



Government of Malawi

Malaria Strategic Plan 2005 - 2010

Scaling up Malaria Control Interventions

**Ministry of Health
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Foreword

Malaria is a major public health problem in Malawi. It is the leading cause of morbidity and mortality in children under five years of age and pregnant women. It is the most common cause of outpatient visits, hospitalization and death. Malaria is also a development problem as it has a serious socio-economic impact on families and the nation, through loss of work, school absenteeism and high levels of expenditure on treatment.

The government of Malawi through the Ministry of Health and its partners are committed to controlling malaria in the country. As part of the malaria control strategies, the Ministry has developed several guiding malaria documents one of which is the National Malaria Strategic Plan for 2005 to 2010. Using the Strategic Plan as a guide, Annual Action Plans will be developed every year.

While the purpose of the Malaria Strategic Plan for 2001 to 2005 encompassed renewed efforts to reduce malaria morbidity and mortality in the context of multi-sectoral implementation of malaria control activities, the Malaria Strategic plan for 2005 to 2010 will focus on “scaling up” of malaria control activities in the context of the Essential Healthcare Package (EHP) and sector-wide approaches.

The main strategic areas that have been identified for the scale-up of malaria control activities, include, among others, Malaria Case Management, Intermittent Preventive Treatment (IPT) of pregnant women with SP and malaria prevention with special emphasis on the use of Insecticide Treated Mosquito Nets (ITNs).

I am hopeful that concerted efforts to implement this Malaria Strategic Plan with the support of global, regional and national partners will enable Malawi to significantly reduce the health and socioeconomic burden of malaria.

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Minister of Health

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List of Abbreviations

ACPR	Adequate Clinical and Parasitological Response
CDC	Centers for Disease Control and Prevention
CHAM	Christian Health Association of Malawi
CHSU	Community Health Sciences Unit
CMS	Central Medical Stores
CPAR	Canadian Physicians for Aid and Relief
DFID	Department for International Development
DHO	District Health Officer
DIP	District Implementation Plan
DMCC	District Malaria Control Coordinator
DOT	Directly Observed Therapy
DP	Development Partners
DPHS	Director of Preventive Health Services
EHP	Essential Health Package
GDP	Gross Domestic Product
HC	Health Centre
HDI	Human Development Index
HIV	Human Immunodeficiency Virus
HEU	Health Education Unit
HMIS	Health Management Information System
HMM	Home Management of malaria
HSA	Health Surveillance Assistant
ICC	Interagency Coordinating Committee
IDSR	Integrated Disease Surveillance and Response
IEC	Information, Education and Communication
IMCI	Integrated Management of Childhood Illnesses
IPT	Intermittent Preventive Treatment
IRS	Indoor residual Spraying
ITN	Insecticide Treated Nets
JICA	Japanese International Cooperation Agency
KCH	Kamuzu Central Hospital
MBC	Malawi Broadcasting Cooperation
MOH	Ministry of Health
MSF	Medical San Frontier
MSH	Management Sciences for Health
NGO	Non-governmental Organisation
NMCP	National Malaria Control Programme
PoW	Programme of Work
PSI	Population Services International
QECH	Queen Elizabeth Central Hospital
RDT	Rapid Diagnostic Testing
RHU	Reproductive Health Unit
SADC	Southern Africa Development Community
SP	Sulfadoxine-pyrimethamine
SWAp	Sector Wide Approaches
TWG	Technical Working Group
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization
WVI	World Vision International

Executive Summary

Malaria remains a leading cause of mortality and morbidity in Malawi, especially in pregnant women and children under five years. In response to this prevailing malaria burden, the Ministry of Health will implement a national malaria control program that aims to reduce the burden of malaria to a level of no public health significance.

To guide the allocation of resources and coordination of the malaria control program, the Ministry of Health developed a five-year Malaria Strategic Plan in line with the national health planning framework. During the period between February and April 2005, in consultation with the National Malaria Taskforce and under the guidance of the National Malaria Advisory Committee and technical support from WHO and financial assistance from UNICEF, the Ministry of Health developed a 2005-2010 Malaria Strategic Plan. Following a consensus building process it was agreed that the 2005-2010 Strategic Plan would focus on scaling up malaria interventions. The plan outlines three strategic areas to be scaled up over the plan period. The strategic areas include case management, intermittent preventive treatment and vector control and personal protection interventions using insecticide-treated mosquito nets. Each strategic area consists of a description of strategic objectives and associated activities to achieve the stated targets over the plan period.

The strategies will be implemented within the context of the SWAp and national plan of work guided by the national policies and guidelines. Implementation of the strategic plan will be through annual work plans, which will be based on activities outlined in the annual national malaria control programme plan. Resource implications for the identified activities have been outlined in the plan. Monitoring and evaluation for the strategic plan will be based on annual joint reviews and mid-term reviews involving all stakeholders in malaria control.

The plan has been developed in an uncertain environment of increasing levels of poverty, a shortage of drugs, increasing drug resistance, critical shortage of human resources and impact of HIV/AIDS. To fully implement the strategic plan, it is estimated that over **MK9, 658, 629, 880** will be required for the planned period 2005 to 2010.

1.0 BACKGROUND

1.1 Country Profile

1.1.1 Geography

Malawi is a landlocked country in East Central Africa. It is bordered by Mozambique, Tanzania and Zambia. The country covers an area of about 118,500 square kilometers with a savanna type climate, having dry and rainy seasons. The altitude ranges from 1,000 to 2,000 meters above sea level.

1.1.2 Demography

The estimated population for 2002 in Malawi was about 11.9 million (Human Development Report 2004); with approximately 15.9% of persons living in urban areas. 46.2% of the population is children under 15 years of age. The average household size is 5.7 persons, with an estimated 1.9 million households. The literacy rates for males and females are 72.1% and 48.6% respectively. Malawi has very poor health and economic indices; the infant and child mortality rates are 104 and 189 per 1000 live births respectively. The country's gross domestic product (GDP) per capita is estimated at US\$177(HD Report 2004). A summary of the demographic health indicators is shown in Table 1.

Table 1: Health Indicators in Malawi

Indicator	Malawi
Crude Birth Rate	3.13 %
Crude Death Rate (1987)	1.4 %
Fertility Rate Females 15 – 49	6.1%
Under 5 Mortality Rate	189 per 1,000
Infant Mortality Rate	104 per 1,000
Life Expectancy at Birth - Male	37.5 years
Life Expectancy at Birth - Female	38.2 years
Average Life Expectancy	37.8 years
Annual Growth Rate	1.9%
Maternal Mortality Rate	1,120 per 100,000

Source: Malawi Demographic and Health Survey 2000(MDHS) & Human Development Report 2004

1.2 Organisation of National Malaria Control Programme

The NMCP was established under the Directorate of Preventive Health Services within the Ministry of Health. The malaria control secretariat is located at the Community Health Sciences Unit (CHSU), which also houses other disease control programmes.

1.2.1 Programme Staffing

Four officers at the national level form the core management and coordination team. The Programme Manager reports to the Director of Preventive Health Services. There are three zonal officers who are also responsible for their respective districts in each of the three regions (zones). At the district level, the District Malaria Control Co-ordinator (DMCC) co-ordinates district-based malaria control activities under the District Health Officer (DHO) who is the head of district health services.

1.2.2 Programme Coordination

In Malawi, Roll Back Malaria has brought together major partners involved in health. These include WHO, UNICEF, World Bank, UNDP and DFID, USAID/CDC, JICA, Research Institutions, the College of Medicine (Malaria Alert Centre) and NGOs such as CHAM, Africare, MSF, WVI, PSI, Plan Malawi, MSH, Action Aid, CPAR and Project Hope. There is also coordination with line ministries and government departments such as Education, Environmental Affairs, Fisheries, Defence, Internal Security, Information, Finance, Malawi Broadcasting Corporation and other Media Houses.

The districts have established partnerships at both district and community levels for implementation of malaria control activities with the guidance of the National Malaria Policy.

1.3 Health Service Delivery

Health services in the country are provided by three main agencies; these are the Ministry of Health 60%, the Christian Health Association of Malawi (CHAM) 37%, Local Government 1% and other providers (private hospitals and clinics, commercial companies, the Army and the Police) account for the remaining 2%.

Apart from the above providers, there is also a large and active traditional health sector. The Herbalist Association of Malawi has a membership of approximately 75,000. Private shops also sell basic drugs such as the first line anti-malarial drug. At the time of writing this Strategic Plan the first line drug for malaria for Malawi is sulfadoxine-pyrimethamine (SP).

1.3.1 Human Resources in the Health Sector

Like many African countries Malawi is experiencing a critical shortage of health workers at all levels of the health care delivery system (see table 2 below). The table compares the establishment with the number of staff in post in the public health services. Of particular concern are those categories that provide primary health care - the pillar of the health care delivery system. Only 56% of Nurse/Midwives, 32% of doctors and 67% of clinical officers and 48% of medical assistants are in place.

Table 2: Current and Required Human Resources In Malawi

	MOH target	Currently working	Currently vacant	% actual staff to target
Doctors	433	139	294	32%
Nurses	8440	4717	3723	56%
Clinical Officers	1405	942	463	67%
Medical Assistant	1500	718	782	48%
Laboratory Technician	507	251	256	50%
Pharmacy Technician	285	93	192	32%
Environmental Health Officers	1662	304	1358	18%

Source: Martin-Staple 2004

1.3.2 Accessibility

Accessibility to health facilities for rural populations is generally good. Using a 5 km radius as a yardstick, accessibility is estimated at 54%. Using an 8 km radius as a guideline, accessibility increases to 80%. Based on a 10 km radius, accessibility is 90%. Using the 8 km standard and including urban population, then accessibility is 84% nationally. (Source: Malawi National Health Facilities Development Plan 1999 - 2004). Despite having good accessibility, there is lack of information on utilization of these services.

1.3.3 Procurement and Distribution of Drugs and Other Malaria Commodities

The Central Medical Stores (CMS), part of the Ministry of Health, has the responsibility of procuring drugs and other medical supplies for public and CHAM health facilities. CMS distributes drugs and medical supplies directly to all Government health facilities. Quantification of anti malarial drugs and other malaria control commodities is the responsibility of the National Malaria Control Programme. The Pharmacy, Medicines and Poisons Board has the responsibility of registration and quality control of all drugs.

1.4 Malaria Burden

Malaria is a major public health problem in Malawi, especially among children under the age of five years. Malaria is a disease of poverty - it affects the poorest and keeps them poor. Malaria illness keeps adults from work an average of 25 days per year, which translates into lost income. In addition to lost income, the cost of drugs to treat malaria can easily overwhelm family' resources, especially those of low-income families. In Malawi, it is estimated that low-income families spend more than one – quarter (28%) of their yearly income to treat malaria illness.

Malaria accounts for 40% of all outpatient visits. Anaemia, most of which is considered to be attributed to malaria, is estimated to be responsible for about 40% of all under five hospitalisation and 40% of all hospital deaths in under five children (World Bank report 2000). Table 3 below shows that malaria is the number one cause of admissions among under five children.

Table3: Ten Leading Causes of Hospital Admissions in Children (2003) In Malawi

Disease Condition	Proportion of top 10 causes of children admissions
Uncomplicated Malaria	39%
Pneumonia	15%
Anaemia	10.6%
Tuberculosis	10.5%
Unknown	7.6%
Diarrhoea	7.3%
Cerebral malaria	3.3%
Abscess/ Cellulitis	2.6%
Cut/open wound	2.2%
Kwashiorkor	1.8%

Source HMIS 2003

The 2003 HMIS report indicates that between 250,000 – 350,000 malaria outpatient cases were being reported monthly by the health facilities throughout the country. This resulted into having about 3.5 million episodes of malaria reported in the outpatient departments in 2003. However, according to the recent report of a community survey, more than 50% of the malaria cases do not get treatment at health facilities. Therefore, it could be estimated that Malawi experiences well over 6 million malaria episodes annually.

1.5 Drug Resistance

Over 85% of malaria infections in Malawi are due to *Plasmodium falciparum*. Malawi adopted SP as the first line treatment for malaria in 1993. The resistance of the malaria parasites to SP has been increasing with time. Data from six sentinel sites that was collected in 2004, show that resistance to SP (ACPR) ranges from 25 – 31%. As a result of this resistance of *Plasmodium falciparum* to SP, the Ministry of Health is implementing a drug policy change plan.

1.6 Vector Resistance

Anopheles funestus, *Anopheles gambiae* and *Anopheles arabiensis* are the three vectors of malaria identified in Malawi. Although, Indoor Residual House Spraying is done in the country's sugar estates, the main strategy for controlling malaria vectors is the use of insecticide treated mosquito nets. The National Malaria Policy recommends pyrethroids for treatment and re-treatment of mosquito nets. A recent study by the National Malaria Control Programme in 2004 has shown that all the malaria vectors are susceptible to pyrethroids.

2.0 IMPLEMENTATION STATUS OF THE MALARIA STRATEGIC PLAN 2001-2005

2.1 The Purpose of the Strategic Plan

The purpose of the Malaria Strategic Plan encompassed renewed efforts to reduce malaria morbidity and mortality in the context of multi-sectoral implementation of malaria control involving government, NGOs, private sector, civil societies, research institutions and communities. The renewed efforts were guided by six pillars: building and strengthening partnership among all stakeholders, promoting ownership of malaria activities at all levels of health care delivery, contributing to health sector reforms, strengthening the Health Information System and research, integrating malaria control activities into primary health care and other social economic development programmes, increasing coverage of cost-effective interventions e.g. ITNs and strengthening community participation in the management of uncomplicated malaria e.g. through home management strategies.

2.2 Overview of 2001 – 2005 Strategic Plan

The 2001 – 2005 Strategic Plan had eight priority areas as follows:

- 1) Organisation and management of the health system
- 2) Disease management
- 3) Provision of anti-malarial drugs and malaria control related materials
- 4) Disease prevention
- 5) Disease surveillance, epidemic preparedness and response
- 6) Sustainable control, Advocacy and IEC
- 7) Human Resource Development
- 8) Research, including interdisciplinary operational research.

The goal statements for the strategic plan were:

- 1) To ensure that the malaria policy would be integrated into the overall organization and management of the health system, so that by 2005 the health system would be well organized and had enough resources to realize the vision of the Abuja declaration on RBM.
- 2) To ensure prompt and proper malaria case management at all levels by the year 2001
- 3) By the year 2005, the majority of people would have access to a dependable source of affordable first line anti-malarial drugs and malaria control related materials
- 4) To maximise reduction in malaria through best possible use of personal and community preventive measure
- 5) By 2005, Malawi would have the capacity to collect and interpret data for implementation, monitoring and evaluation of preventive and control measures
- 6) To promote continual implementation of effective interventions to control the burden of malaria
- 7) To strengthen capacity building at all levels of the health delivery system
- 8) To develop and strengthen the capacity and capability at all levels to conduct research on issues of direct relevance to the control of malaria and incorporate mechanisms for feeding back research results into practice.

2.3 Achievements

A survey conducted with financial support from UNICEF on ITN coverage in 2004, showed that malaria control interventions had made tremendous progress in Malawi. A summary of the results is attached in Annex 2. The achievements described below make reference to the summary.

2.3.1 Organisation and Management of the Health System

The National Malaria policy was developed and disseminated at national level. Coordination among different malaria partners was strengthened by regular meetings of Technical Committees and the National Malaria Advisory Committee and annual review/planning meetings. The capacity of the NMCP was strengthened and the number of staff in the national programme increased from two to four out of the targeted 6 members of staff. Due to increased staff numbers, the NMCP has been able to improve and support supervision to districts. One of the notable achievements is the development of the Malaria policy that guides the implementation of malaria control activities in the country.

The programme has also been able to source vehicles and motorcycles that are being used by the programme and the districts respectively. With the decentralization of health services and the introduction of the DIPs at district level, malaria control has been integrated into the general disease programmes with the DHO as the overall in charge in accordance with the Sector Wide Approach (SWAp). At central level (and in some districts), job descriptions have been developed for malaria control staff members. Finally, in order to improve the referral system and communications, radios and phones were installed in some health centres and districts. Communication between NMCP and DHOs has improved. IDSR was introduced and is currently being implemented in all districts, Coordination between the NMCP and partners has greatly improved in the last five years.

2.3.2 Disease Management

The Malaria Control Programme has recorded a number of achievements in the area of case management. The most notable achievement is the improved management of malaria cases in the health facilities. There were few drug stock-outs in the facilities as anti malarial drugs were made available most of the time. The programme also strengthened its collaboration and coordination with IMCI in case management. With this collaboration, NMCP has been responsible for training health workers in severe case management in secondary health services while IMCI covers those in the primary health facilities. Most of the trained health workers were supervised after training. The WHO training manual for severe case management was adopted and adapted. Most of the health facilities have set up a mechanism for Directly Observed Therapy for SP for case management of under five children.

2.3.3 Malaria Drugs and Supplies

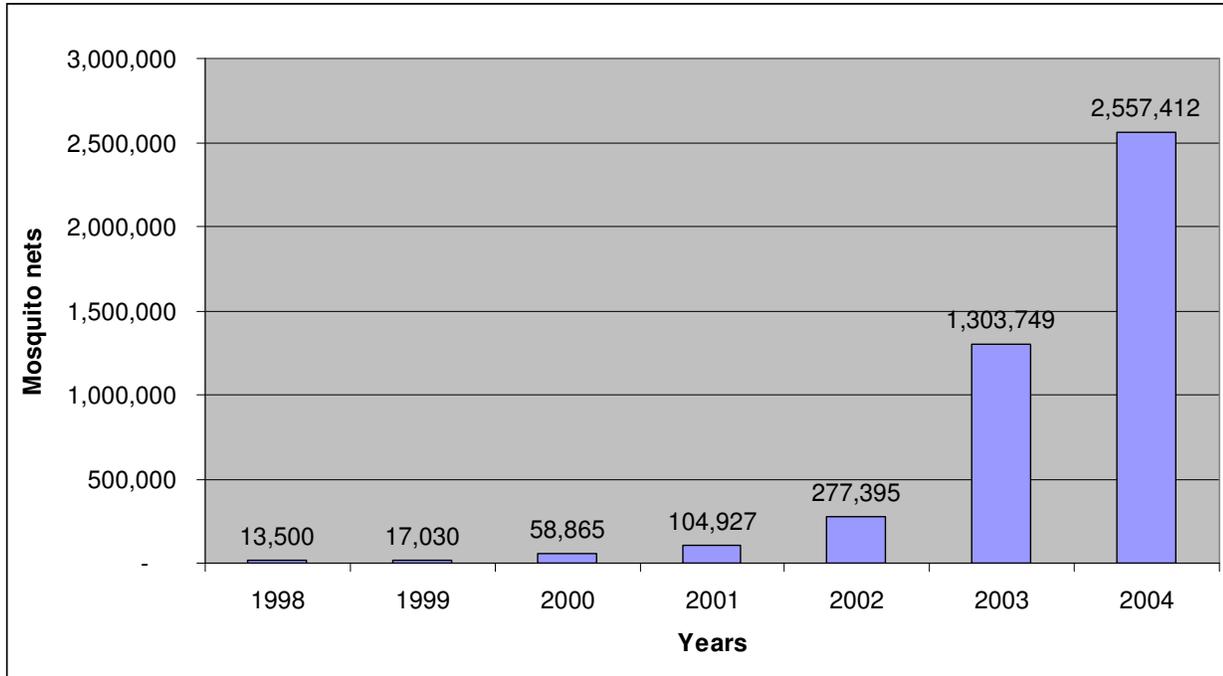
The programme was able to quantify the malaria drugs required for the country and procurement was done by the Central Medical Stores. Donors supported the procurement of additional anti malarial drugs such as SP for case management and/or for IPT. Laboratory services have been expanded to some busy health centers in addition to hospitals (District Hospitals, Central Hospitals and CHAM Hospitals).

2.3.4 Disease Prevention

Over 2.5 million mosquito nets have been distributed throughout the country (refer to figure 1). The major distribution channels included health facilities, community based organizations and the private sector (social marketing). Distribution of these nets was made possible through the development of ITN guidelines with roles of the different partners defined. Within the last five years, the programme has managed to create such a high demand for the nets that supply is not able to fulfill.

ITN re-treatment has increased from 7% in 2002 to 61% in 2004 (NMCP 2004). The net ownership of at least one net per household is at 43% while the usage is at 35% for under five children and 31% for pregnant women (NMCP/UNICEF 2004).

Figure 1: CUMULATIVE NUMBER OF NETS DISTRIBUTED IN MALAWI (1998 – 2004)



Source: NMCP 2004

2.3.5 Surveillance, Epidemic Preparedness and Response

The Malaria Control Programme was able to collect monthly data from all districts. Data collection was further strengthened with the recruitment of district data entry clerks and procurement of computers by HMIS and the introduction of IDSR in all districts. The community data collection mechanism that was initiated in Mwanza district using the Village health register is to be expanded to other districts. The Ministry of Health expanded the health passports initiative that was started by CHAM at Embangweni Mission hospital and later adopted by the Lilongwe District Health Office.

2.3.6 IEC/Advocacy

IEC campaigns on malaria prevention and control were carried out during the SADC Malaria Week and Africa malaria day. IEC materials such as posters, billboards, radio and TV programmes were produced during the said period to disseminate information to the general public. A draft communication strategy was developed that will facilitate implementation of IEC activities.

2.3.7 Human Resource Development

In-service training of health workers in malaria case management/IMCI at districts levels was done and basic entomology course was also conducted at the Malaria Alert Centre for district programme staff. Some members benefited from pursuing long and short term training courses abroad; two people were sponsored for an MSc in Epidemiology and one for Entomology, while five went for short courses.

2.3.8 Operational Research

Many partners contributed to the malaria research agenda. Regular SP efficacy studies in the six sentinel sites to monitor SP resistance were ongoing. The various research results have influenced the review of the treatment policy. There have also been research scholarships that have been offered by the Gates Malaria Partnerships through the College of Medicine.

2.4 Challenges and Gaps

Despite achievements cited above, the programme still faces a number of challenges and gaps in its implementation.

2.4.1 Organisation and Management of Health System

Shortage of staff remains one of the most critical areas of the health delivery system in Malawi. The recommendations from the functional review of the civil service are yet to be implemented. Zone Officers who are based at Blantyre, Lilongwe and Rumphu District Health Offices are too busy to combine district and zonal activities. Besides, despite considerable support from all partners, funding for malaria control activities is still inadequate. There are shortages of ambulances, utility vehicles, and computers in some districts resulting in inadequate supervision in some areas. .

2.4.2 Disease Management, Malaria Drugs and Supplies

Increasing resistance of malaria parasites to SP, poor quality of SP currently in use, shortage of anti malarial drugs for both case management and IPT remain big challenges to effective treatment. Other major areas of concern include: (a) delay in initiating treatment of malaria within twenty four hours of onset of symptoms and (b) although there has been training of health workers in malaria case management, not all were trained and follow up of those trained has been inadequate in some cases.

2.4.3 Disease Prevention

Despite the remarkable achievements in ITN coverage, the limited supply of mosquito nets remains a challenge. The role of Indoor Residual Spray (IRS) in malaria control in Malawi is still being debated. Other critical issues include: assessment of net usage, how to reach the poorest of the poor that constitutes 30% of total households and other vulnerable groups such as orphans, the elderly and HIV+/AIDS patients. Preventing leakage of nets to neighboring countries and other untargeted groups also presents a major challenge.

2.4.4 Surveillance, Epidemic Preparedness and Response

Although the NMCP was able to collect malaria data from all districts either through the HMIS or directly, there was lack of timeliness and completeness of the data. Unavailability of strategic reserves of malaria commodities for emergency situations is still a major challenge for epidemic preparedness and response.

2.4.5 I.E.C. / Advocacy

The need for a strategic framework for IEC and Advocacy and a review of the school curriculum with the Ministry of Education to update malaria related sections in the school curriculum, remain urgent issues for action as is the review of the Public Health Act by the Ministry of Health and involvement of relevant Ministries in malaria control activities

2.4.6 Human Resource Development

Shortage of health workers and reduced capacity to retain those available for effective implementation of malaria control activities are major issues. In addition, resources for further training abroad and locally are inadequate resulting in poor capacities for specialized areas such as the post of malariologist. There is need to conduct a review of health worker's pre-service curriculum on all aspects of malaria control in the health training institutions.

2.4.7 Research / Operational Research

Development of a research policy and strengthening of the Ministry's Health Sciences Research Unit is a critical step in strengthening the coordination and implementation of malaria research to support policy in Malawi.

3.0 CRITICAL GAPS AND CHALLENGES

A lot remains to be done to achieve the overall targets set by the Ministry of Health - to reduce malaria burden to a level where it is no longer a significant public health problem. In addition to addressing the critical challenges and gaps that were encountered during the implementation of the 2001 – 2005 plan, additional initiatives are necessary for successful implementation of the 2005 – 2010 strategic plan. Some of the issues, challenges and gaps highlighted below formed the basis for the development of the new plan.

Key issues of the program that should be addressed for successful scaling up coverage and improving quality of services are outlined below:

3.1 Organization and Management of Health Systems

a) Challenges

- ◆ Making functional the health facilities that are currently closed or partially operational, basically due to lack of personnel and drugs

b) Gaps

- ◆ Inadequate funding
- ◆ Lack of an institutional framework to clarify roles of different partners, reporting lines and coordination of malaria control activities
- ◆ Inadequate malaria data collection, management and dissemination at all levels
- ◆ Inadequate communication in the form of fax, telephone, e-mail and logistical support at all levels.

3.2 Disease Management and Drug Supply

a) Challenges

- ◆ Strengthening of laboratory support for correct diagnosis in view of the drug policy review
- ◆ Strengthening and coordinating home management of fever cases
- ◆ Provision of necessary supplies and equipment in health facilities
- ◆ Following up supervision after training and proper deployment of trained personnel
- ◆ Accelerating policy review on first line anti malarial drug
- ◆ Strengthening Central Medical Stores' capacity for timely procurement and distribution of adequate anti malarial drugs

b) Gaps

- ◆ Inadequate availability of high quality anti malarial drugs in the country
- ◆ Inadequate security of drugs throughout the distribution chain

3.3 Disease Prevention

a) Challenges

- ◆ Advocate for the distribution of ITNs to the vulnerable groups at no cost to the beneficiary
- ◆ Growing leakage of ITNs to other countries
- ◆ Improper use of ITNs
- ◆ Low uptake of second dose of IPT

b) Gaps

- ◆ Inadequate supplies of ITNs
- ◆ Lack of interventions to complement ITNs e.g. IRS

3.4 Disease Surveillance, Epidemic Preparedness and Response

a) Challenges

- ◆ Malaria mapping for Malawi
- ◆ Strengthening of Integrated Disease Surveillance and Response to enable the monitoring of disease trends and early detection of outbreaks in the context of HMIS
- ◆ Strengthening of malaria sentinel sites for drug sensitivity studies, monitoring data for Roll Back Malaria indicators
- ◆ Strengthening of HMIS

3.5 Information Education and Communication and Advocacy

a) Gaps

- ◆ Inadequate information, education, communication and advocacy for malaria.

3.6 Human Resource Development

a) Challenges

- ◆ Provision of incentives for staff retention
- ◆ Continuing pre and in-service training to improve staff skills and expertise

b) Gaps

- ◆ Shortage of human resource for delivery of services at all levels including the community level

3.7 Operational Research

a) Challenges

- ◆ Coordination and monitoring of all research activities in malaria
- ◆ Development of a malaria research agenda to respond to the needs of Malawi
- ◆ Coordinated dissemination and utilization of research findings

4.0 STRATEGIC FRAMEWORK 2005 - 2010

4.1 Introduction

Although 2001 – 2005 Malaria Strategic Plan has made considerable advances, more still needs to be done as can be deduced from the challenges, gaps and critical issues highlighted in the preceding chapter. In the 2005 – 2010 Strategic plan, the focus will be on the scaling up of interventions so as to significantly reduce the malaria morbidity and mortality in the country.

In January 2005, the Ministry of Health constituted a Malaria Task Force to oversee the development of the 2005 – 2010 Malaria Strategic Plan, taking into account the new environment occasioned by the introduction of SWAp. The Malaria Task Force approved the timeline for the development of the plan through a consultative process that was inclusive of all major stakeholders. Due to time and resource constraints it was not possible to conduct a full evaluation of the implementation of the 2001 – 2005 strategic plan. But it is planned that this evaluation will be conducted in the 2005 – 2006 malaria annual work plan and the results will feed into subsequent annual plans.

4.2 Vision

The vision for the National Malaria Control Programme is to keep all people in Malawi free from the burden of malaria.

4.3 Mission

The mission is to reduce the malaria burden to a level of no public health significance in Malawi.

4.4 Strategic Areas

For the 2005 – 2010 plan, three strategic areas have been identified for the scale-up of malaria control activities. These are:

- a) Case management,
- b) Intermittent Preventive Treatment (IPT)
- c) Insecticide Treated Mosquito Nets (ITN)

4.5 Strategies

The following are the strategies that will be used in scaling up the implementation of 2005 -2010 malaria control activities.

- 1) Improving case management at health facilities
- 2) Improving community and family practices for malaria case management
- 3) Provision of adequate doses of SP to pregnant women
- 4) Scaling up of ITNs distribution and use
- 5) Introducing IRS in 4 selected areas
- 6) Effective monitoring of malaria vector control
- 7) Developing human resources capacities
- 8) Strengthening IEC and advocacy for malaria control
- 9) Improving communication and logistics
- 10) Supporting operational research and monitoring and evaluation

4.6 Cross-cutting Issues

The cross cutting strategic areas which have implications for any or all activities in the above strategic areas have been reflected and taken into account in developing the objectives. These are:

- a) Programme management (institutional framework);
- b) IEC and advocacy;
- c) Operational research;
- d) Monitoring and evaluation
- e) Disease surveillance
- f) Human resource development.

Mobilization and implementation of activities will be done in context of the SWAp and Essential Health Package and will involve all partners.

4.7 Targets

The programme targets that are contained in the Abuja Declaration have been incorporated into the Malawi Roll Back Malaria targets and these are:

- a) The general target is to halve malaria mortality and morbidity by the year 2010 with further reduction of morbidity and mortality figures of 2001 by 75% by 2015.
- b) Specific targets in the main three areas of intervention are as follows:
 - ◆ At least 80% of those suffering from malaria fever have access to and are able to use correct and appropriate treatment within 24 hours.
 - ◆ At least 80% of the population has access to appropriate treatment by 2010
 - ◆ At least 80% of pregnant women have access to malaria prevention by 2010, and
 - ◆ At least 80% of children under five and pregnant women sleep under insecticide treated nets by 2010.

Core monitoring and evaluation indicators are contained in Annex 1 .

5.0 INSTITUTIONAL / IMPLEMENTATIONAL FRAMEWORK

The National Malaria Control Programme is an integral part of the Ministry of Health of Malawi and is responsible for the control of malaria in the country. In line with the Plan of Work (POW) 2005-2010 for the health sector in Malawi “the institutional arrangements for the implementation of the POW revolve around the collaboration of all the various stakeholders in the health agenda” (POW). The POW goes further to say that “for the POW to achieve its targets and objectives at the end of the plan period, political commitment, the spirit of partnership and trust amongst the various stakeholders must prevail. At the end of it all it is the health of each and every individual that should benefit from the improved performance of the health sector”. Malaria control in Malawi will follow the same philosophy.

In order to scale up the implementation of malaria control interventions during the period 2005 to 2010, the National Malaria Control Programme (NMCP) will be in charge of implementing and coordinating all malaria control activities in the country. The NMCP will report to the office of the Secretary for Health through the office of the Director of Preventive Health Services.

5.1 Implementation of Malaria Control

Delivery of malaria control interventions will be carried out using the district health system with the district health office as the MoH’s coordinator of all health matters at district level. Implementation will involve MOH, communities and households, CHAM, NGOs and the private sector. Reporting of implementation at district level will be done through the office of the DHO using the existing tools. Referral to higher levels of care will be done as described in the Malawi EHP.

5.2 Policy, Coordination and Resource Mobilization

Malaria control financing and implementation remain as major challenges that need to be addressed through a multi-sectoral approach as amply discussed in the POW 2005-2010. The NMCP will work in collaboration with other stakeholders involved in malaria control in the financing of malaria control activities. The major stakeholders for malaria control remain UNICEF, WHO, JICA, NORWAY, USAID, DFID, SIDA, World Bank, European Union, NGOs, other bilateral agencies, research and training institutions and the private sector. As malaria control is diverse in nature, coordination of inputs, partners and control activities is critical. The many players on the ground require coordination to ensure that their activities conform to the country’s malaria control strategic and annual plans. Coordination is the responsibility of the Ministry of Health’s NMCP.

Coordination of partner involvement including financial involvement in malaria control will be done through the Interagency Coordinating Committee (Malaria ICC). The ICC is the major organ responsible for resource mobilization in addition to the resources made available for activities funded through the SWAp. Technical inputs will be discussed and coordinated through the Technical Working Groups with sub committees on various technical areas of malaria control. The National Malaria Policy Advisory Committee, reporting to the Secretary for Health, is responsible for advising the MoH on malaria policy issues. The NMCP is secretariat to all of these committees.

The National Research Council is the overall body responsible for sanctioning research in Malawi. In Health, the National Health Sciences Research Committee is responsible for approving all research conducted in health in line with the requirements of the MoH. The MoH Research Unit is secretariat to the committee and responsible for research dissemination in the MoH. All research protocols in malaria should pass through the institutions described above and the National Malaria Control Programme should be informed of any approved and intended research.

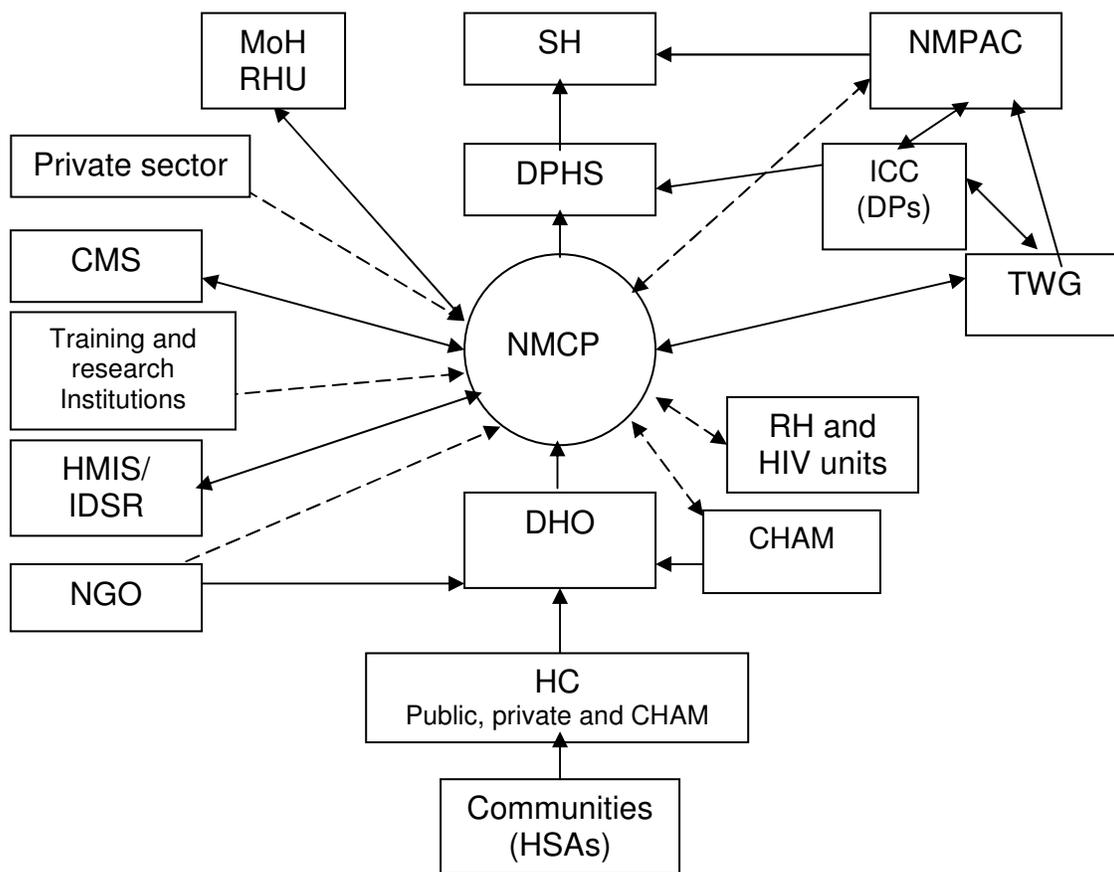
5.3 Capacity Building

Cognizant of the fact that malaria is the leading cause of morbidity and mortality in Malawi, this plan proposes that the NMCP be clearly defined in terms of the workload and personnel available to carry out the tasks. In this regard, a programmatic evaluation is proposed in order to assess the need to engage additional personnel in the programme in order for it to effectively play its role in malaria control. Additional professional/ technical posts may be proposed such as a Case Management Officer, IEC Officer and a Monitoring and Evaluation Officer.

5.4 Collaboration with other Programmes within the MoH

IDSR will be the main collaborator for the data collection from the districts for surveillance, detection and response. The DHO will be validating all data before being communicated to the Epidemiological Unit from which the Malaria Programme will be getting its data. HMIS is the main stakeholder for data collection, processing and dissemination. This data has the advantage of being more complete and being used mainly for validating trends and for planning purposes.

Figure 2: NMCP COORDINATION STRUCTURE, MINISTRY OF HEALTH, MALAWI



KEY	
SH	Secretary for Health
DP	Development Partner
DPHS	Director Preventive Health service
NMCP	National malaria Control Programme
DHO	District Health Office
HSAs	Health Surveillance Assistants
NGO	Non Governmental Organization
CMS	Central Medical Stores
TWG	Technical Working Group
NMPAC	National Malaria Policy Advisory Committee
ICC	Interagency Coordinating Committee
MoH RU	MoH Health Sciences Research Unit
RH	Reproductive Health Unit
HIV	HIV Unit
--	Liaison / Consultative reporting
-----	Direct Reporting

5.5 Monitoring and Evaluation

Implementation of the Malaria Strategic Plan 2005-2010 will be planned, monitored and evaluated at given intervals. Annual meetings with all stakeholders will be conducted at the end of the malaria season. These meetings will review implementation of the previous season and plan for the following season. A national annual action plan will be produced before the start of the new financial year. Within the year, quarterly ICC meetings will be held to which the NMCP will report on progress of implementation of the annual plan. Technical Working Groups will meet at least quarterly. Sub groups to this working group will meet when deemed necessary. On a monthly basis, IDSR will provide surveillance data to the NMCP and the HMIS will provide quarterly malaria surveillance data. Implementation will be reported monthly, quarterly and annually from all partners. All reports will be shared with all partners.

Evaluation of programmatic issues of malaria control in Malawi will be conducted on a yearly basis at the annual meetings. A full evaluation will be done during the mid term review of the strategic plan during the 2007-2008 financial year. The Mid Term Review is the only chance for reviewing the Malaria Strategic Plan in view of emerging policy and implementation issues. At the end of the strategic plan, another evaluation will be carried out. During the strategic plan period three malaria health facility surveys will be conducted at the beginning of the plan period, during the 2007-2008 plan period and at the end of the plan period. Two surveys will be conducted at mid point and at the end of the plan period. All these surveys and evaluations will assess the 3 core Abuja Declaration/ RBM indicators (Annex1) and the Malawi RBM Core Indicators (Annex 2).

6.0 STRATEGIC PLANNING MATRIX

6.1 Case Management

6.1.1 Goal Statement

To ensure prompt and appropriate malarial case management at all levels of health care by the year 2010

6.1.2 Strategies

- 1) Improve case management in health facilities
- 2) Improve community and family practices for malaria case management

STRATEGY	OBJECTIVE	ACTIVITIES	TARGETS	INDICATORS	COST MK
Improve case management in health facilities	To review and adopt a new drug policy by end of 2006	Conduct drug efficacy studies	One five arm efficacy study conducted by December 2005	Number of Five arm efficacy studies conducted	19,535,650
		Conduct Consensus Building meetings	One consensus meeting conducted by March 2006	Number of Consensus meetings conducted	2,220,300
		Revise, adopt and implement new drug policy	Revised policy by 2007	Revised Drug policy in place	121,500,500
	To increase the proportion of health centers with laboratory diagnosis for malaria to 60% by 2010.	Introduce microscopy in 60% of health centers	60% of all health centers to have malaria diagnosis capacity by 2010	Proportion of health centers with laboratory facilities for malaria diagnosis	16,341,300
		Assess the effectiveness of RDTs in selected districts	Two districts to implement RDTs by 2007	Number of districts	54,336,600
		Review implementation of RDTs	By 2007 RDTs reviewed	Review Conducted	1,386,300
	To make available by 2005 and maintain quality of essential drugs in all health facilities	Quantification of anti malarial drugs yearly	Required drugs quantified	Required Quantities available.	230,000
		Procurement and distribution of anti malarial drugs	Required quantities procured	Amount of required quantities procured	2,900,454,000
			100% of health facilities to receive the required drugs	% of facilities receiving the required drugs	
		Monitor the quality of anti malarial drugs	Every batch to be monitored	% of batches monitored	4,500,000
	Monitor the use of anti malarial drugs	Bi-monthly visits to facilities	% of facilities visited	964,800	
	To manage correctly at least 90 % of uncomplicated and severe malaria by 2010.	Training of health workers in malaria case management	All untrained health workers	Number of untrained health workers trained	32,860,000
Follow up of the trained health workers		All trained health workers to be followed up.	Number of trained health workers followed -up	1,744,200	
Include malaria case management in school curriculum of Training Institutions for health workers		Case management included in school curriculum of Training Institutions for health workers	Number of Training Institutions for health workers that have included malaria case management	2,126,400	

STRATEGY	OBJECTIVE	ACTIVITIES	TARGETS	INDICATORS	COST MK
Improve case management in health facilities (cont'd)	To manage correctly at least 90 % of uncomplicated and severe malaria by 2010 (cont'd)	Provision of commodities for malaria case management	100% of facilities to have the required commodities for case management	% of facilities with required commodities	113,000,000
		Strengthening of referral services at all Levels	Functioning referral system at all levels	Proportion of facilities with functioning referral system.	96,441,000
		Monitor the efficacy of anti malarial drugs in six sentinel sites annually.	Drug efficacy study yearly	Number of studies conducted.	25,320,400
		Conduct periodic monitoring of morbidity and mortality of malaria	Two yearly monitoring of morbidity and mortality trends through HMIS	Number of surveys / conducted to monitor morbidity and mortality due to malaria	6,803,360
		Conduct the periodic surveys to determine cases correctly managed	Every two years	Number of surveys conducted.	6,803,360
		Conduct Malaria prevalence surveys as part of malaria mapping	Conducting malaria prevalence survey conducted	Malaria prevalence survey conducted	7,073,360
		Develop and conduct IEC and advocacy activities for malaria case management	IEC and advocacy activities developed and conducted	Proportion of districts with IEC materials. Number of IEC activities conducted	See ITN
	To conduct studies on the feasibility of IPTi options for Malawi	i) Identification of implementing partners and selection of study sites iii) Conducting studies iv) Disseminating study results v) Assessing possible policy implications of study results	Conducting pilot studies in 3 sites	i) IPTi studies conducted in at least 3 sites in Malawi ii) Policy on IPTi reviewed for Malawi.	34,258,250
Improve community and family practices for malaria case management.	To increase access to prompt and effective malaria treatment at community level by 60% by 2010.	Conduct a survey to assess the cases getting prompt and effective treatment at community level	60% of the cases properly managed	% of cases properly managed	6,616,000
		Sensitization of community on case management	2 radio messages, 2 TV and video messages	Number of radio, TV and video messages developed and broadcasted.	800,000
		Training of HSAs on case management within the context of EHP	8,000 HSAs to be trained	% f HSAs trained	9,057,000
		Provision of adequate commodities	All HSAs to have commodities	% of HSAs with commodities	4,244,000
		Provision of referral services	Functioning referral system at community level to Health facilities	Proportion of communities with functioning referral system	32,000,000
		Provision of supportive supervision	HSAs to be supervised monthly.	% of HSAs supervised on monthly basis.	12,161
		IEC and advocacy for improved family and community practices	IEC materials developed and advocacy activities initiated	Proportion of communities with IEC materials on family and community practices	0

		Expansion of Village registers to all villages	Village register in every villages	Proportion of villages with village registers	0
		Total for Case Management			3,500,616,780

6.2 Intermittent Preventive Treatment (IPT)

6.2.1 Goal statement: Maximize reduction of malaria in pregnant women through the use of Intermittent Preventive Treatment.

6.2.2 Strategy

- 1) Provision of adequate doses of Sulfadoxine - Pyrimethamine (SP) to pregnant women.

STRATEGY	OBJECTIVES	ACTIVITIES	TARGETS	INDICATORS	COST MK	
Provision of adequate doses of Sulfadoxine-Pyrimethamine (SP) to pregnant women	To review IPT policy by December 2006	i) Organizing consultative meeting to review the IPT policy	i) Four consultative meetings conducted by December 2006	i) Number of meetings conducted	2,168,900	
		ii) Disseminating and distributing the policy to all stakeholders	i) One policy dissemination meeting conducted by December 2006	ii) Revised policy in place		
	To scale up uptake of second dose of SP for IPT from 59% to 90% by 2010.	i) Promotion of directly observed treatment (DOT) for SP	i) sensitization meetings for health workers conducted	i) 6000 copies of policy document distributed by December 2006	i) Number of Dissemination meeting conducted	2,220,300
			ii) Develop and implement an IPT community awareness campaign	ii) Number of policy copies distributed	0	
		ii) Provision of SP, in all health facilities and community distribution points	i) Number of meetings conducted	11,180,000		
			ii) Number of IPT community campaigns	2,604,000		
		iii) Development & Provision of IEC materials, in all health facilities and community distribution points	i) 90% of health facilities supplied with SP	i) Number of health facilities supplied with SP	66,000,000	
			90% of health facilities supplied with IEC materials	i) Number of health facilities supplied with IEC materials	1,957,000	
	To scale up uptake of second dose of SP for IPT from 59% to 90% by 2010. (cont'd)	iv) Provision of Equipment for DOT, in all health facilities and community distribution points	90% of health facilities supplied with equipment for DOT	i) Number of health facilities supplied with Equipment for DOT	4,000,000	
			ii) 4000 HSAs to be provided with SP, IEC materials and equipment	ii) Number of HSAs provided with SP, IEC materials and equipment		
		v) Extension of the distribution of SP from health facility to community level through the HSAs	i) 4000 HSAs distributing SP for IPT	i) % of HSAs distributing SP for IPT	8,457,000	
			ii) Monitor the uptake of second dose of SP	i) 90% of pregnant women taking second dose of SP	i) % of pregnant women taking second dose of SP	1,366,000
	To conduct biennial SP IPT effectiveness study in pregnant women	i) Carrying out research on efficacy of SP ii) Dissemination of research results to all stakeholders iii) Conduct Community survey to determine coverage of 2 nd SP dose	i) Two efficacy studies conducted	i) Number of efficacy studies conducted	7,861,800	
			i) One national dissemination meeting conducted	i) Number of Dissemination meeting conducted	2,555,500	
National Survey conducted every 2 years			Number of surveys conducted	8,420,700		
			Total for IPT		118,791,200	

6.3 Insecticide Treated Mosquito Nets (ITNs)

6.3.1 GOAL STATEMENT: Maximize reduction of malaria through appropriate use of ITNs and other vector control measures.

6.3.2 Strategies

- 1) Scale up of ITN distribution
- 2) Introduce IRS in selected rural areas
- 3) Effective monitoring of malaria vectors

STRATEGY	OBJECTIVE	ACTIVITIES	TARGETS	INDICATORS	COST MK
Scale –up of ITN distribution	Increase household ownership of ITNs from 43% to 90% by 2010	Procure and distribute at least 1million nets and insecticides per year.	At least 90% of households owning ITNs by 2010	% of H/H owning ITNs	2,652,800,000
	Increase nets usage of ITNs in pregnant women and under-fives from 31% and 35% respectively to 80% by 2010	Increase awareness of appropriate net usage	At least 80% of pregnant women and U/5 children sleeping under ITNs by 2010.	% of pregnant women and U/5 children sleeping under ITNs	8,640,000
		Develop and distribute ITN IEC materials	At least 2 TV & VCR messages developed	Number of TV & VCR messages developed	7,475,200
			At least 2 jingles and radio messages developed annually	Number of Jingles and Radio messages developed	
			20,000 posters developed and distributed annually	Number of posters developed annually	
	20, 000 leaflets produced and distributed annually	Number of leaflets developed annually			
	Increase net re-treatment from 61% to 90% by 2010	Conduct annual re-treatment campaign	Re-treat all nets	% of nets re-treated	1,983,772,000
	Increase net ownership to 80% in the poorest of the poor H/H by 2007	Train nurses on ITN management	At least 90% of nurses from both public and private sectors trained by 2006	% of nurses trained	22,292,000
		Train community committees on ITN management	At least 80% community committees trained by 2006	% of community committees trained	11,146,000
		Procure and distribute nets and insecticides for the poorest of the poor	At least 80% of the poorest of the poor owning ITN by 2007	% of the poorest of the poor owning ITNs.	282,000,000
Conduct community surveys to assess ITN coverage and utilization		At least two surveys conducted by 2010	Number of surveys conducted	See IPT	

STRATEGY	OBJECTIVE	ACTIVITIES	TARGETS	INDICATORS	COST MK
Scale –up of ITN distribution (continued)	Establish strategic ITN reserve for emergency by 2006	Procure emergency supply of nets and insecticides and store at strategic sites.	30,000 nets and insecticides kits at any point in given time for emergency	Number of nets and insecticide kits in stock.	992,400
	Increase the number of ITN warehouses from 4 to 10 by 2010	Construct district based warehouses	At least 6 additional ITNs warehouse are constructed by 2010	Number of ITNs warehouses constructed	30,000,000
	Reduce misuse of ITNs and cross border leakage	Conduct spot checks to verify name of people procuring ITNs	1 random verification per district per year	% of ITNs leaking to other countries	5,441,000
		Conduct ITN review meetings with stakeholders to discuss ITN distribution and associated issues	1 ITN review meeting per year	# of ITN distribution review meeting annually	5,870,000
		Advocacy to influence neighbouring country to reduce cost of nets through multiple approaches e.g. international and cross border meetings	1 ITN review meeting with Mozambique, Zambia and Tanzania	# ITN review meetings annually with Tanzania, Mozambique and Zambia.	3,271,500
Introduce IRS in selected rural areas	Introduce IRS in 4 selected areas by 2006	Determine local efficacy of insecticide to use in 4 areas	Efficacy of insecticide to be used in 4 areas assessed by 2005	Suitable insecticide for IRS in 4 areas selected	0
		Conduct geographical reconnaissance in selected areas	IRS needs for the 4 areas quantified by 2006	Number of structures to be sprayed determined	1,306,000
		Procure insecticides, pumps and other logistics and deliver to 4 areas	Required insecticides, pumps and other logistics procured and delivered by Oct 2006	Amount of insecticide, number of pumps and other logistics procured	30,100,000
		Recruit temporary spray operators and train	Recruitment and training of spray operators by September 2006	Number of spray operators recruited and trained	9,026,800
		Inform, educate and communicate with communities about IRS	Development and dissemination of IEC materials by 2006	IEC materials developed and disseminated	209,200
		Supervise spray operations	Daily supervision of spray operators conducted	Supervisory checklists and reports	3,061,600
		Review the implementation of IRS	Implementation reviewed by 2006	Review conducted	432,500
Effective monitoring of malaria vector control	Establish 1 Insectary by 2007.	Procurement of materials and construction of the Insectary	One Insectary constructed by 2007	Number of Insectary established by 2007	4,136,800
	Monitor vector bionomics once every year	Conduct vector surveillance at 6 sentinel sites annually	At least one study on vector density, identity, and behavior in a year at sentinel sites	Number of studies conducted in a year	11,138,400
		Conduct bioassays on treated ITNs and sprayed wall surfaces	At least one testing at sentinel sites annually	Number of bioassays conducted	
		Conduct vector susceptibility testing biennially	At least one vector susceptibility study at sentinel sites	Number of susceptibility tests	

		Total ITNs		5,073,111,400
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6.4 Programme Management

6.4.1 GOAL STATEMENT: To ensure that the malaria policy will be integrated into the overall organization and management of the health system and has enough resources to realize the vision of the Abuja declaration in the context of SWAp

6.4.2 Strategies

- 1) Develop human resources
- 2) Strengthen IEC for malaria control

STRATEGY	OBJECTIVE	ACTIVITIES	TARGETS	INDICATORS	COST MK
Strengthen IEC for malaria control	To support international malaria days	Commemorate Africa malaria day	Africa malaria Day commemorated annually	A report of commemoration	5,510,000
		Commemorate SADC malaria week and Day	SADC malaria week and Day commemorated annually	A report of Commemoration	9,595,000
Develop human resource	By 2010, 100% of health facilities have qualified staff to manage malaria cases	Contribute in training of health workers	At least 5 training institutions supported	Number of institutions supported	15,000,000
		Training of Personnel in higher degree qualification	Trainings done	Number of training done for high academic degree for case management	47, 500,000
		Recruitment of 2400 HSAs	2400 HSAs recruited by 2009	% of HSAs recruited	720,000,000
Monitor implementation of strategic plan	To monitor the implementation of the strategic plan yearly	Conduct annual malaria review and planning meetings	1 annual review and planning meeting	Number of review and planning meetings per year	26,619,000
		Conduct biannual, NMAC; ICC and TWG meetings	At least two meetings of each per year	Number of meetings	32,600,000
		Monthly data collection through IDSR and HMIS	Malaria data report produced per year	Number of reports produced per year	2,614,000
		Conduct Health facility survey	At least two surveys	Number of surveys conducted	12,287,400
		Conduct placenta malaria studies	At least one survey per year in	Number of surveys conducted	2,763,800

STRATEGY	OBJECTIVE	ACTIVITIES	TARGETS	INDICATORS	COST MK
Programme management support	To strengthen the capacity of NMCP	Recruitment of 3 officers at NMCP	At least 3 officers recruited	Number of officers recruited	7,200,000
		Construction of the Malaria Office Complex	Malaria Office Complex constructed by 2008	Malaria Office Complex constructed	50,000,000
		Procurement of 5 vehicles for NMCP	5 vehicles purchased by 2008	Number of vehicles purchased	16,050,000
		Training in programme/ project management	3 national level and 5 other managers trained in malaria control programme management	Number of officers trained in malaria control programme management	25,740,000
		Procurement of a mobile video unit, a video camera, and 5 digital cameras	5 digital cameras, 1 LCD, 1 Overhead project	Number of equipment procured	1,287,000
	Provide supportive supervision twice every year	Conduct support supervision at all levels	At least twice every year	Number of supervisory visits conducted	11,736,000
	Improve communication and information sharing	Installation of LAN at NMCP	LAN in the NMCP installed by end 2006	LAN activated in the NMCP	1,625,000
		Telephone and fax connection at NMCP	Telephone and fax connected in the NMCP by 1 st quarter 2006.	Telephone and fax connected in the NMCP	2,070,000
		Procurement of Computers and accessories	4 replacement laptops purchased.	Number of laptops replaced	2,913,300
			Total for Programme Management		

6.5 Budget Summary

Case management	MK	3,500,616,780
Intermittent Preventive Treatment (IPT)	MK	118,791,200
Insecticide Treated Mosquito Nets (ITNs)	MK	5,073,111,400
Programme management	MK	993,110,500

Grand Total **MK9,658,629,880**

Annex : 1 Malawi Roll Back Malaria (RBM) Monitoring and Evaluation Core Indicators

	INDICATOR	DEFINITION
1	Crude death rate (under five)	Numerator: # of deaths of children (died at the age of less than 60 months) Denominator: total number of children aged less than 60 months at the time of the interview
2	Mortality attributed to malaria (all ages)	Numerator: # of deaths attributed to malaria reported per year Denominator: total number of inpatient deaths (U5) reported.
3	Mortality attributed to malaria (U5)	Numerator: # of deaths (U5) attributed to malaria reported per year. Denominator: total number of inpatient deaths (U5) reported.
4	Mortality attributed to malaria (5 and above)	Numerator: # of deaths (5 and above) attributed to malaria reported per year. Denominator: total number of inpatient deaths (5 and above) reported.
5	Morbidity attributed to malaria (all ages)	Numerator: # of malaria cases (uncomplicated/ severe) reported per year Denominator: total number of outpatient cases seen.
6	Morbidity attributed to malaria (U5)	Numerator: # of malaria cases (uncomplicated/ severe) in children U5 reported per year. Denominator: total number of U5 outpatient cases seen.
7	Morbidity attributed to malaria (5 and above)	Numerator: # malaria cases (uncomplicated / severe) in 5 years and above reported per year. Denominator: total number of 5 years and above outpatient cases seen.
8	Case fatality rate (U5)	Numerator: # of deaths attributed to malaria inpatients in children U5. Denominator: total number of malaria cases in children U5 admitted.
9	Case fatality rate (5 and above)	Numerator: # of deaths attributed to malaria in patients in 5 year and above. Denominator: total number of malaria cases in 5 years and above admitted.
10	% of U5s with malaria attack/ fever getting appropriate treatment within 24 hours of onset	Numerator: # of children under 5 who were reported to have fever in the previous 2 weeks and reported to have received the locally recommended treatment within 24 hours of onset of fever. Denominator: total number of children under 5 surveyed who are reported to have had fever in the previous 2 weeks.
11	% of 5 yrs and above with severe malaria correctly managed at health facilities.	Numerator: # of 5 years and above with severe malaria correctly managed at health facilities. Denominator: total number of 5 years and above admitted at health facilities.
12	% of health facilities with no stock outs of nationally recommended anti-malarial drugs continuously for one week during the last 3 months	Numerator: # of health facilities with no stockout of CQ (tab of injection), quinine and Fansidar continuously for one week during the last 3 months. Denominator: total number of health facilities surveyed.
13	% of U5s sleeping under mosquito nets	Numerator: # of children under 5 years who slept under a mosquito net during the last transmission season. Denominator: total number of children under 5 surveyed.
14	% of U5s sleeping under treated mosquito nets	Numerator: # of U5 sleeping under treated mosquito nets with insecticide within the past 12 months. Denominator: # of children under 5 who slept under a mosquito net during the last transmission season.
15	% households having at least one ITN	Numerator: # of households surveyed having at least one ITN. Denominator: total number of households surveyed.
16	% of pregnant women sleeping under treated mosquito nets	Numerator: # of pregnant women (currently or within the past 6 months) who are sleeping / slept under and ITN during the pregnancy. Denominator: total number of pregnant women (currently or within the past 6 months) surveyed.
17	% pregnant women on anti-malarial chemoprophylaxis according to national policy.	Numerator: # of pregnant women (currently or within the past 6 months) who took malaria prophylaxis during pregnancy. Denominator: total number of pregnant women surveyed.

Annex : 2 Coverage of Utilisation of Insecticide Treated Nets and Malaria Prevention and Treatment Practices at the Community Level in Malawi (March 2004)

Authors: John Kadzandira and Alistair Munthali, Centre for Social Research, University of Malawi with funding from UNICEF		
Objective of Study: to determine the progress Malawi has made towards achieving the Abuja Targets		
Specific Objectives		
a) to determine the coverage and utilization of ITNs for malaria prevention, especially for U5s and pregnant women.		
b) to establish factors that prevent people from using ITNs		
c) to determine the proportion of U5 and pregnant women with reported fever in previous two weeks accessing correct and appropriate treatment within 24 hours of onset of fever		
d) to determine the utilization of presumptive intermittent treatment by pregnant women.		
Sample procedure: 360 households were sampled from each district		
Population		Malawi
Estimated Total Population		11,838,690
Proportion of households knowing that mosquitoes transmit malaria (%)		87.3
Proportion of households heads knowing that sleeping under an ITN can prevent malaria		73.1
Proportion of heads of households knowing groups at most risk (U5s or PW)		89.6
Proportion of household heads reporting seeing/ heard messages about malaria		85.4
Proportion of household heads reporting seeing/ heard messages about ITNs		83.2
Knowledge of signs and symptoms of malaria by caretakers (% of caretakers)	fever	76.5
	vomiting	42.2
	diarrhoea	21.1
	weakness	20.5
	body pains/ stiffness	55.7
	convulsions	7.9
	do not know	0.4
	no answer	0.1
Proportion of mothers or caretakers recognizing danger signs of malaria	convulsions	30.6
	fever	41.8
	neck stiffness	5.5
	weakness	23.1
	chills	24.2
	reduced appetite	8.6
	vomiting	32.0
	frequent crying	2.8
	restlessness	11.6
	diarrhoea	15.5
	do not know	5.1
no answer	0.6	
Proportion of U5s who had fever two weeks prior to survey		39.0
Proportion of pregnant women who had fever two weeks prior to survey		22.9
Proportion of U5s who took an appropriate anti malarial within 24 hours of onset of fever		17.5
attendance of ANC during last pregnancy in the past 12 months		95.1
# of clinic visits during pregnancy as reported by women (ANC visits) - 3 or more visits		82.2
# ANC visits from card (3 or more)		71.8
# IPT doses received as reported by women (2 or more doses)		46.8
# estimated number of treated or untreated mosquito nets in Malawi (March 2004)	estimated # of nets	1,802,313
	% of nets in past 12 months	72.9
	% of households with at least one net	42.5
	% of households with an ITN	33.8
	average # nets in owning households	1.9
	average # ITNs in ITN owning households	1.7
Proportion of heads of households citing various reasons for not possessing nets (%)	nets are expensive	70.4
Distribution of nets by colour	green	67.4
	blue	23.1
Distribution of nets according to their shapes	rectangle	69.5
	round	30.5
Distribution of nets according to their condition	% of nets without holes	75.4
Sources of nets	health facility	56.6
	community distribution	4.6
	shops	32.9
	NGO	4.1
	other	0.2

	do not know	1.6
Prices at which nets from health facilities and community based groups were bought	K50 - K100	86.3
Proportion of pregnant women residing in households with health facility nets	no nets	56.7
	health facility nets available	32.9
	only non-health facility nets	10.4
Types of nets available in the household (% of children)	no nets	54.5
	health facility nets available	38.4
	only non-health facility nets	7.2
Estimate of net leakage from health facilities/ VHC into local shops	% of health facility nets sold outside	9.8
Utilization of mosquito nets by U5s	all nets	38
	ITNs	35.5
Utilization of mosquito nets by pregnant women	all nets	34.1
	ITNs	31.4

Annex: 3 Anti malarial Drug Policy Change Plan in Malawi

The Malaria **Policy Advisory Committee** of the Ministry of Health met on 30 October 2004 at the Malaria Alert Centre in Blantyre and resolved that:

A new Five Year Plan (2005-2010) for continuing Malaria Control in Malawi should be prepared; A Task Force shall be appointed to take the lead in writing the document, co-opting additional individuals to assist as necessary;

A component of the Five Year Plan will be a **Change Plan** outlining a schedule for effecting a change in Malawi's anti malarial drug policy;

The Change Plan should recognize the need to change Malawi's first-line therapy for uncomplicated malaria, and to base the change on evidence for efficacy, safety, affordability, convenience and availability of the chosen alternative/s;

The Change Plan should include a plan for studies to be conducted in Malawi in the immediate future (Q1-3, 2005) that will provide further evidence to support a rational choice of therapy;

The Change Plan should be prepared urgently, as a 'Fast Track' section of the Five Year Plan;

To effect this, a meeting should be scheduled within six weeks in which objectives will be identified, tasks and targets will be assigned and the Change Plan will be finalized and made ready for submission to the Secretary for Health.

The **Change Plan Meeting** was convened at KuChawe Inn on 8-9th January, 2005. This document is the result of that meeting, and outlines a Change Plan for Malawi's Anti malarial Drug Policy.

1. What has gone before

A Malaria Control Programme was inaugurated in Malawi in 1984

In 1984 drug trials (6 sites in Malawi, 224 children with uncomplicated malaria) demonstrated the following 7-day outcome after treatment with **chloroquine (CQ) 25mg/kg**:

parasitaemic at 7 days: 35-59%

febrile or ill at 7 days: 3-5%

Chloroquine was therefore chosen as first-line therapy for Malawi¹.

In 1986-90, *in vivo* studies at six sentinel sites revealed deteriorating efficacy of CQ, with RIII rates rising to 75% in some sites, while 14-day efficacy of **sulfadoxine-pyrimethamine (SP)** was 90-100% (100% parasite clearance at 7 and 21 days in one study²).

In 1990, the decision was made to change the national policy from CQ to SP

The change was effected by 1993, to include all patient groups in the country. CQ was removed from the national drug list and largely withdrawn from all outlets, remaining available in only a few private pharmacies.

The essential elements of the new policy included:

presumptive diagnosis of uncomplicated malaria

prompt treatment with SP for presumed malaria, with added paracetamol for symptomatic benefit

SP to be made available at shops as well as health facilities

pregnant women to be given 2 doses of SP, one dose each in 2nd and 3rd trimesters, irrespective of fever or symptoms

severe malaria disease to be referred to hospital and treated with quinine

treatment policy and guidelines to be distributed widely

Sentinel sites continued to be used for *in vivo* assessments of the efficacy of SP in the treatment of malaria

Several separate research groups conducted additional studies of anti malarial drug efficacy during the period 1993-2004.

2. SP and other efficacy studies in Malawi 1990-(2006)

SP efficacy. The most consistently available information throughout this period⁵, allowing for comparisons of equivalent data between studies, has been the 14-day '**adequate clinical**

response (ACR) (WHO 1996), defined as *absence of febrile parasitaemia* on day 14. [Fever alone is not a failure, and parasitaemia alone is not a failure] The ACR for SP has remained at ~80+% for the past 6 years⁶ (Fig 1).

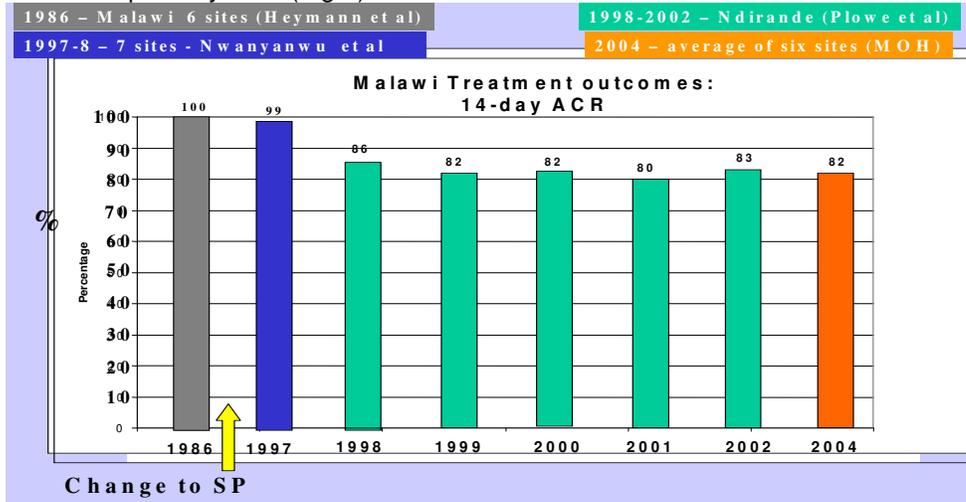


Figure 1 – 14-day Adequate Clinical Response in SP studies

However, **parasitological responses** have been less satisfactory⁶ – Figure 2. NB: re-infections have not been distinguished from recrudescing parasites in these studies – the true success rates are likely to be higher than those shown in the graph, especially at 28 days.

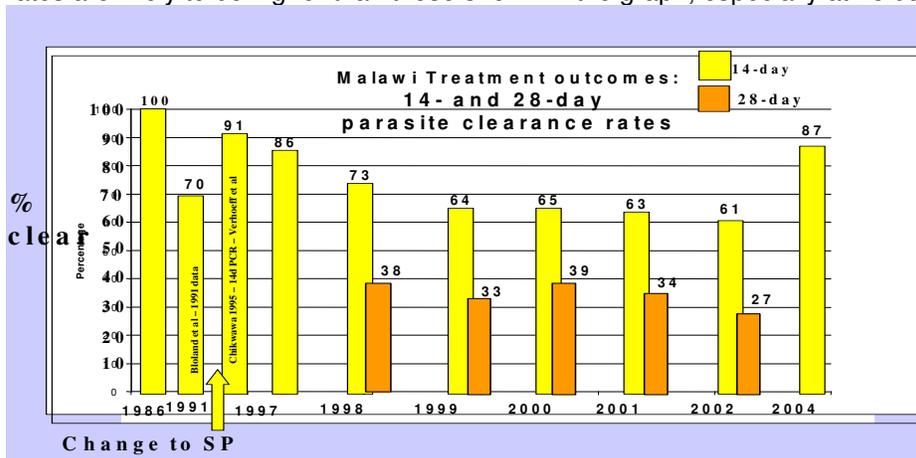


Fig 2 – 14 and 28-day parasite clearance rates in SP studies

Pharmaceutical Studies of SP formulations used in Public Health facilities (CMS tendered drugs - Pharmanova and S.Kant brands) and in 2 studies (Machinga SP / HIV ANC study - 2004 and MoH Sentinel SP Efficacy Study 2004 – Roche SP) in Malawi

DATA: The following tests were conducted in June 2004 by the Centers for Disease Control for the MoH Malawi. These tests provided the same findings as those obtained earlier in 2004 on different batches from the same manufacturers:

Content Analysis: All tablets from all 3 manufacturers passed the content analysis.

Dissolution Tests:

Sulfadoxine (SDX) dissolution passed for all three brands, i.e. Roche, Pharmanova, and S. Kant. Although Pharmanova and S. Kant passed SDX dissolution, the average percent area was significantly less than Roche.

Pyrimethamine (PYR) dissolution for Pharmanova and S.Kant brand tablets failed at all 3 levels of dissolution testing - S1, S2, and S3.

The specific tablet analyses conducted by the CDC laboratory and the specifications and standards used for the testing have been provided to the MoH/NMCP and PMPB.

ACTION STEPS: The following action steps have been recommended:

1) MoH and PMPB plan to establish the capacity in country to test drugs for dissolution, as well as content.

USAID and CDC are working with the MoH and the Pharmacy, Medicines and Poisons Board (PMPB) to obtain Dissolution Equipment and a High Performance Liquid Chromatography (HPLC) device in order for the PMPB and CMS to have the capacity in-country to conduct both content analysis and dissolution testing on anti-malarial drugs, anti-retroviral drugs, anti TB drugs, and other essential drugs. This equipment will allow the PMPB and CMS to conduct tests on a routine basis and in a timely manner on drugs entering the market through the tendering process as well as testing drugs that can be obtained through a routine drug surveillance system. Timeline for start-up is March 2005, and the PMPB, USAID, and CDC are responsible for implementation.

2) Assure the availability of SP of high quality for both efficacy study use as well as for patient/client case management and prevention. This recommendation was made by the National Malaria Advisory Committee. The MoH, CMS, and PMPB, are responsible for implementation.

Studies comparing SP with other drugs in Malawi

Most of the recent in vivo field studies have documented the efficacy of SP without comparison with an alternative treatment. However the following comparisons are available.

2.4.1 **Chlorproguanil-dapsone (CD or 'Lapdap') vs SP** in Malawian children with uncomplicated malaria (Blantyre 1999)⁷. Children were randomly assigned to Lapdap or SP at their first malarial episode, and then received the same allocated therapy for all subsequent malaria episodes during a twelve month period. Results:

	<u>SP group</u> n=224	<u>CD group</u> n=222
Treatment 'failure'* by episode	20%	5% (p<0.0001)
Incidence of severe malaria (Severe anaemia (Hb < 5g/dl))	4% (none)	4% (1 individual)
Febrile malaria per child-year	2.6	2.0

(*'failure' = MPs +ve on day 7)

2.4.2 **CD vs SP** as part of an international multicentre study of efficacy and toxicity of Lapdap (Blantyre 2000)⁴. **Treatment failure** rates (= MPs+ at day 14):

	<u>SP group</u>	<u>CD group</u>
Malawi (SP n=71, CD n=285)	6%	1% (p = 0.03)
All sites (SP n=343, CD n=1366)	11%	4% (p<0.0001)

SP-artesunate vs SP for uncomplicated malaria in children – one of several WHO-funded multicentre studies (Blantyre 2000)⁸, comparing SP alone vs [SP + art x 1day] vs [SP + art x 3 days]

	<u>SP</u> n=150	<u>SP + art-1</u> n=151	<u>SP + art-3</u> n=149
14d treatment failure (non-ACR)		8%	2%
MPs +ve at 28 days	68%	48%	15%
			0%

Studies still in progress **comparing SP with alternatives** in Malawi:

<u>Treatment groups</u>	<u>n</u>	<u>site</u>	<u>dates</u>
<u>D Bell et al</u>	SP	125	Chileka HC
	SP + chloroquine x 3 days	125	
	SP + amodiaquine x 3 days	125	
	SP + artesunate x 3 days	125	
<u>N Kayange</u>	SP	500	Zingwangwa HC
	coartem x 6 doses	500	
	CD x 3 doses	500	
<u>C Plowe</u> <u>T Taylor</u>	SP	105	Ndirande HC
	CQ	105	

Other current studies of **anti malarial drugs** in Malawi:

<u>D Wootton</u>	CD	125	QECH and HCs 2003-4 (dose-finding study) (completed Nov 04)
	CD + art 1mg/kg	125	
	CD + art 2mg/kg	125	
	CD + art 4mg/kg	125	
<u>WHO</u> <u>(proposed)</u>	CD-artesunate (part of multi-centre safety study)	?400	?Bvumbwe HC 2005-6

3. The characteristics of anti malarial policy drug/s – (a) ideal; (b) acceptable

WHO/CDS/RBM/2001.33 - Report of an informal consultation, WHO, Geneva, 13–17 November 2000, lists the following;

Properties of antimalarial drugs that may influence their selection

- Efficacy and half-life
- Acceptability and adherence to treatment (including different formulations)
- Effectiveness
- Quality
- Adverse effects
- Drug interactions and contraindications
- Use in special groups, e.g. pregnant women and infants
- Capacity of health system to implement policy
- Cost, cost-effectiveness, and affordability of various regimens
- Reported resistance and/or cross-resistance
- Useful therapeutic life

4. Options for new policy that exist and have received consideration in arriving at the design of this Change Plan

	Efficacious	Safe	Affordable	Convenient	PK-matching	Available
SP/CQ	±	+++	+++	++ (1 dose/day x 3d)	++	+++
SP/AQ	++ (?)	++(?)	+++	++ (1 dose/day x 3d)	++	+++
AQ/AS				++ (1 dose/day x 3d)	--	
LapDap/AS				++ (1 dose/day x 3d)	++	
Co-Artem	+++	++	±	++ (BD x 3 days, but co-formulated)	--	+ (?)

5. Gaps that exist in our current knowledge that affect our capacity to make an informed decision

- Cost of effecting change
- Cost of different anti malarial regimens
- CT (including ACTs and non-ACTs) efficacy and effectiveness: sentinel site based (may not wish to rely strictly on HC based studies)
- IPTp: which regimen?
- Safety of ACTs in pregnancy and in infants
- Delay of drug resistance by ACTs: do they?
- Impact of ACTs and other CTs on morbidity and mortality: is there any?
- Impact of ITNs on drug efficacy
- Role of drug vendors on drug access and home management of malaria (HMM)
- Presumptive diagnosis and treatment
- Asymptomatic parasitaemia rates among children and adults (ACR vs ACPR), effects of asymptomatic parasitemia (especially in malnourished)
- Is recrudescence less dangerous than new infection? (ACR vs ACPR)
- Behavioural issues, compliance
- Drug availability within health systems
- Rapid diagnostic tests, availability of these drugs (internationally)
- Consumption of first vs. second-line drugs

6. A plan for studies to be conducted in Malawi in 2005 that will provide data helpful to the choice of new policy drug/s.

This will require (1) a list of suggestions for studies that could provide crucial information, followed by (2) a selection of these that will be carried forward. Once the selection has been made, the following need to be defined in sufficient detail for the studies to be launched:

objectives

design – enrolment criteria, observations, endpoints

sample size with rationale

site/s, time-line, starting and completion dates

principal investigator, co-investigator/s

staff requirements, site requirements

supervision, review, quality control
budget – salaries, equipment, reagents, transport, subsistence, supervision, QC procedures
analysis plan, report production, critique/reviews to be sought

NB Where studies are proposed comparing SP with an alternative therapy, study design must be such that, if the efficacy of SP deteriorates to the point of dangerous inadequacy, this can be recognized, trials can be stopped and a change to an alternative national therapy can be introduced through an accelerated mechanism.

Studies proposed

- Efficacy and effectiveness, at sentinel sites
- Comparative, longitudinal studies on case management at district level, assessing efficacy, drug R, morbidity, mortality
- Monitoring “all-cause” M&M in sentinel districts
- Knowledge and behavioural ? (KABP) studies for assessment of vendors/storekeepers and HMM (home malaria management issues) vis-à-vis compliance
- Assess predictors of treatment failure and of emergence of resistance
- PK studies: population based (to assess variance)
- Pharmacovigilance studies.

One efficacy study was discussed in some detail as it would guide a change in first line treatment; to start ASAP.

Randomised blinded efficacy study, comparing;

1. SP
2. AQ+SP
3. CoArtem
4. AQ+AS

Extra numbers to be recruited to the AQ+SP group as it is a strong candidate for a treatment change

At a later time, other treatments to consider include, LapDap+AS (CDA) once available, and SP+CQ depending on the results of the CQ vs. SP study which is soon to start. These studies could continue on to provide longitudinal data over a longer period of time.

The study will include symptomatic adults and children and the sample size calculation will be done with statistical help.

Endpoint – WHO efficacy endpoints – ACPR, LCF, LPF at Day 14 and 28

Technical committee to decide upon an ACPR rate acceptable for any policy change.

Reinfection vs recrudescence?

Protocol to be written using the standard WHO version and modified as required.

Ideally this will be ready by 2.15pm Wednesday, Jan 12th, 2005!!

7. A plan for monitoring of health indicators during the period before and after a policy change is effected. Note – this is different from #6. #7 requires a separate plan for monitoring of health indicators in large populations in areas where SP remains the primary policy. Having such monitoring in place during the period *before* instigation of a new policy will allow documentation of the health impacts of the new policy *after* it has been introduced, an opportunity that was not available after the previous change of first-line drug policy.

Monitoring Drug Policy

Efficacy (under ideal circumstances): **study mode**
 Clinical, parasite: need standard methods
 Can we come up with a standard definition that we can stick with?
 Compliance/Use ('access') (bears on effectiveness): **study mode**
 % patients needing Rx who received Rx in 24 hours
 Tolerance: **large scale surveillance**
 Focus on more severe reactions and reactions impairing compliance
 Monitoring for adverse effects and attributing them to drug is very complicated...
 Impact (possibly most importantly): **large scale surveillance**
 Population level: morbidity and mortality trends (e.g., anemia, all-cause mortality)
 Must be assessed in context of coverage of other interventions, esp ITNs (drug therapy is not the only effector...)
 Malawi (via the DHS) had the ability to demonstrate a drop in childhood mortality during the 90's....coincident with the use of SP.
 Several indicators appear to be workable: anemia (as an indicator of morbidity), 'survival' is another (but the challenge is measuring malaria-specific mortality is very difficult - - all-cause mortality is a decent proxy).

A commitment to on-going (as opposed to sporadic) monitoring

Key indicators
 Data sources
 Systems requirements
 Responsibilities and roles/financing
 Building therapy/drug monitoring in overall malaria program and health system M&E

8. A plan for involvement of stakeholders throughout the period of the policy change

- Wellcome Trust – Human resources**
- Malaria Project – Human resources**
- Malaria Alert Centre - - Human resources**
- WHO – Technical resources**
- GFATM -- ? Financial (not here yet...)**
- MACEPA - ?Financial**
- US-AID - - Financial**
- MSH-technical support, human resources**
- CDC-technical support**

9. Time Line [for the fast track activities]

Meetings		PT	PTS		T		T		PT		T	T	PTS
Working meeting		sg											
International consultations	+		+							+			+
'Change-Plan'		++											
Protocols/SOPs			+++										
Clinical trial/s				+++	+++	+++	+++	+++	+++				
Analyses										+++	+++		
Writing/interpretⁿ												+++	
Advisory Committee meetings			+										
Recommendation to Ministry of Health													+++
Month		Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov

| 2005

PT = joint meeting of PAC + TWG; T = meeting of TWG; sg = meeting of TWG sub-group for clinical trials (+co-opted members as needed); S = meeting with stake-holders.

Reference

1. Khoromana CO, Campbell CC, Wirima JJ, Heymann DL. In vivo efficacy of chloroquine treatment for *Plasmodium falciparum* in Malawian children under five years of age. *Am J Trop Med Hyg* 1986; 35(3): 465-471.
2. Heymann DL, Khoromana CO, Wirima JJ, Campbell CC. Comparative efficacy of alternative primary therapies for *Plasmodium falciparum* infections in Malawi. *Trans Roy Soc Trop Med Hyg* 1987; 81: 722-724
3. Nwanyanwu OC, Ziba C, Macheso A, Kazembe P. Efficacy of sulphadoxine-pyrimethamine for acute uncomplicated malaria due to *Plasmodium falciparum* in Malawian children under five years old. ____2000;
4. **Allouche A, Bailey W, Barton S, Bwika J, Chimpeni P, Falade CO, et al. Comparison of chlorproguanil-dapsone with sulfadoxine-pyrimethamine for the treatment of uncomplicated falciparum malaria in young African children: double-blind randomised controlled trial. *Lancet* 2004; 363: 1843-1848.**
5. Bloland P, Kazembe P, Oloo, Himonga, Barat & Ruebush. Chloroquine in Africa: critical assessment and recommendations for monitoring and evaluating chloroquine therapy efficacy in sub-Saharan Africa. *Tropical Medicine and International Health* 1998; 3(7): 543-550.
6. Plowe CV, Kublin JG, Dzinjalama FK, Kamwendo DS, Mukadam RAG, Chimpeni P, Molyneux ME, Taylor TE. Sustained sulfadoxine-pyrimethamine clinical efficacy for uncomplicated falciparum malaria in Malawi after ten years as first line therapy: a five year prospective efficacy study. *Brit Med J* 2004; 328:545-548.
7. **Sulo J, Chimpeni P, Hatcher J, Kublin JG, Plowe CV, Molyneux ME, Marsh K, Taylor TE, Watkins WM, Winstanley PA. Randomised clinical trial of chlorproguanil-dapsone (*Lapdap*) versus sulfadoxine-pyrimethamine for sequential episodes of uncomplicated falciparum malaria in Kenya and Malawi. *Lancet* 2002; 360:1136-1142.**
8. Garner P et al – Meta-analysis of SP-artesunate studies in Africa *Lancet* 2003....