The implementation of a new Malaria Treatment Protocol in Timor-Leste: challenges and constraints

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Background	Timor-Leste changed its malaria treatment protocol in 2007, replacing the first-line for falciparum malaria from sulphadoxine-pyrimethamine to artemether-lumefantrine. This study explored the factors affecting the implementation of the revised treatment protocol, with an emphasis on identifying key constraints.
Methods	A mixed method approach drew on both qualitative and quantitative data. The study included data from District Health Services in seven districts, community health centres in 14 sub-districts, four hospitals, five private clinics, one private pharmacy and the country's autonomous medical store. In-depth interviews with 36 key informants, five group interviews and 15 focus group discussions were conducted. A survey was also undertaken at community health centres and hospitals to assess the availability of a physical copy of the Malaria Treatment Protocol, as well as the availability and utilization of artemether-lumefantrine and sulphadoxine-pyrimethamine.
Results	Many factors impeded the implementation of the new malaria protocol. These included: inadequate introduction and training around the revised treatment protocol; unclear phasing out of sulphadoxine-pyrimethamine and phasing in of the revised treatment, artemether-lumefantrine, and the rapid diagnostic test (RDT); lack of supervision; lack of adherence to the revised guidelines by foreign health workers; lack of access to the new drug by the private sector; obstacles in the procurement process; and the use of trade names rather than generic drug description. Insufficient understanding of the rapid diagnostic test and the untimely supply of drugs further hampered implementation.
Conclusion	To effectively implement a revised malaria treatment protocol, barriers should be identified during the policy formulation process and those emerging during implementation should be recognized promptly and addressed.
Keywords	Malaria, treatment protocol, malaria treatment, plasmodium falciparum, sulphadoxine-pyremethamine (SP), artemether-lumefantrine (AL), policy implementation, implementation science, Timor-Leste

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KEY MESSAGES

- Implementing a new treatment protocol requires effective introduction and training of prospective users, adequate supplies of the new drugs, efficient ongoing procurement, and regular monitoring to ensure availability and proper use.

- Potential barriers to implementation should be identified early during the formulation of a new treatment protocol so as to identify mechanisms and strategies to overcome them.

- Changing a treatment protocol not only requires modifying the behaviour and prescribing practice of health workers, but also needs the involvement of other parts of the health system, as well as the co-operation and support of patients, to ensure implementation.

Background

The Ministry of Health in Timor-Leste changed its case management protocol for the treatment of falciparum malaria in 2007 by replacing sulphadoxine-pyrimethamine (SP) with artemether-lumefantrine (AL) as the first-line treatment for uncomplicated *plasmodium falcifarum* infections (Ministry of Health 2007). At the same time the Ministry of Health introduced the rapid diagnostic test (RDT) for diagnosis (Ministry of Health 2007). These modifications marked the second change of first-line anti-malarial treatment for uncomplicated malaria (Ministerio da Saúde 2005); the first occurred after the country gained independence in 2002, at which time chloroquine (CQ) was replaced with SP (Ministry of Health and WHO 2002).

In 2005, the Inter-Agency Working Group on Malaria recommended the use of artemisinin-based combination therapy (ACT) in complex emergency situations, and it has since become widely used as the standard treatment for malaria in many countries (WHO 2005). A number of countries in the South-East Asia region, including Thailand, Myanmar, Bangladesh, Bhutan and Indonesia, have switched to ACT in recent years (WHO 2006a) and Timor-Leste followed suit in 2007. By the end of 2009, 77 out of 109 malaria-endemic countries had adopted ACT in their national drug policy (WHO 2009).

A number of factors influenced the change in treatment for malaria. According to the World Health Organization (WHO), the main determinants of treatment policy change were therapeutic efficacy, appropriate utilization of effective anti-malarials, changing patterns of malaria-associated morbidity and mortality, consumer and provider dissatisfaction with existing policies, the country's economy and the availability of new products (WHO 2006b).

In Timor-Leste, development of the new Malaria Treatment Protocol (MTP) began in 2005 and was completed by June 2007. 'Socialization', a process of informing and 'sensitizing' staff to the new protocol, took place between October and December 2007 and was conducted by the National Commission for Protocol Finalisation (NCPF). While there is no 'local' definition of 'socialization', the term is common in Timor-Leste.[1] 'Socialization' or 'sosialisasi' in Bahasa Indonesian is understood as a process whereby a policy or a programme, promoted by people perceived to be in a 'higher level' position (policy makers or managers), is made known to those at a 'lower level' (implementers or community), so that the policy or programme can be implemented.

Once awareness of the MTP was raised through the process of socialization, implementation of the newly approved protocol began in January 2008. It encountered significant challenges, however, and this study was designed to explore and document the challenges and constraints in the first 6 months of implementation.

Methodology

This study used a mixed methods approach combining document reviews, in-depth interviews with key informants, group interviews, focus group discussions and a survey. Data were collected between April and July 2008. Ethical clearance was obtained from the Ethics Committee of the University of New South Wales, Sydney, Australia and the Timor-Leste Ministry of Health. Study participants gave informed consent which stressed that their participation was voluntary and they had the right to withdraw from the study if they wished to do so.

Fieldwork was conducted at District Health Services (DHS) in seven districts (Aileu, Baucau, Bobonaro, Covalima, Manufahi, and Viqueque), community health centres (CHCs) in 14 sub-districts, in four hospitals (the National Hospital and three regional referral hospitals), five private clinics and one private pharmacy. The *Serviço Autónomo de Medicamento e Equipamentos da Saúde* (SAMES, the country's autonomous medical store, with responsibility for procuring, distributing and storing medicines, medical equipment and consumables for all government health facilities) was also included. The selection of districts and sub-districts was purposeful; it targeted districts and sub-districts that had implemented the Global Fund grant from 2003 to 2006.[2] The hospitals and the private health facilities were selected using convenience sampling. If a district in which a hospital was present was selected, that hospital was automatically included. Private health facilities were only drawn from those in Dili where most of the private clinics and pharmacies are located. Site visits to health facilities and SAMES were undertaken.

Documents reviewed included minutes of meetings discussing the MTP implementation, reports and Ministry of Health directive letters related to the MTP. These documents were accessed from the Ministry of Health. Table 1 summarizes the methods used.

In-depth interviews were conducted with officials at the DHS. Group interviews and focus group discussions were held mainly with health workers at health facilities. Overall, 36 key informants were interviewed, of which 28 were officials from the DHS, five were from private clinics, one from a private pharmacy, one a CHC staff member and one a SAMES official.

Table 1 Summary of methods used in the study

Data collection methods	Health facilities and offices								
	MoH	DHS	National hospital	Referral hospital	CHC	SAMES	Private clinic	Private pharmacy	Total
Survey		0	1	3	14	0	0	0	18
Key informant interviews		28	0	0	1	1	5	1	36
Group interviews		3	1	0	1	0	0	0	5
Focus group discussions		0	0	3	12	0	0	0	15
Document review	Yes	No	No	No	No	No	No	No	

Notes: MoH = Ministry of Health; DHS = District Health Services; CHC = community health centre; SAMES = Serviço Autónomo de Medicamento e Equipamentos da Saúde (Central Medical Stores).

The CHC staff interview was opportunistic and occurred when a planned focus group discussion could not be conducted. As an alternative, a midwife who was on duty that day was interviewed on site.

Five group interviews (three with DHS staff, one with CHC Suai staff and one with doctors from the National Hospital) were conducted. Fifteen focus group discussions (12 with staff at CHCs and three with staff at referral hospitals) were held. All qualitative interviews were conducted in the local language, Tetum. The key informant interviews and group interviews were conducted by JM, a Timorese health professional and researcher. Focus group discussions were facilitated by JM and FB. 'Group interviews' and 'focus group discussions' differed (Patton 2002; Hennink 2007). A group interview was an in-depth interview targeted at a group of people with the intention of gaining information and insights from the interviewees, with communication being bi-directional between the interviewer and the interviewees without involving discussion between the group participants. Focus group discussions were used to allow participants in the group to discuss issues or research questions amongst themselves as well as with the researcher, with the researcher(s) playing a facilitating role. The communication in focus group discussions is thus multi-directional.

The key research topics explored in this study were:

- How was the new MTP introduced to health workers at health facility level?
- Was the new MTP implemented?
- What were the constraints to implementation of the new MTP?

Since private health facilities had not implemented the MTP at the time of the study, the question asked of them concerned the involvement of private health facilities in the implementation of the MTP. All interviews and focus group discussions were tape recorded and lasted approximately 1–1.5 hours. The transcription and translations of these qualitative data were conducted by JM and checked by AZ to clarify intended meaning.

The qualitative data were coded and analysed using Nvivo 7, a software package developed for this purpose. Using the Nvivo 7 software, the researchers coded text, and identified and analysed the key themes. Insights from the key informant interviews were triangulated with documents and focus group discussions. Triangulation was also undertaken between the qualitative and quantitative findings. In addition, a workshop was held to present the preliminary results of this study, which served as an opportunity for the lead author to validate data and insights.

Quantitative data collection took place through a survey conducted in 14 CHCs and four hospitals. The quantitative data collection focused on government health facilities because at that time only government health facilities had access to AL and RDTs. Private health facilities were not included in the survey because the government did not have a policy to involve them in the MTP implementation at that time.

The survey assessed the physical availability of the third edition of the MTP and its flowcharts, the availability of AL, the availability of SP, the number of staff attending socialization of the new MTP, and the actual utilization of AL and SP taken from the patients' registers from January to June 2009. These data were collected on the same day of the visit to these health facilities. They were then tabulated and imported into MS Excel for analysis. Six CHCs and one hospital that did not have records on SP and AL utilization were excluded from the analysis. However, the qualitative data from these six CHCs, one government hospital and six private health facilities were incorporated in the analysis.

Results

This study revealed multiple barriers to the implementation of the new MTP. These were grouped under five main categories, discussed below, identified through the qualitative data analysis:

- Poor socialization;
- Insufficient quantity of MTP copies at health facilities;
- Constraints to implementation at government health facilities;
- Central Medical Stores (SAMES) constraints in supporting implementation;
- No clear policy of involving private health facilities in the implementation.

Poor socialization of the new MTP

The socialization was conducted by the members of the NCPF which comprised staff from the Ministry of Health, WHO, CARE International and the Timor-Leste Medical Association. It was conducted in all 13 districts of the country and in six hospitals. The socialization was to be conducted over 2 days in each district. However, in some districts, it took place in as little

as 3 hours (in Viqueque) to half a day (in Baucau and Covalima). The variation in time devoted to socialization of the MTP in districts reflected a lack of uniformity and provided insufficient time for health workers to learn about it.

Each health facility visited had at least two staff who had attended socialization. The trained health workers were expected to then train their fellow health workers, in a cascading 'Training of Trainers' approach. This failed to happen in many districts, limiting the number of health workers who fully understood the new MTP. Health workers who did not attend socialization were less likely to use RDTs and AL.

> ''First, for us nurses, many of us have not attended training yet. Secondly, Coartem®[3] is [readily available] here, it is not that we do not know, but we do not understand [how] to use it ... To be honest I am still blind about this. Regarding Coartem®, I don't know. I don't know; I have not attended training yet.'' (participant in FGD with CHC staff)

The limited time allocated, lack of staff trained and the unwillingness of trained staff to train their colleagues at health facilities reflected the poor socialization process.

Insufficient quantity of the MTP at health facilities

Overall, more than 90% of those interviewed had the protocol available at their workplace. However, the quantity was insufficient as each health facility was provided with only one physical copy of the MTP. Fewer than 20% of the surveyed health facilities had an MTP flowchart at the time of survey. The flowcharts were produced later in early 2008 and at the time of the fieldwork the production had been completed, but had yet to be widely distributed. The CHC managers

demanded the Ministry of Health supply more copies of the MTP to facilitate implementation. According to these managers, one copy of the MTP was insufficient as many staff were simultaneously involved with clinical consultations.

Constraints to implementation at government health facilities

Untimely supply of AL and RDTs and the availability of SP prompting the return to former treatment

The Ministry of Health issued two letters in January and March 2008, respectively, requesting all health facilities to implement the new MTP. However, these letters were not followed by an adequate supply of AL to health facilities and did not mention the need for health staff to withdraw SP, the previous drug used for treatment.

Both CHCs and hospitals continued to prescribe SP to patients; use of both AL and SP in government health facilities is presented below (Figure 1). Among eight CHCs that possessed data on AL utilization, an increasing trend of AL utilization and a decreasing trend of SP utilization are apparent. Comoro CHC had much higher AL utilization compared with the other seven CHCs; this reflected its location in Dili district which implemented a pilot project on the RDT and AL before the new MTP was approved for countrywide implementation. This pilot project was funded by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Among three referral hospitals, Suai used comparatively more AL than Maliana and Baucau (Table 2); this can be attributed to AL being used in Suai before the approval of the MTP during a malaria outbreak in June–July 2007. This suggests that prior experience in using AL and the RDT improved AL uptake compared with facilities without this experience.
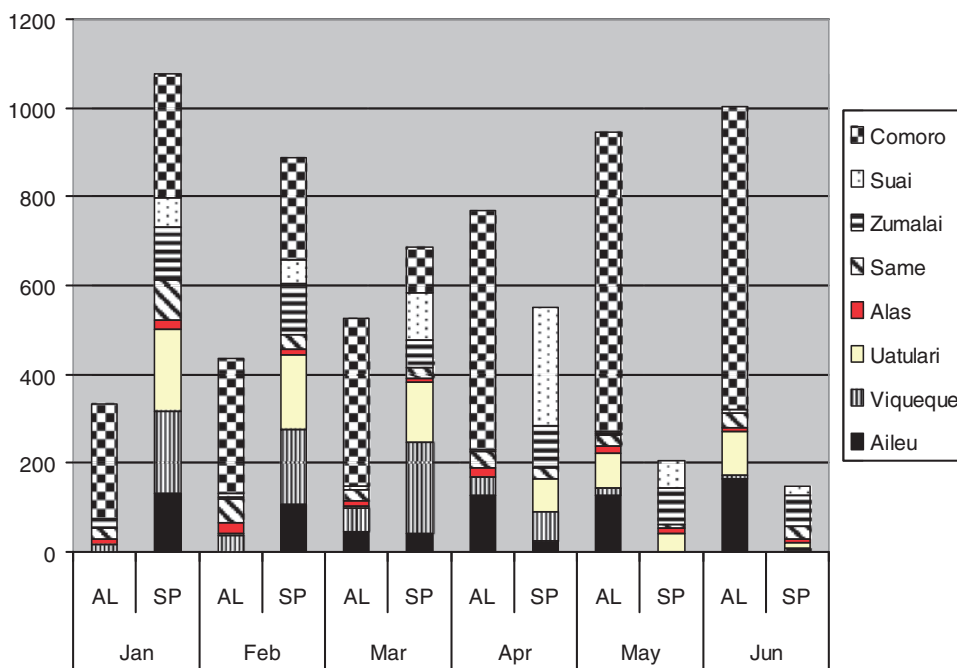
Figure 1 Malaria cases treated with artemether-lumefantrine (AL) and sulphadoxine-pyrimethamine (SP) in eight surveyed community health centres, January–June 2008

Table 2 Number of malaria cases treated with artemether-lumefantrine (AL) and sulphadoxine-pyrimethamine (SP) at the outpatients department of three referral hospitals in Timor-Leste, January–June 2008

Month	Hospitals					
	Suai		Maliana		Baucau	
	AL	SP	AL	SP	AL	SP
January 2008	198	88	25	25	0	126
February 2008	210	35	10	5	3	104
March 2008	236	132	6	137	5	48
April 2008	401	40	7	154	3	37
May 2008	165	33	4	64	2	30
June 2008	134	4	1	67	3	29
Total	**1344**	**332**	**53**	**452**	**16**	**374**

At the time of the visit (April–July 2008), around 20% of the health facilities experienced a stock-out of AL. In some cases AL was completely unavailable; in others some dosages were not available. In addition, nearly 60% of the health facilities visited had a stock-out of RDTs. This was also confirmed by interviewees.

> ''The problem now with Coartem® for 25–35 kg, it is almost 3 months now, we have not had supplies from SAMES, and some Coartem® has already expired.'' (FGD with CHC Comoro)

> ''The problem is medicine, they only give us a small amount of AL, so we still use 'Fansidar [SP]'.'' (Doctor at referral hospital)

In many instances, health workers continued to use SP in health facilities because either they did not have RDTs or they did not have enough AL.

> ''Sometimes when our RDTs have finished, we just use suspect [syndromic] diagnosis, so we still give patients 'Fansidar' [SP].'' (Midwife at a CHC)

The unreliable supply of AL and RDTs, along with stock-out, led to some health workers reverting to the previous malaria treatment.

Lack of trust in the RDT

Many health workers believed that the RDT was not sufficiently sensitive to detect malaria parasites and that it could only detect cases in which patients were seriously ill and/or with high parasite density. Between 1 and 4 cross $(+)^4$ signs are often used by laboratory technicians to indicate the density of parasites detected under a microscope using magnification between 500 and 600 times (Bruce-Chwatt 1985). Health workers believed that the RDT was only able to detect cases with three or four crosses, but not one or two.

> ''For me, RDT, it is not effective. Because sometimes when patients come, you see clinically [that it is] really malaria, but when you check it, it is always negative.'' (Nurse at CHC)

> ''RDT can only detect when it is [microscopically] positive +++ and ++++, but it can't detect + and ++.'' (Laboratory analyst at CHC)

This suggested that health workers did not have confidence in the RDT because of their reliance on clinical symptoms and signs.

Practicality and patients' preferences dictating prescribing behaviour

Although the new MTP recommends AL for treating *P. falciparum*, in practice it appears that patients' preference for a short course of treatment and doctors' opinions on AL also contributed to the continued use of SP.

> ''In my experience, usually patients want a short treatment; because of short therapy, of course Fansidar has to go first. For those that are not tolerant of Fansidar, for example [they experience] headaches and [feel] dizzy after taking Fansidar, or perhaps they have tried Fansidar and failed, for this then we would go to Coartem®.'' (Doctor at the National Hospital)

> ''People take Fansidar because it is practical, three tablets, that's it.'' (Doctor at the Regional Hospital)

Health workers continue to use SP given its convenience and general acceptance by community members. The two quotes above were from doctors; they may influence other health workers, especially nurses and midwives.

Lack of experience of expatriate doctors in treating malaria

Timor-Leste has had a large Cuban Medical Brigade working in the country since 2004. From 2005 to 2011, there have been more than 200 medical doctors working in the CHCs and hospitals. Cuban doctors acknowledged that they were unfamiliar with treating malaria, but when they did, they used CQ and SP.

> ''Well, one experience we have here is to do with treating malaria because in Cuba, it is not an illness frequently found, we do not have malaria cases in Cuba. The first time treating malaria is here in Timor . . . since we work here we use SP and Chloroquine, and they give result[s] to patients.'' (Cuban doctor working at Regional Hospital)

> ''I am from the pharmacy [department]; so far the use of Coartem is not very much. They use more SP and Chloroquine, Dr M [Cuban doctor] always gives SP and Chloroquine.'' (Pharmacist at Regional Hospital)

This lack of adherence to treatment guidelines by foreign doctors and health workers resulted from their not being included in the socialization activities and was another barrier to implementing the new MTP.

Central Medical Store (SAMES) constraints in supporting implementation

Despite having autonomous status, SAMES has not operated entirely autonomously; rather it is centrally managed by the government (República Democrática de Timor-Leste 2004). This gave little flexibility for SAMES to separately procure drugs (including antimalarials) in a timely manner and thus created obstacles to successful drug procurement.

There was also poor communication between the Department of Communicable Disease Control in the Ministry of Health and SAMES regarding drug procurement. The Ministry of Health could have advised SAMES to begin procuring AL before the MTP was approved, but instead the Ministry relied on AL donated by WHO during the period of instability in 2006 (Martins *et al.* 2009). Later on, SAMES procured AL under a different brand name, Riamet®, from Australia. However, health workers did not want to use Riamet®, because the name was different from Coartem®, and thus was not recognized by them, even though both Coartem® and Riamet® have the same content. The use of trade-name brands created difficulties because Coartem® can only be accessed through WHO procurement channels—the Novartis Pharma AG. The advantage of procuring Coartem® via WHO was that it provided a lower price for supply to the public sector in malaria-endemic countries (Mutabingwa 2005; Bosman and Mendis 2007). For example, when Coartem® was accessed through WHO and Novartis, the price was US$2.40 for an adult treatment dose, but when AL was packaged by other manufacturers the cost could be as high as US$12.00 in endemic countries (WHO 2003).

No clear policy of involving private health facilities in the implementation

With the exception of the Bairo Pite Clinic, one of the not-for-profit private clinics in Dili, all private clinics continued to use SP because they did not have access to both AL and RDTs. The Bairo Pite Clinic was an exception because it receives its supply of AL and RDTs from abroad. At the time of fieldwork there was no government policy on the provision of AL to private clinics.

Policy makers recognized that private clinics should also have access to the revised MTP, but were concerned about whether or not the publicly-funded drugs could be used by the private sector for profit.

> *"The concern was that we would not have a scheme to ensure that publicly funded medicines were not charged when we give to the private sectors."* (Minister for Health 2001–2007)

The private sector argued that they also served the Timorese population, so they too should be provided access to the new anti-malaria drug. The private sector actors were willing to purchase the drug if the government made it available.

> *"For me, this [AL] belongs to government, why don't they give it to private facilities, because we also provide service to everyone? This new drug, it is better to give to private clinics also in whatever way, if they want us to buy, we would buy it."* (Church-run clinic)

Following up the implications of treatment change for all actors in the sector is clearly required.

Discussion

Despite the official adoption of the revised MTP, an increasing uptake of AL utilization and health workers' positive impressions about the protocol, implementing it presented challenges. Analysis is limited to assessing the obstacles in the implementation of the new MTP 6 months after its introduction (January–June 2008). The discussion highlights five issues for consideration:

- Management issues impeding treatment protocol implementation;
- Centralization of procurement and the use of trade name Coartem® impeding protocol implementation;
- Problems relating to prior prescribing behaviour habits;
- Problems of adherence to the treatment protocol by foreign health workers;
- Lack of consideration of private health facilities in the implementation of the treatment protocol.

Management issues impeding treatment protocol implementation

Management issues identified as barriers to revised treatment implementation were inadequate socialization, no clear policy on phase-in of AL and phase-out of SP, untimely supply of RDTs and AL, lack of information about the RDT's effectiveness, and a lack of monitoring.

Socialization is an important aspect of introducing a proposed change and provides an opportunity for health workers to understand the rationale and purpose of the change. In Timor-Leste's case, the new MTP had been insufficiently socialized which led to poor implementation. This was in contrast to Kenya and Zambia, where cascade training was effectively conducted by national experts with health workers at lower levels of the health system (Amin *et al.* 2007; Sipilanyambe *et al.* 2008). This cascade training facilitated the implementation of the new treatment protocols in both countries. Had the training plan proposed by the MTP socializers in Timor-Leste been implemented as planned, it could have addressed the concerns raised by some health workers at the health facility level and thus helped the MTP implementation.

Unclear phase-in and phase-out strategies jeopardized MTP implementation, which can be noted from the Ministry of Health's two letters addressed to all health facilities in January and March 2008 requesting them to implement the new MTP. However, this was not followed with an effective supply of AL and the withdrawal of SP. The availability of SP in health facilities meant health workers could continue to use SP. In Kenya, the continued availability of the previously recommended drugs affected utilization of the new treatment regime (Zurovac *et al.* 2004). This situation deteriorated further through the untimely supply of AL and RDTs to health facilities which led to stock-outs. The stock-outs of AL and RDTs, and discovering expired AL in the surveyed health facilities, clearly demonstrated weaknesses in the supply system and a lack of effective monitoring. A consistent lack of drug supplies has been documented elsewhere as one of the factors contributing to health workers not using the recommended anti-malarial drugs (Williams and Jones 2004; Wasunna *et al.* 2008). Addressing stock-outs requires an ability to make an accurate prediction of needs and to meet requests in a timely fashion.

Attention needs to be directed towards understanding what happens once guidelines have been changed and how the new guidelines are to be implemented. Inadequate monitoring and

Table 3 Summary of comparison between a 'perfect implementation' against the 'reality' of the 2007 Malaria Treatment Protocol (MTP) implementation

Perfect implementation (idealized situation)	Reality with the 2007 MTP implementation	Comments and limitations observed
Preparatory steps		
Write and disseminate all relevant 'policy documents'	Yes	The MTP was written and distributed to health facilities
Develop and pre-test all training materials	No	Not done
Sensitize and train public and private health care workers	Partially implemented	Equivalent to socialization of the MTP
Sensitize consumers and media about the impending changes	No	No public awareness and media campaigns conducted
Ensure sufficient drugs supplies and distribution to the periphery	Partially implemented	Initially the MoH only relied on WHO donation of AL
Mobilize adequate resources	Partially implemented	Only WHO mobilized resources, only later followed by the MoH, which meant there was a gap in AL procurement
Plan and officially launch the new policy	Yes	Launching of the new MTP by Minister for Health on 12 June 2007
Implementing the policy		
Publicize the date by which the replacement drug/s is/are to be introduced	No	The actual date of the replacement of SP with AL was not set, nor was a clear date established for the withdrawal of SP
Use the media to assist in delivering public health messages that communicate the change	No	No media campaigns were conducted
Begin site visits to ensure that the process of implementation is underway	Partially implemented	Visits were conducted in an unsystematic way
Encourage and acknowledge good performance by health workers	No	Not done
Rapidly address problems that are detected, for example, site-specific re-training	No	Not done
Monitoring and evaluation		
Identify, in advance, indicators that will measure success, in terms of process and public health impact	No	No indicators were set
Institute timetable for periodic monitoring of indicators	Partially implemented	No periodic timetable was set. At the time of fieldwork, the MoH and WHO began ad hoc supervisory visits.

Source: Adapted from Williams *et al.* (2004).

Notes: MoH = Ministry of Health; WHO = World Health Organization; AL = artemether-lumefantrine; SP = sulphadoxine-pyrimethamine.

supervision leads to improper application of treatment guidelines (Williams and Jones 2004). Up until the time of fieldwork, only one of the seven districts had actually been visited by the national supervision team. A lack of monitoring at all levels hampered the MTP implementation, at least during the first 6 months.

Table 3 summarizes an ideal situation for a 'perfect implementation' of any treatment protocol (Williams *et al.* 2004) vs the reality that unfolded in the implementation of the MTP in Timor-Leste. Many of these idealized steps for a successful policy or treatment protocol implementation were not followed.

Another issue impeding MTP implementation was the lack of understanding about the RDT, which contributed to the misinterpretation of RDT results. Examination with light microscopy has always been regarded as the gold standard for malaria detection. However, in low resource settings, microscopes may not be available at smaller health facilities, or they may be available but skilled laboratory staff to utilize them are lacking. RDT was developed to bridge this gap. The RDT is known to be capable of detecting parasites when density reaches ≥ 100 parasites/µl (Guerin *et al.* 2002; Moody 2002); it is quite sensitive and may remain positive even if the parasites have been cleared from the blood stream (Moody *et al.* 2000; Moody 2002; Wongsrichanalai *et al.* 2007). This study found that health workers used the RDT incorrectly as a means of assessing the 'parasite clearance', which can result in a false impression that AL was ineffective. This misinterpretation of RDT results needs to be adequately addressed in order to assist MTP implementation.

Problems relating to changing the behaviour of health staff

Prescriber adherence to treatment protocols is a crucial factor for the success of any new drug policy. Many studies have

shown that health workers often fail to comply with treatment guidelines (Ofori-Adjei and Arhinful 1996; Paredes *et al*. 1996; Zurovac *et al*. 2004; Ngasala *et al*. 2008). Multiple factors influence the prescribing behaviour of health workers, including physician expertise and clinical competence, drug use practices, poor diagnostic support, perceived effectiveness, side effects, the patient's conditions, patient preferences, the patient's demands/pressures and peer group pressure, and cost-related issues (Brugha and Zwi 1998; White 1998; Bloland and Ettling 1999; Cantrill 2000; Rowe *et al*. 2005; Klein *et al*. 2006; Chandler *et al*. 2008).

Introduction of the MTP required a change in the clinical behaviour of health staff to implement the new policy. Challenges in accepting new practices are an important factor leading to health workers' resistance to change. The availability of the previously recommended drugs was an obstacle as there was a tendency for health workers to revert to a clinical diagnosis when the RDT was out of stock. On other occasions, health workers continued to use SP when stock was available or when they suspected malaria although the RDT result was negative. Accurate knowledge of the RDT, adequate supplies and drug stocks should be ensured to prevent health workers reverting to their previous practices. Providing a supportive and well-resourced environment would encourage health workers to change their behaviour and enable them to implement the MTP.

Difficulty integrating foreign health workers into national treatment protocols

This study found that Cuban doctors, providing valuable support to the health system, were less likely to adhere to the new MTP and that they lacked experience of treating malaria. This was because malaria has been eradicated in Cuba; WHO-PAHO 2001 recorded no indigenous cases of malaria in the period 1992–1996 (WHO 2001).

In Timor-Leste, Cuban doctors were provided with a 2-week orientation prior to deployment to rural postings. This orientation covered the country's political and economic situation, culture, language and also health policies including treatment guidelines (MTP included). The lack of adherence to treatment protocols, at least for malaria, suggests that the orientation has not helped foreign health workers comply with some of the Ministry of Health guidelines. An earlier study also documented the lack of trust expressed by some patients towards the Cuban Medical Brigade due to their unfamiliarity with local diseases and treatment (Zwi *et al*. 2007). It is important to ensure that development partners, providing valuable support, utilise and reinforce national treatment guidelines and standards.

Centralization of procurement and use of trade name Coartem® impeding protocol implementation

Complexities in procurement including the central management of SAMES and the use of Coartem® instead of its generic name 'artemether-lumefantrine' further undermined the policy changes. Centrally managed procurement meant SAMES did not have the flexibility to initiate the procurement process without first receiving authorization from the National Procurement Office. The use of the trade name Coartem® also restricted the ability of SAMES to access other suppliers. The Ministry of Health should consider changing the drug name

from its trade name, Coartem®, to 'artemether-lumefantrine' in the current MTP.

Lack of consideration of private health facilities in implementing the treatment protocol

Despite limited development of the private health sector in Timor-Leste, private health care providers should still be considered in policy implementation in key health areas, including the implementation of treatment protocols.

At the time of the study, there had not been any policy directions to incorporate private clinics into the revised MTP. Concerns surrounded how the use of publicly funded medicines by the private sector could be justified. However, there should be mechanisms to allow the private sector to access RDTs and AL. During the time of the fieldwork, discussion between the Ministry of Health, WHO and the private sector was underway to define appropriate policy and to find ways for the private sector to be involved.

Evidence from the literature suggests that private health providers in low-income countries often lack the ability to deliver a range of services and yet are often perceived to be more attractive to patients (Brugha and Zwi 1998). Excluding the private sector from implementing the MTP will only deny access to proper treatment of malaria to some people who seek care at private health facilities. It also sends a message that the government is competing with private facilities, which undermines the government's efforts to ensure improved and standardized practices by all providers in all health facilities.

Study limitations

The mixed methods approach provided a clear understanding of problems related to the implementation of the new MTP from both qualitative and quantitative aspects. Views from policy makers have been captured at national level and from health workers at district level. Staff at both public and private health facilities have reflected on the implementation of the MTP. However, this research did not include views from malaria patients and the wider community regarding their experience with AL. Funding limitations and time constraints prevented researchers from including the community in this study. Future research should examine community and patient acceptance.

Conclusion

The implementation of the new MTP was hampered by several factors, including inadequate socialization, unclear phasing in of AL and phasing out of SP, a lack of understanding about the RDT procedures, untimely supply of AL and RDTs, lack of supervision, resistance from health workers to change from SP, lack of adherence by foreign health workers, lack of access to the new drug by the private sector, obstacles in the procurement process, and the use of trade names.

For effective implementation of the MTP, the above-mentioned barriers must be taken into consideration during policy formulation and should be addressed during implementation. This requires policy makers and implementers to develop a robust implementation plan.

Timor-Leste's experience has provided important lessons regarding the presence of and need to address these potential

barriers. Failure to do so will undermine the successful implementation of revised treatment protocols.

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Competing interests

The authors have no competing interests to declare.

Endnotes

[1] This is very different from the literature where socialization is defined as the process by which individuals become members of a society (Partington 2004).

[2] A paper evaluating the implementation of the Global Fund grant from 2003–2006 is in preparation. Given that many of the districts and services examined had received Global Fund support and resources, they are likely to reflect better rather than poorer experiences amongst the districts.

[3] Coartem® is the trade name for artemether-lumefantrine.

[4] The sign+ indicates the density of parasites when detected under microscope (Bruce-Chwatt 1985): $+ = 1$–10 parasites per 100 thick film fields; $++ = 11$–100 parasites per 100 thick film fields; $+++ = 1$–10 parasites per one thick film field; $++++ = >10$ parasites per one thick film field.

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