The process of changing national malaria treatment policy: lessons from country-level studies

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Widespread resistance of *Plasmodium falciparum* parasites to commonly used antimalarials, such as chloroquine, has resulted in many endemic countries considering changing their malaria treatment policy. Identifying and understanding the key influences that affect decision-making, and factors that facilitate or undermine policy implementation, is critical for improving the policy process and guiding resource allocation during this process. A historical review of archival documents from Malawi and data obtained from in-depth policy studies in four countries (Tanzania, South Africa, Kenya and Peru) that have changed malaria treatment policy provides important lessons about decision-making, the policy cycle and complex policy environment, while specifically identifying strategies successfully employed to facilitate policy-making and implementation. Findings from these country-level studies indicate that the process of malaria drug policy review should be institutionalized in endemic countries and based on systematically collected data. Key stakeholders need to be identified early and engaged in the process, while improved communication is needed on all levels. Although malaria drug policy change is often perceived to be a daunting task, using these and other proven strategies should assist endemic countries to tackle this challenge in a systematic fashion that ensures the development and implementation of the rational malaria drug policy.

Key words: malaria, drug policy, treatment policy, treatment guidelines, policy development

Introduction

The formulation and implementation of ‘rational’ malaria treatment policies presents a challenge for most endemic countries. For many of these countries, chloroquine (CQ) has been the drug of choice for first-line treatment of uncomplicated *Plasmodium falciparum* malaria for many decades. Widespread chloroquine resistance in *P. falciparum* parasites has resulted in Ministries of Health contemplating the need to introduce new malaria treatment policies.1 Rational policy formulation and implementation entails an inherently complex and often daunting process requiring: (1) collection of scientifically valid evidence, (2) presentation of this evidence in a manner that will garner political attention, (3) consensus-building about the need for a change, (4) drafting a new policy that is consistent with the specific national drug policy framework, (5) implementation of the new policy, and (6) monitoring and evaluation to inform subsequent policy development.

Identifying and understanding the key influences that affect decision-making, and factors that facilitate or undermine policy implementation, is critical for improving the policy process and guiding resource allocation during this process. Given the limited spectrum of antimalarial options currently available, and the compelling arguments for using combination therapies despite greatly increased costs and more complex treatment regimens, this is an ideal time to examine the context in which decisions to change policy occur, particularly from the perspective of involved stakeholders, conditions under which changes are deemed warranted, challenges that countries face during the formulation and implementation process, and strategies that appear to facilitate the process of change.

This paper examines the decision-making process in formulating and implementing national malaria drug policies, discusses the policy cycle with particular reference to malaria treatment guidelines, and highlights additional complex issues. As there is currently no template for understanding how the process occurs at an operational level and a dearth of literature about the process of malaria treatment policy change, a descriptive approach is adopted, using illustrative data from policy research conducted in Tanzania, South Africa, Kenya and Peru, and a historical review of archival documents from Malawi. Similarities across countries are examined and elements that are context-specific identified, with the primary focus being on that portion of the policy cycle from decision-making to implementation of treatment policy change. We offer a number of recommendations that should be considered by countries facing the challenge of developing new malaria treatment policies.

Background

Definition of national antimalarial treatment policy

Ideally, a national antimalarial treatment policy should consist of evidence-based recommendations on the rational use of available antimalarial drugs in that country, with clear guidelines for health care workers providing early diagnosis and prompt treatment (WHO 1994). The focus of this policy is to guarantee access to antimalarial drugs that are safe, affordable, effective, acceptable and of good
quality for community members infected with malaria (WHO 2001).

Considerations when changing treatment policy

While the components of rational policy have been delineated, little is known about the process of decision-making for selecting a replacement drug and altering national malaria treatment policies. Documentation describing how specific countries have addressed this challenge is limited, although attention has recently been focused on gaining an improved understanding of the process (Shretta et al. 2000; Williams et al. 2001, 2002; Kamya et al. 2002; Durrheim et al. 2003). Treatment efficacy studies have historically provided the primary data used to justify malaria drug policy changes (Ringwald et al. 2002). However, there is an emerging recognition that efficacy data, although a necessary component for deciding effective treatment policy, are not alone sufficient or necessarily the primary factor driving the decision to change (Barat et al. 1998; Bloland et al. 1998; Fevre and Barnish 1999; Shretta et al. 2000; EANMAT 2001; Kamya et al. 2002; Williams et al. 2002; Durrheim and Williams in press).

Policy is usually determined through complex interactions among key stakeholders, including public agencies, private market sector, consumers, regulatory agencies and the scientific community. Important influencing factors include perceptions of policy legitimacy, support/opposition from competing interest groups, degree of congruence with existing values, perceived logistical feasibility, and anticipated future benefits/costs if adopted (Bloland and Etting 1999). The weighted influence of each factor is not known but clearly varies between situations. Health policy analysts have been criticized in the literature for ignoring the profoundly political nature of change and for only providing prescriptive suggestions for changing policy, without including information on the process of change or reasons for policy reform failures or success (Walt and Gilson 1994; Reich 1995). Robust analytical frameworks that capture the complexity of the context in which policy is to be applied are not yet available (Atun et al., in press).

Many countries are currently considering changing their malaria treatment policies as the association between drug resistance and malaria mortality is now widely acknowledged and artemisinin-based combination therapy is becoming more generally available to Ministries of Health. Decisions are being made regarding this more expensive treatment, with its complex dosing regimens for first-line treatment of uncomplicated malaria, without proper consideration of the context in which it will be deployed, and this might seriously compromise its field effectiveness (Bloland et al. 2003). Policy context, process, content and the actors involved are all critical elements of the health policy cycle and deserve careful consideration when contemplating malaria treatment policy changes (Walt and Gilson 1994). Unfortunately, a detailed discussion of all of these factors is beyond the scope of this paper but a non-exhaustive catalogue is provided (Table 1). It is pertinent to briefly discuss selected important factors.

Political climate

An understanding of formal and informal power and influence pathways (both public and private) is critical, as policy will not progress unless it is on the political agenda. Availability of donor money, global/national importance of the specific health condition, political stability within a country, competing health and other priorities, differential influence of the Ministry of Health (MoH), previous policy success, and opportunistic timing, all influence receptiveness. Politicians’ personal values and other potential conflicting interests, for example the pharmaceutical industry’s profit motive, may also influence policy success (Zuma 1997). Systems of political governance and the degree of decentralization are additional influential factors.

Fluidity of national borders

The degree to which drugs and people move across national borders can impact on drug policies, particularly during implementation. This may be through illegal drug leakage from a neighbouring country or cross-border migration of displaced persons or itinerant labourers. Ability to access non-registered drugs may influence both provider and consumer drug practices.

Efficacy and effectiveness

Attention to date has primarily focused on antimalarial efficacy studies, rather than effectiveness studies. Given the complexity of the factors listed in Table 1, greater attention needs to be placed on operational effectiveness. Designing rational and appropriate antimalarial drug policy does not guarantee proper use of antimalarials by providers, dispensers or consumers. Acceptability to users and ability of all levels of health care provision (including the most peripheral) greatly influence the effectiveness of policy implementation.

Health care systems

The track-record of health care systems, both public and private, in delivering basic services parallels their ability to implement malaria drug policies (Moerman et al. 2003). Resource constraints may result in countries using drugs with limited effectiveness (Haak 2002). The system must be robust enough to adequately diagnose, correctly prescribe, treat and refer patients, and properly monitor and respond to adverse events. Clandestine economic activities (such as drug supply leakage, informal patient charges, mismanagement of collected user fees) within the public health care system can negatively influence the success of malaria treatment policies and health system credibility (McPake et al. 1999).

Cost

Table 1. Factors influencing development and implementation of rational malaria treatment policies

<table>
<thead>
<tr>
<th>Political</th>
<th>Legal</th>
<th>Socio-cultural</th>
<th>Economic</th>
<th>Biomedical/Technological</th>
<th>Environmental/Epidemiological</th>
<th>Health systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procurement*</td>
<td>Regulatory issues*</td>
<td>Access to prevention, diagnosis, and treatment*</td>
<td>Costs of replacement drug(s)</td>
<td>Therapeutic efficacy</td>
<td>Local transmission patterns</td>
<td>System of training health care workers: public and private; lack of continuing education systems Access to prevention, diagnosis and treatment</td>
</tr>
<tr>
<td>Fluidity of national borders*</td>
<td>Procurement</td>
<td>Acceptability of preventive strategies and treatments</td>
<td>Costs of removing former 1st line drug</td>
<td>Programmatic effectiveness</td>
<td>Drug pressure</td>
<td></td>
</tr>
<tr>
<td>Political stability and climate</td>
<td>Legal trade restrictions</td>
<td>Drug-use practices: both providers in public and private sector and consumers</td>
<td>Availability of drugs</td>
<td>Regulatory status of former 1st line drug</td>
<td>Local epidemiological context</td>
<td>Availability of drugs</td>
</tr>
<tr>
<td>Informal system of power and influence: social networks*</td>
<td>Fluidity of national borders</td>
<td>Treatment seeking behaviours (other than drug use practices)</td>
<td>Procurement</td>
<td>Whether or not former 1st line drug remains in private sector</td>
<td>Presence of displaced populations</td>
<td>Scale of private sector involvement</td>
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<tr>
<td>Formal system of power and influence*</td>
<td>Degree of health sector reform and decentralization</td>
<td>Informal system of power and influence: social networks</td>
<td>Private sector influences</td>
<td>Safety of drug</td>
<td></td>
<td>Formal MoH system of organization</td>
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<tr>
<td>Degree of health sector reform and decentralization*</td>
<td>Impact of special interest groups</td>
<td>Availability of drugs*</td>
<td>Drug use patterns</td>
<td>Changes to National Formulary and Essential Drug Lists</td>
<td>Drug distribution</td>
<td>Attrition rate of personnel</td>
</tr>
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<td>Length of time needed for policy change*</td>
<td>Legal category of drug</td>
<td>Lack of confidence in public health care sector</td>
<td>Replacement drug selection*</td>
<td></td>
<td></td>
<td>Funding allotted to MoH and NMCP</td>
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<tr>
<td>Competing priorities: national and local*</td>
<td>Structural Adjustment Programmes*</td>
<td></td>
<td>Competing health priorities: HIV/AIDS pandemic, burgeoning epidemic of non-communicable diseases</td>
<td>Replacement drug selection</td>
<td></td>
<td>Monitoring of regulations</td>
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<td>Impact of special interest groups*</td>
<td></td>
<td></td>
<td>Vested interests of pharmaceutical industry</td>
<td>Ability to produce quality product locally for own use and export</td>
<td></td>
<td>System of drug distribution</td>
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<tr>
<td>Status of NMCP within structure of MoH</td>
<td></td>
<td></td>
<td>Structural Adjustment Programme</td>
<td>Diagnostic requirements and capability</td>
<td>Quality control of drugs</td>
<td>Degree of decentralization</td>
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<td>Status of MoH in relation to other Ministries in government</td>
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<td>Poor morale of health care workers</td>
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<td>Vested interests of pharmaceutical industry*</td>
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<td></td>
<td>Deficient management skills (especially in terms of drug management)</td>
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* Issues that are cross-cutting and appear in several areas. Note: asterisk is used once per item. NMCP = National Malaria Control Programme; MoH = Ministry of Health.
countries may be loath to waste medication. For countries replaced can impede the adoption of its replacement, as specific tender system. Remaining stocks of the drug to be to political and legal issues, including the nature of the Factors relating to procurement are diverse but closely linked involved at an early stage in this process.

sentatives from pharmaceutical and therapeutics committees new drugs must be incorporated into the standard treatment costs in busy primary health care facilities. Once selected, the and potential adverse events, with attendant opportunity may require additional health worker time for explaining use effect on local malaria transmission. More complex regimens may require additional health worker time for explaining use and potential adverse events, with attendant opportunity costs in busy primary health care facilities. Once selected, the new drugs must be incorporated into the standard treatment guidelines, essential drug lists and formularies, with representatives from pharmaceutical and therapeutics committees involved at an early stage in this process.

Replacement drug selection
The selection of replacement drugs should be guided by safety (particularly for vulnerable populations), therapeutic efficacy, cost/affordability, availability, simplicity of regimen and potential for widespread use (Bloland and Ettling 1999; WHO 2003). The useful therapeutic life of a drug needs to be considered, particularly given the length of time needed for full implementation and the costs involved in changes. Additional considerations include impact on other health programmes, interaction with other therapeutic agents, and effect on local malaria transmission. More complex regimens may require additional health worker time for explaining use and potential adverse events, with attendant opportunity costs in busy primary health care facilities. Once selected, the new drugs must be incorporated into the standard treatment guidelines, essential drug lists and formularies, with representatives from pharmaceutical and therapeutics committees involved at an early stage in this process.

Procurement and new drug introduction
Factors relating to procurement are diverse but closely linked to political and legal issues, including the nature of the specific tender system. Remaining stocks of the drug to be replaced can impede the adoption of its replacement, as countries may be loath to waste medication. For countries that treat large numbers of non-falciparum malaria patients (such as the Amazon Basin), remaining CQ stocks may be used for these cases (assuming adequate levels of efficacy and the ability to distinguish between parasite species). In most endemic areas of Africa, a decision must be made whether to remove the drug from public health facilities. Physical removal is preferable, but this requires a considerable commitment from the health care system to manage the process, and to accept the cost of disposal. Other countries have elected to make the former drug available by prescription only. Another strategy that has been discussed repeatedly is the possible donation of CQ to countries that still rely on it for first-line therapy. Attempts to implement this approach between South Africa and Mozambique were thwarted by a mixture of industry and legal concerns. Even if health staff receive directives to return the drugs to the central pharmaceutical stores, they may find this difficult, as portrayed by a quote from a health care worker in an area in Tanzania where drug shortages were common (Williams et al. 2002):

“It is very difficult to sort out when you still have CQ. You have a few left and it is so difficult to be thrown out.”

Despite written guidelines, prescribers often prescribe and dispense drugs inconsistently (Gilson et al. 1994). This is particularly prevalent in the private health care system where there is little effective regulation of prescribing practices, compounded by the large variety of available drug outlets. Issues of access, rational drug use, training and drug regulation in the private market sector need consideration when changing malaria drug policies.

System of drug distribution
It is essential to include representatives from the distribution and logistics component of the MoH early in discussions about drug policy changes to ensure that the new drugs are available when needed, stock-orders are filled, and previously recommended treatment is physically removed from health facilities. Issues for consideration include distances to facilities, frequency of deliveries, vehicle maintenance, management skills in pharmaceutical stock inventory and the ability to forecast periods in which additional drug supplies may be needed, such as during epidemics (Zuma 1997).

Drug safety
Pharmacovigilance poses a huge challenge in developing countries, particularly where background disease is common (for example, nutritional disorders or HIV/AIDS), health surveillance infrastructure is poorly developed, and the disease itself causes multiple severe symptoms, complicating the interpretation of purported adverse events. Attention should be given to vulnerable populations and, although the focus should be on life-threatening adverse events, minor side effects that might influence compliance should not be neglected (WHO 2002).

The traditional incremental approach of replacing first-line drugs with second-line treatment meant that clinicians
already had some experience with the ‘new’ first-line drug and knew what to expect in regard to safety. However, with combination antimalarial therapies, clinicians have little, if any, experience with new-first-line drugs and limited post-marketing drug safety data (particularly in the high-risk groups of pregnant women and children younger than 5 years) is available (Bloland 2003). Passive surveillance systems have often failed to detect important drug-related events in developing countries (WHO 2002).

Quality assurance

Quality assurance includes the verification of good manufacturing practices (GMP), and the registration and testing of drugs, preferably to meet international pharmaceutical standards. These measures have not been enforced previously (WHO 2003), which has contributed to sub-standard and counterfeit drugs being on the market in endemic countries. Appropriate and adequate storage should be available in all health facilities.

Lead-time to policy change

Limited data have suggested that 18–24 months are necessary to change policy (WHO 2003). However, it is unclear what events anchor this time frame; does it include the time needed to gather preliminary data or does this period start from the point in time when the decision to change has been made and replacement drugs identified? As will be evident from the case studies below, this time frame appears to be an underestimate of the actual time needed from the moment awareness has been raised that a change might be necessary, to having all staff trained in the proper use of the new policy and drugs in place for treatment at the periphery. For example, in Kenya, up to 9 years elapsed between initial acknowledgement of resistance and change in malaria drug treatment policy (Shretta et al. 2000). The Democratic Republic of Congo (DRC) has been used as an example of an abbreviated policy change – initial in vivo studies were conducted in 1999 with a policy change in 2001. However, the policy change is still not fully implemented and thus the process of change remains incomplete.

Reticence to change chloroquine therapy

Despite an abundance of data suggesting that CQ began to lose efficacy in East Africa in the 1980s, most East African countries have been reticent to change their malaria drug policies. It is important to try to understand the origins of this reluctance as it may assist us in promoting more accelerated change in the future. It is also important to identify reasons why willingness to change malaria treatment may differ from other health conditions. Key issues appear to be the availability of affordable alternatives, indecision about ideal timing and an emotional historical attachment to chloroquine.

Protracted debate about the ideal timing of changing drug policy is an important constraining factor. Some countries lean toward conserving effective drugs for second-line therapy, rather than introducing them for first-line therapy and, thus, accelerating their loss due to development of resistance. The limited number of affordable alternatives available has fuelled this debate.

Economic concerns have primarily dictated choice of replacement drugs (EANMAT 2001), with few drugs considered as viable alternatives. Sulfadoxine-pyrimethamine (SP) has generally been considered the most affordable and practical option, but despite its simple regimen and low cost, change has occurred slowly. Concerns included rapid evolution of resistance to SP, lack of anti-pyretic effect, insufficient resources available to cover even a minimal increase in drug costs, and a lack of clarity on how to rationally implement new drug policies in countries where CQ was reported to have widely divergent efficacy levels. Even with widespread use of standardized World Health Organization (WHO) drug efficacy protocols in the mid-1990s, change continued to occur slowly.

In an animated 1999 meeting of scientists, clinicians and MoH representatives discussing the need to change policy in Tanzania, these issues were voiced by clinicians (as recounted by a WHO representative attending the meeting):4

“We have evidence . . . yes! But the Ministry is saying we have no choice before us as SP is not going to last; SP is too costly and we have no money. So, let us go much longer [referring to use of CQ].”

In response, another WHO representative asked:

“Are we going to look at the costs of acquiring drugs or the costs of children dying?”

There appears to be an emotional bond specifically with CQ that has not been obvious in other public health disease control programmes once long-term, trusted drugs have lost their efficacy. Whether this is related to the number of years of safe and effective CQ use, its perceived utility for a wide array of febrile illnesses, uncertainty about what drug to use and when to change, or general inertia, is not clear.

In a recent stakeholder meeting discussing drug policy changes, the comments of a WHO/Roll Back Malaria (RBM) representative clearly illustrate this conundrum:

“How can national malaria control programmes continue to use drugs with such low efficacy? No other [public health] programme does this! How can they do this for so many years? Why is it that we can spend more money on expensive drugs in every area, OTHER than malaria?”

The policy cycle

There are key steps that are necessary for a policy change to occur. Walt (1994) describes four broad stages in policy making: problem identification and issue recognition, policy formulation, policy implementation and policy evaluation (p.45). Using these basic stages and field experience as a framework, it is possible to describe more detailed sub-stages
or steps. Depending on the country, those responsible for these steps will vary, but they will usually enjoy certain formal recognition from the MoH. These steps are:

(1) Create an awareness that a change might be needed:

- Identify a ‘trigger’ to raise awareness (i.e. higher frequency of reported drug failures, pressure from donors).

“The policy process really begins when there is a sensitization to a potential problem, not when you have efficacy results.” (Comments from a donor at a South American drug policy meeting)

(2) Verify the data that triggered the concern:

- Use *in vivo* drug efficacy studies for confirming anecdotal reports of drug failures.
- Conduct a situational analysis (including data on financial, legal-regulatory, socio-cultural, disease impact, and drug effectiveness, availability and acceptability).

(3) Present data in an appropriate language and format that is understood by policy makers and implementers (who may not have a background in public health, health economics or science):

- Change from scientific to programmatic/lay language.
- Present data in a concise manner.

(4) Advocate for change [note: (3) and (4) may be reversed or run concurrently]:

- Target traditional stakeholders [such as public health officials, scientific and academic communities, political officials, affected communities, non-governmental organizations, donors, health care providers (public and private), WHO, drug manufacturers and distributors] and non-traditional (media and private drug vendors).
- Understand the political process governing the process of change within a specific government.
- Identify the optimal timing and nature of the most effective change approaches.

(5) Foster consensus-building among stakeholders that a change is required:

- Engage stakeholders in frequent, open communications about the needed change.
- Indicate the consequences of both changing and not changing policy.

(6) Identify and assess policy options, and select the most appropriate:

- Evaluate alternatives on the basis of affordability, acceptability, feasibility and likely impact (ACTMalaria 2000).
- Include options such as: (a) maintaining the current policy with no changes, (b) modifying the current policy slightly, (c) adopting a new policy, (d) adopting a transitional or provisional policy, or (e) terminating policy.

(7) Agree on the replacement drug/s:

- Evaluate possible replacement drug choices (efficacy and safety, acceptability, adherence, ease of use, formulation, packaging, adverse effects, useful therapeutic life, cost/affordability, use in young children and pregnant women, ability to reduce transmission or slow development of resistance, storage requirements).
- Determine whether the replacement drug is an interim choice or a longer-term option.
- Determine the health service levels at which the drug will be available.

(8) Agree on a time-line for change:

- Ideally this should be formalized.
- To ensure credibility, this time-frame should be realistic.

(9) Develop the policy document, including ancillary documents:

- Specify who is responsible for particular activities.
- Decide on which ancillary documents are needed: implementation plan (with associated budget), monitoring and evaluation plan, standard treatment guidelines, National Formularies, training materials (for both public and private sector), public awareness materials (including press releases), and public health education materials.

(10) Complete all preparatory steps for implementation:

- Write and disseminate all relevant documents.
- Develop and pre-test all training materials.
- Sensitize and train public and private health care workers.
- Sensitize consumers and the media about the impending changes.
- Ensure sufficient drug supplies are available and distributed to the periphery.
- Finalize necessary legal-regulatory actions and obtain official sanctioning of the proposed changes.
- Mobilize adequate resources.
- Plan an official launching of the new policy.

(11) Implement policy:

- Publicize the date by which the replacement drug/s is/are to be introduced.
- Use the media to assist in delivering public health messages that communicate the change.
- Begin district site visits to ensure that the process of implementation is underway.
- Encourage and acknowledge good performance by health workers.
- Rapidly address problems that are detected, for example site-specific re-training.
(12) Monitor and evaluate implementation:

- Identify, in advance, indicators that will measure success, in terms of process and public health impact.
- Institute a timetable for periodic monitoring of indicators.

(13) Plan for next policy cycle [should be done in concert with (12)]:

- Use monitoring and evaluation data for assessing achievement of policy goals.
- Gather additional data as needed.
- Determine whether an updated or complete revision of the policy is warranted (ACTMalaria 2000).

It should be noted that the policy cycle is not linear, but rather an iterative process. Steps may be missed, stalled while awaiting consensus, or re-visited with the availability of new information or in response to pressure from an unexpected source. Some countries adopt interim policies while gathering additional data to inform a subsequent policy (Bloland 2003).

Case study methods

Attempts to examine the process of decision-making as it relates to changing national malaria treatment policy are limited, with studies conducted in only a few countries. This paper collates and briefly summarizes important findings from various malaria treatment policy studies [Shretta et al. 2000; Williams et al. 2001, 2002; Durrheim et al. 2003; Williams, unpublished data (Tanzania); Williams and Vincent-Mark, unpublished data (Peru)]. Historical documents (particularly Steketee et al. 1995) were reviewed to compare strategies and lessons learned from earlier policy changes in Malawi, as none of the authors had personal experience of the Malawi change. During the preparation of this paper, the lead author consulted colleagues who have had direct field experiences in various malaria-endemic countries, WHO/RBM and WHO regional offices, to provide specific information about malaria drug policies in different countries.

After receiving human subject approval and obtaining consent from participants within each individual policy study, data were obtained by a variety of methods: individual and focus group interviews, review of historical documents describing or used to inform the malaria drug policy process, and participatory methods (such as ‘time lines’). Individual and focus group interviews were conducted with key informants selected through a combination of purposive sampling (choosing participants who met a pre-defined purpose – in this case, involvement and/or information about the country-specific policy change) and ‘snowball’ sampling (using participants to identify other key individuals involved in the process). In a narrowly defined situation with a minimal number of key actors involved in the process, such as changing policy, this is an effective way to build an exhaustive sampling frame (Bernard 1994). Malawi, Tanzania, South Africa, Kenya and Peru are used as case studies to capture the variety of social, economic, epidemiological and political contexts in which malaria treatment policy changes occur. These countries were selected due to the availability of descriptive data, with data reviewed for similarities and differences by the authors, who have studied the drug changes in these countries. Unless otherwise specified, themes in the data reflect findings across the countries. Direct quotes from the policy studies and field experiences of the authors and other colleagues are used for illustrative purposes.

Brief summaries of countries studied

Malawi

Malawi is an example of a country that has attempted to institutionalize malaria control capacity at local and national levels, following the development of a national policy, operational plans, treatment and prevention guidelines, and a National Malaria Program between 1984 and 1993.

The process of changing malaria drug policy from CQ to SP occurred from 1991–93, with efficacy and supplemental data used to advocate for change. Meetings early in the process included a wide array of stakeholders, including representatives from private sector pharmaceutical companies. Briefings and sensitization of district health management teams occurred prior to implementation. Other Ministry Heads and the press were invited to the national launch of the new treatment guidelines.

Three important lessons can be gleaned from Malawi: (1) collecting standardized data attracted and sustained the participation of key stakeholders; (2) the dual process of programme-relevant research and programme development ensured that operational research supported malaria programme development; and (3) development of malaria control infrastructure and management capacity was best addressed by training health staff (Steketee et al. 1995). Malawi clearly recognized the need for inclusion of key stakeholders early in the process, collected appropriate data to convince stakeholders that a change was necessary, and carefully devised an implementation plan that included investing in health infrastructure and personnel so that the policy change could be sustained over time.

Tanzania

Although drug resistance studies began to document CQ resistance in the early 1980s, the process of changing policy did not progress until a pivotal meeting of MoH representatives, scientists, stakeholders, clinicians and WHO representatives in May 1999. Despite repeated previous presentations of scientific data arguing for change, those studies had been conducted in an ad hoc and isolated manner, and results were not aggregated. There was distrust of data, compounded by little communication among the scientific community, control staff and MoH officials. Allegations of pharmaceutical company influence were levied against some scientists, and the media provoked an ongoing debate over the loss of CQ. At this meeting, scientists presented findings from studies in sentinel sites that had used WHO-approved standardized
protocols and, for the first time, a discussion could occur from a national perspective, rather than for individual sites. Consensus was reached on the need to change and on the choice of replacement drugs. The process that ultimately resulted in the change of policy was clearly guided by a small number of individuals who were involved in different ways with malaria (research, technical advice, programme responsibilities). Task Forces were developed after the 1999 meeting to plan implementation. National implementation of SP occurred in August 2001.

Challenges that confronted Tanzania included: little guidance on how to determine ‘success’ (which resulted in insufficient funding for monitoring/evaluation); conducting national implementation in the context of health system decentralization; advocating for change using scientific findings presented in technical research language that was not completely understood by policy makers; and continued strong sentiment from certain clinicians that the proposed change was premature as CQ was still anecdotally effective in some geographical locations.

Scientists recognized that they needed to be more active in the decision-making process and the dialogue among stakeholders improved over time. Health economic data supported the proposed changes, particularly by showing the consequences of not changing policy. Those involved in the change improved their understanding of the political process and used judicious timing to present data to policy makers. Other contributory contextual factors included: (1) data from neighbouring countries reflecting wide-scale CQ resistance; (2) patient complaints that CQ no longer worked; (3) a realization that clinicians had begun using other antimalarials because of concerns about patient outcomes; (4) unexpected media pressure; and (5) improved quality of scientific information. Guidance from the newly created regional East African Network for Monitoring Antimalarial Therapy (EANMAT) and WHO/AFRO were seen as critical in improving the collection of evidence-based data.

These changes produced a collaborative model with open sharing of information and ideas. The proposed changes were accepted as a necessity, despite limited continued pockets of political resistance. Thus, even though the plan was acknowledged as imperfect, an alternate drug was chosen, guidelines were labelled as transitional, implementation plans progressed, and studies were planned for testing alternative drug combinations to inform the next policy cycle. This marked a major shift from historical patterns of isolation between departments within the MoH, and between the MoH and other agencies.

Tanzania is a good example of an incrementalist model of policy making (Walt 1994; Hanney et al. 2003). The consensus for policy change occurred in numerous steps, and was influenced by a variety of factors, including scientific knowledge, consumer and media pressure, and the interests and values of selected key stakeholders. Without necessarily assuming it was the ‘best’ decision, the political environment shifted so that consensus could be reached on a decision seen as an intermediary step that could buy time to better prepare for the next change in policy.

South Africa

South Africa provides a different viewpoint from the other southeast African countries described, as South Africa has a history of decentralized malaria treatment policy with different policies in the three malaria-affected provinces. South Africa also provides a unique perspective, as the treatment policy change from CQ to SP recommended for two malaria-affected provinces, Mpumalanga and Limpopo, by the National Health Minister’s Malaria Advisory Group in 1997, was differentially implemented by the two provinces despite similar evidence of CQ failure in both areas. In one province, it was fully implemented within 6 months, while in the other province this took 4 years. This provided an opportunity to explore key factors that influenced implementation.

Several factors were identified that appeared essential for successful policy change in this setting: (1) the need for local standardized data demonstrating treatment failure was demanded by decision-makers as necessary but not sufficient to initiate change; (2) involvement of health management in endorsing the data collection plan and participation of programme staff in collecting the efficacy data (Durrheim et al. 2002); (3) appropriate presentation of this data to a limited number of key provincial policy makers (who had the power to endorse and initiate policy change) to secure support; (4) effectively communicating the potential negative consequences of not changing policy to these key individuals; (5) acquiring sanctioning from credible sources prior to the date of implementation; (6) early engagement of logistic and pharmaceutical components of the MoH to ensure effective procurement, communication and delivery; (7) physical removal of stocks of the replaced drug from public health care facilities; and (8) on-site training, encouragement and monitoring by malaria control programme personnel.

South Africa shared features with Tanzania: the recognition of the need for understandable and trusted scientific data, identification of individuals who could affect and initiate change (‘gate-keepers’), and the necessity of effectively communicating the potential negative consequences of not changing policy. In advance of implementation, necessary stakeholders who would be involved in the actual process of drug deployment and administration were involved and trained.

Kenya

CQ resistance was first reported in non-immune tourists to Kenya in 1978 (Fogh et al. 1979). Kenya experienced a long and difficult process from the initial detection of CQ resistance to the implementation of SP, which was officially launched in August 1998. Several key features characterized the 20 years following the detection of initial CQ resistant infection in Kenya to semi-effective implementation of a revised recommended first-line drug. There was confusion about what constituted ‘failure’, with uncertainty about what the public health consequences of the failure of a drug to
eliminate infection would be. Key decision-makers differed on their selection of preferred sites for monitoring treatment efficacy. It was not clear precisely how much evidence was required to change existing national recommendations: single studies or multiple studies across several epidemiological settings? The Kenyan process would have almost certainly been quicker if there were internationally agreed frameworks to follow. Delay in involving the pharmacy department and drug regulatory authorities retarded the necessary legal sanctioning of the drug policy change.

It was deduced that as policy implementation involves many parts of the health sector, it represents an iterative process that should begin well before launching a policy revision.

Policy makers expected a summary of all available information – epidemiological, social and economic – to assist in decision-making. Limited awareness of decentralized implementers, particularly the Provincial Medical Officers, almost certainly contributed to delays in the official launch of the National Guidelines. Mechanisms to communicate research evidence to those directly involved in policy development and implementation had been extremely limited, and this deficiency also contributed to the tardy policy process.

**Peru**

The epidemiology of malaria in Peru differs historically from Africa as *P. falciparum* accounted for less than 1% of all cases prior to 1990. CQ was used as monotherapy, no second-line drug was available and quinine was used to treat the few failures that occurred. However, by 1994, *P. falciparum* cases had markedly increased, with this trend continued through the second half of the 1990s.

Politically, Peru experienced some unique challenges: (1) the vertical malaria control programme was integrated into the general health services in 1995; (2) follow-up data from directly observed therapy suffered from methodological problems and were mistrusted; (3) El Ninó produced flooding with an increase in cases, accompanying intense media attention and accusations that the MoH was failing; and (4) changes in the government resulted in the MoH experiencing constant, high-level health care staff attrition rates.

Peru's approach to changing policy mirrored some of the strategies adopted in African countries, but particularly emphasized the inclusion of additional stakeholders. Multiple meetings were held to gain consensus about the change and to update stakeholders on the status of proposed changes, including an innovative evening session with the general public. The Pan American Health Organization was involved and supportive of the proposed changes, lending credibility to local researchers. Standardized WHO drug efficacy protocols were introduced, which were supplemented by data from other sectors. Peru had another unique feature in that, during the time of the change, a collaborative public health project on emerging and re-emerging infections (the 'VIGIA Project') was started, which was instrumental in building relationships between the MoH and other stakeholders. The official policy change (site-specific due to differences in transmission patterns in the endemic areas) was announced in June 2000, but due to a major disruption in government, replacement drugs did not reach the periphery until late 2001.

Those most involved in the Peruvian changes reflected on what they felt were some of the key lessons learned: (1) scientific data needed to be oriented to malaria control needs and not driven solely by researchers; (2) problems should not be presented to policy makers without solutions; (3) malaria control should be integrated into the general health care system so that clinicians can better report trends in decreasing drug efficacy; and (4) malaria control issues should be on the political agenda.

**Building on experiences**

To inform rational malaria treatment policies, it is necessary to understand the contexts in which policy is formulated, to identify successful strategies, and to keep learning from critical analyses of situations where the process has been completed or is in progress.

**Challenges**

During the process of policy change, numerous challenges arose that had to be confronted. With the exception of Malawi, there were three shared challenges faced: lack of standardized data, a lack of understanding initially on how to use research findings to influence policy, and poor communication between key stakeholders. In addition, other challenges were faced in individual countries.

(1) **Lack of standardized data on drug resistance**

Countries faced the problem of having efficacy data collected in a haphazard manner, often employing different methods. This was clearly a problem in Tanzania, Kenya and Peru, and the consequences were that data were distrusted, with resultant delays in the process of change. Many countries lacked a system of sentinel surveillance acceptable to key stakeholders. The problem of non-standardized data has previously been noted in the literature (Bloland et al. 1998; Shretta et al. 2000; Durrheim et al. 2001; WHO 2003). In the case of Kenya and Limpopo Province, South Africa, it was not clear how much evidence was needed to guide or initiate a change (Shretta et al. 2000). In addition, when results were presented from isolated studies, conclusions were often viewed with distrust and considered invalid, resulting in long delays while researchers argued the actual status of resistance (EANMAT 2001).

There are currently no clear guidelines on how to spatially and temporally compare resistance data, particularly as the standard for measuring resistance has varied over time between parasitological and clinical resistance. Uganda recently agreed to a regional policy change, but 6 months later amended it as a provisional policy for use in the entire
country, illustrating the current confusion in addressing geographical variations in resistance (Kamya et al. 2002).

(2) Difficulty translating evidence into rational policy
The emphasis on evidence-based policy and health services research has only occurred within the past decade, and much of this emphasis has been in developed countries. In most developing countries, there is no norm for research communities to communicate their findings with the public, health care professionals or policy makers (Trostle et al. 1999; Kitua et al. 2000). In many settings, suspicion and even animosity remain between research institutions and policy makers. In spite of the voiced interest in applying research to policy and practice, little is known about the impact of health services research on the policy-making process, improvements (such as better communication among researchers and policy makers) remain to be made, and there are limited empirical data to support commonly held beliefs about facilitators of, and barriers to, the use of evidence by policy makers (Shortell and Solomon 1982; Sauerborn et al. 1999; Innvar et al. 2002). There were no templates available for how to change malaria policy and it took key, committed individuals, particularly in Tanzania, South Africa and Peru, to better understand the political system in order to advance the agenda for change.

(3) Poor communication between key stakeholders
Historically, there has been a vast gulf between the language used by scientists and that used by officials responsible for control policy (Bedregal and Ferlie 2001; EANMAT 2001; Williams et al. 2001; WHO 2003; Williams and Bloland, unpublished data). Researchers often fail to translate scientific results into usable programmatic language. Conversely, operational needs identified by policy makers or malaria control programme staff members have not been clearly articulated to the scientific community, with little resulting research in key programme areas (Durrheim et al. 2002). MoH officials distrusted data generated without their input, and the parties manifested different priorities and agendas (EANMAT 2001). This was compounded by often very limited communication among MoH departments.

Additional site-specific challenges included:

(1) Prescribing practices that differed from policy
In Tanzania, prior to the policy change in 2001, some clinicians had changed their prescribing practices to drugs other than CQ, feeling that the official change in policy was delayed, thus compromising their patients’ health (Williams et al. 2001).

During a recent meeting to discuss changing malaria treatment guidelines in the Amazon Basin, a WHO representative summarized the current situation in Bolivia:

“We have policy norms, but we do not use them. So what is done in practice is not written as a norm. It is certainly not defined to the health services.”

(2) Inadequate resources, both financial and human
This was particularly obvious from the African country case studies, and not only influenced the choice of drugs, but also impacted on the ability to adequately train health staff and ensure treatment supplies.

(3) Political changes affecting government stability
Peru and other South American countries have experienced political turmoil in their governments. With each re-organization of the MoH, up to 50% of technical staff are lost, particularly senior officials. This destroys continuity and requires rebuilding of key communication channels.

(4) Competition from other and, at times, more pressing national priorities
HIV/AIDS has been a primary focus of Ministries of Health in many countries, shifting attention away from other equally important public health problems, including malaria.

(5) Defensive posture of Ministries of Health when interacting with the media
In most situations, it was clear that little attention had been paid to the potential power and influence of the media. This resulted in defensive responses countering allegations about lack of action.

Successful strategies
Data that were shared across case studies clearly demonstrated strategies that were operationally more successful than others.

(1) Using rigorous evidence
The use of standardized local data was more convincing to policy makers than results from isolated or ad hoc studies. Improving the quality of data presented and demonstrating consistent findings (for example, results of efficacy studies from sentinel sites in Tanzania) have been described as strategies that promote policy change (Shortell and Solomon 1982; Sauerborn et al. 1999; Trostle et al. 1999). Presenting data from various sectors expedited the changes. As one Tanzanian scientist noted:

“We thought that by concentrating on drug efficacy that would be enough. However, you must think of the entire process . . . things like compliance, community responses and how to regulate the drugs.”

Those advocating for change had to demonstrate that the policy change made good economic, social or political sense. They balanced their arguments by showing the negative effects of inaction. A broader social perspective appeared more convincing than a narrow health perspective. This is pertinently captured in a statement by a senior policy-maker in Mpumalanga, South Africa:
“When you are dealing with human life and need a decision, look at the worst scenario. Are we going to only respond to a crisis when our children die?”

(2) Including scientists as part of the decision-making team, rather than only as contributors of research findings, and involving programme staff as fully fledged members of the research team

This practical bridging of the ‘know-do’ divide strengthened both groups and facilitated the change process. In addition, it provided both parties with additional skills and understanding, while engendering mutual respect.

(3) Focusing communication on problem solving, rather than confrontation

In particular, this was seen in Tanzania. The small group of key stakeholders in Tanzania realized that a more positive approach to communication was a better strategy than using the more traditional defensive mode of interaction.

(4) Presenting arguments for change in concert with support from ‘credible’ partners

Discussing the data in forums that included international partners (technical experts such as the Centers for Disease Control and Prevention or WHO) enhanced the credibility of the national scientists and control staff, and was seen as a positive step in gaining support from other stakeholders. Peru, for example, was very pro-active in this regard and organized an evening seminar, including approximately 300 members of the public, to gain support for the proposed changes. International support has been identified in the literature as a promoting factor (Trostle et al. 1999).

(5) Utilizing regional approaches, rather than focusing solely on the home country

Given the fluidity of many national borders and the degree of international travel and commerce, Tanzania and Peru realized that they could no longer think about changing their respective malaria drug policies in isolation. Rather, they needed to understand how other countries in their particular geographical regions were addressing similar problems, by reviewing drug efficacy data from neighbouring countries.

(6) Developing a better understanding of the political system

Identifying key decision-makers and implementers is integral to ‘selling’ the need for change and preparing those persons who might receive questions about the proposed changes in policy. Using the prevailing political and local epidemiological contexts to their best advantage was another successful strategy. This included using the impact of recent malaria epidemics or increased national and regional awareness of malaria resulting from published information on the global malaria control strategy (for example, WHO’s Technical Report on Implementation of the Global Malaria Control Strategy, 1993).

Discussion

Although rational malaria drug policy development is challenging, data from case studies in countries that have undergone policy change demonstrate that there are specific strategies that can assist the process. Reflecting on their own experiences, stakeholders from the countries studied were able to highlight ‘lessons learned’. They recognized the necessity of fostering new models of communication early in the process. Communication between scientists and implementers/policy makers early in the process improves the identification of key research and programmatic issues that impact on policy formulation and implementation, and promotes ‘utilization focused research’. Alerting the peripheral levels, suppliers and private sector of the proposed changes well in advance of the change allows time for acceptance of the change. Detailing a realistic timeline for implementation (recognizing that this usually takes more than 24 months) should promote improved programmatic planning and resource allocation.

Key challenges facing many endemic countries as they consider malaria drug policy changes include a lack of standardized data, limited application of research findings in policy and practice, poor communication within and between organizations, lack of personal and professional compliance with antimalarial drug regimens, inadequate resources, failing public health infrastructure, competing national and local priorities, unstable political dispensations, and defensive patterns of communication with the media.

Governments must promote intra-ministerial cooperation and open communication if policies are to be effective. It was clear that consensus building had to be an iterative process using a model of cooperation, and clear and effective communication. If Ministries of Health are isolated or defensive, then collaboration will be even more difficult. Poor governance, lack of leadership and coordination, and corruption hamper the development and implementation of well-informed policies (Nosten and Brasseur 2002). In addition, Ministries of Health should be mandated and empowered to make policy changes when a need is demonstrated according to predefined criteria.

In most countries, malaria control programmes are stretched beyond their capacities in terms of personnel and financial resources. Unless more creative strategies are developed to offer assistance in critical areas, such as better linkages between researchers and control personnel, research conducted will be inappropriate and unlikely to lead to implementation (Durrheim et al. 2002). Programmes that are tasked with the responsibility of addressing malaria drug policies must also have adequate resources to do so. Official sanctioning is needed, particularly in the context of decentralization.

The availability of standardized protocols has enhanced the collection of efficacy data, but there remains a lack of consensus about inclusion criteria for in vivo studies and the geographical coverage required to inform change. The precise amount of evidence required to initiate action has not
been agreed (Shretta et al. 2000). Clearly, international guidelines and malaria treatment policy frameworks need to be designed to assist decision-makers in malaria-endemic countries to make rational choices for antimalarial drug policy change. Additional remaining questions include: what types of data are critical to the process and who is in the best position to gather these? What is the most effective means of communicating the findings? At what level of resistance should the process of change be initiated (WHO/AFRO 2000)? Kitua (2000) offers a systematic approach, using evidence for determining when a change in policy is required. While this is a solid start, more data are needed to inform this process.

Individual countries can no longer make decisions about drug policies in isolation. There are increasing calls for enhanced information exchanges among neighbouring countries about their respective malaria epidemiology, the status of malaria treatment policies, and approaches that have been used to combat drug-resistant malaria. How a particular country manages malaria may have enormous consequences for neighbouring countries, particularly in areas where national boundaries are relatively fluid. However, despite the obvious regional importance of malaria policies, most policymaking is still organized at a national or sub-national administrative level (Kaul and Faust 2001), although recognition is beginning to occur that a regional approach provides a better platform for confronting malaria control problems. EANMAT (Mutabingwa et al. 2002) and others, such as the Amazon Malaria Initiative (AMI) and the Asian Collaborative Training Network for Malaria (ACTMalaria), focus on partnership and shared common goals in malaria control, with a particular focus on training, research and operational issues. When applicable, the networks should continue to work with regional WHO offices and other partners to ensure that the most recent information on the status of country-level policy is available to all who need it.

Clearly, one of the biggest challenges remaining is inadequate national health care systems. No matter how much external aid is focused on malaria, without functioning local systems that ensure equitable and efficient use of support, the efforts will be meaningless (Kager 2002; Nosten and Brasseur 2002; Moerman et al. 2003). Unless attention is paid to these considerations, efficacious drugs rapidly lose their effectiveness.

**Recommendations**

The successful strategies employed by the various countries that have undertaken malaria treatment policy revision can serve as recommendations for countries considering policy change. In addition, several other recommendations are offered that are gleaned from a variety of sources. Examination of the literature on policy change (with a specific focus on health care policy), suggestions from national malaria control programme managers/staff and malaria control technical experts representing a wide array of institutions in a number of countries on two continents, and data from the case studies, all contributed to the formulation of these recommendations, without particular weighting in their presented order.

1. Malaria-affected countries should institutionalize the process of malaria drug policy review by convening malaria treatment task forces that meet at least annually (and more often as needed) to review the status of the current policy and make recommendations, as needed, to the national malaria control programme and other areas of the MoH. An array of key stakeholders should be identified and represented on the policy task force, including the pharmaceutical department. National consensus-building workshops should be planned early in the policy cycle and tool packages that clearly outline what is needed to inform rational drug policy formulation should be developed. Generic reporting forms that standardize reporting of relevant data and implementation guides, such as guides for drug need quantification, should be developed. Training guides for health care workers in both public and private settings, and guidelines for monitoring drug efficacy, safety of drugs and drug use, should also be developed. The system should be designed so that emerging lessons can be used for intervention.

2. Improved communication is needed among all levels. Translation of evidence into tangible economic terms, such as ‘more effective treatment would reduce inpatient admissions, thus reducing government expenditures’ and ‘without a change in policy the number of deaths are likely to increase by . . .’, might better capture the attention of policy makers.

3. Assessments of existing resources and institutional capacity to implement and sustain malaria policy should be conducted in concert with modifying malaria drug policies. Resources should be directed toward the areas most in need. Modifying policy (malaria or other health policy) without attention to improving general health infrastructure is counterintuitive. Without an adequately functioning health care system, disease control, including implementation of drug policies, will not be feasible (Wongsrichanalai et al. 2000; Moerman et al. 2003).

4. Discussions should be held with drug manufacturers and MoH pharmaceutical services, prior to implementation, regarding several issues: (a) their ability to procure and/or manufacture the needed amounts of drug/s in a timely manner to meet the implementation deadline; (b) the need to improve packaging to enhance proper use of the drug/s; and (c) an accurate time-scale for provision and supply to the periphery of the health service. This is particularly important, as there may be financial incentives for manufacturers to continue promoting a product that is no longer effective, and this may even apply to some policy makers who may have vested interests in a particular drug.

5. Effective surveillance systems should be established in advance of policy changes, with adequate resources dedicated for surveillance so that sentinel sites can be established and maintained over time to monitor drug efficacy and effectiveness. Methodologies should be standardized and consistent across all sites, with particular attention to analysis. Scientific efficacy data should be linked to data...
easily understood by policy makers, such as mortality rates and measures of the public health consequences of disease. Timelines for periodic monitoring should be established in advance. Monitoring of drug use patterns, both in the community and health care settings, should be initiated and maintained. Monitoring of quality drug production must be ongoing and attention given to drug movements across borders.

(6) The focus must increasingly be on evidence-based decision-making, with particular emphasis on operational effectiveness.

Formulating and implementing rational malaria drug policies is a daunting process. However, studying the process of change in selected countries in two continents has demonstrated consistency in the types of challenges that countries face. More importantly, analysis of the data compiled across sites has identified successfully employed strategies based on the lessons learned. As other countries move forward in developing malaria drug policies, the shared experience of those countries that have faced similar situations can be used as a guideline to ease the transition process and enhance the chances of successful development and implementation of malaria drug policies.

Endnotes

1 Throughout the text, for the ease of the reader, the term ‘drug policy’ will be used as an encompassing term to refer to all aspects of developing and implementing a malaria treatment policy, including, but not limited to: drug selection and procurement; drug use by practitioners and the public; legal and regulatory issues relating to drug use; and training of health care workers (public and private).

2 Some countries interchange the terms malaria policy and malaria treatment guidelines. In other countries, such as Tanzania, the term ‘policy’ refers strictly to the national health policy, of which malaria treatment guidelines are a component. Regardless of local terminology used, it is understood in this paper that malaria drug policy is subsumed under countries’ respective national health policies.

3 For a complete discussion of drug management issues, we refer readers to Management Sciences for Health (1997).

4 Data obtained from a retrospective policy analysis of the change from CQ to SP in Tanzania (Williams 2002).

5 The case study summaries are extremely abbreviated versions of the actual events and processes that occurred in each country. For more detail on each country, see the following references: Steketee et al. (1995), Shretta et al. (2000), Williams et al. (2001), Williams et al. (2002) and Durrheim et al. (2003).

6 Malaria is found only in three of South Africa’s provinces. This study compared a change in policy from CQ to SP in two provinces, Mpumalanga and Limpopo, as changes in policy had occurred much earlier in KwaZulu-Natal and data about that change were very limited.

7 Since the information on Malawi is from historical archives only, we cannot determine whether the same challenges were faced during their change of policy. Documentation from that period is quite limited.

References


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