



**World Health
Organization**

The Roll Back Malaria strategy for improving access to treatment through home management of malaria



ROLL BACK MALARIA DEPARTMENT

**THE ROLL BACK MALARIA STRATEGY
FOR IMPROVING ACCESS TO TREATMENT
THROUGH HOME MANAGEMENT OF MALARIA**

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ABBREVIATIONS

CBP	community-based provider
CHA	community health assistant
CHW	community health worker
C-IMCI	community Integrated Management of Childhood Illness
HMM	home management of malaria
IEC	information, education and communication
IMCI	Integrated Management of Childhood Illness
ITNs	insecticide-treated nets
NGO	nongovernmental organization
OTC	over-the-counter
RBM	Roll Back Malaria
TDR	United Nations Children's Fund/United Nations Development Programme/World Bank/World Health Organization Special Programme for Research and Training in Tropical Diseases
WHO	World Health Organization

1. INTRODUCTION AND BACKGROUND

Globally, some 300–500 million episodes of malarial illness occur each year, resulting in over a million deaths. Over 90% of these deaths occur in sub-Saharan Africa, and almost all of them in children. The greatest burden of malarial disease and death is borne by poor people in the poorest countries, whose populations also have the least access to interventions against the disease. Effective interventions against malaria are available, yet the burden persists, largely because most people at risk of malaria are unaware of the interventions that exist to control malaria and because they have little or no access to these interventions for various reasons, including those of affordability. A lack of education, information and access to effective interventions has impeded the success of Roll Back Malaria (RBM)¹ programmes.

Poor physical access to public health facilities is a recognized impediment to the provision of early treatment in developing countries, especially in sub-Saharan Africa, and, in order to cope, communities have resorted to self-medication through the unregulated private and informal sector. Thus, pharmacies, medicine shops or vendors, retail shops and medicines left over in homes are often the first source of treatment at the onset of symptoms (McCombie, 1996). There is also widespread use of poor-quality and inappropriate medicines, and these have most likely contributed to the increasing development of drug resistance.

Since the majority of children who die from malaria do so within 48 hours of onset of illness, the early use of effective antimalarial medicines in or near the home will reduce the burden of malaria in endemic areas. This acknowledged time element is critical to saving children's lives in Africa, and reducing severe malaria morbidity and mortality in non-immune older children and adults in other regions of the world (Lepers et al., 1989; Newton & Krishna, 1998). A strong health-care delivery system would ideally be able to provide early, reliable diagnosis and appropriate, prompt and effective treatment. However, most people at highest risk of malaria,

¹ Roll Back Malaria is a global initiative to reduce the global malaria burden.

particularly in rural areas, live outside easy geographical reach of health facilities, and their access to curative and diagnostic services is, therefore, limited.

Recognizing these constraints, national malaria control programmes have sought to make treatment available as near to the home as possible, whether in the community or in the home itself. This strategy of community-based management of malaria cases is referred to as the home management of malaria (HMM),² following research supported by the United Nations Children's Fund/United Nations Development Programme/World Bank/World Health Organization (WHO) Special Programme for Research and Training in Tropical Diseases (TDR). It ensures early recognition of and prompt and appropriate response (treatment) to malarial illness in children under five years of age within the home or the community. The strategy has the following objectives:

- to enable caregivers to recognize malarial illness early and respond appropriately;
- to ensure that care providers have adequate knowledge and capacity to respond to malarial illness;
- to create an environment that enables the strategy to be implemented by making medicines available as near to the home as possible.

The use of community health workers (CHWs)³ for case management of malaria has been widely resorted to in some countries in Asia, such as India, the Islamic Republic of Iran, Pakistan and Sri Lanka, and, by 2004, nine countries in the WHO African Region were in the process of implementing the strategy. Three countries (Eritrea, Ethiopia and Uganda) were implementing all the key components of the strategy (communication for behavioural change, training of service providers, making drugs available in communities, and supervision and monitoring). The remaining countries in the region were implementing some but not all of the components required for HMM. For example, Madagascar and Nigeria were implementing the social marketing of

² Home management of malaria covers diagnosis and treatment occurring outside the clinical setting, within or near the home.

³ The term community health workers often refers to groups working at the community level, e.g. organized community health workers, village health workers and trained mother coordinators.

prepackaged⁴ antimalarial medicines, and Ghana, Kenya and Nigeria were training private vendors and developing information, education, and communication (IEC) materials.

A WHO Technical Consultation on Home Management of Malaria was held from 27 to 30 January 2004 in Harare, Zimbabwe, with the aim of developing a generic HMM strategy. The participants reflected a wide range of expertise in the development of such strategies, and the meeting brought together managers of malaria control programmes and pilot project officers in the implementing countries of the WHO African Region, as well as researchers, experts and representatives of development agencies working with communities. This consultation was a follow-up to a previous meeting in which researchers had provided the evidence, experience and lessons learnt in implementing HMM, and which had resulted in the WHO publication *Scaling up home-based management of malaria: from research to implementation* (WHO, 2004b). The purpose of the technical consultation was to define the key components of the HMM strategy and to set clear goals and objectives for improving access to treatment at the community level.

This publication therefore presents the available evidence, information, experience and best practices relating to the HMM. It clearly defines the goals, objectives and components of the strategy and outlines the environment that must be developed to enable the various steps of the strategy to be implemented. It is intended to meet the needs of managers of national malaria control programmes within ministries of health, project implementers within communities and policy-makers. It should be used to complement other publications on HMM (WHO, 2002; WHO, 2004a; WHO, 2004b; WHO, 2005). The HMM strategy will help to ensure that effective components are implemented to achieve an acceptable nationwide coverage in order to reduce malaria morbidity and mortality in children.

⁴ Prepackaging is defined as blister packing of a course of treatment into a sealed primary packaging of aluminium or polyvinyl chloride, the treatment being composed of individual doses in easily recognizable subunits.

2. JUSTIFICATION, EVIDENCE AND EXPERIENCE

2.1 Justification

It is now widely acknowledged that access to appropriate and effective treatment for malaria should be provided within 24 hours of onset of symptoms. A strategy to provide such access should take into account poor rural populations in malaria-endemic countries who are particularly inadequately served by the health system (WHO, 2000a). This is the access gap that the HMM strategy addresses, enabling the home to be the first “hospital”. It relies upon the community and the services offered by the formal and informal private health sectors.

HMM is an integral part of malaria case management within the overall RBM strategy and is particularly relevant to ensuring effective care for non-immune people at risk of malaria, such as children under five years of age in high-transmission situations. It may also be applicable to both adults and children in areas of low to moderate transmission, in whom the disease could advance rapidly to severe malaria during epidemics. HMM complements and extends the reach of public health services.

2.1.1 Malaria is often managed in the home

The response to most episodes of fever is initially self-treatment, and over 50% of cases rely exclusively on it. Studies in Ghana, Mali, Nigeria and Zambia have shown that as many as 90% of children with fever are treated at home (Salako et al., 2001; Baume, 2002). Malaria is therefore managed mostly in the home, although treatment, often inappropriate, is obtained through the largely unregulated and informal private sector. Population ratios indicate the relative accessibility of retail drug providers compared with health facilities. Furthermore, studies have shown that by the time most fever patients reach the public sector health facilities, on average three or more days have elapsed since the onset of symptoms (McCombie, 1996).

2.1.2 *Why is home treatment common?*

It is the inability of the public health services to deliver timely and effective treatment for all at risk of malaria that has resulted in the need for the home management of malaria. Although patterns of health-care seeking behaviour in Africa have been shown to be related to cultural beliefs and the perceived cause of the illness, the choice of treatment is greatly influenced by the access that individuals have to health care (McCombie, 1996). The determinants of treatment-seeking behaviour are the distance to be travelled, the cost of care, care providers' attitudes, time spent at the facilities and the overall availability of the services and medicines (Snow et al., 1992). A strategy to enable timely access to treatment will therefore need to address all these issues.

2.2 Evidence and experience

CHWs provide care for a broad range of health issues and are used in primary and community health care in many countries. To assess the effectiveness of the interventions delivered by community, or lay, health workers, a Cochrane review of 43 studies showed that such workers demonstrated promising benefits in promoting immunization uptake and improving outcomes for acute respiratory infections and malaria, when compared with usual care (Lewin et al., 2003). For the purpose of the review, a lay or community health worker was defined as any health worker carrying out functions related to health-care delivery, trained in some way in the context of the intervention, and having no formal professional or paraprofessional tertiary education on which a certificate or degree has been conferred. For malaria, evidence from research demonstrates the benefits of HMM and its impact on malaria morbidity and mortality. Considerable experience of programmes using a variety of approaches to HMM in different country settings makes it possible to define an effective strategy (WHO, 2004b).

The available evidence for the impact of HMM derives from situations in which either CHWs or commercial medicine sellers have been used as service providers, or where a broad communication strategy has been deployed to effect a positive behavioural change for improving malaria treatment.

2.2.1 Community health workers and community drug distributors

Following the concept of primary health care, many countries in the WHO African Region have established community-based programmes using CHWs as a means of improving access to health care (Ewbank, 1993). The success of such programmes in Asia and Latin America has been largely dependent on their integration into the health system, with supervisory and administrative support provided by the national health authorities as well as the community (Okanurak & Sornmani, 1992, Okanurak & Ruebush, 1996, Hossain et al., 2004).

The strongest evidence for the impact of HMM comes from two recent studies in Africa.

- A community-based randomized control trial in Tigray, Ethiopia, which used mother coordinators to train, supervise and provide antimalarial medicines in the community, showed a 40% reduction in overall under-five childhood mortality in intervention areas compared with control areas (Kidane & Morrow, 2000).
- In Burkina Faso, a programme using CHWs and locally prepared unit-dose prepackaged chloroquine led to a 50% reduction in the incidence of severe malaria (Sirima et al., 2003).

Programmes conducted in three African countries as part of a project using CHWs to combat childhood communicable diseases all showed a reduction both in overall mortality and in malaria-specific morbidity and mortality (Becker, Diop & Thornton, 1993; Ewbank, 1993; Foster et al., 1993). In one of these countries, Liberia, there was also an increase in the availability of antimalarial drugs in the homes after three years of intervention, and the all-cause childhood mortality rate compared with baseline was reduced by 28% (Becker, Thornton & Holder, 1993).

Other programmes involving community-based medicine providers have been conducted in Burkina Faso, Eritrea, Ethiopia, Ghana, Nigeria and Uganda (Pagnoni et al., 1997; WHO, 2004b). In Nigeria, such a programme resulted in an increase, from 36% to 48%, in the use of chloroquine in the treatment of children with fever (Salako et al., 2001). These programmes, all of which were based on the use of unit-dose, prepackaged antimalarial medicines, have, in general, been associated with either improved or very high levels of adherence to

recommended treatment regimens (Ansah et al., 2001; Yeboah-Antwi et al., 2001).

2.2.2 *Commercial medicine sellers*

There is a growing interest in the role of the private sector in improving HMM practices because over-the-counter (OTC) medicines⁵ are often the primary source of home treatment, although they are frequently of poor quality and inappropriately used. Short training workshops or distribution of IEC materials through existing medicine suppliers have improved knowledge and practices among trained retailers, as measured through surveys of treatment-seeking behaviour at household level and retail outlets (Oshiname & Brieger, 1992; Marsh et al., 1999; Tavrow, Shabahang & Makama, 2003).

In Kilifi, Kenya, a workshop-based programme resulted in improved selling practices among retailers. Accurate information was given to the patient in 86% of consultations and the use of OTC malaria medicines for treatment of fever in children increased fourfold (Marsh et al., 2004). The estimated cost for replication of this programme was approximately US\$ 18 per outlet per annum. In Bungoma, Kenya, posters on the correct use of medicines distributed through existing supply channels (wholesalers and mobile vendors) reached 25% of all outlets in the district (Tavrow, Shabahang & Makama, 2003).

Retail outlet-based social marketing programmes for prepackaged malaria medicines are being implemented in a number of country sites (Cambodia, Madagascar, Myanmar and Nigeria), often combining public and commercial sector distribution systems, although they have not yet been evaluated.

2.2.3 *Broad communication strategies*

An effective communication strategy has been shown to be the cornerstone of appropriate HMM. The strategy must be multifocal and should target individuals, households and communities, as well as health-care facilities, policy-makers and resource providers. It must be designed to improve understanding of the behaviours and

⁵ Over-the-counter medicines refer to medicines available by ordinary retail purchase, with no need for a prescription or licence.

practices adopted by individuals as well as the underlying reasons for their adoption, as a basis for reinforcing positive behaviours and modifying those that are less beneficial.

In Nigeria, a communication strategy for behavioural change was initiated using both the public and private sectors. Messages on malaria case management, intermittent preventive treatment during pregnancy and insecticide-treated nets (ITNs) were promoted using volunteers, social marketing of unit-dose, prepackaged antimalarial medicines and training of patent medicine dealers (BASICS II, 2004). The channels used included interpersonal communication, traditional communication channels such as “town criers” and local festivals, and social marketing through medicine packaging, radio spots and distribution of booklets to patent medicine dealers. The strategy resulted in an increased knowledge of the role and benefits of ITNs in malaria prevention and an increased awareness of the danger signs of malaria and of the importance of seeking early treatment for febrile children through antimalarial medicines. The key to the success of this programme was the shift from supply to demand creation for health services, increased access to medicines, and community ownership.

In Ghana, the He Ha Ho (Healthier Happier Home) campaign developed in 2000 by the Ministry of Health in collaboration with the Center for Communication Programs of the Johns Hopkins University,⁶ combined a strong communication strategy with the training of medicine sellers in the appropriate use of chloroquine for treatment of malaria. The campaign made use of mass media (a long-standing radio series and television spots), print media (leaflets, booklets, posters and reminder cards) and included the training of medicine sellers, medicine sales persons, students and women’s groups. These methods were effective in creating a high profile for the programme nationally; the radio series and theme song became very popular, resulting in an increase in the appropriate use of chloroquine in the treatment of children with a fever episode. The two key factors in successfully implementing the programme were found to be the implementation of the different components of the communication strategy at the same time and the repetition of key messages.

⁶ For further details, see: http://www.hcpartnership.org/Publications/Fact_sheets/ChildSurvival.pdf (accessed 14 February 2005).

2.2.4 Prepackaged tablet formulations of medicines

Tablet formulations of antimalarial medicines have been shown to be better than syrups for achieving good compliance (91% versus 42%), despite a small increase in cost resulting from packaging (Ansah et al., 2001). Pre-packaging tablet medicines has also been shown to improve adherence to treatment by as much as 20% in the case of multiple-dose regimens (Gomes, Wayling & Pang, 1998; Yeboah-Antwi et al., 2001). Pre-packaging full treatment courses stratified by age or weight enhances rational drug use and improves compliance and ease of use at community level. Prepackaging will have increasing relevance in those countries that are introducing artemisinin-based combination therapies or other antimalarial combination treatments, as these medicines are not currently available as co-formulated or co-packaged treatments. The careful design of packaging materials for prepackaged antimalarials can support appropriate treatment practices by end-users. WHO recommends the inclusion of two inserts in prepackaged medicines, one aimed at prescribers and one at consumers, thereby fulfilling drug regulatory requirements and providing an opportunity to inform end-users (WHO, 2005).

3. GOALS AND OBJECTIVES

HMM is an integral part of an overall malaria case management strategy aiming to improve access to treatment for malaria in areas with limited access to health facilities. The strategy aims to improve the ineffective self-medication practices that are very common in malaria- endemic countries; its overall goal is the early recognition and prompt and appropriate response to malarial illness, especially in children under five years of age, in the home or community. It therefore empowers communities to respond to malaria illness using effective, good-quality antimalarial medicines through community involvement.

3.1 Goals

The goals of the strategy are to ensure the early recognition of and a prompt and effective response to malaria illness in the home and community, especially for children under the age of five years, in order to reduce the morbidity and mortality arising from severe malaria.

3.2 Objectives

The general objective is to reduce severe malaria morbidity and mortality in the target groups. In order to reach this general objective, the following specific objectives of the strategy need to be attained:

- to enable and to increase the capacity of **caregivers** to recognize malaria illness promptly and take early appropriate action;
- to empower service **providers** by imparting adequate knowledge, skills and capacity that enable them to respond to malaria illness appropriately;
- to create an **enabling environment** for implementation.

4. STRATEGIC COMPONENTS

The following components of HMM (Fig. 1) are essential to achieving the general and specific objectives of the strategy:

- An effective communication strategy to ensure correct care-seeking behaviour, and appropriate and effective HMM or febrile illness.
- Training of community-based service providers to ensure that they have the necessary skills and knowledge to manage febrile illness or malaria.
- Availability of and access to effective, high-quality, prepackaged antimalarial medicines at community level.
- Supervision and monitoring of the implementation activities up to the community level.

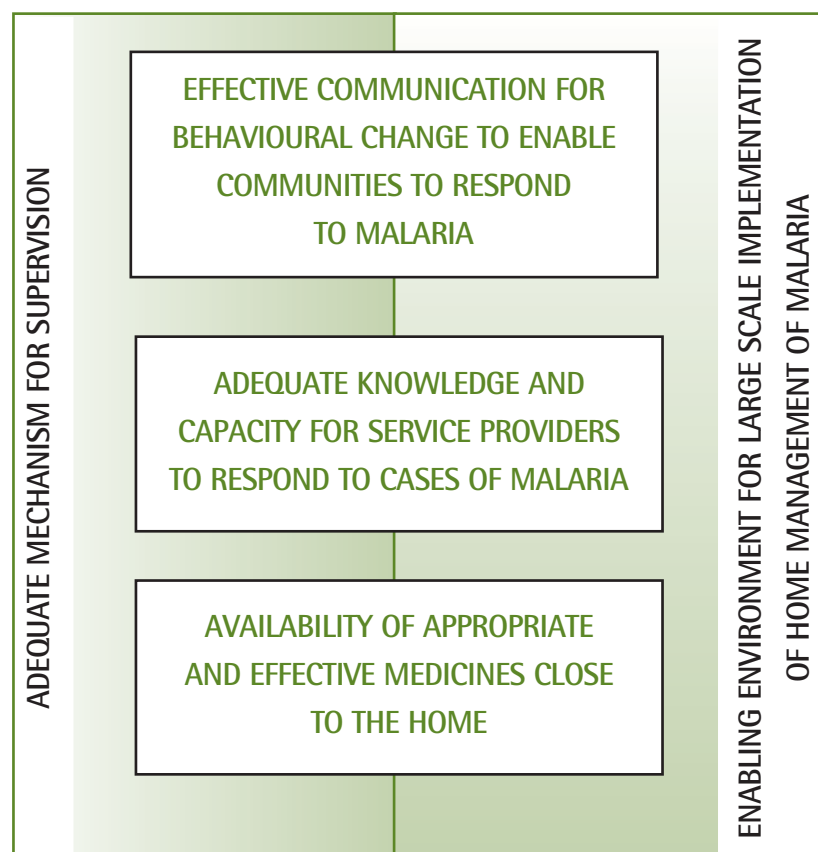
It is imperative that national malaria control programmes implement all the strategic components of HMM as a package; selecting only one or two of the components to maximize coverage and ensure quality of HMM implementation will not achieve the strategy's general objective.

4.1 Effective communication strategy for behavioural change

The cornerstone of HMM implementation is the education of and provision of information to caregivers to enable them to recognize malaria, assess its severity and take appropriate action.

- When there are no signs of severe disease, caregivers should be able to initiate early treatment in the home, using effective medicines which can be obtained from a community resource person, sales outlet or health facility.
- Signs of severe disease should prompt the caregiver to take the child to a trained health worker at the nearest public or private health facility.

Figure 1. Strategic components of home management of malaria



- Following initiation of treatment, caregivers should be able to watch for changes in the patient's clinical condition and for the side-effects of medicines, and take appropriate action in the case of deterioration.
- In all cases, they should complete treatment and offer supportive care. This care will include ensuring there is increased fluid intake, recommended feeding practices and measures to reduce fever.

The development of effective strategies to impart skills and knowledge to caregivers should be based on an understanding of

their current knowledge and behaviour in recognizing and managing malaria. These can be assessed through a situation analysis of the knowledge, prevailing attitudes and practices relating to malaria in particular communities.

The situation analysis should:

- identify the reasons why traditionally adopted practices may be difficult to change, including perceptions of the cause of illness, perceptions of risk, and economic, social and cultural barriers to treatment-seeking;
- define the communication methods to be used to facilitate behaviour change;
- identify the appropriate target groups for the strategy as well as the individuals and groups that may in turn influence the target groups.

The findings of the situation analysis should be used to devise a series of activities, generically described as a communication strategy, which should be designed to reinforce positive behaviours and to modify those that are less beneficial. The communication strategy should use a multidisciplinary, integrated approach. It should ensure access to the “hard to reach”, such as illiterate people, young mothers and marginalized populations. It is necessary to capitalize on all communication opportunities (e.g. in the home, the community or the health facility), using local, non-technical language. Major stakeholders should be included in the process, and documented experiences from other countries should be taken into account.

The key areas to be addressed in all the components of the communication strategy are:

- the link between mosquitoes and malaria;
- the risk of malaria for young children and pregnant women;
- how to recognize uncomplicated malaria and danger signs;
- what actions to take in cases of uncomplicated malaria or those with severe malaria;
- the importance of prompt and complete treatment;
- where to get or purchase good-quality, approved medicines;
- where to go in case of danger signs or if there is no improvement.

4.1.1 Key methods for communication

Interpersonal communication

Several participatory techniques should be used at community level to facilitate community engagement in discussions concerning health and broader development issues. These include: focus group discussions, participatory rural appraisal, participatory learning and action, appreciative enquiry, community dialogue and community theatre. This kind of interpersonal communication can help to facilitate behavioural change by giving individuals the knowledge needed to understand the problem of malaria, to obtain effective treatment and to administer that treatment effectively. This communication strategy can then be implemented through multiple entry points such as community Integrated Management of Childhood Illness (C-IMCI), growth monitoring and community-based malaria control programmes. Although community mobilization activities of this kind are time-consuming, they are thought to be more likely to lead to long-term behavioural change and sustained community development. Malaria-related community mobilization may also serve as a useful entry point for future, further development of community capacity in other areas.

Supportive mass media

Interpersonal communication should be complemented by supportive mass media communication, including electronic media (national and community radio and television) and print media (leaflets, posters, patient information leaflets or inserts which accompany unit-dose prepackaged medicines). The advantage of supportive mass media communication is the ability to reach a large number of individuals in a short space of time. In particular, radio tends to have wide coverage, is cost effective, and is accessible to illiterate individuals. Radio can deliver jingles, talk shows, soap operas, and debate at the community level. Television is also an effective medium for conveying messages, but may not be accessible to the poor living in rural areas. Point-of-service and point-of-purchase information materials such as brochures, leaflets and cards can provide simple instructions to the end-user and should be

actively used by health workers and medicine sellers when working with clients and customers.

The development of mass-media messages and materials must include participatory processes involving target groups and should not consist solely of the pretesting of messages designed by external experts. Appropriate language and local terms should be used to ensure that messages are clear. As far as possible, printed messages should include pictures, so they can be understood by individuals unable to read. All messages must be pretested to ensure that they are easily understood. They should be:

- simple and easy to understand;
- easy to remember, conveying only one or two ideas;
- positive – to encourage positive behaviours and use of effective products;
- specific and action-oriented;
- accurate, feasible and relevant;
- sensitive to local cultural beliefs.

4.1.2 Integration of IEC into health workers training and other sectors

IEC activities can also be integrated into formal education (e.g. school curricula, nurse training, medical education, pre-service and in-service training) and programmes of other sectors (e.g. agriculture and microcredit schemes).

4.1.3 Advocacy

Building partnerships with politicians, decision-makers, donors, and other resource providers is a vital component of the HMM strategy to ensure that the political commitment and resources required to support implementation are forthcoming. Mass media, including television, radio and newsprint, can be an effective channel. One-to-one personal communication and lobbying are often the most effective channels of communication for advocacy at this level.⁷

⁷ Tools for the development of a context-specific national advocacy strategy and plan include materials published by WHO on RBM advocacy (see: <http://www.rbm.who.int/newdesign2/shop/shop.htm>, accessed 14 February 2005).

4.2 Imparting skills and knowledge to community-based providers

Different community-based provider (CBP) groups, such as CHWs, medicine sellers, and community resource persons, can be trained to deliver prompt and effective treatment for HMM, and a combination of different types of CBP groups may allow the greatest coverage in a given country situation. The choice of CBP groups depends on the initial assessment of the available groups in each setting, in terms of their methods of work, their potential for change (i.e. their personal motivation and the practical barriers to change), the community's perceptions of a particular group or groups and the degree to which groups can function optimally in order to achieve the desired outcomes.

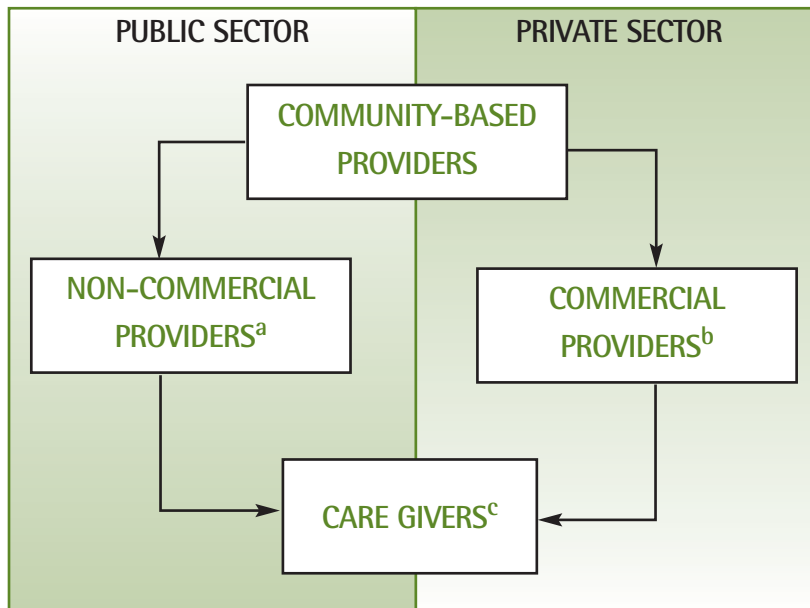
4.2.1 *Community-based providers*

The CBPs could be drawn from the public sector (CHWs, community health assistants, community drug distributors and community-based distributors) or from the private or informal sector (patent medicine vendors, retailers, drug vendors and traditional birth attendants), and, once identified, they will need to be given the necessary skills and knowledge through appropriate training. A generic framework is presented in figure 2. The type of training to be given or educational approach to be adopted (training content, methods and materials), the individuals identified as trainers or managers and the best systems for managing, monitoring and evaluating the CBPs depend on the type or types of CBPs chosen and their normal ways of functioning.

4.2.2 *Training objectives*

The training objectives vary depending on the overall aim of the programme and the type of CBP chosen. However, the overall responsibility and stewardship of community-based health programmes must lie ultimately with the public-sector health system. Integrating HMM strategy training within the existing community-based programmes is the best solution. Integrating such training into other programmes, such as C-IMCI, those for distributors of onco-cerciasis drugs, community mobilizers in expanded programmes on

Figure 2. Public and private sector community-based providers



a Community health workers, community health agents, or community drug distributors.

b Patent medicine vendors, drug shop retailers or drug vendors.

c Heads of household, family members or neighbours.

immunization, community nurses or health agents, has the potential to reduce the resource burden and may even improve sustainability, although possibly at the cost of losing some specificity of the programme. Such integrated programmes fulfil a broad public health agenda that addresses other diseases and may therefore be more acceptable to the community or to local governments.

The training of CBPs within the commercial sector, and especially if commercial-sector trainers are used, might have to be based on a limited curriculum dictated by the amount of time such trainers are willing to spend without compromising their own business. Profit generation underpins activities in this sector, and

medicine sellers are unlikely to attend long training courses unless they are financially compensated for their time. However, since they are already well established in their trade they may not need many additional resources to implement HMM, and this would lead to savings in the long term.

The experience gained from such training programmes has demonstrated the need for training to address the following gaps in skills and knowledge, depending on the specific roles undertaken:

- knowledge and skills to recognize uncomplicated malaria, danger signs and when to refer the patient;
- knowledge and skills to manage malaria appropriately (recommended medications/dosages);
- awareness of the need for prompt and early treatment, and completion of the dose;
- communication skills to counsel and offer health education on other aspects (e.g. ITNs, intermittent preventive treatment during pregnancy);
- recording/reporting tasks;
- drug storage.

4.3 Availability of and access to effective, high-quality, prepackaged antimalarial medicines

The success of the HMM strategy will depend on the community's access to high-quality antimalarial medicines as close to the home as possible. The essential requirements of the strategy are that:

- the first-line antimalarial medicine of the country should be used;
- high-quality medicines should be made consistently available.

Since HMM is an integral although extended component of the national health system, the drug or drugs used should be consistent with the national antimalarial treatment policy – i.e. the first-line treatment for uncomplicated malaria. The first-line drug should be available as an OTC medicine so that it is widely accessible by and available to the communities.

HMM planning must ensure that high-quality drugs are regularly supplied to the CBPs both in the public and in the private commercial sectors. Attention needs to be paid to the packaging of the medicines so that they are convenient to the user and will ensure a high level of compliance.

4.3.1 *Prepackaging antimalarial medicines*

Packaging is technically classified as part of manufacturing, and WHO has published guidelines on the technical specifications for pre-packaging antimalarial medicines in compliance with good manufacturing practice requirements. The specifications cover labelling, package inserts and information and education materials accompanying the product (WHO, 2005). An important component of pre-packaging is patient information on the use of the medicine that is provided with the packaged drugs; this information should be factual and be supported by and consistent with data in the registration dossier, and should be presented in a patient-friendly manner.

A prepackaged drug is defined as a course of treatment in a sealed primary packaging, the treatment being composed of individual doses in easily identifiable subunits. The blister pack should be labelled with at least the proprietary name, batch number,

expiry date and the name of the holder of the manufacturing authority. The expiry date of co-packaged medicines is that of the medicine that has the earliest expiry date. Packaging should demonstrably protect the dosage form from exposure to light and reactive gases, loss of solvent, absorption of water vapour⁸ and microbial contamination, protect against physical damage, be safe for use, be compatible with the dosage form and route of administration and carry the correct information and identification of the product (WHO, 2005).⁹

The advantages of prepackaged medicines are outlined below.

- For local populations, the “authenticity” of the packaging denotes that the medicine is of good quality and that it is sanctioned by the HMM programme (Gomes, Wayling & Pang, 1998; Kilian et al., 2003).
- Prepackaged medicines are more difficult to substitute with fake and substandard medicines.
- Such medicines make the regimen explicit to the user and therefore improve adherence, especially in the case of regimens that require taking combinations of different medicines.
- They provide a channel for patient education through accompanying information inserts.

4.3.2 Medicine supply management

The procurement and supply of medicines should be planned early in the development of a strategy for the HMM. As a first step, the quantities of medicines required for use at the community level should be included in the requirements of the national malaria programme for the first-line antimalarial medicine and will depend on the overall HMM programme coverage.

The public-sector drug distribution systems should be extended to reach the level of the community-based provider if such a system is not already established. The capacity and resource gaps in relation

⁸ For example, artemisinins require moisture-resistant packaging.

⁹ Loss of potency of the active ingredient and reduced concentration of the excipient may occur because of absorption or adsorption of moisture or degradation. Discoloration of either the dosage form or the packaging component and an increase in brittleness of the latter may also occur.

to the adequate storage and distribution of the medicine should be assessed throughout the supply chain. Measures may be needed to strengthen selected distribution points through an assessment of the medicine supply systems of local governments, nongovernmental organizations (NGOs) and CHWs.

In situations where the first-line drug is locally sourced or where the commercial sector is involved, the manufacturing industry and wholesale pharmacies will be key partners in procurement and distribution. However, ministries of health will need to play a stewardship role to ensure the quality of medicines at various points in the supply chain. Problems may arise from differences in the interests of the commercial and public sectors; for example, commercial distribution may focus primarily on areas with high population density and good road access. Thus, in order to ensure equity, mechanisms may need to be put in place to achieve coverage of sparsely populated and remote rural areas.

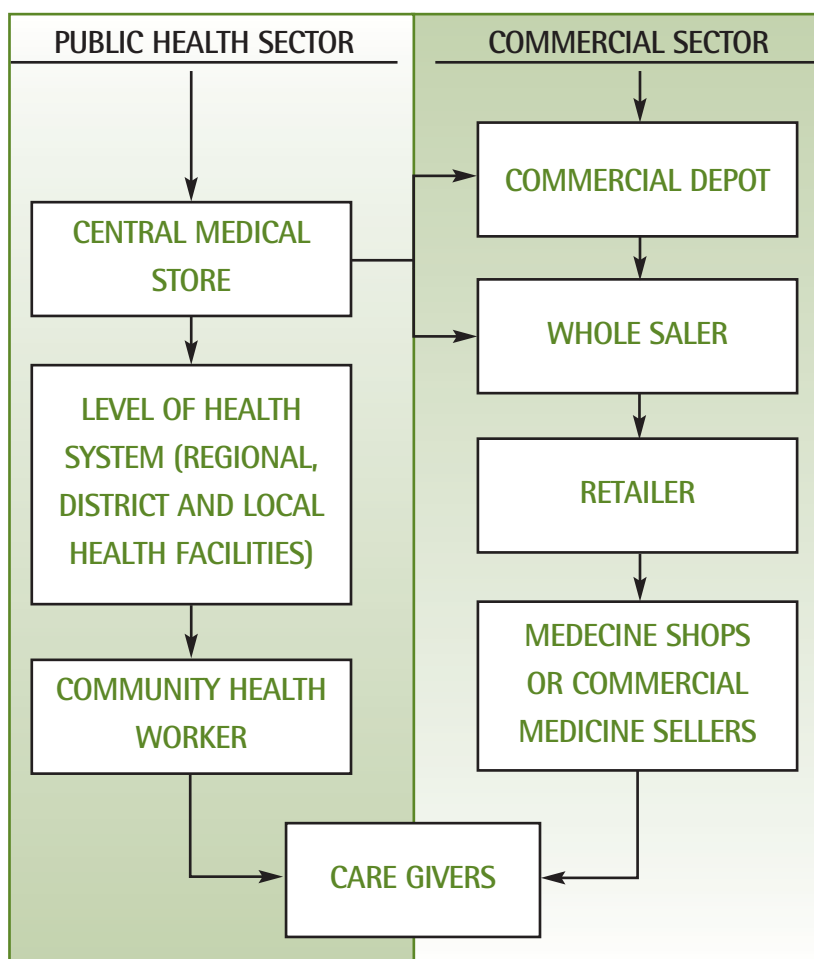
Each of the different drug distribution systems offers a unique advantage, and the likelihood of programme sustainability and success will be enhanced by using more than one system. For example, as illustrated in figure 3, the distribution systems might consist of a combination of the following:

- in the public health sector: central medical store → levels of health system (regional, district and local health facility) → village health worker → caregiver;
- in the commercial sector: commercial depot or through central medical stores → wholesaler → retailer → drug shops or commercial medicine sellers.

4.3.3 Medicine supply system

The furthest point that the medicine must reach is the home. Enabling caregivers to store medicines in their homes may shorten the time needed for seeking care, and could be to their advantage, especially when a family is faced with multiple and frequent events of malaria, as most families are. However, the feasibility, effectiveness, risks and benefits of having stand-by antimalarial treatment in the home itself have not been fully evaluated.

Figure 3. Medicine supply system



4.4 Mechanism for monitoring, supervision and evaluation

The monitoring of activities is vital to the successful implementation of any programme, and its importance cannot be overemphasized in the implementation of HMM. Monitoring enables the progress made towards set goals and objectives to be assessed and problems in implementing the programme, as well as possible solutions to those problems, to be identified, thus moving the programme towards its goal and objectives. Monitoring should

therefore be an integral part of the scaling up of HMM and, as such, part of the overall monitoring system for malaria control activities. It should have the following purposes:

- measuring the progress of activities during implementation, using indicators that usually relate to quality or quantity during a particular time frame;
- highlighting which activities are being carried out well and which less well;
- providing information during implementation about specific problems and aspects that need modification;
- enabling managers to decide on allocation of resources and to identify training and supervision needs;
- providing information on the programme outcomes in terms of behavioural change, accessibility, promptness of treatment and the overall impact of the programme.

Table 1 presents a generalized framework for inputs, processes, outputs and outcomes to be considered in setting up activities for monitoring HMM programmes. With appropriate feedback, the monitoring of basic programmatic inputs, processes and outputs will lead to improved performance and delivery. Outcomes are usually monitored at the population level and can be the result of multiple strategies for improving access to treatment. Monitoring coverage and impact indicators, especially for malaria, requires specially designed instruments such as household surveys for understanding trends in coverage or in all-cause child mortality. The currently recommended tool for assessing coverage and impact is the Malaria Indicator Survey package developed by the Monitoring and Evaluation Reference Group of the RBM Partnership.¹⁰

Evaluations are undertaken to determine the quality of implementation or impact of the programme on the beneficiaries. They are carried out at fixed intervals during the course of the programme. It is important to consider all the contributions of stakeholders in determining the appropriate type of evaluation to conduct. An evaluation assesses how the structures in place have been able to achieve the set objectives; it is therefore essential to set well-considered objectives before the start of activities.

¹⁰ For details of the *Monitoring and Evaluation Reference Group and survey and indicator instruments*, see: <http://rbm.who.int/merg/>, accessed 14 February 2005

Table 1. General framework for monitoring home-based management of malaria (HMM)^a

INPUTS	PROCESSES	OUTPUTS	OUTCOMES	IMPACT
<ul style="list-style-type: none"> • Treatment policies, guidelines and strategies • Financing policies 	<ul style="list-style-type: none"> • Human resources, training • Procurement/supply of antimalarial drugs and other related commodities and supplies 	<p>GENERAL</p> <ul style="list-style-type: none"> • Services delivered • Knowledge and skills acquired • Practice improved 	<ul style="list-style-type: none"> • Changed behaviours • Improved population-based coverage 	<p>1. All-cause, under-five mortality</p> <p>2. Malaria-specific mortality and morbidity</p>
<ul style="list-style-type: none"> • Training materials developed • Technical aids prepared (e.g. dosage charts, posters) • Funds made available 	<p>SPECIFIC</p> <ul style="list-style-type: none"> • Community-based providers trained for HMM • Information, education and communication material developed • Medicines prepackaged 	<ul style="list-style-type: none"> • Recognition of signs and symptoms of malaria • Adherence to treatment improved 	<ul style="list-style-type: none"> • Proportion of children under five years of age with fever in the previous two weeks who received appropriate antimalarial treatment according to national policy within 24 hours of onset of fever • Appropriate health-care-seeking behaviour 	

^a Source: adapted from *Monitoring and evaluation toolkit: HIV/AIDS, tuberculosis and malaria*. Geneva, Global Fund to fight HIV/AIDS, Tuberculosis and Malaria, June 2004 (http://www.theglobalfund.org/pdf/guidelines/pp_me_toolkit_en.pdf)

5. ENABLING ENVIRONMENT

5.1 Policy

The implementation of HMM must occur within the overall framework of the national health policy on community health or primary health care, and must be guided by the overall policy on malaria case management and treatment. Experience has shown that the following issues relating to policy are relevant to the successful implementation of HMM.

- The highest level of political commitment by the national government is required to ensure that the cross-ministerial activities beyond the purview of the ministry of health required for the implementation of HMM are facilitated at the policy level.
- HMM should be supported by the RBM Partnership and operate with technical inputs from national, regional, district or subdistrict level structures. However, the national health system must itself be sufficiently well resourced financially and in terms of human resources to support the HMM activities.
- HMM should operate within the overall delivery strategies for child survival, especially C-IMCI, and all health promotive, preventive and home-care messages should be harmonized.
- A decentralized health system, whereby implementation decisions can be taken locally rather than only at the central level, greatly facilitates HMM implementation.
- A mechanism that will enable the private sector to be fully mobilized and work in conformity with a government's HMM programme should be established. Such a mechanism is especially important in view of the key roles that the manufacturing industry and commercial distributors and providers have to play in HMM.
- The national policy on malaria treatment and the scheduling of drugs within the policy must be supportive of the implementation plans. For example, the first-line antimalarial medicine should be available as a non-prescription medicine or OTC treatment.

5.2 Regulation

HMM functions within a national regulatory framework. Regulatory processes are also needed for the effective implementation of HMM. An early and continuing dialogue with the national regulatory bodies, in particular with drug regulatory authorities, is therefore essential. Antimalarial treatment policies and recommended treatment regimens are the starting point for HMM strategy development (for cost, quality assurance, scheduling, safety, efficacy and the prepackaging of unit-dose treatment courses) and have important influences on the nature of the HMM programme to be developed.

Similarly, regulatory influences on provider groups, including the legal restrictions on service provision that apply to both formal and informal health providers, need to be taken into account. Increased restriction of the use of antimalarial medicines that are not in line with the treatment policy is also an important component of the strategy. To be registered, medicines should be subject to a system of quality assurance incorporating good manufacturing practices, quality control, and the development of standard treatment information that accompanies medicine packages, especially those sold in the private sector.

5.3 Community involvement

Community involvement is important for the success of any community-based programme, including HMM, and can be enhanced by developing community capacity. For community-based programmes to be successful, communities need to be active partners in the planning and implementation of activities. To involve them early will help to create ownership, allow resources to be mobilized, increase the motivation of providers and make the programme sustainable. It is essential that all partners be committed to the empowerment of communities; they should not try to dominate, but rather to contribute to the programme according to their roles and responsibilities. They should share a common objective.

Communities should be involved in the early stages of making decisions on how best to address issues of access to treatment

generally and the need for the medicines to be available at the community level. Members of the community should discuss collectively the health problem from their own perspective, as well as possible interventions, taking into account relevant community knowledge and additional information provided to them.

5.4 Financial resources

Implementing the HMM strategy will require financial resources well in excess of the usual budget for national malaria control programmes because of the larger network of delivery points and the number of people who will use the services. This places a heavy demand on resources, planning and management, and requires intensive support from the public health services, particularly from the local government and peripheral health facilities.

Financial support for implementation is likely to be sought through the local RBM Partnership and the level of that support will depend on the funding sources of the national malaria control programmes or on the donors and partners willing to invest in the strategy. Mobilizing resources at national and local levels through health ministries' structures and through partnerships with existing agencies, such as NGOs and research organizations, and through the communities themselves, will go a long way towards assisting resource mobilization. Existing resources may be shared, and creative ways of mobilizing new resources from all stakeholders should be explored.

5.5 Integration into other programmes

HMM should not be implemented as an independent programme, but should be integrated into the framework of national malaria control programmes, as a means of improving access to antimalarial treatment. Integrating all stages of the process of developing HMM, from the planning stage to the stage of reaching the community, into other health programmes may reduce duplication, thus leading to cost and time savings, and provide consistency in methods and messages. Existing structures and programmes that provide maternal and child health services such as

the Expanded Programme on Immunization and C-IMCI can be used for distributing prepackaged antimalarials to those caring for young children.

5.6 Research and development

Research and development should be undertaken to support research issues arising as a result of implementing the strategy, such as access to effective drugs, the skills and knowledge required of service providers in the management of malaria, and achieving better communication methods. Meetings need to be held to prioritize research topics, review findings and strengthen collaboration between research and control.

The identified research gaps include the following:

a) Access to effective and good-quality antimalarial drugs at the community level:

- innovative tools to enable monitoring, inspection, quality assurance, postmarketing surveillance, and pharmacovigilance at the level of the peripheral health facility and the community;
- innovative tools for pricing and delivery of subsidies;
- innovative tools for regulation.

b) Skills and knowledge required of drug and service providers to manage malaria:

- How can CBPs be trained to use malaria rapid diagnostic tests to improve malaria diagnosis?
- Can CBPs be trained to manage severe malaria at the community level using rectal artesunate?
- Can CBPs manage malaria and other common diseases, e.g. respiratory tract infections in children?

c) Broad research questions:

- How effective is HMM in reducing malaria morbidity and mortality?
- How cost effective is HMM in comparison with other strategies?

- How can non-commercial and commercial CBP systems be made sustainable?
- How does the cost-effectiveness of different operational systems for HMM compare?
- Is HMM combined with the use of artemisinin-based combination therapies practicable?
- Can private and public CBPs work together and how can synergy be maximized?

d) Specific research questions:

- Which factors motivate private and/or public CBPs to start and to continue working in HMM programmes?
- What IEC approaches improve adherence to recommended medicine regimes?
- What are the most effective training methods for CBPs?
- Does HMM change the knowledge, attitudes and practices of caregivers?
- Are unit-dose, prepackaged medicines viable in the private retail sector (supplies, cost-effectiveness)?
- Can patient height be used to determine dosage?
- How can innovative communication tools and approaches be developed?

6. STEPS IN IMPLEMENTING THE STRATEGY

6.1 Preliminary activities

Some preliminary assessments and activities may need to be undertaken before the strategy is designed.

6.1.1 Assess and develop political support

The strategic support provided by the national malaria control programme and the ministry of health must be underscored by broad, high-level political awareness and commitment to the overall aims of the HMM programme. It is important to be able to gain fiscal support through the ministry of finance and other line ministries that have community-based networks such as local governments.

6.1.2 Conduct a situation analysis

The various instruments used for situation analysis are described in several WHO publications (Management Sciences For Health, 1997; WHO, 1999; WHO, 2003; WHO, 2004a; WHO, 2004c).

Programme planning should build on an understanding of the ways in which the health system is delivered, especially in relation to the access of the population to health-care services, the prevailing health-seeking behaviour of the target population and the potential for change across five main areas, described below.

a) Consumers, caregivers and communities

- How are the danger signs of malaria and malaria illness recognized and what are the trusted sources of this information?
- What is the degree of awareness of the range of options that may be chosen, and how accessible and attractive are those options?
- What empowers and motivates caregivers to act?

- Who are the critical actors in the home and at the community level that directly or indirectly influence and support caregivers (e.g. spouse, grandmother, traditional healer, siblings, CHWs, community leaders, other relatives)?
- What are the existing communication structures, roles and methodologies, and what are their quality and impact within the community?

b) Community-based medicine provider groups

- Who are the CBPs currently being used by the population when they seek health care for fever?
- How are the CBPs currently functioning in terms of their knowledge, practices (including types of antimalarial medicines currently provided), attitudes, sources of medicines and health information, supervisory or regulatory systems, motivations and sustainability, and what are the barriers to change and the perceived potential for change?
- What are the community's perceptions, knowledge and practices in relation to provider groups, especially perceptions of appropriate types of providers, common patterns of treatment and the reasons underlying these patterns?
- How accessible to the community would the various potential CBP groups be and how adequately would they cover the target population, particularly vulnerable groups (e.g. those in remote rural regions or in areas of high endemicity, or the most poor in a community)?
- The feasibility of and the resources and partners available for working with CBP groups.

c) Antimalarial medicines, their manufacture and distribution

- Antimalarial medicines recommended for first-line, non-prescription treatment in accordance with national guidelines.
- Characteristics of recommended antimalarial medicines: sources, cost, quality, efficacy, composition and dosage, presentation/packaging, user information, formulation, adverse events, special user groups.

- Delivery and storage systems for existing antimalarial medicines (public sector and private sector systems and those of NGOs): types, efficiency, coverage, potential for improvements.

d) Central and regulatory factors

- Regulatory status of recommended antimalarial medicines.
- Quality assurance mechanisms for medicine manufacture and distribution, and their application.
- Regulatory status of potential provider groups.
- Current curricula for pre-service and in-service training for health providers and other stakeholders in the HMM programme (e.g. teachers) and for schools.

e) Biomedical factors

- Patterns of malaria transmission and their relationship to season and geographical location across the programme area.
- Patterns and levels of malaria parasite drug resistance.

6.2 Build partnerships with key stakeholders

Building partnerships and creating awareness of and support for the HMM programme require the development of a context-specific national advocacy strategy and plan. Partnerships are important at the global, national, district and community levels. Important partners may include community-based groups, key departments of ministries of health, including those concerned with child health (IMCI), planning and health information management and information systems, and high-level governmental partners, other government sectors (especially local government, education, finance and agriculture), academic and research institutions, drug and other regulatory authorities, the medicine manufacturing industry, private and informal health providers, professional organizations, NGOs, mass media, bilateral and global development agencies and donor organizations.

6.3 Address regulatory issues

It is important to seek advice and support from and to develop a dialogue with the drug regulatory authorities and any associated professional bodies on key issues that may affect implementation. Some of the most important issues are:

- registration/licensing of new products or brands and the regulatory implications of packaging, stability, labelling, drug use information and brand name;
- rescheduling of the antimalarial drug, if not yet done, to allow it to be used as an OTC treatment;
- if the antimalarial medicines need to be produced locally, ensure that the manufacturer has sufficient production capacity and good manufacturing practice status in order to ensure they produce quality-assured products and avoid counterfeit brands;
- discussions on the capacity and knowledge required for the selected providers to be permitted to dispense drugs, especially in the case of private-sector providers;
- regulatory requirements applying to promotional material and public information guidelines;
- the need for pharmacovigilance mechanisms for new products or for rescheduled existing products.

6.4 Establish medicine procurement and supply management systems

Two aspects of medicine procurement require consideration: the source (which manufacturers) and the cost (what funds are needed and how they will be obtained). Estimates should be drawn up of the financial and other resources needed in order to implement the overall programme, and both short- and long-term needs should be addressed.

Since drugs are the key to the successful implementation of the strategy, the programme's requirements for medicines within the planned HMM delivery framework, including those of the public-sector and private-sector providers, need to be quantified.

Some of the issues that need to be considered are:

- identifying procurement methods or options (manufacturers, importers, distributors): these should be developed flexibly, adapted to country needs, be based on a process of tendering and include stock management mechanisms (WHO, 2000b);
- developing quality assurance mechanisms (WHO, 1997) and specifications for supplies that should include monitoring of quality and expiry during distribution and standardization of packaging presentations (e.g. age range and composition and dosage for products); identifying methods of managing and scheduling deliveries, including those to districts and to users (Management Sciences For Health, 1997);
- ensuring a “first in, first out” system of stock rotation and maintenance of adequate records at all levels of distribution;
- monitoring the distribution process and providing feedback to national RBM partners (including drug regulatory authorities) on quality, expiry date, prices and safety.

6.5 Address financing mechanisms

6.5.1 Central level

While it is important that HMM operates within the overall budget of the national malaria control programme, it should also be made clear from the beginning that HMM will require greater financial and human resources. Financing mechanisms, costing and pricing, the delivery of subsidies, and strategies for long-term sustainability will therefore need to be developed. Strategies such as cost recovery, pricing and delivery of subsidies that will help to sustain the process of implementation also need to be developed. There will be a need for adequate monitoring and feedback, with continuous reviews and adjustments.

6.5.2 District and community levels

At the district and community levels, there is a need to mobilize resources that could be easily provided towards implementing the strategy. At the district level, the local administration may be in a

position to bear some of the costs, such as that of drug delivery to lower levels and the cost of supervision of the communities, and thus ensure greater sustainability. At the level of the community, some resources could be mobilized to motivate the service providers, to replenish the stocks of drugs and to encourage collective responsibility to ensure that the providers meet community expectations.

6.6 Design a country-specific communication strategy

Following the situation analysis, an overall communication strategy consisting of four essential components must be designed, as outlined below.

6.6.1 *Interpersonal communication*

Interpersonal communication is both continuous and community driven. Strategic guidance is provided by the use of specific workplans that allow issues and tools to be prioritized, thus ensuring that key or sensitive issues are discussed. In order to accomplish this, it is important to:

- identify target populations and appropriate methods and channels for information, and develop appropriate tools and materials;
- train facilitators and community mobilizers in interpersonal skills and tools, aiming for a critical mass at all levels (trainers, facilitators, mobilizers); integrating such training into other programme training (IMCI, family planning, HIV/AIDS) will help to reduce costs and allow a more rapid expansion.

6.6.2 *Mass media*

Develop key messages with full community participation (including formative research and pretesting) and identify the most appropriate channels of communication for the presentation of the materials. Ensure repeated inputs, monitor impacts and develop new themes or presentation formats for messages over time. Some of the most commonly used channels will include:

- television (has primary role in advocacy rather than behavioural change);
- community radio – particularly participatory radio (e.g. fun soap operas with audience discussion) and regular radio spots;
- print media, e.g. posters (these should not be a priority), reminder cards;
- innovative methods, e.g. games for children and adults.

6.6.3 *Integration into other sectoral programmes*

HMM programmes may be supported by the integration of messages into the formal education sector (e.g. primary and secondary schools, medical schools, nursing schools, schools of public health, adult education programmes) or other sectoral programmes (e.g. agriculture, microcredit schemes). Integration measures should include:

- extending curricula to include content relevant to the aims of HMM;
- developing and producing supporting materials;
- introducing more participatory tools into schools, pre-service training and follow-up, and in-service training;
- a mix of interpersonal and mass-media methods is most effective in capturing the attention of people and obtaining the commitment and involvement of all levels (from a high political level to the community level).

6.7 **Develop training materials and tools**

Based on the situation analysis and the agreed implementation framework, develop a training approach by:

- identifying target groups and personnel to be involved in training and monitoring within the implementation framework;
- developing training content and methods for all personnel in consultation with partners, including representatives of the provider groups and trainers. Ensure that messages are integrated into the overall communication strategy;

- developing training tools: manuals, medicine dosage reference charts, workshop summaries and tools for record-keeping and for monitoring and supervision; these tools should be developed through a process of pretesting and piloting before final production.

6.8 Steps in implementing the strategy at the district and community levels

Districts should have the capacity for planning, training and supervision. However, it is also important that communities are sensitized as partners and that they should see the whole strategy as being community directed (WHO, 2002). The key steps may include:

- sensitizing district teams about HMM and building district-level partnerships for planning and implementation (e.g. district health management teams, professional medical, nursing and pharmacist associations, vendor associations, NGOs, IMCI);
- sensitizing the community through the involvement of its members in the strategy by means of assigning clearly defined roles and responsibilities, including the selection of CBP personnel;
- training and implementing communication strategies simultaneously;
- receiving, storing, transporting and ensuring the quality of medicines;
- managing and monitoring exchange mechanisms (fees, subsidies);
- monitoring and supervising the programme: documentation and record-keeping relating to delivery and quality assurance, and the provision of feedback to the next level;
- following up on treatment by providers.

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ANNEX

List of participants at the WHO Technical Consultation on Home Management of Malaria Harare, Zimbabwe, 27–30 January 2004

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