diagnostic tests and any displayed case-management wall charts was recorded. Second, interviews were conducted with all health workers who routinely perform outpatient consultations at each facility. At each facility the list of health workers was provided by the facility in-charge. During the interviews, health workers were asked about their demographics, pre-service training, exposure to in-service training and supervision and access to national guidelines.

Data management and statistical analysis: Data were double entered by two independent data entry clerks using Access 2000 (Microsoft Inc, Redmond, Washington). Data files were compared for errors using a verification programme and referring to original questionnaires when necessary by the first author. Statistical analysis was performed using STATA, version 8 (StataCorp, College Station, Texas). Results from all four districts are combined and descriptive analysis reporting simple frequencies was undertaken at the health facility and health worker level. Finally, key AL implementation indicators were compared with the results of the initial 2006 survey.

Ethical approval: Ethical approval for this study was provided by the KEMRI national ethical review committee (reference number 892) and the Boston University IRB (2004-127B and H24055).

RESULTS

Background description of health facilities and health workers: Two hundred and eleven government health facilities were assessed where 712 health workers were routinely providing general outpatient consultations. Of 211 facilities assessed, 164 (77.7%) were dispensaries, with health centres and hospitals accounting for 32 (15.2%) and 15 (7.1%) facilities respectively. Parasitological capacity to diagnose malaria was available in 79 (37.4%) facilities, most commonly providing malaria microscopy (69/211; 32.7%). Only 17 (8.1%) facilities stocked rapid diagnostic tests. Of 712 health workers, 654 (91.9%) were interviewed, while 58 (8.1%) were absent from facilities and could not be reached during the survey period. The reasons for their absence included annual or study leave, off duty, sickness, and longer in-service training seminars. The average age of 654 interviewed health workers was 38 years (age range: 20-55) and 373 (57.0%) were females. Nurses represented the majority (455; 70.0%) of health workers, followed by the clinical officers (119; 18.2%). Of concern, 77 (10.8%) of the health workers who reported to routinely perform consultations were cadres without any formal clinical qualifications. These included community health workers, support personnel, nurse aids, clerks, nutritionists, public health officers and laboratory technicians. Only three (0.5%) health workers were medical doctors.

Initial AL deliveries and frequency of AL supplies to health facilities: There were important variations in the timing of the initial deliveries of AL to health facilities. Of 211 facilities assessed, 122 (57.8%) received AL according to the planned schedule, between June and September 2006. Sixty six (31.3%) facilities received AL during the last quarter in 2006 and 13 (6.2%) received their first AL supplies during 2007. By the time of the survey, 10 (4.7%) facilities had never received AL. Following the initial delivery of AL, subsequent supplies to all facilities continued to be based on the predetermined quantities (push-system). The frequency of AL supplies varied depending on the facility type. Of 122 facilities which received initial supplies of AL between June and September 2006, the average number of AL deliveries was 2.8; this average being higher in hospitals (4.3) than in dispensaries and health centres (2.7).

Availability of AL and other antimalarial drugs at health facilities: Of 211 health facilities assessed, 201 (95.3%) had in stock at least one of four weight-specific AL blister packs on the survey day. The availability of weight-specific AL packs varied from 76% for the 24 tablet pack to 91% for the 18 tablet pack (Table 1). Of concern, all four weight-specific packs of AL were available in only 61% of facilities. Conversely, the availability of amodiaquine and SP, the drugs which are no longer recommended for the treatment of malaria, was nearly universal: 98% of facilities stocked amodiaquine and 97% SP. Quinine tablets were also widely available (92%).

We also explored stability of antimalarial stocks for the six month period between 1st November 2006 and 30th April 2007 preceding the survey (Table 1). For this analysis we included 176 facilities which had received AL prior to the stock-out evaluation. Two thirds (67%) of facilities experienced stock-outs for at least one of four AL tablet packs. Between 23% and 31% of facilities had stock-outs of the 6, 12 and 18 tablet packs, and as many as 65% of facilities were out of stock for 24 tablet pack. At these facilities, the median number of the stock-out days was also significant: 49 days (IQR: 25-67) for the six tablet pack (27% of time), 54 days (IQR: 26-80) for the 12 tablet pack (30% of time), 65 days (IQR: 34-94) for the 18 tablet pack (36% of time) and 71 days (IQR: 37-109) for the 24 tablet pack (39% of time). More positively, all four AL packs were simultaneously out of stock in only 15% of facilities, with a median number of 29 stock-out days (IQR: 11-58) or 16% of time. In the same period, at nearly all facilities amodiaquine and SP were continuously available (Table 1).

Availability of malaria case-management wall charts: Seven malaria case-management wall charts were developed by the DOMC to support translation of new guidelines into effective practice. Four of these referred to severe malaria, while three charts were of direct relevance to management of uncomplicated malaria and use of AL. These three included an AL dosing chart, an algorithm for assessing and treating children with fever and a malaria outpatient algorithm for older children and adults (7). Of 211 facilities assessed, AL dosing charts were displayed at 68 (32.2%) facilities, the chart for children with fever at 60 (28.4%) and the chart for older children and adults at 64 (30.3%) facilities. All three charts were displayed at only 40 (19.0%) facilities. SP dosage charts were displayed at 22 (10.4%) facilities and non-revised IMCI charts at only eight (3.8%) facilities. The four severe malaria charts were variably present in 4.7% to 32.2% of facilities.

Table 1

Availability of antimalarial drugs on survey day and stock-outs in past six months

Availability of antimalarial drug	On survey day (n = 211)		In past six months* (n = 176)	
	No.	(%)	No.	(%)
Artemether-lumefantrine				
Any tablets of artemether-lumefantrine	201	95.3	117	66.5
Artemether-lumefantrine 6 tablet pack	168	79.6	48	27.3
Artemether-lumefantrine 12 tablet pack	167	79.2	41	23.3
Artemether-lumefantrine 18 tablet pack	192	91.0	55	31.3
Artemether-lumefantrine 24 tablet pack	161	76.3	114	64.8
All artemether-lumefantrine tablet packs	129	61.1	27	15.3
Other antimalarial drugs				
Amodiaquine (any formulation)	206	97.6	19	10.8
Amodiaquine tablets	201	95.3	8	4.6
Amodiaquine syrup	196	92.9	1	8.5
Sulfadoxine-pyrimethamine tablets	204	96.7	9	5.1
Quinine tablets	194	91.9	26	14.8

*Stock out in past six months defined as absence of antimalarial drugs from the stock for at least seven consecutive days

Health workers readiness to deliver AL policy: We assessed health worker exposure to in-service training, supervision and access to new malaria guidelines (Table 2). Of 654 interviewed health workers, 306 (46.8%) had received in-service training including AL recommendations. Most health workers (92.8%; 284/306) had attended malaria specific courses, while only 33 (10.8%) were trained on AL use by the IMCI programme. Among different cadres of health workers, 53.8% (64/119) of clinical officers were trained on AL, 53.0% (241/455) of nurses and none of 42 health workers without formal clinical qualification. Health workers were trained mostly by DHMTs (87.1%; 256/306), and nearly all were exposed to a three day theoretical workshop (95.9%; 282/306). More than half of health workers (385/654; 59%) had access to a copy of the new national malaria guidelines. Only 127 (19.4%) health workers had received at least one supervisory visit in the past six months that included discussion on appropriate use of AL. A supervisory visit including AL discussion and observation of consultations was provided to 86 (13.2%) health workers while 65 (9.9%) health workers had received the same visit which also included feedback.

Comparison of key AL implementation indicators between 2006 and 2007: Table 3 presents the key AL implementation indicators reported during the initial 2006 survey, early after AL implementation and during the 2007 survey carried out six months later. In summary, during both rounds of surveys health facilities were well stocked with all antimalarial drugs, including the no longer recommended amodiaquine which was paradoxically available in nearly all (100% in 2006 and 98% in 2007) facilities. Availability of any tablets of AL was high (88% in 2006 and 95% in 2007); however, all four weight-specific packages of AL were less frequently in stock (58% in 2006 and 61% in 2007). During both rounds of surveys stock-outs of amodiaquine, SP and quinine were uncommon in the six months preceding the surveys; indeed it seems that supplies of these drugs were even better during 2007. Evaluation of AL stock-out was not possible during the 2006 survey; however, the results from 2007 indicated that stock-outs were more common for AL (15% for all AL packs and 67% for any AL pack) than for other antimalarials. There was no increase in coverage of health workers trained on AL use and there was only a small increase in access to national guidelines. While nearly no facility had AL case-management wall charts displayed in 2006 and only 7% of health workers had received supervisory visit including AL in the same year, both of these indicators increased to 19% in 2007.

Table 2

Health worker readiness to deliver AL policy

Health worker characteristic (n = 654)	No.	(%)
Exposure to in-service training		
Malaria case-management training on AL	284	45.0
IMCI	141	21.6
IMCI including use of AL	33	5.0
Any training including use of AL (malaria specific or IMCI)	306	46.8
Access to guidelines		
Malaria case-management	385	59.0
IMCI	259	39.7
Supervision in past six months		
Including use of AL	127	19.4
Including use of AL and observing consultations	86	13.2
Including use of AL, observing consultations and feedback	65	9.9

IMCI = Integrated Management of Childhood Illnesses

Table 3

Comparison of key AL implementation indicators between 2006 and 2007

Health facility characteristic	2006 (n = 193) No.	(%)	2007 (n = 211) No.	(%)
Availability of antimalarial drugs on the day of the survey				
Any tablet packs of artemether-lumefantrine	169	87.6	201	95.3
All tablet packs of artemether-lumefantrine	112	58.0	129	61.1
Amodiaquine (any formulation)	193	100	206	97.6
Sulfadoxine-pyrimethamine tablets	183	94.8	204	96.7
Quinine tablets	154	79.8	194	91.9
Stock-out of antimalarial drugs in past six months*				
Any tablet packs of artemether-lumefantrine	NA		117	66.5
All tablet packs of artemether-lumefantrine	NA		27	15.3
Amodiaquine (both formulation)	10	5.2	4	2.3
Sulfadoxine-pyrimethamine tablets	41	21.2	9	5.1
Quinine tablets	71	36.8	26	14.8
AL case-management wall charts (all three charts)	1	0.5	40	19.0
Health worker characteristics	(n = 227)**		(n = 654)	
In-service training including use of artemether-lumefantrine	105	46.3	306	46.8
Access to national malaria guidelines	126	55.5	385	59.0
Supervision including use of artemether-lumefantrine	17	7.5	127	19.4

*Stockout in past six months are defined as absence of drugs from the stock of at least seven consecutive days
**During 2006 surveys only health workers providing consultations on the day of the survey were interviewed

DISCUSSION

Our evaluation of health facility and health workers readiness following completion of AL implementation activities revealed a number of important findings that must be considered in further strengthening of the delivery of AL policy in Kenya.

Availability of AL: The main prerequisite of any new drug policy is adequate and continuous availability of the recommended drug at peripheral facilities. Our results showed that all four packs of AL were in stock on the day of the survey at 61% of facilities and that 67% of facilities experienced stock-outs of at least one pack in the last six months. The duration of stock-outs was substantial, lasting, for example, more than two months for 24 tablet packs. We emphasize here that implementation of the AL policy includes delivery of four different AL pack sizes (6, 12, 18 and 24 tablets) suitable for management of four different weight categories of patients (5-14kg; 15-24kg; 25-34kg and ≥35kg). Although the strength of all tablets is the same, the blister packaging of individual courses raises the question how these drugs should be dispensed when recommended weight-specific pack is out of stock at the facility. For example, should the 12 pack size of AL be cut in half to provide treatment for 10kg child when the six tablet pack is out of stock? Or, should adult patients be given two available 12 pack sizes when the 24 tablet pack is not available? Various other combinations are clearly also possible.

Drug management documents in Kenya refer to AL drug as four different products (9). Patients' adherence is high when they receive AL blister packs with a weight-specific number of tablets and including pictorial instructions on how to use it (11). Previous studies in Zambia and Kenya have also shown that incorrect weight-specific prescriptions

of AL are rare, and blister packaging is likely to be a factor contributing to this (10,12). However, no clinical guideline or training manual provide instructions to health workers in Kenya on what they should do when the recommended pack size is out of stock and when they are facing a dilemma of cutting AL packages or combining several packs to provide treatment to patients who need it. Two studies have reported that AL is massively underprescribed in Kenya (10,13). Both studies did not examine the impact of pack sizes on AL underprescribing. The stock-out of specific AL pack sizes might be a reason for underprescribing and this is worth exploring in future studies. We recommend that MoH improves supplies of all four AL products and monitor availability of AL at facilities by giving priority to stock-out indicators referring to the availability of each weight-specific AL product. Meanwhile, health workers should be instructed to use AL even if adequate AL pack sizes are not in stock. Although this would be a temporary compromise it would save many lives before an adequate AL supply chain is established countrywide.

Availability of other antimalarial drugs: Universal and continuous availability of amodiaquine since the beginning of AL supplies deserves a special attention. There are two ways to approach this observation. More positively, it could be argued that a widespread availability of this drug gives health workers a treatment tool when faced with AL stock-outs. Obviously, this treatment solution is suboptimal compared to AL but yet more effective than another alternative, SP (4). This treatment practice would be reasonable during the period of transition to AL; however, since we have shown that this process is taking longer than originally envisioned, we are currently faced with, *de facto*, two policies running in parallel in the field, where amodiaquine is still the most frequently available drug. This is happening nearly a year after AL was distributed and phasing-out of amodiaquine from the peripheral facilities was planned (9). The continuous supply of amodiaquine creates confusion among health workers about which drug to use (14), and therefore, it is not surprising that our previous evaluation has shown that even at facilities where AL was available, it has rarely been used while at the same time amodiaquine became the drug of choice (10). Furthermore, protracted use of amodiaquine instead of AL does not allow meaningful estimates of AL needs and establishing of "pull" delivery system based on AL consumption. The realistic AL consumption cannot be established since it should be based on the number of AL prescriptions at facilities which, as indicated previously, rarely occur.

A potential solution to this vicious circle is two-fold and both interventions should occur simultaneously: first, the quantity and frequency of AL supplies should substantially improve, and second, amodiaquine distribution should be discontinued. Only then the true consumption of AL can be monitored, a pull-system be introduced and quantitative facility-based adjustments made. On the other hand, the discontinuation of amodiaquine supply without ensuring AL availability might have serious public health consequences as health workers may have no choice than to revert to abandoned and completely ineffective SP treatment policy (which is currently available for IPT in pregnancy) and/or to massive prescribing of quinine risking development of resistance to life-saving therapy for severe malaria.

Health workers exposure to in-service training on AL and job aids: The MoH's cascade, in-service training organised at the national, provincial and district level to support introduction of AL into clinical practice was completed by the end of 2006. At the district level, front-line health workers were trained during a series of 2-3 consecutive workshops over 2-3 months resulting in training of less than half of the providers. The survey revealed that 11% of health workers providing outpatient consultations were without formal clinical training and none of these providers had been trained. The coverage of trained health workers is below the modest target of 60% set up by the MoH (15). There is an urgent need to find solutions to quickly expand this coverage. Otherwise, rare prescribing of AL might continue as absence of exposure to AL training was reported as a factor contributing to this practice in Kenya (10).

Probably the most suitable solution to rapidly increase effective coverage of trained health workers and reach formally non-qualified health workers is on-job training. This training modality is likely to be the least expensive option as it could be organised during supervisory visits through already trained facilitators who are mostly members of DHMTs. Unfortunately, a cascade in-service training during

2006 did not include component of on-job training for non-trained health workers. The intention of the training programme was to train maximum number of front-line health workers according to a structured three-day curriculum. Inevitably some of non-trained health workers were spontaneously orientated on-job by their peers on basic AL prescribing, however this was unlikely to be done in systematic manner. Given the qualitative issues encountered during the formal training it is unlikely that this limited on-job extension was optimal (14). To increase effectiveness of on-job training, the curriculum should be shortened to one day, the topic of uncomplicated malaria should be focused and a component of observed clinical practice should be introduced. This exercise can also provide an opportunity to revisit practices of previously trained health workers and correct some of the inappropriate training messages delivered previously, such as compulsory testing prior to prescribing AL across all age groups and acceptable use of amodiaquine despite of AL availability (14). However, prior to implementation of this exercise guidance from the DOMC should be sought in revising training materials, securing additional funds and providing evaluation of the effectiveness of this intervention.

Finally by the time of our 2007 survey health workers had been variably exposed to job aids recommending use of AL: 59% had access to revised national guidelines and 19% worked at facilities with displayed AL case-management wall charts. As opposed to the delivery of guidelines to health workers, the distribution of wall charts to support training and implementation of new policy is the activity whose implementation failed during the cascade training programme undertaken in 2006. In 2007, following completion of the in-service training only a limited number of facilities had received wall charts. In Kenya, case-management wall charts had shown a positive impact on treatment practices during transition period to SP (16). This simple and inexpensive intervention should be prioritized by the MoH. As previously suggested, supervisory visits coupled with on-job training could be a suitable opportunity to display the charts at facilities and strengthen case-management following instructions provided in charts and guidelines.

In conclusion, our study of health facility and health worker readiness to deliver AL policy was undertaken three years after the policy had been changed in Kenya, one year after implementation started in study districts and six months after the initial evaluation was completed. This provided sufficient time to evaluate if the new policy reached the periphery of health system and what coverage of front-line facilities and health workers has been achieved with the planned activities. Ideally, all facilities should be stocked with adequate and continuous supplies of AL, all health workers should be trained on AL use, and access to job aids, such as guidelines and wall charts, should be universal. More pragmatically and recognising operational difficulties in providing universal coverage with the new policy, lower targets of 80% or 60% are commonly set; this was respectively specified by the Kenyan MoH to evaluate key implementation indicators such as proportions of facilities without stock-out of antimalarial drugs and coverage of trained health workers on AL use (15,17). However, findings of our study suggest that the policy implementation targets have not been met: 67% of facilities have stock-out of at least one pack size of AL, 47% of health workers are trained, 59% have access to guidelines, and only 19% of facilities have AL case-management wall charts. Our evaluation focused only government facilities and we cannot comment on the progress made in private and mission health sector. Future evaluations should include all health sectors in Kenya. Yet, it is obvious that the implementation of the new malaria treatment policy is not a set of single field activities that can be implemented over a few months; it is likely to be a process stretching over several years and requiring further coordinated efforts through the routine programmatic activities as suggested in this study.

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