

**Final Report of the
External Evaluation of
Roll Back Malaria**

Annexes

List of Annexes

Annex A	Letter from Dr. Samba and Dr. Feachem to Panel of Experts, May 1996	85
Annex B	Highlights from the RBM Internal Review Final Report	89
Annex C	Drug Wars in Burundi: an extract from Access News, MSF	91
Annex D	Malaria in India	93
Annex E	Slow Disbursement in India	95
Annex F	International Resource Mobilization and Financing of RBM	97
Annex G	Malaria Research	105
Annex H	Assessment of the Roll Back Malaria Monitoring and Evaluation System	109
Annex I	Roll Back Malaria in Complex Emergencies – RBM-CE	113
Annex J	Technical Dimensions for Roll Back Malaria	117
Annex K	The Stop TB Partnership	123
Annex L	The Global Alliance for Vaccines and Immunization	127
Annex M	Malaria Control Strategy of the African Development Bank Group	131

Annex A

- 1. Letter from Dr. Samba and Dr. Feachem to Panel of Experts, May 1996**
- 2. Attached hypothesis**
- 3. Revised hypothesis based on responses from Panel of Experts, September 1996.**

May 28, 1996

Dear ...

Despite many decades of control efforts, malaria remains a leading cause of illness, death, suffering, and poverty in Africa. For reasons that have been much discussed and written about, the traditional armory of preventive approaches is not being fully or consistently used in the most affected areas. New weapons are becoming available, and there is much current interest in the effectiveness of impregnated bednets.

In the medium term, an effective malaria vaccine is anticipated and its widespread utilization will undoubtedly assist in the control of this disease.

The WHO Regional Office for Africa and the World Bank are interested in exploring a hypothesis (which we attach) with experts in health and development in Africa. WHO and the World Bank are prepared to be advised by Experts on how to intensify malaria control activities in Africa and to seek views on the most appropriate policy and approaches for reduction of malaria burden under the current economic and social environment.

The purpose of this letter is to invite you, a known authority and expert in this field, to express your opinions about the attached hypothesis and related matters. What we seek is five pages of your frank personal thoughts on how it would be best to move forward internationally and nationally on malaria control in Africa. In particular, we would like your review and commentary on the hypothesis. If you agree with it, please tell us why. If you disagree with it, please tell us why and please also propose an alternative hypothesis (which might be that we can do little other than 'business as usual').

We hope you will be willing to contribute your wisdom and experience to this international brainstorming process. We attach a list of the others who have been invited to assist us in the same manner. We will appreciate receiving your thoughts on the subject by June 30, 1996. We will then assemble all the opinions received and come back to you with a proposed next step.

As you will appreciate we are in a very exploratory mode. We do not have a firm position: we do not know where this process will lead us: and we seek the best advice and opinion before making up our minds on these matters.

We send you our personal thanks for taking the time to study this letter and hope that you will be willing to assist us in the manner requested.

With best regards,

Yours sincerely,

Dr. Ebrahim M. Samba
Regional Director
WHO Regional Office for Africa

Dr. Richard G.A. Feachem
Senior Adviser
World Bank

Attachment: Hypothesis

The Hypothesis

The hypothesis concerning malaria in Africa is contained in six statements.

1. Notwithstanding the potential of new tools (such as impregnated bednets in the short-term and a malaria vaccine in the medium-term) a 'business as usual' approach to malaria control in Africa will probably mean that by the year 2050 this disease continues to be a major cause of ill health, death and suffering.
2. There is a potential for a large, long-term, focused initiative to accelerate the pace of malaria reduction.
3. This initiative might operate on a focused geographical basis, selecting initially a small number of areas (perhaps three or four) where rapid progress in malaria control is technically feasible. The initiative would start by establishing effective malaria control in these areas and then move systematically outwards from them to eventually embrace the whole continent.
4. An important purpose of this initiative would be i) to strengthen and sustain ongoing high level political and social commitment both in Africa and among the OECD nations to the task of malaria control and ii) to achieve concrete results in reduction of malaria burden by using effectively the tools available (disease management and wide use of personal protection with bednets) at health services and community levels.
5. The existence of an African malaria initiative would be an incentive to well-focused malaria research investments leading to new products and tools which could be rapidly tested and applied in major ongoing control programmes.
6. Any such initiative would need to take a 30-year time horizon and set a modest goal for the year 2010, a more ambitious goal for the year 2020, and achieve malaria control across Africa by the year 2030.

May, 1996

Revised Hypothesis

The hypothesis concerning malaria in Africa is contained in six statements.

1. Notwithstanding the potential of old and new tools (impregnated bednets in the short-term and a malaria vaccine in the medium-term), the inappropriate application of these tools, a 'business as usual' approach to malaria control, and a lack of action in many countries while awaiting a 'magic bullet' will probably mean that by the year 2050 this disease will continue to be a major cause of ill health, death and suffering in Africa.
2. There is an urgent need for a large, long-term, focused initiative to enable significant and sustained malaria reduction. This initiative should offer flexibility rather than a blueprint and operate on a programme approach with strong political commitment and under strong regional and local leadership.
3. This initiative might operate on a focused geographical basis, selecting initially a small number of areas (perhaps three or four) of similar socio-ecological settings where rapid progress in malaria control is technically and politically feasible. The initiative would start by establishing effective malaria control in these areas and then move systematically outwards from them to eventually embrace the whole continent.
4. An important purpose of this initiative would be: i) to strengthen and sustain ongoing high level political and social commitment, both in Africa and among the OECD nations to the task of malaria control, ii) to foster meaningful community participation and the involvement of the private sector and NGOs and iii) to achieve concrete results in reduction of malaria burden by using effectively the tools available (such as disease management and wide use of personal protection with bednets) at health services and community levels. Further effectiveness of the initiative could be ensured through i) improved capacity of health systems addressed in part by significant training of personnel to work in the malaria programmes, ii) integration of initiative into existing health delivery system and applicable 'special programmes' at the district level and iii) a combination of horizontal and vertical delivery.
5. The existence of an African malaria initiative would be an incentive to well-focused malaria research investments leading to new products and tools which could be rapidly tested and applied in major ongoing control programmes.
6. Any such initiative would need to take a 30-year time horizon and set a modest goal for the year 2010, a more ambitious goal for the year 2020, and achieve malaria control across Africa by the year 2030.

September 18, 1996

Annex B

Highlights from the RBM Internal Review Final Report

Communications and Advocacy

Successes

Placed malaria on global political agenda
 Increased funding for vaccine development and malaria research
 Included malaria in Global Fund to Fight AIDS, TB and Malaria (Global Fund)
 Supported resolution of DDT controversy
 Removal of taxes and tariffs from net materials and insecticides

Future Challenges

Support to communications and advocacy at country level
 Strengthen communications capacity at regional and country levels
 Enlist expertise of private sector
 Greater use of out-sourcing

RBM Partnership/Institutional Arrangements

Successes

Engagement of a wide number of partners
 Increased support from USAID, Asian Development Bank (ADB), Japan International Cooperation Agency (JICA), and World Bank
 Completion of strategic plans in more than 15 countries
 Development and broadening of country partnerships at the country level

Future Challenges

Separate Secretariat role from WHO internal structures
 Improve Secretariat's accountability to the Partnership
 Improve pace of activity at country level
 Greater commitments by partners at all levels
 Proactive engagement of NGOs and business community
 Converting 'loose ties' into commitment and responsibility for country action
 Define and strengthen WHO regional activities
 Clarify regional role of linking partnerships to the global level

Capacity Development

Successes

Production of capacity development strategy
 Dissemination of WHO training materials
 Innovative approaches to training

Future Challenges

- Greater priority to capacity development within WHO
- Broaden technical training (including managerial, advocacy and partnership skills)
- Improve planning and handling of consultancy assignments
- Identify specific capacity gaps at country level

Technical Support/ Research and Use of Evidence

Successes

- Progress in prioritization of effective interventions
- Prominence to drug policy issues
- Increased collaboration with IMCI in Africa
- Improved linkages between research and malaria control at global, regional and country levels
- Focus on high priority research areas, such as combination therapy trials
- Emphasis on research related to field operations and delivery of interventions

Future Challenges

- Work more closely with other agencies to improve and develop technical consensus
- Reconsider the Technical Support Networks
- Draw on technical expertise of other partners
- Improve responsiveness to changing country needs
- Identify high priority areas for research
- Greater emphasis on health systems and social and economic research

Monitoring and Evaluation

Successes

- Development of a Global Framework for Monitoring Progress
- Collection and analysis of baseline data begun in 16 African countries

Future Challenges

- Avoid duplication of data collection efforts
- Achieve stronger consensus around M&E operations
- Develop rules for notification of malaria epidemics
- Obtain accurate baseline for measuring RBM progress

Resource Mobilization and Administration

Successes

- Mobilized seed-corn funding to jump-start action at country level
- Development of a workplan for increasing country capacity

Future Challenges

- Focus on the PRSP process
- Improve coordination with country planning cycles
- Investigate new opportunities for working with the Global Fund
- Mobilize private sector resources
- Mobilize local resources and examine linkages with other partnerships

Annex C

(For illustrative purposes only – the Evaluation Team did not conduct an independent assessment of the Burundi example)

Drug Wars in Burundi

An extract from the February 6, 2002 edition of
Access News

The newsletter of the Campaign for Access to Essential Medicines of
Médecins Sans Frontières

MSF in Burundi – thrown out for flouting ineffective treatment protocol

In October 2000, Burundi was devastated by a malaria epidemic worse than it had ever seen: almost 3 million people were infected within a six month period and thousands died. MSF, which has a long history of working in Burundi, immediately set up an emergency response to deal with the outbreak. But the toughest battle was not conducted against malaria itself: MSF staff spent months arguing the nature of the treatment protocol with national authorities.

When the epidemic started in October 2000, Burundi's national protocol recommended chloroquine for first-line malaria treatment, and Fansidar[®] (generic name sulfadoxine-pyrimethamine) for second-line treatment. From the start, the MSF team on the ground suspected that chloroquine would be ineffective, given the high levels of resistance already recorded in the region. The team suggested using a combination based on artesunate, a faster-acting more potent drug, but were refused by national authorities. All the same, they began treating children with an artesunate combination at the nutritional centre in Ngozi, with the tacit understanding of regional authorities.

In an effort to better understand the dynamics of malaria in Burundi, the government carried out resistance testing in early 2001 and organized a consensus meeting with WHO and other partners to discuss the results. The studies conducted by MSF were excluded because the government claimed that they had not followed the official protocol. But they may have been excluded because the results were particularly telling: in the province of Kayanza, for instance, resistance to chloroquine was 100 percent, resistance to Fansidar[®] 74 percent, and resistance to a combination of both drugs, 57 percent. Although all studies showed resistance levels higher than 25 percent - the level at which WHO recommends a switch in first-line treatment – the Ministry of Health (MOH) decided to adopt a 'transition' protocol with Fansidar[®] as first-line treatment, quinine as second-line, and Coartem[®] (a fixed dose combination of artemether and lumefantrine) in case of epidemic only.

MSF, once again, protested against this decision and increased the pressure on the Ministry by announcing it was introducing artemisinin drugs into all its programmes in Burundi. Colette Gadenne, head of the MSF mission, publicly challenged the Minister of Health on his refusal to authorize the organisation's use of artemisinin derivatives even though they are available in most private pharmacies in Burundi and prescribed to patients who can afford the commercial price. The government swiftly revoked Ms. Gadenne's credentials and halted the team's activities in the province of Kayanza for a period of two months. MSF was also threatened with legal action if government edicts, including treatment protocols, were not followed in the future.

Beyond the complexities of relations with national authorities, this story is a good illustration of the difficulties and controversy surrounding the issue of malaria treatment protocol change. MSF believes that switching to a protocol containing artemisinin derivatives is critically important in order to effectively treat patients with malaria. Many countries are ready to make the change in protocol, but cannot implement it because of the increased expense of purchasing newer, more potent medicines. Chloroquine costs as little as \$0.10 per dose, while a combination containing an artemisinin derivative, such as Coartem[®], costs a minimum of \$2.20 per adult treatment. It is therefore essential that international donors support governments that are ready to make the switch, especially countries such as Burundi that face periodic epidemics.

By Caroline Livio and
Philippe Ribeiro

Annex D

Malaria in India

(Extracted from the Report of the Mid-Term Review Mission for the World Bank/India Malaria Control Project)

Currently, the incidence of malaria infections in India is declining, and is lower than it has been in any year since 1971. The incidence of confirmed malaria infections in the year 2000 was 2 per 1000 persons per year, which represents 1,914,000 cases. Of these confirmed infections, 52 percent were *Plasmodium falciparum* (987,000 cases, annual incidence 1 per 1000 persons) and the remainder *P. vivax* (927,000 cases, annual incidence 0.95 per 1000 persons). Infections with *P. malariae* are only occasionally diagnosed. Deaths from confirmed malaria were estimated at 872 in the year 2000, giving an annual incidence of 0.9 per 100,000 persons. The true numbers of infections and deaths from malaria are much higher than the numbers of cases detected and confirmed by the public health care system. Estimates of 15 million new cases (incidence of 15 per 1000 per year) and 20,000 deaths (21 per 100,000 population per year) have been proposed.

After the malaria eradication campaign began in India in 1953, the number of cases fell to its lowest level of about 100,000 cases in 1965. In the late 1960s and early 1970s, the incidence began to rise steeply, particularly for *P. vivax*, reaching a peak of 11 cases per 1000 persons per year in 1976. Intensification of control efforts brought the incidence down to around 2 per thousand in 1987, but it has proved difficult to maintain it at or below this level. There was a significant increase in cases in 1995-6 and a second smaller increase in 1999. *Plasmodium vivax* caused the majority of malaria cases until very recently (1999) when incidence of the two species became about equal. This change in proportion of the two species was due more to decline in *P. vivax* than increase in *P. falciparum* incidence.

The control strategy adopted in 1953 was widespread residual spraying of houses with DDT. This continued to be the mainstay until 1995, when the Malaria Action Plan put more emphasis on early case detection and treatment by outreach workers, focal spraying in high-risk areas, and prediction and containment of epidemics. The insecticide used for house spraying was changed to other insecticides in some areas when resistance to DDT was demonstrated, but DDT is still widely used in India for malaria prevention. Impregnated mosquito nets have not yet been introduced on a large scale in India. The first-line drug for malaria treatment is chloroquine in all except a few areas where chloroquine resistance has been demonstrated. Primaquine is also given to all confirmed cases (except pregnant women), as a one-day gametocytocidal dose to *P. falciparum* positives and as a five-day course to *P. vivax* positive cases.

Malaria is most common in the northeastern states and in the belt of central states stretching from Rajasthan, Gujarat and Maharashtra in the west to Orissa and Andhra Pradesh in the east. Orissa state, which has about 3 percent of the country's population, accounts for about 20 percent of the country's malaria cases and 50 percent of the country's confirmed malaria deaths. Malaria, particularly *P. falciparum*, is most prevalent in the tribal upland areas where the incidence has changed little in recent years. In urban areas, malaria is a serious and increasing problem.

Annex E

Slow Disbursement in India

In September 1997, the World Bank approved a \$120 million IDA credit for malaria control in India. The closing date for this project is March 2003. As of November 2001, only one quarter of the available funds had been disbursed. This project is by far the largest World Bank loan to malaria control ever.

The project focuses on implementing RBM strategies in 100 districts in seven states, having a total population of 62 million people. The particular emphasis of the project is:

- early detection and prompt treatment;
- selective vector control;
- use of impregnated bednets;
- epidemic response; and,
- institutional strengthening.

The selected districts were ones in which malaria incidence was high, the proportion of *P. falciparum* was over 30 percent, and at least a quarter of the population were from ethnic minorities.

The project has improved early detection and treatment, decreased use of DDT, maintained the surveillance system, and made some recent progress in decentralization. Overall, however, the project has not been successful. Particular problems include:

- there has been little progress in shifting the traditional programme of residual spraying of houses with DDT to more selective and appropriate approaches to vector control;
- there has been very little progress with ITN use in India in general, or within this project;
- the ability to detect and control epidemics of malaria remains weak;
- institutional capacity for malaria control at the state level is very deficient and has not strengthened greatly; and,
- there has been little activity in the field of community education.

The World Bank India Project experience illustrates the need for locally differentiated approaches, especially in large countries. The appropriateness of different mixes of interventions varies across India. The choice of both drugs and insecticides also varies in line with different resistance patterns. In addition, some states, such as Gujarat, have moved ahead vigorously with effective malaria control activities while other states, such as Orissa, lag behind. Orissa is now responsible for 20 percent of all reported malaria cases and 50 percent of deaths in India. There is a need for different responses in different states, both by the national government and by external RBM Partners.

Annex F

International Resource Mobilization and Financing of RBM

The work of the Evaluation Team on RBM financing is merely a first step to construct a picture of the resource flows. Prior to this evaluation, information of this kind was not mobilized and reported to the Partners. More work is necessary to obtain a complete and accurate picture.

Assumptions and Data Deficiencies

A number of Partners have not organized their accounting systems to facilitate estimating international financial flows for malaria. We have no data on how much money is mobilized by country governments and individual households in malarious countries. The most difficult aspect of estimating annual international flows relates to the level of disbursement from the World Bank and other regional development banks; information regarding disbursements from health and other project loans is difficult to trace to specific activities.

From bilateral donors such as DFID and USAID, most of the financial information is based on project funding levels, which may not reflect actual disbursements for action against malaria. For example, USAID may fund technical assistance projects for health communication or IMCI which may make a considerable contribution to malaria control, but none of the investment will show up as being for malaria. In addition, the project may not have a life of only one-year. Thus expenditure on malaria may actually occur over a longer period than the year in which the funds are allocated to a particular implementing contractor.

A number of assumptions were required to estimate annual financial disbursements from bilateral and multilateral sources. High and Low estimates resulted from these various assumptions for several of the main partners. For both the Africa Development Bank and the World Bank, similar high and low rates of disbursement have been used from the portfolio of health and other projects having a component addressing malaria. The assumed disbursement rates for the development banks were as follows: a) years 1 and 2 (high) 10 percent of the loan funds each year, and (low) 5 percent, b) years 3 and 4 (high) 20 percent of the loan funds each year and (low) 10 percent, c) year 5 (high) 30 percent and (low) 15 percent, d) year 6 (high) 10 percent and (low) 15 percent, years 7 and 8 (low) 15 percent and e) year 9 (low) 10 percent. Thus, it is conceivable that the low estimate can generate a larger disbursement in a later period than the high estimate. This ignores the likelihood that projects will be terminated rather than extended if disbursement rates are low and performance is weak.

We have used the assumed disbursement rates presented above to estimate disbursements for the entire portfolio of project lending for the development banks. The World Bank's malaria portfolio comprised 40 projects in 1998 and 58 projects in 2002. The African Development Bank's malaria portfolio comprised ten lending activities with a malaria component as of 1998, and 20 in 2002. Thus, even if a large project such as the World Bank Indian Malaria Control project, initiated in 1997 at a level of \$164.8 million, were to be closed prematurely, total disbursements from an entire malaria support portfolio would not be altered by more than 15 percent in any given year (see notes to Tables 1 and 2 for additional details).

With the exception of DFID, it was assumed that the bilaterals disbursed their funds for RBM in the year they were initially allocated to a particular country malaria control programme or technical assistance project implementing agency. In the case of DFID the disbursement flows were based on the same assumptions as for the development banks. If the life of the project was known to be less than five years, then the disbursement rates were adjusted upwards.

Given the lack of readily available information on malaria research funding from public and private sources, especially for vaccine development, it was difficult to learn if financing for such purposes in 2002 had significantly changed from 1998. For this report, it is assumed that 1998 funding levels continue to reflect 2002 levels (See Tables 1 and 2 below).

Historical Flows

During the period of the first significant global effort to eradicate malaria, from 1948 to the mid-1960s, international malaria spending was high.¹ Between 1972 and 1975, WHO's spending on malaria in current dollars was more than double RBM's average annual expenditures of approximately \$35 million.

If WHO's current RBM and other malaria expenditures equaled those of the 1972-1975 period, it would be spending more than double (between \$85 to 90 million) RBM's annual expenditures of about \$35 million for 2002. However, after admission of defeat in the 1970s, international expenditures dropped to a low level, with the exception of the procurement of anti-malarials by international donors out of the funds provided for general health development initiatives.

During the early 1990s there was increased interest in developing a new strategy to at least control malaria via the increased use of insecticide-treated nets (ITNs). This initiative, along with the effort of the IMCI programme to provide rapid and effective treatment to a selected set of diseases known to lead to high rates of mortality among children under five has paved the way to a renewed interest in rolling back malaria.

A report of the Malaria Consortium estimated that international malaria spending amounted to approximately \$265 million in 1998. This estimate reflects a five-year \$165 million World Bank India Malaria Project signed that same year. Excluding the India project, the reported level of 1998 commitments were about \$100 million, nearly twice the levels reported in 1994.²

According to the Malaria Consortium report, the largest share of financing in 1998 (44 percent = \$51 million) was for research, mainly for a malaria vaccine, and for other pharmaceutical products. WHO financing for malaria was about \$2.4 million, or about 2 percent of the total for that year. World Bank disbursements in 1998 were between \$22 to 24 million, with another \$1 to 2 million from the African Development Bank (AfDB). The bilateral support shown in Table 1 is comprised of funds from USAID (disbursed about \$10 million in 1998), with the remaining bilateral funds coming from a number of other donors, including Australian Agency for International Development (AusAID), DFID, JICA, Italy, the Netherlands, Canada and Belgium.

¹ See for example pages 26 and 27, WHO, *Proposed Programme and Budget Estimates for the Financial Year 1 January–31 December, 1974*, Official Record No. 204 (Geneva: WHO, 1972), which shows malaria eradication the largest single disease specific programme, comprising about 8% of total WHO proposed expenditures (over \$ 6.2 million) in each year from 1972 to 1975.

² Annex A, Table 4, p. A72, in J. Martinez, J. Hill, and S. Meek, *Global Co-ordination of Malaria Control Efforts: Issues and Options for Supporting Country Strategies*, (London: Malaria Consortium, July 1998).

Financial Flows in 2002

By 2002 estimated international spending (in terms of annual disbursements) will be \$125 million per year, nearly a two-fold increase from 1998 (see Table 2). This estimate does not include the amounts which are envisioned for 2002 from UNICEF, which has just begun its RBM programme, AFRO, which also has its own sources of some funds, or the EC which is revisiting its commitment to RBM. This level of spending is expected to grow as more countries demonstrate progress towards achieving the Abuja or Millennium goals established by the international community.

Table 2 shows funding through the RBM Secretariat within WHO and its Regional Offices amounted to around \$35 million per year, or about 28 percent of the total estimated international spending on malaria in 2002. This is a considerable increase over 1998, when similar financing sources accounted for about 4 percent of total funding and only \$2.4 million. The two Tables also show a considerable increase in funding by WHO for malaria amounting to \$8.7 million.

Most of the funds channelled through the Secretariat came from bilateral sources. The bilateral support to RBM is over 70 percent of total RBM estimated expenditures, with the remainder coming from multinational supporters (World Bank, EC). Two bilaterals (USAID and DFID) contribute nearly 80 percent of the financing tracked through RBM financial systems. The Italians and Japanese are the other major bilateral supporters in 2002 (about 15 percent of the bilateral total). Other international donors to RBM in 2002 include Australia, Belgium, Canada, Germany, Luxembourg, the Netherlands and Norway.

WHO Geneva and its Regional Offices contribute about 25 percent of the total RBM Secretariat expenditure for 2002. Some of these funds (about \$3.3 million in 2002) are allocated to country-specific programmes to control malaria.

Malaria Financing in 2002: Outside RBM

International support for malaria outside of the funds funnelled through the RBM Secretariat has reached nearly \$90 million per year (about 72 percent of the estimated total for 2002). Bilaterals (mainly the US Government (USAID) and DFID) contribute nearly 60 percent of that amount with multinationals contributing the remainder.

Clearly identified country-specific control programmes comprised over \$76 million or 60 percent of total estimated expenditures in 2002 (Table 2). Some of these funds were funnelled through the RBM (about \$6.5 million) but mostly they were financed directly by bilaterals or multilaterals (nearly \$70 million). This level of expenditure is probably double the absolute level in 1998. Finally, some of the funds shown in Table 2 as going to general support of the WHO Secretariat were also utilized on a country-specific basis, most notably for developing country strategic plans and implementation guidelines. It is assumed that more RBM funds will go to countries in the years immediately ahead when countries will seek to implement their plans.

Country governments receiving international support typically finance local resource procurement, especially personnel. Thus, for 2002, depending upon the relative prices of locally available resources compared with internationally procured items, about 50 percent of the total cost of a malaria control programme is financed locally, implying recipient countries are annually contributing resources valued between \$70 to 80 million.³ If one includes these locally mobilized

³ DW Dunlop and M Over initially raised the distinction between local as contrasted to internationally procured inputs and the implications for their financing. See Dunlop DW and Over M, 'Financing the Foreign Exchange Costs of Health Programmes in Third World Countries', pp. 99-126, in Sorkin A ed., *Economics of Human Resources in Economic Development*, JAI Press, 1988.

resources in estimates of international resource mobilisation for malaria in 2002, the total would amount to around \$200 million.

During the 1990s, most internationally financed malaria projects were used to finance procurement of internationally manufactured insecticides, drugs or other items, e.g. bednets. For example, for the 23 World Bank projects where information was available on the specific procurements within the malaria component, insecticides comprised 62 percent of the funds. Drugs, e.g. chloroquine and SP, required another 16 percent, and the remainder was used for equipment, bednets and many other items.⁴ While all international inputs are vital to the success of each country control programme, insecticide procurement has been a large component of World Bank support. This may imply Bank financing being at odds with RBM programme priorities, e.g. early case treatment and widespread use of ITNs, although additional information regarding the World Bank supported malaria control programmes may be required to fully justify this view.

Finally, over 70 percent (\$19 million out of \$26 million) of the total specific programme and technical assistance expenditures, e.g., malaria in pregnancy and bednet treatment, vaccine research and research on new anti-malarials, are supported by funds which flow outside the WHO/RBM mechanism. Much of these resources comes from USAID or DFID.

Country Focus

While it is difficult for WHO and Regional Offices to focus international funds to a few 'target' countries, the funds related to malaria control activities flowing outside the RBM mechanism are highly targeted. This is most easily shown in the financing of RBM activities in Africa (See Table 3). The Table shows both WHO funds for specific country malaria programmes along with the additional funding provided by other international donors for both preventive and early treatment programmes. Of the 44 countries listed in Table 3, 33 obtain the majority of their external funding for malaria from non-Secretariat and non-WHO sources. The top ten countries for 2002 in terms of total external funding obtained have been allocated over 70 percent of total estimated expenditures.

Even within WHO/RBM country-specific funding, the top ten African countries in terms of disbursements in the 2000-2001 biennium spent over 53 percent of the total, and six countries in Africa were not allocated or did not spend any funds on malaria.

The Relationship Between Malaria Control Planning and International Financing for RBM

Table 3 also shows the level of international support on a per capita basis for the countries in Africa, the most malarious region. In 2002, for the 44 countries listed, it shows that per capita expenditure levels amounted to between seven and eight US cents, or between \$47 and \$54 million in total. In order for those international resources to be effectively utilized, local resources must be committed in about equal measure.

As has already been shown, while this level of support has grown rapidly, the levels are still low relative to what might be required to effectively control malaria in the region in the near future. The Commission on Macroeconomics and Health estimated that to control malaria with the tools currently available, it will require 0.6 to 0.9 US dollars per capita by 2007 and 2015 (in 2002

⁴ If the World Bank India Malaria Control project is excluded from the analysis, the allocations for the remaining 22 projects are as follows: 54% for insecticides, 20% for drugs, and the remainder for many other inputs. See World Bank, Roll Back Malaria FY 99, Status Report. (Washington D.C.: World Bank, 2000).

US\$) respectively.⁵ This means that total annual financial support for malaria control programmes in Africa will need to be increased by about 4 fold by 2007 and 5.5 and 6.5 fold by 2015. Only a handful of African countries have begun to achieve a level of support for their RBM programmes to have a chance in the short-term to control malaria to the level established at Abuja, Nigeria. This list of countries includes Benin, Eritrea, Mauritania, Namibia, Senegal and Zambia, along with Comoros and Sao Tome. These are highlighted in Table 3. Other countries, including the Gambia, Guinea Bissau, Madagascar, Malawi, Mozambique, Uganda and Tanzania may be reaching about 50 percent of the 2007 target as of 2002.

The RBM Secretariat has been involved in supporting many African countries to develop country strategic plans (CSPs) for addressing their malaria problem. Twelve CSPs have been developed and summarized by the Secretariat.⁶ The proposed financial aspects of the combined CSPs are presented in Table 4. The financing priorities of the combined set of plans embodied in the Table suggest relative equity between early treatment and prevention from the spread of malaria, with over 40 percent being allocated to early treatment of malaria. Further, these plans show that the incremental costs of early treatment for malaria appear to be generally met by the combined set of CSPs, with about \$0.2 per capita allocated, above the suggested figure of \$0.1 for 2007 in the Commission on Macroeconomics and Health report to WHO.⁷ However, the preventive target of \$0.6 per capita is only one-third met, at a level of \$0.23 per year (see Table 4). Thus, more resources may be required for preventive interventions in the near future.

Finally, for the twelve countries whose proposed CSP programme expenditures are summarized in Table 4, the level of external resources garnered for their implementation beginning in 2002 shows only 15 to 18 percent of the required expenditure mobilized. Expenditures amounting to about \$0.45 per capita has been planned across the eight programmatic areas, but the level of resource commitment for 2002 is only \$0.07 to \$0.08. This finding suggests a considerable additional resource mobilization chore ahead to achieve the goals of RBM.

⁵ Table A2.2, p 161 in Sachs J, *et al*, ed. 2001. *Macroeconomics and Health: Investing in Health for Economic Development*, Commission on Macroeconomics and Health.

⁶ WHO/RBM. 2001. *Summary of 12 African Strategic Plans to Roll Back Malaria*. WHO.

⁷ Table A2.2, p 161, Sachs J, *et al*, ed. 2001. *Macroeconomics and Health: Investing in Health for Economic Development*, Commission on Macroeconomics and Health.

Annex F – Table 1: Summary of Estimated Expenditures for Malaria by International Organizations/Donors, 1998

Sources of Financial Support	Uses of Financial Support (Million US\$)									Share of Total	
	Within RBM				Sub-total	External to RBM			Sub-total		Total
	General/ Extra Budget	Specific Programs	Country Specific	General/ Extra Budget		Global TA & Specific Programs	Country Specific				
WHO HQ	0.800			0.800				0.000	0.800	1.2	
Regional Offices of WHO (1)	1.600			1.600				0.000	1.600	2.5	
1. Total WHO	2.400			2.400				0.000	2.400	3.7	
2. Bilateral Through RBM Secretariat				0.000				0.000	0.000	0.0	
3. Multilateral Through RBM Secretariat				0.000				0.000	0.000	0.0	
Total RBM	2.400	0.000	0.000	2.400				0.000	2.400	3.7	
4. Bilateral Outside RBM Secretariat (2)				0.000	NA	NA	NA	24.400	24.400	37.9	
5. Multilateral Outside RBM Secretariat (3)				0.000	NA	NA	28.436	37.256	37.256	57.9	
6. NGOs				0.000			3.300	3.300	3.300	5.1	
Total Outside	0.000	0.000	0.000	0.000	NA	NA	NA	64.956	64.956	100.9	
Total RBM and Outside Support	2.400	0.000	0.000	2.400	NA	NA	NA	64.956	67.356	104.7	
Share of Total	3.0	0.0	0.0	3.7	NA	NA	NA	100.9	104.7		

Notes:
(1) Estimated to be twice the size of HQ staff allocations in 1998.
(2) The allocations between general, specific TA or research, or country specific expenditures are not available for 1998.
(3) Multilateral support includes the World Bank and the African Development Bank, along with the EC, and other UN agencies.
The estimate provided in this table includes the large India Malaria Control Project of the World Bank (US \$164.8 million) signed in 1997.
The figure for the multilateral disbursements would decline by about US\$ 2.5 million, if the India project was excluded.

Sources: Annex Table A4, pg. A72, J. Martinez, J. Hill, and S. Meek, *Global Coordination of Malaria Control Efforts: Issues and Options for Supporting Country Strategies* (The Malaria Consortium, July 1998), and internal memorandum from the African Development Bank and the World Bank.

Annex F – Table 2: Summary of Estimated Expenditures for Malaria by International Organizations/Donors, 2002

Sources of Financial Support	Uses of Financial Support (Million US\$)									Share of Total	
	Within RBM				Sub-total	External to RBM			Sub-total		Total
	General/ Extra Budget	Specific Programs	Country Specific	General/ Extra Budget		Global TA & Specific Programs	Country Specific				
WHO HQ	2.536	0.000	2.710	5.246				0.000	5.246	4.2	
Regional Offices of WHO	2.924	0.000	0.557	3.481				0.000	3.481	2.8	
1. Total WHO	5.460	0.000	3.267	8.727				0.000	8.727	7.0	
2. Bilateral Through RBM Secretariat	14.931	7.766	2.973	25.670				0.000	25.670	20.5	
3. Multilateral Through RBM Sect.	0.750	0.000	0.209	0.959				0.000	0.959	0.8	
Total RBM	21.141	7.766	6.449	35.356				0.000	35.356	28.2	
4. Bilateral Outside RBM Secretariat				0.000	1.914	18.807	33.590	54.311	54.311	43.3	
5. Multilateral Outside RBM Sect. (2) (3)				0.000	0.000	0.000	37.548	37.548	37.548	29.9	
6. NGOs (1)				0.000			3.300	3.300	3.300	2.6	
Total Outside	0.000	0.000	0.000	0.000	1.914	18.807	74.438	95.159	95.159	75.8	
Total RBM and Outside Support	21.141	7.766	6.449	35.356	1.914	18.807	74.438	95.159	130.515	104.0	
Share of Total	16.8	6.2	5.1	28.2	1.5	15.0	59.3	75.8	104.0		

Notes:
(1) For NGO funding, it is assumed that 2002 levels of financing are at least equal to 1998 estimated levels, as investigated by the Malaria Consortium in 1998.
(2) The figure for the multilateral disbursements would decline by about US\$ 4.1 million, if the World Bank India Malaria Project was excluded.
(3) Estimates of financial flows from UNICEF and the EC are not known for 2002, but are potentially significant, i.e. greater than 5 million each.

Sources: Internal financial statements from the RBM secretariat, WHO, USAID Malaria budget documents for 2002, DFID internal memorandum, African Development Bank internal memorandum, and World Bank internal memorandum.

Annex F - Table 3: Estimated Expenditure on Malaria in the African Region by Country, programme and Donor, 2002																									
Country	Population / millions		WHO/RBM		Disbursed	AFRO Funds		World Bank Loans (est. Disbursed)		African Dev. Bank Loans (est. Disbursed)		UNICEF		USAID		DFID		Italy (through WHO/HQ RBM)		Totals		Per Cap Totals			
	2000	2002	Budget Ceiling	Obligations		High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low		
	2000	2002																							
1. Algeria	31.09	32.35	0.060	0.049	0.007																				
2. Angola	12.67	13.37	0.195	0.096	0.006																				
3. Benin	6.26	6.59	0.171	0.168	0.114			0.033																	
4. Botswana	1.55	1.59	0.090	0.093	0.056																				
5. Burkina Faso	11.24	11.76	0.320	0.447	0.113													0.437							
6. Burundi	6.83	7.14	0.120	0.089	0.063																				
7. Cameroon	9.37	9.84	0.177	0.188	0.124			0.050																	
8. Cape Verde	0.39	0.40	0.040	0.038	0.038																				
9. CAR	2.41	2.49	0.120	0.122	0.067																				
10. Chad	7.80	8.23	0.191	0.207	0.070			0.063																	
11. Comoros	0.56	0.59	0.206	0.073	0.130			0.585																	
12. Congo	2.92	3.07	0.120	0.088	0.046																				
13. Cote D'Ivoire	15.36	15.88	0.206	0.183	0.100			0.120			1.300														
14. Dem. Rep.	50.88	53.88	0.252	0.209	0.036																				
15. Equatorial	0.45	0.47	0.080	0.028	0.012			2.250																	
16. Eritrea	4.08	4.28	0.150	0.143	0.043			3.000																	
17. Ethiopia	63.83	66.67	0.838	1.032	0.527			0.463			0.231														
18. Gabon	1.27	1.32	0.100	0.096	0.083																				
19. Gambia	0.64	0.67	0.178	0.146	0.114																				
20. Ghana	19.27	20.17	0.344	0.355	0.070			0.040																	
21. Guinea	7.34	7.66	0.276	0.185	0.081			0.000																	
22. Guinea Bissau	1.16	1.20	0.110	0.104	0.097			0.060																	
23. Kenya	30.26	31.42	0.299	0.293	0.191																				
24. Liberia			0.125	0.102	0.059																				
25. Madagascar	15.27	16.11	0.270	0.389	0.187			1.080																	
26. Malawi	10.99	11.48	0.220	0.202	0.158																				
27. Mali	11.22	11.88	0.177	0.186	0.145			0.340																	
28. Mauritania	2.68	2.81	0.148	0.101	0.078			1.560																	
29. Mozambique	17.51	18.15	0.363	0.442	0.355			0.000																	
30. Namibia	1.68	1.75	0.175	0.165	0.115			0.500																	
31. Niger	10.74	11.42	0.172	0.169	0.095			0.000																	
32. Nigeria	126.0	132.3	0.458	0.459	0.099			0.500																	
33. Rwanda	8.41	8.77	0.243	0.155	0.064			1.330																	
34. Senegal	9.45	9.91	0.202	0.258	0.200			0.100																	
35. Sierra Leone	4.97	5.16	0.141	0.123	0.045			0.100																	
36. South Africa	41.95	42.88	0.060	0.058	0.035																				
37. Swaziland	1.01	1.05	0.100	0.098	0.063																				
38. Togo	4.62	4.84	0.177	0.295	0.258																				
39. Uganda	21.73	22.74	0.201	0.678	0.441			1.000																	
40. Tanzania	33.31	34.73	0.505	0.564	0.351			0.420																	
41. Zambia	9.95	10.33	0.257	0.306	0.208			0.500																	
42. Zimbabwe	11.95	12.27	0.240	0.476	0.143																				
43. Sudan	29.48	30.73																							
44. Sao Tome	0.15	0.15						0.040																	
Total	660.7	690.5	8.877	9.957	5.419	0.000	12.47	9.431	3.552	2.277	0.000	24.700	6.997	4.197	0.887	54.025	46.911	0.08	0.07						

Annex F – Table 4: Africa Total Planned Expenditure for RBM Activities in 12 Countries, 2001/2 for 1st Year of Five Year Plans, in Millions of Dollars						
Programme	Estimated programme totals Year 1	No. of programmes Mentioned in Plans	% of Total	Per Capita US\$	% of Planned	
Systems Strengthening/Capacity Building, HRD, Research, HMIS, Reform, Institutional Support	15.706	n=15	10.5	0.05		
Case Management (inc. Malaria & Nutrition & Drug/commodity Procurement)	44.957	n=15	30.0	0.14		
Epidemic Control	10.461	n=9	7.0	0.03		
ITNs and Personal Protection (including IPTs)	52.679	n=10	35.2	0.16		
Vector Control (including Community based Malaria Control and Biological Control)	14.823	n=9	9.9	0.04		
Management and Coordination	6.805	n=8	4.5	0.02		
Partnerships (and Social Movements)	1.986	n=7	1.3	0.01		
Monitoring and Evaluation (and Surveillance)	2.320	n=8	1.5	0.01		
Total	149.737		100.0	0.45		
Total Per Capita Expenditure	0.45					
Total Level of Resource Commitment per Table 2						
High Estimate Millions US\$	28.358			0.08	18.0	
Low Estimate Millions US\$	23.636			0.07	15.0	

Source: *WHO Summary Document on Malaria Strategic Planning in Africa, 2001*, and Table 2

Annex G

Malaria Research

Research

Research and the use of evidence-based decisions have been important elements of RBM. The global advocacy of RBM has partly contributed to increased investment in malaria research. New malaria research programmes have been initiated, for example Medicines for Malaria Venture (MMV), and existing ones have been strengthened. TDR allocation for malaria research has increased substantially in the last few years. However, even with this progress there is still a need for more support for malaria research to improve the use and delivery of existing tools, and to develop new tools and strategies. During Phase 2, RBM must increasingly focus on operational and implementation research.

Research Priorities

The current approach to defining global malaria research priorities depends on the knowledge and understanding of malaria experts, research institutes and funding agencies. It is not clear how far RBM Secretariat has been successful in influencing the global research agenda, and whether current research is contributing towards the achievement of RBM targets in the short or long term. The Secretariat should continue to advocate for more research. However, particular attention should be given to research topics that may contribute to achieving RBM targets. Emphasis should be on (a) improving the uptake of existing strategies and tools to attain high coverage and the desired impact; (b) creating an enabling environment to support the implementation of malaria control within the context of health sector reforms at the household, community, district, national and international levels; and (c) to develop and evaluate new strategies or tools for malaria control.

Research and Control

The importance of reducing the gap between research and control has been well-emphasized. The Secretariat has created an enabling environment for researchers to collaborate with control managers. It is only by working together that researchers appreciate the challenges facing malaria control managers. In addition, it enables researchers to identify research questions that are of particular relevance to control. It also allows researchers to promote the utilization of research findings to the malaria control community. An example of good practice is East Africa where researchers and malaria control managers work together on issues relating to anti-malarial drug resistance and treatment guidelines through the East African Network for Monitoring Anti-Malarial Treatment. In various other countries, malaria stakeholders work to ensure that operational research priorities are included within the Country Strategic Plans. The main advantage of researchers and control staff working together is facilitation of communication and exchange of information between the two parties. However, at the regional level, the link between AFRO and other African research institutions is weak.

Constant communication between researchers and control experts at national, regional and international levels is crucial for setting a relevant research agenda and for the success of malaria control. One example of lack of adequate communication has arisen with regards to the issue of safety of SP in infants. SP is a drug that has been in use for many years, and several countries have adopted it as the first-line malaria treatment. However, some researchers have recently noted that there is no adequate data on safety of SP in infants. Ideally, this question would have been already resolved prior to encouraging widespread use of SP and, more importantly, prior to recommending SP as a first-line drug in national treatment guidelines.

Alliance of Health Policy and Systems Research

The initiation of the new joint programme between the RBM Secretariat and the Alliance for Health Policy and Systems Research (AHPSR) represents a major step forward towards the goal of balancing disease interventions and health systems research issues. The AHPSR was established in 1999 by the Global Forum for Health Research in collaboration with World Health Organization. Its mandate is to contribute to health development, and to improving the efficiency and equity of health systems through research on policy. Another goal is to contribute to strengthening research capacity in areas of health policy and systems research.

The Alliance currently sponsors three projects involving malaria: malaria and social security in Colombia; human resource management for malaria control at district level in Uganda; and the impact of the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) on the availability of anti-malarial drugs in Mozambique. In the future, the Alliance intends to emphasize scaling up malaria control and prevention within the context of health system strengthening, decentralization, and sector wide approaches.

The research programme under the AHPSR is unique because it requires the involvement of policy makers from beginning to end, from the development of research projects to proper strategies for dissemination and utilization of research results. In Phase 2 of RBM, there is a need to further strengthen the link between RBM Secretariat and the Alliance. The goal must be to mobilize more resources for malaria research and to contribute to strengthening research capacity, which is still very weak in most malaria-endemic countries. It will be beneficial for AFRO to be actively involved in these areas of research in order to supplement its biomedical expertise, given the importance of health systems research to decision-making.

TDR

TDR is the Special Programme for Research and Training in Tropical Diseases, supported by UNDP, the World Bank and WHO. It is considered a research arm of RBM. The goal of collaboration between TDR and RBM is to review progress, identify gaps and define priorities in intervention research, product development and capacity strengthening in research and development (R&D) for malaria. Research priorities undertaken by TDR include strategies to improve the home management of uncomplicated malaria, the safety and efficacy of anti-malarial combination therapies, the development of rectal artesunate, and the rapid diagnosis and development of new drugs and other tools (e.g. Lapdap-artesunate triple combination, evaluation of insecticide-treated nets, intermittent treatment in pregnancy and malaria intermittent treatment in infancy).

The inclusion of implementation research within the research portfolio of TDR creates an opportunity for moving interventions from proof of principle to evaluating real life situations. This is an important interface between research and control. It is only after taking this step that a technical strategy can be rationally defined. Current examples of malaria interventions that must

be evaluated for their effectiveness include intermittent treatment for infants and anti-malarial combination therapies. However, implementation research is expensive. Therefore, RBM must work in collaboration with TDR to mobilize resources. In Phase 2 of RBM, TDR will have an opportunity to initiate more operational research, particularly related to social, economic and behaviour studies on utilization of interventions.

TDR and RBM communications need further strengthening through the appointment of a focal person for research within the RBM Secretariat. Given the need to broaden the research capabilities of malaria-endemic countries on issues relating to health sector reform, it will be important for the TDR Health Sector Reform Group to work closely with the AHPSR in this area.

MIM

The Multilateral Initiative for Malaria (MIM) in Africa is an international partnership that focuses on building malaria research capacity in Africa and promoting research with immediate value to control programmes. Currently, MIM provides financial support to more than 23 research projects in Africa, ranging from studies on home management of malaria; natural products and drug development; entomology and vector studies; pathogenesis and immunology; epidemiology; and anti-malarial drug resistance. RBM provides financial support to some of these research projects (e.g. Malaria Transmission Intensity and Mortality Burden Across Africa Project – this project, in addition to answering specific research questions, also collects other data for monitoring and evaluation of RBM across the region).

In the future, MIM should strengthen its ties to the malaria control community, to jointly identify research priorities for malaria control and to share progress and results on a regular basis.

European Clinical Trials Platform

European Clinical Trials Platform (ECTP) is a new initiative that aims to accelerate the development of new interventions against malaria, HIV/AIDS and TB by increasing the effectiveness of European investment in clinical trials in collaboration with developing countries; by mobilizing resources for developing these interventions; and by accelerating candidates through the developmental pipeline. Core functions of the Platform include supporting the networking and pooling of EU national trials activities (including the infrastructures needed in EU to support these trials, notably Phase I trials); supporting the development of trials infrastructures in developing countries (notably Phase II-IV trials), with a focus on capacity building and training; sponsoring clinical trials by putting together financial packages that attract external sources of co-financing for this purpose, particularly in partnership with biopharmaceutical industry; and developing a European, rather than national, presence in international initiatives for R&D for the three poverty-related diseases. RBM should establish contacts with the ECTP and play an active role in promoting its research agenda. This would supplement RBM's research links to other institutions in addition to TDR.

Medicines for Malaria Venture

The Medicines for Malaria Venture (MMV) is a joint public and private partnership dedicated to the discovery of new anti-malarial drugs. MMV's objectives are to discover, develop and commercialize one new anti-malarial product every five years. The goal is to make the new products affordable for the populations of malaria-endemic countries. MMV is needed because the pharmaceutical industry has reduced its engagement in anti-malarial drug discovery and development. Commercial returns on these new products are not considered adequate for the large investment required. MMV is supporting several projects at different stages – from

exploratory, discovery, pre-clinical and development stages. RBM Secretariat should continue to provide support to MMV to ensure the availability of new drugs on a regular basis. Given that resistance to insecticides is likely to increase, there is a need to explore similar ventures to support R&D for new insecticides.

The Search for a Malaria Vaccine

Many institutions are heavily involved in R&D for the development of a malaria vaccine, including the Malaria Vaccine Initiative, the European Vaccine Initiative, the National Institutes for Health, Wellcome Trust, Australian Medical Research Council, GlaxoSmithKline, US Department of Defense, WHO/TDR, African Malaria Intervention Network (former African Malaria Vaccine Testing Network) and USAID. Several antigens have been identified, two of which have recently undergone field trials. A trial of the RTSS vaccine in Gambian adult males has resulted in significant reduction in the rate at which they were infected after vaccination, although the protection was not long lived. A combination of three blood stage antigens has been tested among children of five to nine years in the Wosera District of Papua New Guinea. This study detected significant decreases in the parasite density and the frequency of parasite episodes greater than 1000 per micro litre, and a major switch in the MSP2 genotype of parasites.

There are nine vaccine candidates in or close to clinical trials. These have been developed and tested by various groups, including Medical Research Council, GlaxoSmithKline, US Ministry of Defence, USAID, National Institutes for Health, University of Maryland, New York University, University of Oxford, London School of Hygiene & Tropical Medicine and Institut Pasteur. Considering the growing interest in the vaccine and the need to speed up development and testing, there is a need to consider establishing mechanisms to coordinate malaria vaccine initiatives.

Annex H

Assessment of the Roll Back Malaria Monitoring and Evaluation System

Kate Macintyre, Erin Eckert, Amara Robinson

Executive Summary

Introduction

The Roll Back Malaria Partnership is currently undergoing an evaluation of its progress after three years of implementation. One objective of the RBM Partnership is to develop an effective monitoring and evaluation (M&E) system to assess RBM progress towards its objectives and determine whether its goals have been met at the country, regional and international levels. USAID, as primary funder of this monitoring and evaluation system, particularly for the Africa Region, has requested a specific assessment of the M&E system at the regional and global level. The results of this assessment will feed into the larger external evaluation and will provide recommendations to improve the capacity of RBM to monitor its effectiveness.

The methods used here have consisted of document reviews, database reviews, summary analysis of indicators and methodology, and key informant interviews in Harare, Geneva, Atlanta and by phone with nearly all other partners. The consultancy took place between November 2001 and January 2002.

- WHO/AFRO: three staff from RBM and one person from integrated disease surveillance
- WHO/HQ: five staff from RBM, two from integrated disease surveillance, two from TB
- Interviews and general discussions were also held with most of the individuals involved in or with a close interest in M&E of RBM, with members of the Partnership, with several malaria experts from RBM itself, and externally.

Framework

The framework for M&E for RBM is comprehensive in its coverage of all areas relevant to Roll Back Malaria. It emphasizes local control over data collection efforts by developing standardized approaches and encouraging countries to pick indicators appropriate to their epidemiologic profile. The framework uses minimal new data collection, instead relying on existing mechanisms and tapping into larger survey efforts, such as the Demographic and Health Surveys (DHS), where appropriate. This reliance on ongoing data collection efforts while improving

existing systems is laudable but has potential to increase problems in acquiring the desired data in a timely fashion.

The conceptual framework spells out the elements of a malaria programme but does not clarify the processes, outputs and outcomes within each element. In addition, there is no guidance on the appropriate selection of indicators at different levels, except to urge countries to choose one process and one outcome indicator for each element. The 'evaluation' aspect of M&E is not evident in the framework documents either, which could limit efforts to empirically prove the merits and cost-effectiveness of various programmes.

Databases and Platforms

Monitoring and evaluation depends on high quality valid and reliable data on the target programme. Several databases are in use, or are being created. However, many challenges remain if these databases are to play a solid role in M&E. In many cases the databases are not complete and some of the data are of questionable quality. It is particularly concerning that the baseline surveys are still not complete.

At the country level, various sources of data exist including national health information systems, national surveys such as the DHS or the UNICEF Multiple Indicator Cluster Survey (MICS). These sources provide information for programme monitoring and impact assessment on a regular basis. WHO/AFRO has also developed a methodology for collecting country baseline data which is currently being implemented in Africa. In addition, RBM has contracted with the INDEPTH network of demographic surveillance sites to collect specific indicators on malaria morbidity and mortality to inform the programme on disease trends.

Indicators and Sources of Data

There is a lack of consistency in indicators and definitions reported across countries and regions within RBM. The biggest issue is a lack of clarity on the definition of the indicators and target population covered. This lack of consistent guidelines and practices is a minor problem within a given country but can create more serious problems when it is aggregated at the regional or international level and compared with data from other countries that use different definitions or data sources.

The guidelines require countries to report on the five 'global' indicators and suggest selecting indicators to cover outcome and process levels as well. However, many countries have difficulty in recognizing the process/outcome/impact hierarchy. RBM (either regional or international) could greatly assist in this effort by providing technical assistance to individual countries to develop their M&E plans.

The RBM M&E framework suggests many different sources of data for most of the key indicators, including four of the five global indicators, which leads to confusion as to the most appropriate mechanism to obtain the needed data. A large number of the proposed indicators are population-based, yet the bulk of the data used are derived from routine health information systems or facility-based information and do not use the most accurate denominator estimates. The RBM guidelines currently provide no guidance on the appropriate *selection* of data sources. Indeed, in AFRO Region community surveys are being implemented without the rigid sampling methodologies necessary to be representative. This can create confusion and controversy when an indicator derived from one source is not the same as one calculated from another. Finally, there is an inconsistency in definitions of the suggested indicators, particularly the 'global' or 'core' indicators. These inconsistencies lead to confusion and ultimately jeopardize attempts to aggregate data at the regional or international level.

Organizational Capacity

Many of the shortcomings of the M&E system of RBM are due to organizational or structural issues within the RBM offices. The M&E team at headquarters is tasked with: a) coordinating an internal M&E working group; b) developing and implementing a work plan to track progress of RBM at all levels; c) developing a geographical information system for RBM; d) developing and testing tools for malaria M&E; and e) coordinating reporting on RBM and related activities. In addition to the M&E team at WHO/HQ, individuals within the programmatic components of RBM have M&E responsibilities. Several individuals working in other units such as Stop TB are also collaborating on aspects of RBM M&E; however, the organizational structure of RBM does not clearly define the roles and responsibilities of these individuals vis-à-vis the M&E team. Likewise, budget allocations for M&E activities are not clearly defined among the groups. This confusion leads to redundancies in some activities and gaps in others.

At WHO/AFRO, the M&E team is understaffed, consisting of one epidemiologist and one data manager. Both individuals are frequently on other activities within RBM and the larger WHO office. Other Regional Offices do not have dedicated M&E staff. This is a serious shortcoming given that all the data for international monitoring must come through the Regional Offices first.

There is no clear delineation of responsibilities between the regional bureaus and WHO/HQ for monitoring and evaluation activities, nor is there any formalized chain for reporting or deadlines. RBM is caught between the stated goal of helping countries develop their monitoring systems and the demand to produce accurate, timely tracking for the overall initiative. However, given the constraints mentioned above, this review suggests that technical assistance for the development of monitoring systems should be viewed as a separate, but equally important, activity from the monitoring of international efforts, at least in the early years of the initiative.

Recommendations

1. Recommendations for establishing systematic evaluation of RBM

- 1.1 Establish a strong M&E Team at the RBM Secretariat and in the Regional Offices. We see this as needing at least three separate initiatives:
 - Increase the number of qualified M&E staff both at HQ and in the Regional Offices, especially AFRO.
 - Streamline the management structure so that there is more authority to drive the evaluation decisions.
 - Establish a reference group to provide periodic consultation on specific technical issues related to monitoring and evaluation.
- 1.2 Establish and maintain a plan and timeline for RBM M&E reports at the regional and global levels. Reports that are essential in the near future include:
 - A baseline report for measures (dating from approximately 1998-1999) of impact, outcome and process indicators from settings where these data exist.
 - Progress reports describing specific issues such as evaluation of priority interventions, or monitoring the effect of a major policy change (e.g. change in first-line drug policy).
 - A format for annual reporting on progress with specific indicators and a timeframe for reporting must be established.
 - A global report on malaria, produced every few years, like the TB Global Report, would be very helpful at the international level.

- 1.3 Establish a transparent system for assessing data quality and standardization across countries, especially for the core indicators. The current M&E framework allows for local adaptation of many indicators thus potentially rendering some indicators incomparable. Certain indicators, when established as ‘global’ or at least as ‘regionally critical,’ must be exempt from country modification.
- 1.4 Establish methods for documenting sources of data within the specific databases used for M&E purposes, and the extent to which they are representative of a country situation. Currently, data sources for country indicators are not documented when the data are aggregated to the national or regional level, thus confusing interpretation.
- 1.5 Establish clear guidelines for data collection protocols and sampling strategies used to collect malaria-focused data in countries. For those indicators which can be obtained through standard survey methodologies, these should be used. For other indicators, RBM needs to provide clear and consistent recommendations on how to collect the necessary data, and technical assistance in data collection when necessary.
- 1.6 Establish a complete malaria database at the global level. Currently, no such database exists at the global level (although the AFRO Regional Office is compiling one for that region). RBM must be proactive in collecting data and holding countries to reporting requirements and deadlines.
- 1.7 Develop clear terms of reference for the HQ M&E unit as a whole. Management needs to clarify how the *cross-cutting* programmes like M&E should interact with the *vertical* teams. Current collaboration is based more on personal relations than on a defined structure.

Annex I

Roll Back Malaria in Complex Emergencies – RBM-CE

Dr. Ronald Waldman

The complex emergency component of the Roll Back Malaria initiative was evaluated separately, but essential findings and recommendations are presented here. These are based on an extensive review of all available documents, interviews with key people in the Secretariat, the donor community, WHO/AFRO, non-governmental organizations (NGOs), and the Technical Support Network. In addition, a field trip was made to Kinshasa and to Goma, in the Democratic Republic of Congo, where the evaluator worked closely with an RBM-CE employee and was able to observe her work and to conduct a series of interviews with donor, NGO and local partners.

Essential to the recommendations presented here is the finding that RBM-CE differs from the main body of RBM in three important ways:

- 1) its array of donors,
- 2) its key implementing partners, and
- 3) its potential array of technical interventions.

Some of the donor partners of RBM, such as the World Bank, are not traditionally involved in complex emergencies. In addition, although DFID and USAID are major donors to relief efforts in emergencies, the divisions of those organizations which deal with emergencies are not always in optimal contact with the more development-oriented divisions and have separate operating budgets. In many ways, USAID's Office of Foreign Disaster Assistance and DFID's Conflict and Humanitarian Affairs Department can be considered as different organizational donors from their parent agencies. In addition, other organizations that are principal actors in complex emergencies, such as the Office of the United Nations High Commissioner for Refugees, the World Food Programme, and the Bureau of Population, Refugees, and Migration (BPRM) of the United States Department of State, as well as a variety of others that are major stakeholders in complex emergencies, are not involved in RBM.

While RBM implements its ground-level activities primarily through Ministries of Health, and considerable effort is spent orienting and energizing these government bodies, RBM-CE more often than not finds itself using NGOs as its field-level partners. The reasons for this are multiple, and they vary considerably from one emergency to the next, but the fact is that governments are frequently part of the cause of complex emergencies and cannot be relied upon to be actively involved in the provision of health care to affected populations.

This aspect of RBM-CE has been a serious problem. WHO, which houses the RBM Secretariat, is an organization composed of, and directed by, its member states; NGOs working in emergencies are, in general, less accountable to governments (with the exception of their donors, who have been, for the most part, relatively undemanding). Partly for this reason, although there have been others, WHO has often been considered to be ineffective in its response to complex

emergencies. On the other hand, the NGOs, several of which are partners in the Technical Support Network of RBM-CE are often the first and the most important intervenors in emergency settings. It was the view of both WHO and NGO contributors that in addition to differences in style, there are real ‘cultural’ differences between the NGO community and the UN bodies. RBM-CE recognized this from the start – initially it was situated in the WHO’s Division of Emergency and Humanitarian Assistance (WHO/EHA) and operated distinctly from the main body of RBM.⁸ When RBM-CE was moved from WHO/EHA to the Secretariat, a move that was felt, at the time, to be of potential benefit, a number of actions caused problems.

These included the rapid development of funding proposals by RBM-CE and their dissemination to some of the emergency-oriented donors mentioned above; according to some, this occurred without adequate consultation and review by WHO staff. Also, staff were hired for deployment to complex emergencies by RBM-CE without adequate consultation and consent from the Regional Offices. Finally, where malaria control activities and/or policies suggested by NGOs working in the field were in conflict with those of Ministries of Health, RBM-CE tended to side with the NGOs while the more traditional (and more developmentally oriented) components of RBM argued the MOH side. Contributing to all of this is the fact that the current RBM-CE manager comes from an NGO background and has had little experience working within WHO, while malaria staff at WHO have limited experience with the NGO community and its approaches. The two modes of operation have not been adequately wed.

A third area of discordance between RBM and RBM-CE is on the technical level. It is generally accepted that the principal objective of emergency interventions is to reduce the mortality rate of the affected populations to baseline levels as rapidly as possible. Longer-term solutions to disease control problems, while recognized as being extremely important, sometimes have to wait until the situation stabilizes. In emergencies where malaria makes an important contribution to excess levels of preventable mortality, different measures may have to be implemented from those which are recommended in more stable, and more developmental, situations.

In Goma, for example, programmes to disseminate and monitor the use of impregnated bednets were being developed. These programmes require time for their implementation – community participation is essential to their success and in order to elicit community involvement intense health education activities are required. Yet, in the interim, no new prevention activities were being sponsored by the NGOs or by the authorities. However, in order to ‘buy time’, the indoor residual spraying of dwelling units might be an effective way of reducing malaria transmission until other measures could be implemented.

For treatment as well, different policies could be considered for different situations. If urgent reduction of malaria-specific mortality in a relatively small area is the goal, as is most frequently the case in complex emergencies, the most effective available treatment regimen might be recommended, at least for a limited period. On the other hand, the development of a rational national strategy that includes the abandonment of one treatment regimen and the adoption of another, including the designation of first- and second-line drugs for treatment, their purchase and distribution, and careful monitoring and evaluation of their effects, has proven to take considerable time – years, in most instances. In the interval, adherence to national-level policies that recommend the use of ineffective drugs might preclude the ability of NGOs and others working in emergencies to achieve their short-term goals.

⁸ WHO/EHA is undergoing a thorough evaluation at the same time as the RBM evaluation is being conducted. Many of the contributors to this report felt that serious changes might be recommended in the way that WHO has approached complex emergencies, including the possible placement of this activity at the Cabinet level and in an advisory rather than a technical role. But definite conclusions regarding the organizational placement of RBM-CE must await those findings. One possible solution is, nevertheless, offered here.

In addition to these real and potential differences in approach, RBM-CE has developed a research agenda that is separate from that of RBM. Field trials of factory-treated bednets that do not require re-impregnation are planned – in Goma, both the NGO responsible for central drug supply (ASRAMES) and at least one NGO operating in the region (IRC) have purchased large quantities of these nets. (Interestingly, the National Malaria Control Programme Manager discussed that programme’s intention to develop a strategy for distribution of nets that require re-impregnation at the community level). Another example of research specific to RBM-CE is the development of insecticide-impregnated plastic sheeting. Complex emergencies are frequently accompanied by the displacement of large populations. Shelter is an important problem that is frequently addressed by the distribution of large quantities of plastic sheeting for makeshift dwellings that serve to protect refugees and the internally displaced. RBM-CE has been exploring the commercial possibility of developing such material and is in the process of field-testing it.

The point of the discussion above is to establish a case for the structural separation of RBM-CE from the RBM Secretariat. This idea is not new, and mention has already been made of the original location of RBM-CE in WHO/EHA. What is new is the development of a Control of Communicable Diseases in Complex Emergencies Unit within the Communicable Diseases Cluster of WHO. This unit seeks to identify the major causes of communicable disease morbidity and mortality in emergency settings, to garner the technical resources of WHO and its operational partners in emergencies (including NGOs) in order to address these problems, to develop norms (in the form of standards and guidelines), and to suggest and sponsor research.

For many reasons, including those discussed above, RBM-CE appears to fit better with the new Control of Communicable Diseases in Complex Emergencies Unit than it does with the Secretariat of RBM. This report recommends that RBM-CE be separated from RBM and that it be located with the Control of Communicable Diseases in Complex Emergencies Unit of the Communicable Diseases Cluster of WHO.

Annex J

Technical Dimensions for Roll Back Malaria

The Roll Back Malaria (RBM) Strategy builds on the Global Malaria Control Strategy endorsed in Amsterdam in 1992. The RBM Strategy has six technical elements, which include early detection and rapid effective treatment, multiple preventions (e.g. insecticide-treated nets, selective and sustainable vector control, prevention of malaria during pregnancy), focused research, coordinated action for strengthening existing health services, policies and community-level effort, and dynamic global movement supported by a coalition of partners working toward a common approach. This section evaluates RBM tools and strategies for addressing the global burden of malaria.

Early Detection and Rapid Treatment

Early detection and treatment is the main approach for malaria control in most endemic countries. In most areas treatment is being done outside formal public health facilities. A recent finding of a study on the training of mothers in early recognition and proper malaria treatment showed a 40 percent reduction of under-five mortality in Tigray, Ethiopia (Kidane and Morrow *et al*, 2000). In several studies on compliance to treatment, the training of shopkeepers in selling full courses of anti-malarial drugs in a blister package has been shown to improve compliance and reduce waiting times for the patients (Marsh *et al*, 1999, Yeboah-Antwi *et al*, 2001). Also, RBM has supported important studies to improve the approach of home management and advocate its application. As a result, several countries intend to promote the approach of home management, as shown in country strategic plans.

Definitive malaria diagnosis requires detection of malaria parasites or parasite antigens by microscopy. The RBM Secretariat has facilitated the development of consensus through informal consultation meetings on the use of new rapid malaria diagnostics and anti-malarial drugs, including combination therapies. Rapid diagnostic tests have an important role to play in areas of low to moderate transmission, where most of the infections are symptomatic. In Cambodia, a rapid test together with a combination of mefloquine-artesunate in blister package is widely promoted in both public and private health facilities.

However, in high-transmission areas diagnosis typically depends on clinical algorithms. The role of microscopy is more limited, in part due to its widespread unavailability, but also in part due to the fact that high prevalence of the malaria parasite means that it is not associated with illness. Nevertheless, the role of definitive diagnosis using microscopy or rapid detection tests will become increasingly important in these high transmission areas. These are areas in which resistance to the most commonly used anti-malarial drugs is increasing, and the more expensive combination therapies are likely to become the first-line drugs of choice.

Anti-malarial Drugs

RBM Secretariat organized informal consultative meetings to review and update recommendations on the use of anti-malarial drugs for prevention and treatment of uncomplicated malaria.

Chloroquine

Drug resistance has become a major problem in malaria case management in several countries. Chloroquine, a drug that has been cheap and widely available for many years, has developed resistance to *P. falciparum*. Resistance to chloroquine is widespread in East, Central and Southern Africa, compelling several countries to change first-line treatment to either sulfadoxine-pyrimethamine (SP) alone, a combination of SP and chloroquine, or a combination of SP and amodiaquine. In West Africa, chloroquine resistance varies but tends to be lower than it is in East Africa, and no changes have yet been made in first-line treatment. There is a high level of chloroquine resistance in South Asia, South-East Asia, the Oceanic countries (Papua New Guinea and Vanuatu), the Amazon Basin, and in some coastal areas of South America. However, the drug is still first-line treatment in Afghanistan, Malaysia and Yemen. It is also used in combination with primaquine in Bangladesh, India, Myanmar and North Vietnam. In the Oceanic countries, it is used in combination with SP in adults, while in South America it is used in combination with primaquine in Venezuela.

Chloroquine is still effective against *P. vivax* and is commonly used in Ethiopia and South-East Asia to treat malaria associated with *P. vivax* infections.

Amodiaquine

The drug is efficacious in most parts of Central, East and West Africa, and the northern Pacific coast of South America. However, there is cross-resistance with chloroquine, and moderate to high-level resistance has been reported in Papua New Guinea, some parts of East Africa and in the Amazon basin. Amodiaquine is also being used in combination with SP in Papua New Guinea, and is second-line treatment in Tanzania and Kenya.

Sulfadoxine-Pyrimethamine

Since the emergence and spread of *P. falciparum* resistance to chloroquine, SP has been the drug of choice for malaria treatment in Botswana, Ethiopia, Kenya, Tanzania, Malawi and South Africa. The drug is efficacious in most parts of West Africa. In Uganda and Ethiopia it is recommended as a first-line treatment in combination with chloroquine. However, SP resistance is increasing in certain areas of East Africa. There is low-level resistance in the Indian sub-continent, Central and Southern Africa, and in the coast of South America. High-level resistance is found in South-East Asia and in the Amazon Basin.

Quinine

The drug is commonly used for treatment of complicated malaria. It is highly efficacious in most endemic areas, with the exception of a few areas in South-East Asia and South America. Quinine is used in combination with tetracycline as a first- and second-line drug in Brazil, Cambodia and Peru. In Guyana it is used in combination with clindamycin as first-line drug, while in Venezuela it is being used in combination with doxycycline as a second-line drug. In Bangladesh, quinine is combined with SP, and in Thailand it is being used in combination with tetracycline and primaquine as a second-line drug. However, compliance to a combination of quinine with tetracycline remains a problem.

Mefloquine

The drug is mainly used in South-East Asia and part of South America. It is not widely used in Sub-Saharan Africa. Resistance has spread in Brazil in South America, and in the border areas between Cambodia, Myanmar and Thailand in South-East Asia. Mefloquine is used in combination with primaquine in most parts of Thailand. It is also used in combination with artemisinin derivatives as first-line treatment in multi-drug resistant areas in Thailand, Cambodia and part of Vietnam.

Artemisinin derivatives

Artemisinin derivatives include artesunate, artemether, arteether and dihydroartemesinin. The derivatives are effective in clearing parasites rapidly but the recrudescence is high when used as monotherapy. There are several cases reported on *in vitro* resistance but not yet confirmed by *in vivo* testing. Artemisinin derivatives as monotherapy have been used in Bhutan, parts of Vietnam, and in China, particularly in the Yunnan and Hainan provinces. Other monotherapies include halofantrine, atovaquone-proguanil and artemisinin. Other potential monotherapy compounds under trial include chlorproguanil-dapsone.

Artesunate suppositories

Artesunate suppositories have been proven to be effective in preventing mortality. Studies are underway to evaluate community effectiveness of suppositories when applied at home to reduce malaria mortality.

Combination Therapies

A consultative meeting was convened by RBM Secretariat to review the evidence for combination therapy, its criteria for selection, and its use in different epidemiological settings, particularly in Africa. Combination therapy of anti-malarial drugs is the simultaneous use of two or more blood schizonticidal drugs with independent modes of action and different biochemical targets in the parasite.

The aim of combination therapy is to improve efficacy and to slow the development of resistance to an individual component. This strategy has been successfully applied to the treatment of tuberculosis, AIDS, leprosy and cancer. In Thailand, a combination of artemisinin and mefloquine has maintained an efficacy of greater than 96 percent since its introduction in 1994, compared to less than 50 percent efficacy of mefloquine alone. There was incidence reduction of clinical malaria and reversal of mefloquine *in vitro* resistance (Nosten *et al*, 2000, Price *et al*, 2001). RBM Secretariat, in collaboration with TDR, has supported studies to establish the safety and efficacy of combination therapies in Africa. The effectiveness of combination therapy in delaying the development of resistance has not yet been established in Africa. Two large-scale projects are underway in South Africa and Tanzania.

The artemisinin-based combination therapy includes fixed and non-fixed combinations. The only fixed dose of artemisinin-based combination is artemisinin-lumifantrine. Non-fixed combination includes artemisinin derivatives and either mefloquine, amodiaquine, chloroquine or SP. Trials have been conducted to detect the safety and efficacy of these combinations, with the exception of artemisinin mefloquine. The safety and efficacy of this combination has been well-established and is widely used in South-East Asia. Other potential combinations are chlorproguanil-dapsone-artesunate, dihydroartemesinin-piperaquine-trimethoprim, dihydro-artemesinin-piperaquine trimethoprim-primaquine, pyronaridine-artesunate, and paphthoquine-dihydroartemesinin.

Multiple Prevention Methods

Insecticide-treated Materials

Studies have shown that ITNs and curtains provide significant protection against malaria in almost all epidemiological situations. In Tanzania, studies have shown that treated mosquito nets reduce child mortality by 30 percent and parasitaemia and anaemia by 60 percent and 50 percent respectively. Despite an increase in net coverage, re-treatment has been a major challenge. RBM Secretariat has commissioned field studies of long-lasting mosquito nets. These nets may offer a useful response to the problem of low re-impregnation. Preliminary results are encouraging and

the Secretariat is exploring possibilities of transferring the long-lasting net technology to manufacturers in malaria-endemic countries.

Vector control

Vector control methods have been shown to be effective in reducing malaria transmission and thus preventing epidemics. Insecticide house spraying is the main approach for vector control in low-transmission areas (e.g. Southern Africa). The main insecticides applied for house spraying are organochlorine, organophosphates, carbamates and pyrethroids. In-house spraying has been saved from a global ban. Other methods for vector control through environmental management or using biological control are applied in a few selected settings, depending on epidemiological conditions. RBM Secretariat has published and disseminated guidelines for selective vector control.

Intermittent preventive treatment for malaria in pregnancy

Intermittent administration of SP, once during the second and third trimesters, has been proven to reduce severe anaemia in pregnant women and improve the birth weight of infants.

Intermittent treatment in infancy

Recently, a new approach for malaria control has been evaluated in Tanzania and is showing convincing results. Administration of SP during immunization has reduced 60 percent of clinical malaria incidence and 50 percent of severe anaemia. The new approach will require validation in other endemic settings. In areas where efficacy results have been obtained, the effectiveness of intermittent treatment in infancy must be tested before it is adopted as an RBM technical strategy for malaria control.

Drug quality

Low quality and counterfeit drugs present major problems to malaria control. In 1999, RBM convened a meeting in Geneva to discuss this issue with drug quality control officers from several countries in Africa. Following the meeting, a study to assess the quality of anti-malarial drugs was initiated. So far no major progress has been made to ensure that good quality drugs are available to all malaria patients. Guidelines for purchasing anti-malarial drugs need reinforcement and quality control laboratories in endemic countries need further strengthening. There is a need to establish a link between WHO-accredited laboratories and national quality control laboratories to standardize methodology. Standard approaches to test quality must be re-evaluated, and mechanisms to reinforce regulations, with the support of WHO member countries, need serious attention. Tanzania is experiencing a problem with low quality SP even as it changes treatment policy, reflecting the fact that countries need technical support during the process of changing and adapting to new treatment guidelines.

Change of treatment guidelines

The main challenge in the most affected countries lies in changing treatment guidelines. AFRO developed a framework for changing malaria treatment guidelines about four years ago, yet it has neither been published nor widely circulated to date. In addition, several countries (Tanzania, Kenya, Uganda, Burundi) changed treatment guidelines with technical assistance from both regional and headquarters offices, but there is little evidence to indicate whether the framework has been applied effectively.

Even after reaching a decision to change treatment guidelines, countries still confront difficulties operationalizing the new treatment guidelines. They face different influences from other stakeholders, particularly the media, private sector, politicians, pharmacists and clinicians.

Strong technical support to countries undergoing this process is greatly needed. The current emphasis of RBM technical missions is restricted to identifying alternative drugs, and not to assisting countries with the overall process of changing and adapting new treatment guidelines. Efficacy is not the only important consideration. Countries must consider other important factors, such as cost, cost-effectiveness, availability, side effects and treatment-seeking behavior.

Diversity or common strategy

Countries have developed strategic plans for rolling back malaria based on local epidemiological situations. The RBM technical elements are included in the Country Strategic Plans. Most of the CSPs mentioned the role of both public and private health sectors in early diagnosis and effective treatment. They include shops and community health workers in case management. The CSPs for Uganda and Zambia consider scaling-up home management. Some CSPs include drug quality and guidelines on drug donations. Some consider pre-packing anti-malarial drugs in order to increase compliance. Treatment policy is clearly discussed in others.

On treatment delivery, the CSPs emphasize home management and IMCI as possible channels for treatment. IMCI, if effectively supervised, has the potential to improve case management at health facilities through its focus on training health workers and improving drug availability.

CSPs typically include ITN components. Some have advocated the use of social marketing, involving both public and private sectors, for net distribution. The public sector will play an important role in demand creation and in preparing an enabling environment (e.g. removal of taxes and tariffs) for people to access nets and insecticides.

A further evaluation of ITNs was conducted in South-East Asia, based on the ecology of malaria vectors. Malaria vectors are different, particularly in biting and resting behaviours. In Cambodia, *An.minimus* bites in the early evening. Yet most of the evidence on the effectiveness of ITNs comes from areas where the main malaria vector bites at night (i.e. during normal sleeping hours).

Several CSPs include other methods for vector control besides ITNs, for example, insecticide residual spraying (Eritrea, Ethiopia), and environmental management and larviciding using chemicals or biological agents (Eritrea and Ethiopia in specific sites). Surprisingly, the CSPs for Nigeria, Ghana and Senegal have also included larviciding and other methods for environmental management. These methods require further study. In many countries environmental management is widely believed to be an important component of malaria control despite the fact that there is little evidence of its effectiveness.

In particular, the role of environmental management methods as part of malaria control needs to be investigated in urban settings. Some experts still believe that environmental management is a cost-effective method in urban areas with dense populations. However, few studies compare this approach to the use of ITNs in urban areas. Studies evaluating ITN effectiveness have typically been carried out in rural rather than urban areas.

Annex K

The Stop TB Partnership

The goal of the Global Partnership to Stop TB (hereafter, the ‘Stop TB Partnership,’ or ‘the Partnership’) is to eliminate tuberculosis (TB) as a public health problem and, ultimately, to obtain a world free of TB. The Stop TB Partnership aims to promote a wider and wiser use of existing strategies to interrupt TB transmission through increased access to drugs and treatment; to adapt existing strategies to meet new challenges posed by emerging threats, such as multi-drug resistance and HIV-related TB; and to accelerate the elimination of TB through research for new diagnostics, drugs and vaccines. It promotes the use of the Global Drug Facility (GDF), which is a project of the Stop TB Partnership.

The Stop TB Initiative, a precursor of the Partnership, was launched in November 1998 by the Director-General of WHO, and was endorsed by the Amsterdam Declaration of Stop TB in March 2000. The Partnership was formed at the Bellagio meeting of the interim Stop TB Coordinating Board in February 2001. The Secretariat of the Stop TB Partnership is located within the Communicable Diseases Cluster at WHO, and in fact exists administratively within a WHO unit called by the same name, ‘Stop TB.’ The Partnership, although based at WHO, is a network of international organizations, countries, financial donors from the public and private sectors, governmental and non-governmental organizations, and other entities and individuals who have expressed interest in the Stop TB mission. The Stop TB Partnership is comprised of the following components: the Partners’ Forum, the Coordinating Board, the Working Groups, the Technical Advisory Group (STAG, which determines policy through WHO), the Global TB Drug Facility and the Secretariat.

The **Stop TB Partners’ Forum**, the main assembly of the Partners, consists of representatives of all the Partners. The Forum meets at least once every two years upon convocation issued by the Executive Secretary. The Forum’s mandate is:

- ❑ to identify problems and new challenges, and to exchange information among Partners;
- ❑ to consolidate and increase Partners’ commitment to Stop TB’s objectives, and to reinforce high-level political commitment to the Stop TB Partnership;
- ❑ to create and exploit opportunities for advocacy, communications and social mobilization; and
- ❑ to review overall progress towards implementation of the goals of the Stop TB Partnership, review reports presented by the Coordinating Board, and make recommendations to the Board.

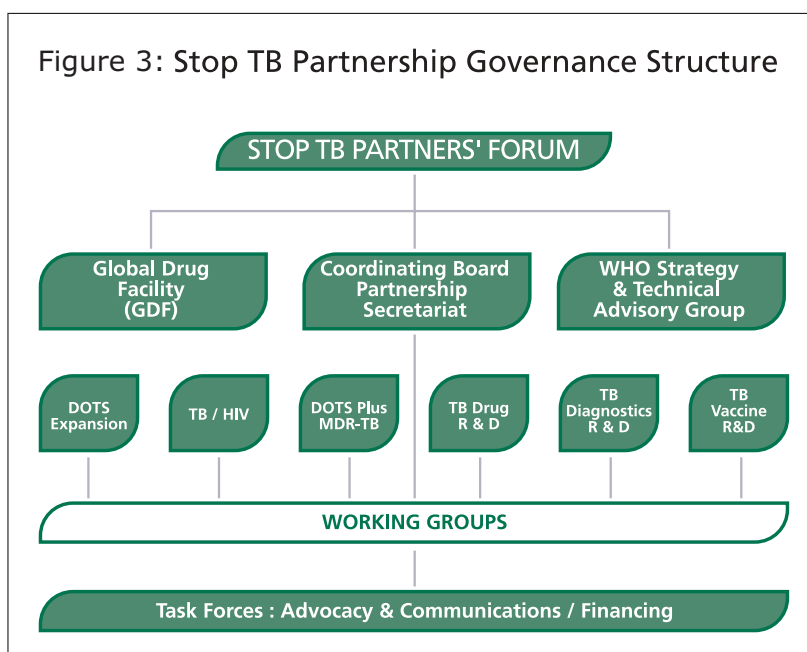
The **Stop TB Coordinating Board** is the coordinating mechanism for the Stop TB Partnership. To function effectively, it depends largely on the good will and cooperation of the Stop TB Partners, since the Board itself is not a legal entity. The composition of the Board reflects the major groupings and the diversity of the Stop TB Partnership, and consists of 27 members selected from amongst the Partners as follows: Working Group Chairs (6); representatives from six regions (nationals of countries in the six geographic regions of WHO) (6); high-burden country representatives (4); financial donors, public and private (4); international organizations having a health mandate (WHO, World Bank, UNICEF) (3); representatives from

NGOs/technical agencies (3); and the chairperson of the WHO TB STAG. To improve the workflow between its bi-annual meetings and electronic conferencing (when needed), the Coordinating Board created a Working Committee of six of its members to participate in weekly telephone conferences with the Secretariat. The mandate of the Coordinating Board is:

- to set priorities for action in accordance with WHO technical advice and in light of recommendations of the Forum;
- to approve the workplan and budget of the Secretariat;
- to mobilize resources, and to identify funding gaps and priorities;
- to coordinate and promote advocacy and social mobilization;
- to review the progress of the Stop TB Partnership toward implementation of its goals, and to adopt appropriate rules or guidelines to ensure the proper functioning of the Partnership; and
- to facilitate, coordinate and review the activities of the various working groups.

The **Secretariat** is the implementation arm of the Stop TB Coordinating Board. The Secretariat's staff is provided partly by WHO and partly by staff seconded from partner organizations. The head of the Secretariat is appointed by the Director-General of the WHO in consultation with the Coordinating Board. Administratively, this position reports to the Director of Stop TB, the head of a WHO programme department contained within the Communicable Diseases cluster. In principle, the Secretariat is accountable to the Stop TB Coordinating Board. Its specific functions include:

- Preparation of an annual work plan and budget for the Stop TB Partnership, including plans and budget for the Secretariat;
- Support for the procurement, quality control, and monitoring and evaluation functions of the Global TB Drug Facility, in conjunction with other agencies;
- Maintenance of close and regular contact with the Working Groups to facilitate coordination and to support their work;
- Development of effective communication strategies to support the Stop TB campaign
- Information sharing within the Stop TB Partnership; and
- Administrative support to the Board, the Working Groups and the Forum.



The **Working Groups** are the primary vehicles for coordinating activities of the Partnership. Working Groups are created and dissolved as needed (and recommended) by the Board. The existing six working groups include one which focuses on DOTS expansion, one which addresses HIV-related TB, one focused on multi-drug resistant (MDR) TB, and three which concentrate on the development of new tools (drugs, diagnostics and vaccines) for combating TB. The membership of the Working Groups is open and inclusive. Each of the Working Groups has independent governance mechanisms, but works under the umbrella of the Global Partnership to Stop TB. In some cases, the Working Groups are already fully-fledged organizations in their own right (e.g. the Global Alliance for TB Drug Development).

One of the six Working Groups – the Working Group on DOTS Expansion – is responsible for providing technical advice to countries on behalf of the Stop TB Partnership. The DOTS Expansion group works closely with the Regional Offices of WHO, with technical Partners, and with TB Medical Officers assigned to more than half of the 22 high-burden countries. The WHO TB Medical Officer serves as technical advisor, coordinator and advocate, and is intended as a source of knowledge and expertise for the National Programme Officer (NPO) to draw on. Although the WHO TB Medical Officers sit either at the WHO country offices or National TB programme offices, and are officially WHO employees, they are frequently seconded from other partners within the Stop TB Partnership.

Annex L

The Global Alliance for Vaccines and Immunization

The Global Alliance for Vaccines and Immunization is a partnership of organizations involved in global immunization efforts. GAVI was launched in January 2000 to address flagging interest in childhood immunization, and is dedicated to ensuring that all children, however poor, have equal access to routine immunization with the six basic vaccines against polio, diphtheria, whooping cough, tetanus, measles and tuberculosis. It aims to increase access among poor children in developing countries to vaccines that are widely available to children in the industrialized countries, such as hepatitis B, Haemophilus influenzae B (Hib) and yellow fever. Finally, its goal is to promote research and development for new vaccines against major killers of the world's poor, including HIV/AIDs, TB and malaria.

A major focus in GAVI's first two years of existence has been to support expanded immunization programmes in developing countries. All countries with incomes of less than \$1000 GNP per capita are eligible for financial support, although exceptions were made to include China, India and Indonesia due to their large poor populations. Eligible countries have been encouraged to apply for financial assistance in response to specific calls for proposals.

Partners' Meetings provide the primary forum for a gathering of stakeholders and like-minded constituencies to exchange views on matters relating to the Alliance. The provisional agenda for the Partners' Meetings is prepared by the Executive Secretary of the Secretariat in consultation with the Working Group and the Chair of the GAVI Board. Meetings are held approximately every two years.

The **GAVI Board** is the main decision-making body of the Alliance. It comprises 15 members, and meets on a bi-annual basis. There are four renewable members: the Bill and Melinda Gates Foundation, UNICEF, the World Bank and WHO. There are eleven additional rotating members responsible for representing the collective expertise of the broader alliance and the perspective of their individual constituencies. These include representation from foundations (1), developing country industry (1), OECD industry (1), research institutions (1), technical health institutions (1), non-governmental organizations (1), developing country government representatives (2), and OECD government representatives (3). The main functions of the GAVI Board are to:

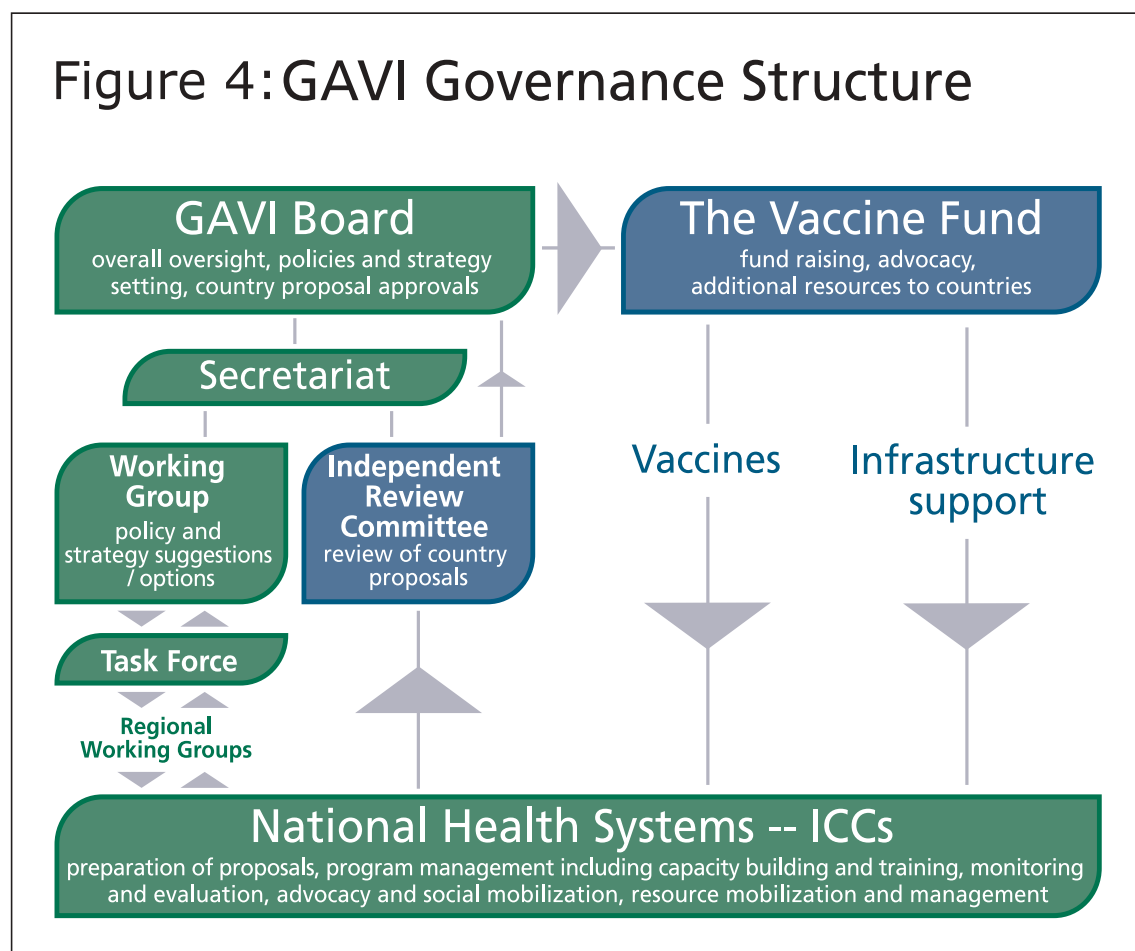
- Review, approve and update joint objectives and milestones;
- Consider the recommendations of the Independent Review Committee, approve support for country immunization programmes, and request disbursements of the Vaccine Fund;
- Monitor the activities of Partners in undertaking certain strategies and activities;
- Approve the budgets of the Secretariat and task forces;
- Contribute to fundraising and advocacy, through its members;
- Nominate the Executive Secretary;
- Shape the strategic vision and direction for the Alliance; and
- Stimulate GAVI partners to adopt new approaches and behaviours.

The **Vaccine Fund Board** is tasked with the responsibility of raising global awareness of the GAVI immunization goals, to disburse existing funds in support of these goals, and to raise additional funds. The Board meets on an annual basis, although its members are expected to work actively to support the Fund throughout the year.

The **Working Group** is the implementation arm of the Alliance. Working Group members represent the Partner agencies and are tasked with translating GAVI priorities into their respective agency workplans. The Working Group currently consists of nine members, namely WHO, UNICEF, the World Bank, the GAVI Secretariat, the Global Fund for Children’s Vaccines, the Gates Children’s Vaccine Program at the Program for Alternative Technology in Health (PATH), the University of Maryland School of Medicine, USAID, and Wyeth-Ayerst Labs. The main functions of the Working Group are to:

- ❑ Communicate major Board decisions – such as new Fund policies and country proposal decisions – to partner constituencies at the regional and national levels;
- ❑ Monitor progress in identifying issues arising from Partners (including task forces, regional working groups, and countries) that require Board decisions);
- ❑ Prepare background documentation for the Board to facilitate its decision-making;
- ❑ Oversee the operations of GAVI structures, including the coordination of task forces and the monitoring of its progress.

The **Secretariat** is the administrative arm for the Alliance, supporting the activities of the Board and the Working Group. It contains five professional staff and two secretaries, and is housed in the European Regional Office of UNICEF in Geneva. Its main responsibilities revolve around coordination of the partners and managing the review of country proposals to the Vaccine Fund.



Four **task forces** were established to address specific issues of concern to the Board. Task forces are funded and managed by their respective lead agencies, but supplementary funding may be provided by the Secretariat when appropriate. The expectation is that the task forces will be created and dissolved in response to changing circumstances and needs of the Alliance. The four existing task forces are:

- ❑ Financing (Co-chaired by the World Bank and USAID);
- ❑ Research and Development (Co-Chaired by WHO, NIH, and Chiron Vaccines);
- ❑ Advocacy (Chaired by UNICEF); and,
- ❑ Country Coordination (Co-Chaired by WHO and the Government of Norway).

The **regional working groups** were created to provide technical expertise on demand to countries, and to coordinate technical support and information sharing between the national and international levels. In some cases, they are strongly linked to WHO regional activities. In the future, it is envisaged that the regional working groups will take an active role in overseeing, analyzing and supporting the work of national Interagency Coordinating Committees.

At the country level, the primary vehicle for promoting the goals of the Alliance are the **Interagency Coordinating Committees (ICCs)**. Many ICCs were originally focused on polio eradication, but have now expanded to coordinate the broader Partnership activities around immunization. The roles and functions of the ICCs vary considerably from country to country, depending on the size, strength of the government, and the presence of other health system coordinating groups (such as SWAs). However, they are involved in coordination of capacity building and training; monitoring and evaluation; establishing appropriate linkages with broader health and development frameworks; advocacy and social mobilization; and financial expertise.

Annex M

Malaria Control Strategy of the African Development Bank Group

Executive Summary

1. Malaria remains a serious impediment to socio-economic development in Africa. Out of the annual clinical cases of malaria in the world, estimated at 300-500 million, approximately 90% occur in Africa. More than 1 million people die of malaria annually, the majority of whom are in the African region. The poor are most at risk from malaria deaths as 58% of all deaths in the world occur among the poorest 20% of the world's population. Employed persons and principal child carers can lose up to 10 productive days for each time when they themselves or their children contract malaria. Direct costs borne by individuals, households and governments include the costs of treatment and prevention. Studies on the macro-economic impact of malaria indicate that countries with a substantial high burden of malaria grew at 1.3% per year less, and that a 10% reduction in malaria was associated with a yearly 0.3% increase in Gross Domestic Product.
2. The high burden of this disease in Africa is due to the fact that malaria endemicity affects a significant number of countries where the transmission is stable. Moreover, the situation is worsening due to limited investments in malaria control, development of malaria parasites resistance to drugs and mosquito resistance to insecticides as well as weak health systems. Realizing that malaria impedes socio-economic development and poverty reduction, the African Development Bank's Health Sector Policy, adopted in 1996, recognizes malaria as one of the major diseases in Africa requiring priority investment. Meanwhile, the resurgence of malaria has necessitated that the Bank re-examine its malaria control activities to date, and re-assess further actions it can support to combat this disease. The Bank, therefore, is proposing a multi-sectoral Malaria Control Strategy for its operations to complement Roll Back Malaria (RBM) activities in the Regional Member Countries (RMCs).
3. This document presents a strategy that is formulated on the basis of the epidemiological situation, and the social and economic impact of malaria in the Bank's RMCs. The Malaria Control Strategy reflects the measures presently being promoted in international malaria control initiatives, and describes the Bank's past investments and lessons learnt in malaria control. It also defines the goal, objectives, guiding principles, priority areas and specifies the Bank's multi-sectoral approach.
4. The goal of the Bank's Strategy is to complement actions being taken to promote accelerated economic growth with equity and poverty reduction as central goals in Africa. Its objective is to contribute to the reduction of the social and economic burden of malaria in Africa by:
 - Increasing the Bank's support to RMCs to enhance the formulation and implementation of appropriate and evidence-based malaria control interventions in various sectors and in emergency assistance;

- ❑ Ensuring that Bank-financed projects, particularly those in non-health sectors (agriculture/rural development and infrastructure, education, private etc), integrate effective and appropriate environment and social management plans to mitigate against the potential impact of malaria transmission; and
 - ❑ Exploiting opportunities to reinforce knowledge, attitude, practices and behaviour change to build awareness of malaria control strategies as part of human resources development.
5. The Bank endorses the elements and principles laid down by the RBM initiative that has the overall objective of reducing the global burden of malaria by 50% by 2010. The initiative launched by WHO, UNDP, World Bank and UNICEF is now supported by other development partners including the African Development Bank. In addition, the Bank will be guided by the following principles:
- ❑ Selectivity and focus: Promoting a wide-range of interventions in malaria control that are proven to be efficacious in averting mortality and disability, and also cost-effective, given the complex interaction between malaria parasites, vector mosquitoes and human populations;
 - ❑ Feasibility of approaches and affordability: Supporting the integration of malaria control measures across sectors of RMCs to maximize the use of available resources including co-financing mechanisms;
 - ❑ Empowerment: Assisting individuals, families, communities, governments, institutions, private sector and media among others to contribute towards national efforts in malaria control, and at a sustainable level of effort; and
 - ❑ Participatory approaches and strategic partnerships: Involving beneficiary communities and the sub-groups within them, and working through strategic partnerships with specialized lead agencies in implementing best practices to assist multi-sectoral malaria control actions in RMCs.
6. The main priority areas for malaria control which the Bank will support in partnerships with RMCs include:
- ❑ Formulation and implementation of malaria interventions in various sectors in RMCs targeting vulnerable groups particularly those in rural areas as well as communities and workers at increased risk of malaria infections due to environmental and occupational factors, as part of poverty reduction actions;
 - ❑ Development of appropriate frameworks, at country level, that promote good environmental and social assessment, and management of conditions favorable to reducing malaria transmission;
 - ❑ Improvement of existing public services and infrastructure to strengthen the implementation of the malaria control interventions, and related cost-recovery mechanisms where issues of equity will not marginalize poor and vulnerable groups;
 - ❑ Promotion of macroeconomic policies that can enhance malaria control programmes through such actions as the reduction or exemption of taxes and tariffs on anti-malarial products including local production of these products, on both large scale and micro-enterprise basis, within the context of appropriate fiscal and regulatory frameworks;
 - ❑ Advocacy for public-private sector partnerships that encourage participation of Africa-based companies in national malaria control programmes; and
 - ❑ Advancement of operations research, at country and regional levels, aimed at increasing the availability of new anti-malarial drugs including vaccines, and tools for mosquito vector control as well as exploring new opportunities such as the integration of known safe and effective African traditional medicines into the health systems of RMCs.

7. The Bank will employ the strategies that will complement and support country programmes as outlined in the Country Strategy Papers (CSPs), and prevailing sector operational policies, underlining the following:
 - Policy dialogue and technical assistance to enhance malaria control concerns and support RMCs to create favourable macroeconomic policies and frameworks;
 - Multi-sectoral strategies and targeted approaches to mainstream malaria control measures in Bank-financed operations including malaria risk assessment with a view to developing mitigation against increased transmission associated with development projects;
 - Reinforcement of knowledge, attitude, practice and behaviour change through malaria information and sensitization activities; and
 - Development and sustainability of effective partnerships to mobilize domestic and external resources to address malaria control as well as ensure that communities receive an appropriate mix of synergistic multi-sectoral interventions.

8. The Bank's Malaria Control Strategy builds on the Global Malaria Control Strategy adopted by Regional Member Countries and lead specialized agencies. It optimizes the Bank's comparative advantage of capacity and capability for multi-sectoral support to RMCs. This document is complemented by specific measures and actions recommended for Bank investment that constitute the multi-sectoral Malaria Control Operational Guidelines.

