Financing Mechanisms for Malaria

Report of the
All Party Parliamentary Malaria Group
(APPMG)

using evidence presented to the
APPMG in 2006

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3. Financing delivery

3.1 Delivering malaria prevention and treatment

3.1.1 Insecticide treated nets (ITNs)

3.1.2 Indoor residual spraying (IRS)

3.1.3 Intermittent preventive treatment (IPT)

3.1.4 Improved access to effective malaria treatment

3.2 Resource allocation

3.3 Health system strengthening

3.3.1 Forecasting for malaria

3.3.2 ‘Corporatisation’ of government service delivery

3.3.3 Purchasing private services

3.4 Enabling and regulating the private sector

3.4.1 Medical Transparency Alliance (MeTA)

3.5 Human resources

3.5.1 Human resource planning and recruitment

3.5.2 Managing performance and attrition

3.6 Operational Research

3.7 Monitoring and evaluation (M&E)

3.7.1 RBM Monitoring and Evaluation Reference Group (MERG)

3.7.2 Health Metrics Network (HMN)

3.8 Operational Research

3.9 Milestones

3.10 Intellectual Property Rights (IPRs)

3.11 Country-level initiatives to increase sustainable funding

3.12 Global initiatives to increase sustainable funding

3.12.1 The Aid Guarantee Facility (AGF)

3.12.2 UNITAID (International Drug Purchase Facility)

3.12.3 The International Finance Facility (IFF) (including IFFim)

3.12.4 Debt Conversion

3.12.5 Air-Ticket Solidarity Levy

4. Financing Malaria Research and Development

4.1 Current situation

4.2.1 Push Mechanisms

4.2.2 Pull Mechanisms

4.3 Research and development in malaria prevention

4.4.1 Vector Control

4.4.2 Intermittent Preventive Treatment (IPT)

4.4.3 Malaria Vaccine

4.5 Research and Development Milestones

4.6 The role of IPRs in research and development

References

ANNEX 1 List of presentations made to the APPMG during 2006

Abbreviations
Contents

Figures

Figure 1.1  Estimated incidence of locally transmitted clinical malaria episodes (any species), country level averages, 2004  1
Figure 1.2  Estimate of World Poverty  1
Figure 1.3  Breakdown of Estimated Costs to achieve Malaria Targets  4
Figure 1.4  Resource needs for malaria worldwide  4
Figure 2.1  International Funding for Malaria Control, 1994-2004  5
Figure 2.2  Sources of International Funding for Malaria Control 2005  6
Figure 2.3  Share of funds channelled through financing agents East and Southern Africa  6
Figure 2.4a  Public and Private Health Expenditure, Angola, Guinea & Kenya 2003  7
Figure 2.4b  Internal & External sources of health expenditure, Angola, Guinea & Kenya 2003  7
Figure 2.5  Donor Commitments for health in 7 African Countries, 1997-2001  14
Figure 2.6  Pledges to the GFATM  17
Figure 2.7  Performance of GFATM funded malaria programmes  17
Figure 2.8  Levels of the supply chain that MMSS works at  21
Figure 3.1  Reduction of taxes and tariffs in Africa  24
Figure 3.2  Potential flow of funds and products with a Global ACT Subsidy  29
Figure 3.3  Cost-effectiveness ranges and means in a very low income sub-Saharan Africa country with moderate to high malaria transmission  29
Figure 3.4  Potential IFIm donor pledges and disbursements  40
Figure 3.5  How the IFIm operates  40
Figure 4.1  R&D Investment in 2004  41
Figure 4.2  The long road to a new medicine  42
Figure 4.3  Research stages  42
Figure 4.4  Gaps in Malaria Drug R&D  43
Figure 4.5  Push and Pull Funding  43
Figure 4.6  Value added through effective PPPs  44
Figure 4.7  Neglected Disease R&D Projects December 2004  45
Figure 4.8  The IRFF  46
Figure 4.9  AMC prices over time  50

Case Studies

Case Study 1.1  Household story  2
Case Study 1.2  The economic burden of malaria in Malawi  2
Case Study 2.1  User Fees for Malaria Treatment in Sierra Leone  12
Case Study 3.1  Distributing ITNs through vaccination programmes  25
Case Study 3.2  Malaria Risk Mapping  31
Case Study 3.3  Essential workforce needed to achieve the MDGs  32

Tables

Table 2.1  Sources of Health Expenditure, Sub-Saharan Africa  8
Table 2.2  Achievement of targets for Government Spending on Health, Sub-Saharan Africa  10
Table 2.3  Private Prepaid Plans as a Percentage of Total Health Expenditure  13
Table 2.4  Commitments and Disbursements of major donors  14
Table 3.1  Estimating overhead health systems costs  23
Table 3.2  Estimated numbers of ITNs and costs assuming 100% ANC and EPI attendance  24
Table 3.3  Sample Malaria Essential service Package  30
Table 3.4  Action at country level milestones, 2005-2010  35
Table 3.4  Action at country level milestones, 2011-2015  36
Table 3.4  Global advocacy and finance milestones, 2005-2010  36
Table 3.4  Global advocacy and finance milestones, 2011-2015  36
Table 4.1  Breakdown of Cumulative Philanthropic and Public Funding to Drug PPPs  45
Table 4.2  Action at country level milestones, 2005-2010  51
Table 4.2  Action at country level milestones, 2011-2015  52
I am delighted to introduce and endorse the All Party Parliamentary Malaria Group’s Second Report entitled “Financing Mechanisms for Malaria”. So much has been achieved in malaria control since our first ground breaking APPMG report published in June 2005 and this is a timely expansion of the work we have been doing in advocating the urgent way forward to combat malaria.

Malaria is known to kill over 1 million children under five every year and probably kills many more. It affects countless others, especially pregnant mothers. There are between 500,000,000-600,000,000 cases of malaria every year and it costs Africa $12 billion in economic terms every year. The suffering and economic hardship caused in Asia and Latin America is also significant. Malaria is treatable; suffering from malaria is avoidable.

The cost of successfully preventing and treating malaria worldwide has been estimated to be around $3 billion per year. This is a reasonable cost, but the money is not yet on the table, so there is a need to explore the mechanisms to finance malaria control to advise on which may work best and to advocate widely to raise the money. The purpose of this report is to examine alternative methods of financing the prevention and treatment of malaria across the world, and especially in Sub-Saharan Africa, including recent innovative initiatives.

African Government leaders recognised the unacceptable burden of malaria which led them to sign the Abuja Declaration and Plan of Action in 2000, committing their governments to halve the burden of malaria by 2010. In 2006, they reconvened to assess their progress; although their targets had not been met they recorded appreciable progress and agreed there should be accelerated action towards universal access to malaria services.

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At the White House Malaria Summit, in December 2006 the Gates Foundation committed a further $833.5 million in new grants to combat the disease; specifically, grants to expand access to insecticide-treated nets (ITNs), treatment, and other malaria control tools, speed research on vaccines and other new prevention methods and boost global advocacy to fight the disease.

The All Party Parliamentary Malaria Group has been a catalyst in bringing together many organisations in the field of malaria to work for the common good. We have all come a long way; and so much has been achieved. It has given organisations, scientific institutions, NGOs and MPs the opportunity to listen to one another. Everyone has come to appreciate that there is no one solution to malaria control; it has to be a combined effort.

During the last year, the Group has had presentations on a range of established and innovative financing mechanisms. This report is based on these presentations. It explores options for financing scaling up of malaria control and supporting essential research initiatives. More recently, in January 2007, in the UK, the Official Opposition pledged to commit $1 billion per annum through DFID in a future Conservative administration for the provision of mosquito nets and medicines dedicated to the fight against malaria until the MDG on malaria has been met.

Many of the member organisations in the All Party Parliamentary Malaria Group, are engaged in important work to alleviate the problem:

• The London School of Hygiene & Tropical Medicine has been engaged in applying intermittent preventive treatment for African children in areas with seasonal malaria patterns. Research is being carried out on drug resistance of the Plasmodium falciparum parasite; the deadliest of the malaria species and in developing novel mosquito control strategies.

• The Liverpool School of Tropical Medicine is leading malaria research programmes aimed at developing new drugs and insecticides to combat insecticide and drug resistance, as well as mapping gene flows and mating barriers; cellular responses to human malaria infection and research to reduce the adverse effects of malaria in pregnancy.

• The Malaria Initiative (PMI) is engaged in important work to alleviate the problem:

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There are other early success stories too; for instance, the range of pharmaceutical companies discovering and developing new antimalarial products is increasing, such as Sanofi-Aventis, Pfizer and companies based in the Far East. NGOs such as Médecins Sans Frontières and AMREF have increased their malaria work. The Coalition Against Malaria was launched in the UK, France, Ethiopia and Cameroon in 2006. Coalitions are being built in Mozambique and Belgium with others in the pipeline. The Coalition aims to challenge the global community to do much more to bring down the suffering caused by malaria.

There is much activity but without imaginative, innovative and above all sustained mechanisms of financial support, of sufficient scale (about US$3 billion per year), better functioning health care systems, skilled and motivated health professionals and universal access to prevention and treatment, malaria will continue unnecessarily to blight millions of people living in tropical and sub-tropical climates. Currently it is causing avoidable suffering and causing a lasting shadow over the world’s efforts in making poverty history. To rid the world of poverty, first we must enable people to live, and keep them healthy.

This is an authoritative, up-to-date report, drawing on the best evidence to generate new sustainable funding for combating malaria, building on what has gone before especially recent boosts to funding. I am grateful to all who participated and helped us prepare the report. I place on record my gratitude to all my Parliamentary colleagues, of all parties and from both the House of Commons and the House of Lords, who have devoted their time, energy, advocacy and encouragement to the All Party Group’s work, and particularly to my fellow Officers who have worked hard with the authors and experts to ensure this excellent report is produced. I commend it to you and urge you to study it and challenge all those in decision-making and publicly influential roles to rise up to the challenge, produce the resources and get the job done!

There is much still to be done but it can be done – and the great, exciting story about malaria is that it is DO-ABLE! Combating, even eliminating malaria is the prize and opportunity for the world that remains to be grasped.

Stephen O’Brien MP, Chairman
Executive Summary

1 The need for taking action

Malaria is a devastating disease. Forty per cent of the world’s population, 3.2 billion people in 107 countries, are at risk of contracting malaria. We have the tools to prevent and treat malaria, yet each year it is estimated to cause up to 500 million cases and up to 3 million deaths. Of those deaths, a large proportion are of children under age five in Sub-Saharan Africa. Malaria disproportionately affects the most vulnerable, and the majority of countries affected are also amongst the poorest countries in the world.

Malaria has a vastly detrimental effect both on individuals and whole countries. A large proportion of the cost of malaria treatment and prevention in poor countries is met by out-of-pocket expenditure, often taking a considerable proportion of the income of poor households. In Ghana, for instance, malaria care can cost up to 34% of poor households’ income, which can be disastrous. Each year malaria costs Africa US$12 billion in lost Gross Domestic Product (GDP). It has slowed economic growth in African countries by 1.3% per year. The compound effect of this slowdown over the last 20 years has caused their GDP to be 32% lower than it would have been in the absence of malaria.

It is now accepted that malaria must be tackled urgently and intensively, and that endemic countries, the international community and the private sector must make a concerted effort to tackle malaria. If this happens, the price (in terms of lives saved, morbidity avoided and increased economic growth for countries affected) will be enormous. The Millennium Development Goals (MDGs) cannot be met without increased resources for all aspects of malaria control, including treatment, prevention, strengthening health systems, developing new tools for prevention, diagnosis and treatment and research on the best ways to deliver effective interventions.

The World Malaria Report 2005 estimates that to support the minimum interventions necessary to achieving the MDGs by 2015, and the MDGs for malaria by 2015 for the 82 most affected countries, a total of US$3.2 billion per year is needed.

Given the continuing rise of resistance to the drugs and insecticides used to treat and prevent malaria, there is a need for constant research and development to ensure that, when resistance to existing tools develops, there are new, effective alternatives readily to be put in place. Continual development of new drugs at the rate dictated by emerging drug resistance would cost at least US$30 million a year. The international community still largely neglects the need for systems and socioeconomic research to make better use of new and existing interventions. The greatest need, however, is to support the actual delivery and use of measures that we know can control malaria, but are not reaching those who need them.

A total of just over US$3 billion per annum to meet the malaria MDGs and Abuja targets is not impossible to mobilise.

2 Existing Financing

The most recent estimates currently available of international malaria-specific funding indicate that approximately US$600 million were spent on malaria control in 2004. Seventy-five per cent of this funding went to Sub-Saharan African countries.

The majority of international funding for malaria control is now channelled through the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Malaria allocations from the GFATM are currently US$1.8 billion for the next five years (27% of GFATM spending). Domestic sources of funding for malaria control must be substantially increased as the GFATM funds spent on malaria, for East and Southern Africa, are currently 11% of malaria funding channelled through donors and NGOs, 47% through the public sector (some of which is financed from donor budget or sector support), and 41% through the private sector. The World Bank reports that out-of-pocket spending accounts for 93% of private spending and more than 60% of health spending in low-income countries. In both Sub-Saharan Africa and South Asia, roughly half of all health spending is out-of-pocket [1]. This type of spending is inequitable, hitting the poor hardest.

The financial resources devoted to malaria control from international donors have grown dramatically, increasing 10-fold in the last ten years. Despite this, there remains a large finance gap that needs to be filled through increased donor funding and increased malaria-endemic country spending on malaria control and health systems. Without these increases, the Abuja targets and Millennium Development Goals related to malaria will not be met. Progress is being made towards filling this gap. Over the next three years existing Global Fund commitments, the World Bank, Malaria Booster Programme and the US President’s Malaria Initiative have committed US$767 million a year.

If this progress is met by increased resources from other donors, through existing and new mechanisms, then there is hope that the tide of malaria can be turned.

Endemic countries’ domestic financing mechanisms for malaria include government spending from taxation income, user fees, and risk pooling mechanisms such as private or voluntary insurance. There are strong equity and efficiency reasons for the abolition of user fees, particularly in relation to their effect on access for the poor. Private or voluntary insurance plays a very small role in health expenditure in Sub-Saharan Africa and malaria-endemic Asian countries, accounting for an average 2.8% of total health expenditure in Sub-Saharan Africa, and 1.9% in malaria-endemic Asian countries. Not least of the considerable difficulties in implementing insurance schemes in many settings, is that often those who most need to be insured can least afford to pay premiums.

Most research and development (R&D) into new prevention and treatment tools for malaria is funded by the private sector – pharmaceutical and petrochemical (insecticide) companies, or through Public-Private Partnerships (PPPs). Drug research and development is expensive and time consuming, and PPPs can perform a vital role in supporting the private sector to invest in R&D for less profitable diseases, such as malaria. Evidence from some PPP-supported drug development projects indicates that they performed better than projects from either industry or public-sector alone, in providing health value for developing country patients, breakthrough innovation, and cost-efficiency.

3 Financing Access and Delivery of Malaria Control Programmes

Efforts to have the malaria burden by 2010 invoke a number of interventions including early diagnosis and treatment with artemisinin-based combination drugs, intermittent preventive treatment during pregnancy, and vector control with insecticide–treated mosquito nets (ITNs) or indoor residual spraying (IRS).

Some ITN programmes have brought about impressively rapid increases in ITN coverage at national scale (e.g. utilising national immunisation campaigns in Togo and Niger), and others have managed steady progress through more sustained delivery systems. However, the combination of sustained delivery, high coverage, and national scale-up operation remains elusive, and most young children in Africa and other malariaous countries still do not have the protection afforded by ITNs, 330 million of which are needed for full coverage by 2008. Major distractors include the shortage of funds, lack of public awareness, and poor infrastructure and logistics. A comprehensive approach to ITN distribution, using a mix of delivery models such as health care facilities, routine vaccination campaigns and commercial sales is needed to achieve complete and sustained coverage.

In areas of unstable or epidemic malaria, indoor residual spraying (IRS) with approved insecticides has rapid, reliable short-term impact and can be targeted to high-risk communities on a regular basis or in response to changing transmission patterns. However, it is demanding in planning, logistics, skills and achieving coverage levels. Financial costs per person protected are generally quite low for IRS in these settings.

Intermittent treatment of pregnant women with sulphadoxine-pyrimethamine (SP) has been shown to reduce the risk of maternal anaemia, placental parasitaemia, and low birth weight in a number of Asian countries. Not least of the considerable financial cost of drug resistance has required the switch to new artemisinin-based combination therapies (ACTs). Access to accurate blood tests for diagnosis, where practicable, is now critical to reduce unnecessary treatment of people without malaria. Both ACTs and the diagnosis to support their effective usage cost more than previous first-line drugs and clinical (symptomatic) diagnosis. ACTs range from US$1–2.80 per dose compared to chloroquine at US$0.10, while the cheapest Rapid Diagnostic Tests (RDTs) to detect Plasmodium (the most dangerous type of malaria) cost US$0.01–0.07 each. Countries were only able to attempt this transition with the promise of increased and sustainable funding.

As ACTs cost considerably more than previous first-line malaria treatments, those who need them most often cannot afford them. To deal with this issue (and to slow down the escalating spread of resistance, which could increase if artemisinin and potential partner drugs were used widely in monotherapy), a global subsidy for ACTs has been proposed. A subsidy would save lives and lower the burden of malaria, discourage monotherapy by lowering the prices of ACTs, stimulate the ACT market and maintain the impetus to reduce new antimalarial drugs [2]. A global subsidy would allow ACTs to flow...
Executive Summary

4. Financing Research and Development

Whilst we have effective tools against malaria in the form of ACTs, ITNs, long lasting insecticidal nets (LLINs) and insecticides for spraying malaria parasites and mosquitoes can rapidly develop resistance. There is a need for continual research and development into drugs, diagnostics and insecticides to keep one step ahead of resistance. There are also hopes of developing new methods to prevent malaria, through Intermittent Preventive Treatment for infants (IPTi), children and other target groups, and the possibility of a vaccine. Implementation research to improve existing tools and delivery systems, and develop new ones is an essential and neglected area for support. Malaria research is an area we cannot afford to neglect.

In 2004 it was estimated that US$323 million was invested in malaria R&D. In October 2005, the Bill and Melinda Gates Foundation became the largest private donor to malaria research in the world, committing US$258.3 million to malaria research and development. Malaria is a neglected disease for drug development. Between 1975 and 2004 1,556 new drugs were approved, only 8 of which (0.5%) were for malaria. Drug development is expensive and time consuming, yet the rise of drug resistance makes it vital. Research and development into both treatment and prevention of malaria can be financed through ‘Push’ or ‘Pull’ mechanisms. Push mechanisms operate at the point where the expenditure is being made, while the research is taking place before the launch of the drug. Examples of Push mechanisms include direct funding of research conducted by academic institutions or private companies. This helps the organisations undertaking research, reducing their dependence on the uncertain possibility of income once the drug has been launched. It allows smaller organisations, which would not otherwise be able to afford the upfront costs of research, to play a role in drug development.

However, there is no guarantee to the funder that money put into research will result in a successful, effective drug. Many drug R&D projects are not successful. Public Private Partnerships are one of the most important Push mechanisms for malaria treatment R&D. PPBs help to fund R&D, and have the additional benefits of providing social venture capital and expertise. PPBs projects account for around 70% of drug R&D for neglected diseases. Analysis into neglected drug development has shown that drugs resulting from projects using a PPP model are more likely to be appropriate for use in developing countries than drugs resulting from an ‘industry alone’ approach. PPBs struggle with under-funding and reliance on short-term grant funding.

Pull mechanisms are designed to provide R&D incentives through the promise of future rewards, generally related to market size and potential revenue, once the drug has been launched. Potential pull mechanisms include differential pricing, advanced market commitments (AMCs), and global bulk purchasing mechanisms. Pull mechanisms have the advantage that money spent on research only goes to successful drugs, whereas with push mechanisms there is always the significant risk that no effective, practical drug will result. However, whilst this reduces the amount of risk for the donor, it shifts the burden of risk onto the organisation conducting research. Where companies are unwilling to risk investing in R&D for a product that if successful could have good returns, but may fail, pull mechanisms are ineffective. Smaller companies particularly, may be unable to afford the large costs of R&D in the hope of future revenue. Thus, push mechanisms may be more effective in such circumstances. However, many pull mechanisms do have added benefits in terms of reducing the price of new drugs for end users.

5 Making best use of available and new financing

It is vital that all funds available for malaria control are used in the most effective way. Malaria control requires sustained programmes to provide treatment and preventive interventions. Thus, predictability is an important issue in aid financing. Aid is often unpredictable. Donor commitments are often short term, whilst spending obligations are long term. Commitments are consistently higher than actual disbursements. The Paris Declaration on Aid Effectiveness of March 2005 emphasised the need for increased focus on ownership, harmonisation, alignment, results and mutual accountability.

Aid effectiveness is also determined by the policies and institutional environment of the recipient country. Governance is important to ensure resources achieve the intended results. Legitimate concerns exist over capacity, accountability, transparency and corruption levels in many countries. Conflict and HIV/AIDS have had a major effect in reducing the capacity of many countries, and the policies of many donors have also contributed to undermining national capacity. Accountability is vital to ensure aid effectiveness. Recipient governments must be answerable to all their people, including the poor and marginalised. Linked to this is a need for transparency, which can reduce the potential of resources being misused, and promote good governance.

Despite these challenges, the 2005 African Governance Report found that governance in Africa is improving overall, with progress made in democratic transitions, political inclusiveness, voice and accountability and economic management. More action by donors and recipients is needed to improve effectiveness, but with the right policies in place, aid directed against malaria can be cost-effective and have a dramatic effect.
Recommnedations

Recommendations to donor governments

Financing access and delivery

• Work with endemic countries to reduce the level of out-of-pocket expenditure on malaria treatment. Ways of achieving this include a global subsidy on ACTs and the abolition of user fees for health services.

• Support developing countries that wish to abolish user fees for health services, to allow health services to respond to the increased demand and provide a good, efficient service to those who need it.

• Complement investments in treatment with support for prevention, to ensure that the need for treatment is reduced.

• Honour commitments made in the Doha Declaration to help developing countries access inexpensive medicines, through assisting them to use the safeguards within the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement. Pressure should not be put on developing countries to sign up to agreements that eliminate these safeguards.

• Work with other donors and Ministries of Health to avoid duplication of efforts and ensure a coherent and harmonised approach (e.g. the Three Ones).

• Support the strengthening of health system capacity to absorb and utilise nets and drugs effectively. Health system and human resource development are crucial to sustainable change.

Financing research and development

• Employ a combination of push mechanisms (mechanisms that directly cover research costs) and pull mechanisms (mechanisms that encourage R&D through creating an incentive in terms of the potential market) to encourage R&D on a comprehensive range of malaria interventions, and ways of delivering them at scale.

• Increase the currently low level of support for Public Private Partnerships (PPPs). This support could be channelled through innovative mechanisms such as the International Finance Facility for Neglected Diseases (IFFnd) and International Research and Development Facilitation Fund (IRFF) if they are established.

• Allocate sufficient funding to implementation research, in addition to development of new tools, to ensure tools available provide greatest benefit by reaching those who need it.

• Support for R&D into malaria vaccines should continue, whilst at the same time increasing funding for delivery of existing malaria control interventions, as a suitable vaccine is still some years away, and people are dying unnecessarily now.

Recommendations to malaria-endemic countries

• Work towards meeting commitments on increased health expenditure. Currently, only Liberia is meeting the 2001 Abuja Declaration on HIV/AIDS, Tuberculosis and other Infectious Diseases target of allocating 15% of public expenditure to health. Most African countries (including Liberia) have not reached the Commission on Macroeconomics and Health (CMH) target of spending US$34 per capita on health per year.

• Urgently work to eliminate or reduce taxes and tariffs on importation of ACTs, ITNs and insecticides used for malaria control. These can increase costs to end users, decrease the population coverage achievable with available funds, unnecessarily punish the poor and delay these essential commodities reaching those who need them.

• Actively seek to reduce out-of-pocket expenditure on malaria treatment, as it can exacerbate poverty and prevent people from accessing effective treatment.

• Strengthen mechanisms of accountability at all levels, from the community upwards.
1. The need

1.1 Malaria burden

Malaria is a devastating disease. Forty per cent of the world’s population, 3.2 billion people spread over 107 countries, are at risk of contracting it. We have the tools to prevent and treat malaria, yet each year an estimated 500 million clinical malaria episodes and up to 3 million deaths occur. Of these deaths, around 1 million are of children under the age of five in Sub-Saharan Africa. Malaria disproportionately affects the most vulnerable people, and the majority of countries affected are amongst the poorest in the world, as shown in figures 1.1 and 1.2.

1.1.1 Vulnerable Groups

The people most at risk of malaria infection vary in different parts of the world. In much of Africa, all are at risk, but especially rural populations. In South-East Asia adult men working in the forests are at higher risk of infection [3]. Once infected, children under age five are most likely to die of malaria, and pregnant women are particularly at risk from the disease. People living with HIV/AIDS (PLWHA) are also highly vulnerable, as the two diseases interact. Malaria raises the viral load in people with HIV, whilst HIV increases the prevalence and density of parasitaemia, intensifies the frequency and severity of clinical episodes and alters the response to antimalarial treatment. A recent Science article estimates that among an adult population of 200,000 in Kenya, disease interaction between malaria and HIV may have been responsible for 8,500 additional HIV infections and 980,000 excess malaria episodes since 1980 [4]. The prevalence of malaria in Sub-Saharan Africa may be an important factor in promoting the spread of HIV in the region [4]. This indicates a need for measures that can tackle both diseases, such as strengthening health systems, improving coordination between malaria and HIV programmes, and providing effective antimalarial treatment and ITNs to PLWHA.

1.1.2 Climate Change and Malaria

It is unclear exactly what effect climate change will have on the geographical range and intensity of malaria. Some forecasts predict that malaria will move into more temperate regions as temperatures increase, possibly leading to an increase in range and levels of malaria. Others believe that if climate change reduces the amount of rain and standing water in endemic countries, it could reduce malaria levels in these areas. Thus, adequate monitoring and surveillance are important to ensure any trends linked to climate change are identified and appropriate action is taken swiftly to deal with any change in malaria burden.

1.2 Economic effect of the existing malaria burden

Malaria has a vastly detrimental effect both on individuals and countries, as case studies 1.1 and 1.2 illustrate. As chapter 2 explores, a large proportion of the cost of malaria treatment and prevention in poor countries is met by out-of-pocket expenditure, often taking up a considerable proportion of the income of poor households. In Ghana, malaria care can cost up to 34% of poor households’ income [5]. When the opportunity cost of income is considered because of illness of an individual or through the necessary time spent caring for the person affected, is added to these direct costs, the effect on households can be devastating.

Case Study 1.1 Household story

A two year old child who lived in Lamala village in eastern Africa had been crying all morning and his mother was worried, as his forehead was very hot. She had cancelled her morning’s work selling mangoes in the market, because she could not leave him alone. Instead she sent her older daughter to the market, as they needed money, because she could not leave him alone. Instead she sent her older daughter to the market, as they needed money, so the daughter missed school. In the afternoon the boy looked worse, so his mother walked three miles with the child on her back to the nearest clinic. Unfortunately, the clinic had closed early, as drugs had run out so the mother borrowed $1 from her friend near the clinic and took the bus to the drug store in town. The shopkeeper said the proper treatment now cost $2, and no, he could not give her credit. He suggested that she buy one day’s treatment instead of three, and see if the child got better. That used up the bus fare, so she walked home arriving very late. The child was much better after the medicine, but on Sunday the fever started again, and he started having fits. The clinic was closed. Where was the money going to come from to take the child into town again?

At the macroeconomic level, malaria also has an enormously negative impact. Each year malaria costs Africa US$12 billion in lost Gross Domestic Product (GDP). It has slowed economic growth in African countries by 1.3% per year; the compounded effect of which over the last 35 years has caused GDP levels to be 32% lower than it would have been in the absence of malaria [6].

Case Study 1.2 The economic burden of malaria in Malawi

Malaria is a major problem in Malawi, with around 3 million reported cases in 2003 [7]. Children under age five can expect to get malaria 3 to 4 times a year. 40% of public health expenditure in Malawi is spent on combating malaria, and 30–50% of inpatient admissions are due to the disease [8]. In a country with an annual Gross National Income per capita of $160 in 2005, the cost of domestically financing effective prevention and treatment of malaria is impossible without external assistance [9].

1 Out-of-pocket expenditure refers to expenses that have to be paid by the sick at the time of illness.
1. The need

1.3 Existing commitment to tackling malaria

It is now accepted that malaria needs to be tackled more intensively and that endemic countries, the international community and the private sector all have a role to play. The Millennium Development Goals (MDGs), agreed in 2000, are at the heart of the global development agenda, with major international commitment to meeting them. Combating malaria is essential to achieving the MDGs. Thus commitment to the MDGs necessitates concerted action to tackle malaria.

The African Summit on Roll Back Malaria, held in Abuja in 2000, was attended by 44 of the 50 malaria-affected countries in Africa. It resulted in the Abuja Declaration of April 2001, which committed those countries to halve malaria mortality by 2010, and called for increased resources to tackle the disease. As part of this commitment, African Union countries pledged to allocate 15% of national budgets to the health sector [10]. In May 2006, the African Union rededicated itself to intensifying efforts to meet Abuja and MDG targets [6].

Malaria and the Millennium Development Goals (MDGs)

The achievement of 6 out of the 8 MDGs is linked to combating malaria.

- **MDG 1 – Eradicate Extreme Poverty**
  - Malaria keeps poor people poor, consuming up to 25% of household incomes.

- **MDG 2 – Achieving Universal Primary Education**
  - Malaria, a leading cause of absenteeism in children and teachers, impairs attendance and learning and can cause lasting neurological and cognitive damage in children.

- **MDG 4 – Reduce Child Mortality**
  - Malaria is the leading cause of child mortality in Africa, accounting for 20% of all child deaths.

- **MDG 5 – Improve Maternal Health**
  - Malaria is four times more likely to strike pregnant women than other adults, and has life-threatening implications for both mother and child.

- **MDG 6 – Combat HIV/AIDS, Malaria and Other Diseases**
  - Malaria control will reduce mortality and mortality due not only to malaria but to other diseases (e.g. People living with HIV/AIDS are at greater risk of contracting malaria).

- **MDG 8 – Develop a Global Partnership for Development and provide access to affordable essential drugs**
  - Malaria medicines are currently expensive for developing countries, and in short supply; the public-private partnerships currently under way to improve access to affordable malaria drugs can serve as a basis for improving access to other essential medicines.

Source [11]

1.4 Costs of tackling malaria

Meeting the MDGs requires increased resources for malaria control, including prevention and treatment, strengthening health systems, and research and development of new tools for prevention, diagnosis and treatment. The World Malaria Report 2007 estimates that supporting the minimum interventions necessary to achieve the Abuja targets by 2010 and the MDGs for malaria by 2015 for the 82 most affected countries, a total of US$3.2 billion per year is needed. US$1.9 billion of this would be needed for African countries, and US$1.3 billion for the rest of the world. Included in this costing are interventions to:

- “provide long-lasting insecticide treated nets (LLINs) free to high-risk populations groups, and replace them after four years of use”
- introduce Artemisinin-based Combination Therapies (ACTs) in all areas with significant *P. falciparum* transmission and rapid diagnostic tests (RDTs) where malaria is less intense and many fevers derive from causes other than malaria
- provide sulfadoxine-pyrimethamine (SP)-based intermittent preventive treatment to all pregnant women where malaria transmission is stable
- ensure the availability of adequate supplies of specific therapies and general clinical support to treat cases of severe and complicated malaria
- improve epidemic prevention and response capabilities, including enhanced surveillance systems and application of indoor residual spraying where malaria transmission is unstable
- support particular elements of the health infrastructure that are critical for the efficient implementation of scaled-up antimalarial efforts (including transportation and laboratory equipment)
- train community health workers and existing health facility staff in prevention measures, new treatment protocols and diagnostics
- produce and distribute...communications [aimed at communities] that reinforce knowledge of malaria prevention, early recognition of symptoms, and the need to seek treatment promptly
- reduce critical gaps in human resources, including health professionals, epidemiologists, entomologists and workers in other relevant technical fields [12]

Figure 1.3 shows how this money would be apportioned among interventions [7].

These estimates do not include the cost of research and development into new prevention and treatment technologies. Given the continuing rise of resistance to the drugs and insecticides used to treat and prevent malaria, constant research and development is needed to ensure that when resistance to existing tools develops, new, effective measures will be ready. Medicines for Malaria Venture (MMV) estimates that the cost of developing one new fixed dose ACT is US$200 million. Continued development of new drugs at the rate dictated by emerging drug resistance will cost at least US$30 million a year, a figure which is likely to rise [7]. Research and development for preventive interventions and operational research to establish effective delivery strategies also need to increase to combat malaria effectively. A total of just over US$3 billion per annum to meet the malaria MDGs and Abuja targets is not impossible to achieve. However, the countries most affected by malaria are also amongst the poorest in the world. The international community must provide a serious increase in funding at the same time that endemic countries increase support from domestic resources if the ambitious but vital Abuja and MDGs targets are to be met.

Source [12]
2. Existing Financing

2.1 Amounts

The most recent estimates available for international malaria-specific funding indicate that around US$600 million were spent in 2004, a dramatic increase from international funding levels in 1994 (US$55.7 million). This indicates a ten-fold rise over 10 years, illustrated in Figure 2.1. Seventy-five per cent of this funding went to Sub-Saharan African countries [14].

```
Figure 2.1 International Funding For Malaria Control, 1994-2004

[Source: [13], [14]]
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Accurate figures on the amount spent in combating malaria are difficult to obtain, partly because funding that affects malaria control is often for the health system as a whole, making it difficult to separate how much is spent on malaria in particular. Thus, the estimates above should be considered indicative rather than conclusive. The figures above do not include domestic funding of malaria control, yet in many poor countries out-of-pocket expenditures account for a major part of malaria prevention and treatment expenditure, and endemic country governments often provide an important proportion of malaria funding. These figures also give no indication of the effectiveness of this spending, which is important to justify increased malaria spending. Aid effectiveness is discussed further in Section 2.5.2.

```
Figure 2.2 Sources of International Funding for Malaria Control 2005

Source [15]
```

2.2 Funding sources

This section examines the various sources of funding for malaria control. However, the focus is on malaria-specific flows; as it is very difficult to attribute general health system funding, although it is recognised that such funding is a significant and essential contribution to controlling malaria.

2.2.1 International sources

The majority of international malaria-specific funding is now channelled through the GFATM, with bilateral and multilateral aid playing a smaller part (see Figure 2.2). In rounds 1-4 of the GFATM, US$961,000,000 was committed to malaria. Malaria allocations on a five-year basis are currently US$1.8 billion. However, actual amounts disbursed are significantly lower, and there have been problems with the performance of some malaria grants (see section 2.6.1.1).

This distribution is likely to change significantly over the next few years. The launch of the US President’s Malaria Initiative (PMI) is expected to contribute an additional US$240 million a year, while the World Bank Malaria Booster Programme will contribute US$500 million over three years.

```
Figure 2.2 Sources of International Funding for Malaria Control 2005

Source [15]
```

2.2.2 Sources and channels of domestic funding

2.2.2.1 Governments and individuals

Domestic sources of malaria control funding often provide the majority of funds spent on malaria. The proportion spent by households and governments varies considerably between countries, but the Africa Union estimates that for East and Southern Africa, approximately 11% of malaria funding is channelled through donors and NGOs, 47% through the public sector (some of which is financed from donor budget or sector support), and 41% through the private sector [16].

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Figure 2.3 Share of Funds Channelled Through Financing Agents East and Southern Africa

Source [15]
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² Figure 2.1 uses data for 1994-1998 from Martínez et al., 1998: Global Co-ordination of Malaria Control Efforts: Malaria Consortium and its 1994-2004 From Waddington et al., 2005: Trends in International Funding for Malaria Control and the GFATM (for data on the GFATM, see the GFATM website). The dramatic fall seen in the figure in 1998-9 can be largely explained by fact that the 1998 figure was a forecast from the information in the Martínez et al. report, and the 1999 figure reflects the small numbers of responses Waddington et al. had to their survey for that year compared to the Martínez report, rather than a major decrease in actual funding. This reflects the difficulty in tracking resources retrospectively.

[Source: [13], [14]]
```
2. Existing Financing

Domestic governments are the main source of malaria-control programme funding, accounting for 71% of funding in Africa, 80% in Asia and 96% in the Americas [7]. Table 2.1 illustrates private spending, government spending and external resources as a percentage of total health expenditure in Sub-Saharan Africa [17]. This indicates the diverse sources of health expenditure within Africa, with external resources accounting for 36% of health expenditure in Sao Tome and Principe, and only 0.5% in South Africa. Government expenditure accounted for 84.2% of health expenditure in Angola, and just 16.6% in Guinea. Similarly, private expenditure as a percentage of total health expenditure ranges from 83.4% in Guinea, to 15.8% in Angola. Figure 2.4 also includes Kenya, which is more typical of the region as a whole.

Table 2.1 Sources of health expenditure, Sub-Saharan Africa

<table>
<thead>
<tr>
<th>Country</th>
<th>External resources for health as % of total health expenditure</th>
<th>General government expenditure on health as % of total health expenditure</th>
<th>Private expenditure on health as % of total health expenditure</th>
</tr>
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<tr>
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<td>11.5</td>
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<td>Zimbabwe</td>
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<tr>
<td>SSA Average</td>
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<td>41.9</td>
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</tbody>
</table>


Figure 2.4a Public and Private Health Expenditure, Angola, Guinea and Kenya, 2003

Figure 2.4b Internal and external sources of Health Expenditure, Angola, Guinea and Kenya, 2003

Note: SSA = Sub-Saharan Africa
2. Existing Financing

Despite their Abuja Declaration commitment to spend 15% of the national budget on health, the only Sub-Saharan Africa country currently meeting this target is Liberia (according to World Health Statistics 2006, based on 2003 data). However, it should be noted that only four African countries have a lower absolute expenditure than Liberia. ³ Table 2.2 shows how close Sub-Saharan African countries are to meeting this target [17]. The Commission on Macroeconomics and Health (CMH) estimate that countries should be spending at least US$34 per capita on health, in order to buy a package of essential services. It was assumed that this was public spending. It has been argued that it is better to focus on this US$34 target, rather than 15% of national budget, as it is based directly on estimated costs of delivering a package of essential services [16]. As Table 2.2 illustrates, many countries are closer to meeting this US$34 target than 15%, with nine Sub-Saharan African countries already meeting it. While several countries are considerably exceeding the target of US$34 per capita government spending on health, most countries are not meeting it. The regional average is just below the target. Even where countries are reaching US$34, it does not mean these resources are going towards the priority services identified by the CMH on which this target was based. Per capita government spending on health ranges from US$1 in the Democratic Republic of Congo and Burundi, to US$382 in Seychelles. The percentage of government budget for health varies from 2% in Burundi to 17.6% in Liberia. These ranks change from year to year with some countries achieving but not maintaining their targets.

2.2.2 Private Sector

The private sector is heavily involved in malaria prevention and treatment in many developing countries, through private health facilities, shops and drug sellers. The private sector can sometimes reach populations that the public sector does not. Whilst private health insurance does exist in some places, its use is very limited, and the majority of private-sector treatment is paid for out-of-pocket. (see sections 2.5.1.2 and 2.5.1.3 for more). The quality of treatment and care offered by the private sector is variable, with ineffective drug use common in some places (see Section 3.4).

2.2.2.1 National Non-Governmental Organisations (NGOs), Community-Based Organisations (CBOs) and Faith-Based Organisations (FBOs)

National NGOs, CBOs and FBOs are major players in delivering malaria treatment and prevention, often working in areas where the public sector is not present. These activities may be funded by international donors, individual donations or user fees.

2.2.2.4 Informal Sector

The informal sector often plays a significant role in malaria treatment in many countries. It is often more accessible than the formal sector in rural areas. This sector includes traditional healers as well as drug and prevention commodity retailers ranging from shops to markets to itinerant vendors. Like the private sector, it is usually paid for out-of-pocket.

Table 2.2 Achievement of Targets for Government Spending on Health, Sub-Saharan Africa

<table>
<thead>
<tr>
<th>Country</th>
<th>General government expenditure on health as % of total government expenditure</th>
<th>Per capita government expenditure on health at average exchange rate in US$</th>
<th>Target of US$34 per capita</th>
<th>Target of 15% of government spending spent on health</th>
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<td>Not on target</td>
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<tr>
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<tr>
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<td>Not on target</td>
</tr>
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<td>Gabon</td>
<td>1.3</td>
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<td>0.05</td>
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</table>


Note: The table indicates how closely each country meets the target of 15% of national budget spent on health, based on World Health Statistics 2006.
2. Existing Financing

2.3 The financing gap

Despite the recent years’ increases in malaria funding, there is still an enormous financing gap. In 2004, international resources for malaria control (excluding R&D) amounted to US$600 million. Based on the World Malaria Report 2005 estimated cost of combating malaria, at US$3.2 billion, this leaves a US$2.6 billion gap that needs to be filled through increased donor funding and increased malaria-endemic country spending on health. Otherwise, the Abuja targets and malaria-related Millennium Development Goals will not be met. Currently, this gap costs up to 3 million lives every year and exacerbates the poverty of the world’s most vulnerable people.

2.4 Progress in filling this financing gap

Progress is being made towards filling this US$2.6 billion gap. Over the next three years, the US President’s Malaria Initiative, the World Bank Malaria Booster Programme and existing Global Fund commitments together could amount to US$767 million a year. If this progress is met by donor funding, there is still an enormous financing gap that needs to be filled through increased donor funding and increased malaria-endemic country spending on health. Otherwise, the Abuja targets and malaria-related Millennium Development Goals will not be met. Currently, this gap costs up to 3 million lives every year and exacerbates the poverty of the world’s most vulnerable people.

2.5 Existing financing mechanisms

2.5.1 Existing domestic financing mechanisms

2.5.1.1 Taxation and government spending

Although exact proportions vary as Table 2.1 and Figure 2.4 illustrate, government spending forms an important part of overall health expenditure in malaria-endemic countries. Revenues to allow this spending are usually raised through taxation. The IMF and World Bank suggest that taxes be judged according to their performance on the following criteria [1]:

- Revenue adequacy and stability: the tax should raise significant revenue, be stable and likely to grow over time
- Efﬁciency: the tax should minimize economic distortions
- Equity: the tax should treat different income groups fairly
- Ease of collection: the tax should be simple to administer
- Political acceptability: use of the tax should be transparent and clear, to promote acceptability

Developing countries face signiﬁcant constraints in implementing taxation systems because of low incomes, large infor mal sectors, and weak administrative structures. However, there is some evidence of success in strengthening taxation systems in some developing countries according to a recent World Bank Policy Research Working Paper. Revenue collected can be allocated towards purchasing goods and services from public or private providers through government agency, social insurance funds, private insurance agencies, employers or individuals and households.

2.5.1.2 User fees

Out-of-pocket expenditure makes up a large percentage of health spending in developing countries. The issue of user fees for healthcare is contentious and emotive. The introduction of user fees in many African countries was encouraged by donors in the late 1980s and 1990s, at a time when developing countries were facing a fall in aid and public expenditure. It was argued that charging user fees would increase the resources available at public health facilities, and increase the quality of service. However, opponents argue that fees make treatment inaccessible to the poor, or force them into debt. Where fees have been introduced, use of health services has dropped. In Rwanda, use of health services halved when fees were introduced in 1996 [18]. User fees can make people look for cheaper treatment, which is often less effective, or force them into catastrophic financial decisions. When Uganda abolished user fees in March 2001, attendance at health care facilities immediately increased by 50-100% [19]. This beneﬁted the poor most.

Case Study 2.1 User Fees for Malaria Treatment in Sierra Leone

The cost of a course of treatment for a child suffering from malaria in Sierra Leone is 18,000 leones, or £12.4. This is the equivalent of 14 days’ wages for the average Sierra Leonean. In Britain the equivalent would be paying £72 for treatment. The cost of malaria treatment for adults is double that of children – 28 days’ wages [18]. This has a catastrophic effect, with people delaying seeking treatment, using less effective or dangerous drugs, or going into debt to pay for it.

There are strong equity and efficiency arguments for the abolition of user fees, particularly in relation to the effect it is likely to have on the poor. However, this needs to be carried out carefully to ensure the system can cope with the increased demand and loss of revenue. Another problem to consider is that of ‘under-the-counter’ fees, which are likely to prove more difﬁcult to remove.

There is now increasing international support for the abolition of user fees, in particular from the World Health Assembly. The Africa Commission report recommended the removal of fees for basic healthcare. Donor countries need to support malaria endemic countries who want to remove user fees to do so, for example by providing resources to enable the health systems to cope with the increased demand. As long as user fees remain in place, the poor are not going to have adequate access to life saving treatments.

2.5.1.3 Risk pooling mechanisms

In a risk-pooling scheme, every participant pays into a pool, and draws on it in relation to health need. There are four broad categories of risk pooling for health: a national health system, social health insurance, voluntary or private health insurance, and community based health insurance. The principles behind them are similar: people pay in advance for cover should they need health care. If they fall ill, the insurer covers all or most of the cost of health care. For this kind of risk pooling mechanism to work, it needs both high and low risk people in the scheme, in order to cover the costs. In this way it plays a risk redistributive role. Payments into the insurance scheme may be weighted according to income or wealth, thereby also playing a redistributive role with regards to income or wealth.

Private or voluntary insurance plays a very small role in health expenditure in Sub-Saharan Africa and malaria endemic Asian countries, accounting for an average of only 2.8% of total health expenditure in Sub-Saharan Africa (shown in table 2.3) and only 1.9% in malaria-endemic Asian countries [17]. Difficulties of adverse selection arise, and if the pool of risks insured is not wide enough, insurance schemes can struggle to meet costs. Another difﬁculty with insurance schemes is that often those who most need to be insured (the poor, women and children) can least afford to pay the premium.
2. Existing Financing

Table 2.3 Private prepaid plans as a percentage of total health expenditure

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Source: World Health Statistics

2.5.2 Aid

Aid is vital if the MDGs and Abuja targets are to be met. Endemic countries cannot finance the necessary treatment and prevention interventions alone, particularly with the increasing necessity for many countries of switching to more expensive ACTs. International resources for malaria control have risen significantly in recent years, as figure 2.1 illustrates, but the financing gap is still large. In 1970, rich countries pledged in a UN General Assembly Resolution to give 0.7% of their GDP as aid. This target has been reaffirmed in many international agreements since. Only Norway, Sweden, Luxembourg, Netherlands and Denmark had met this target by 2005, although 11 of the remaining 17 donor nations had set a timetable to increase aid to this level by 2015.

Aid is important to malaria control, but the mechanisms through which it is channelled heavily influences its effectiveness and likely impact. Aid must reach the poor, and consideration must be given to how funding programmes will reach the bottom economic quintiles in endemic countries. These bottom quintiles are often missed as they usually have poor access to existing health facilities and live in hard-to-reach rural areas. Three main characteristics of any aid are its levels of earmarking, conditionality and accountability. Earmarking is often ineffective because of fungibility, but can be politically important to donors who want to support some aspects of the government’s work but not others, and want their contribution to be attributed to something specific. Fungibility is an issue with all forms of aid, but becomes more significant the more specific the funding is for project specific funding than general budget (for example, it is likely to be a bigger problem to increase aid to this level by 2015).

Predictability is crucial to aid effectiveness. Malaria control requires sustained programmes to provide treatment and preventative interventions. “Funding must be maintained over decades, if progress is to be sustained” [11]. However, aid is often unpredictable (see figure 2.5), creating many problems for governments trying to budget within existing government systems, additional reporting to donors, or parallel accountability that bypasses government. Accountability can occur through existing aid less predictable, but again can be important for project specific funding than general budget (for example, it is likely to be a bigger problem to increase aid to this level by 2015).

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2. Existing Financing

The Paris Declaration on Aid Effectiveness of March 2005 highlighted the need for increased focus on ownership, harmonisation, alignment, results and mutual accountability. This is reflected in the shift by several donors away from project support towards Sector Wide Approaches (SWAs) and budget support, which allows for increased ownership and harmonisation. It is important that aid effectiveness is measured, to justify expenditure of public resources and ensure best use of available resources. The RBM partnership identified specific global indicators of progress in combating malaria. These include two impact indicators:

- Malaria death rate (probable and confirmed cases) among target groups (under-fives and others);
- Number of malaria cases, severe and uncomplicated (probable and confirmed) among target groups (under-fives and others);

And three outcome indicators:

- Proportion of households having at least one insecticide-treated mosquito net;
- Percentage of patients with uncomplicated malaria getting correct treatment at health facility and community level, according to the national guidelines, within 24 hours of onset of symptoms;
- Percentage of health facilities reporting no disruption of antimalarial drug stock (as specified in the national drug policy) for more than one week during the previous three months [22].

Other important indicators of malaria aid effectiveness, in line with the Paris Declaration on Aid Effectiveness, include [23]:

- Whether the aid is aligned on national priorities;
- Whether the aid uses public financial management systems in partner countries which adhere to broadly accepted good practices;
- Whether the aid uses country procurement systems which adhere to broadly accepted good practices;
- Whether the aid avoids use of parallel implementation structures;
- Predictability of aid;
- Percent of bilateral aid that is untied;
- Whether there is transparent and monitorable performance assessment.

Aid effectiveness is also determined by the policies and institutional environment of the recipient country. Governance is important to oversee correct use of resources. There are legitimate concerns over the levels of capacity, accountability, transparency and corruption in many countries.

Weak capacity is a major problem in many endemic countries, preventing them from absorbing aid and implementing programmes. Conflict and HIV/AIDS have had a major effect in reducing the capacity of many countries. Donor policies have often contributed to undermining national capacity through poaching of government staff to work on discrete projects (see Section 3.5 for more details), and overloading governments with additional reporting and accounting burdens that bypass national budgeting and accounting. Tied aid has raised the cost of goods and services, and restricted private sector development in recipient countries [8].

Accountability is also vital to ensure aid effectiveness. It is vital that governments are answerable to all their people, including the poor and marginalised. Mechanisms to allow this must be in place, including institutional structures and processes; the justice system, media and participation of people in these institutions. Transparency is also linked, allowing people to hold their government to account for its actions. Budget transparency particularly can reduce the potential for misuse of resources and promote good governance [8].

Corruption is a major concern, and results from weak governance. Procurement is an aspect of health development assistance that is particularly vulnerable to corruption. More transparent procurement policies are necessary in both endemic and developed countries, in addition to strengthening international institutions seeking to curb corruption. Despite these challenges, the 2005 African Governance Report found that governance in Africa is improving overall, with progress being made in democratic transitions, political inclusiveness, voice, accountability and economic management [24]. More action is needed, but with the right policies in place, aid can be effective and reduce the burden of malaria.

The following section will outline the main aid instruments.

2.5.2.1 General budget support

General budget support encourages partnerships between donor and recipient countries. It allows countries to set their own priorities, encouraging a more efficient allocation of resources, and reducing transaction costs. Accountability to donors comes from the Finance Ministry rather than line ministries (e.g., Ministry of Health). It allows cross-cutting issues to be addressed systematically. However, there is a danger of limited ownership by the line ministry. Impact cannot be attributed to the budget support. It requires strong leadership from the central government and may marginalise civil society. How general budget support benefits malaria control depends on whether the recipient government prioritises malaria.

2.5.2.2 Sectoral budget support

In sectoral budget support, donors provide budget support within an agreed policy programme, institutional or financial framework at the sectoral level. An example is the Sector Wide Approach (SWA). SWAs are increasingly popular with donors, particularly in African education and health sectors. All funding is in support of a single comprehensive sector policy. SWAs are country led, and have joint accountability — to the citizens of the recipient country and to the donor. SWAs are designed to encourage a coherent sectoral approach, reducing transaction costs through coordination of inputs. They are results focused and should increase the predictability of funding. Aner, the affect of sectoral support on malaria’s control depends on its importance to the recipient government.

2.5.2.3 Earmarked budget support

With earmarked support, donors fund specific components of the government sector policy framework. It allows for coordination at the country level, but also allows the donor to have some input as to how funds are spent.

2.5.2.4 Project type support

Projects support the government sector policy framework, but are managed independently, with accountability to the donor.

2.5.2.5 Stand alone projects

Stand-alone projects are based on donor identified priorities, rather than government sector policy priorities. Project accountability is to the donor, rather than to government.

2.5.3 Financing research and development

Most research and development into new prevention and treatment tools for malaria is funded through Public Private Partnerships (PPPs) or by the private sector — pharmaceutical and insecticide companies. In 2004, 25% of active drug development projects for neglected diseases were conducted by multinational companies (MNCs) working alone on a not-for-profit basis, while 70% were through PPPs with small-scale businesses or MNCs [25]. Drug research and development is expensive and time consuming, and PPPs can perform a vital role in supporting the private sector to invest in R&D for malaria and other diseases. Evidence indicates that PPP-supported drug development projects performed better than ‘industry alone’ or ‘public sector alone’ projects, in terms of health outcomes for developing country patients, breakthrough innovation and cost-efficiency [25]. See section 4.2.1.1 for more details.
2. Existing Financing

2.6 Major donors, international partnerships and organisations tackling malaria

2.6.1 Key multilateral donors

2.6.1.1 The Global Fund to fight HIV/AIDS, Tuberculosis and Malaria (GFATM)

The GFATM is a major player in financing malaria control, channelling a large proportion of the money spent on combating malaria. It is a financial mechanism rather than an implementing entity, pooling resources from donors, assessing proposals from countries, and disbursing funds. The GFATM does not fund R&D, and seeks to use existing implementation systems rather than creating parallel ones, wherever possible. The GFATM supports programmes that reflect national ownership by public and private sectors and civil society, and pursues an integrated and balanced approach to prevention and treatment. The GFATM has signed grant agreements for malaria programmes worth US$1.280.178.609, of which US$901,214,929 has been disbursed so far. This covers programmes in 70 countries. As Figure 2.6 shows, the majority of money pledged to the GFATM comes from bilateral donors, with the United States and France taking the lead. The private sector contributes US$654,272,487 to the United States and France taking the lead. The GFATM funding comes in two phases, with phase 2 funding only released if phase 1 results (i.e. years one and two) are satisfactory. Figure 2.7 categorises malaria programmes that have reached the end of phase 1, and shows 29% not performing adequately and jeopardising phase 2 funding. This partly explains the significant differences between the amount of money in signed grant agreements and the amount that has actually been disbursed.

2.6.1.2 World Bank Booster Programme

The World Bank has recently significantly increased its involvement in malaria control, through launching the Global Strategy and Booster Programme, designed to accelerate progress towards malaria control. The Booster Programme for Malaria Control will provide increased financing and technical support for efforts to increase coverage of malaria treatment and prevention over the next five years. So far US$1.72 million of funding has been approved by the World Bank Board, covering 9 countries. Total funding for 2006-2008 is predicted to be US$427.5 million. The Bank is also planning to mobilise external resources (including public and private sectors), to increase ITN and antimalarial drug production and reduce taxes and tariffs on these commodities. The Booster Programme is designed to complement the work of the GFATM, WHO, UNICEF and Bill and Melinda Gates Foundation. It plans to mainstream malaria control in the Poverty Reduction Strategies that developing countries are required to produce. The funds will be disbursed through three mechanisms through enhancing Poverty Reduction Support Credits and health SWAps to support malaria control through supporting malaria control projects at country and subregional level and through supporting combined HIV/TB and malaria control projects.

2.6.1.3 European Union (EU)

The European Union funds malaria-related activities through several routes. As Figure 2.6 shows, the European Commission (EC) contributes 7% of the GFATM’s resources. The EC also funds malaria control activities in emergency settings through the Humanitarian Aid Office of the European Union (ECHO). The EU provides a limited amount of funding for other malaria control and research activities.

2.6.2 Key bilateral donors

2.6.2.1 UK and the Department for International Development (DFID)

DFID plays a significant role in international malaria control efforts. It is a board member of RBM, and has contributed to funding the partnership. DFID has pledged £41,945,581 to the GFATM (7% of the total pledged to the fund to date), and given it significant political support. DFID also funds a number of malaria programmes bilaterally, and DFID-funded SWAps and budget support will also have an impact on malaria through increasing capacity. DFID is one of the few bilateral donors to support research into malaria treatment and prevention through public-private partnerships, including MMV.

Together with the UK Treasury, DFID has led the way in developing and promoting innovative financing mechanisms for development, including the International Finance Facility and Advance Market Commitments (discussed in sections 3 and 4), which have the potential to raise significant resources for both malaria and overall development. The UK is also home to several foundations that are important funders of malaria research and development, including the Wellcome Trust and the Medical Research Council.

2.6.2.2 USA and the President’s Malaria Initiative (PMI)

As can be seen from Figure 2.8, the United States is the biggest donor to the GFATM, so far pledging over US$3.5 billion which is 25% of pledges to the GFATM. USAID has a budget of $69 million for malaria control activities in 2006, covering 15 countries. In addition to this, the President’s Malaria Initiative was announced in 2005. This is a $1.2 billion, five-year initiative that aims to cut malaria related deaths by 50% in target countries. The PMI target countries are Angola, Benin, Ethiopia, Ghana, Kenya, Liberia, Madagascar, Malawi, Mali, Mozambique, Rwanda, Senegal, Tanzania, Uganda and Zambia. The PMI supports IRS, ITNs, ACTs and IPTp in the
2. Existing Financing

2.6.3.2 The private sector and distribution

The private sector is a key player in the battle against malaria, with a vital role in many areas, including producing and manufacturing effective prevention and treatment products, researching and developing new technologies, protecting employees and contributing resources to efforts against malaria at both global and local levels. Companies in many different sectors can and do assist prevention and treatment programmes, and help to raise awareness and understanding of the disease.

2.6.3.3 Protecting employees and communities

Malaria affects many businesses, through employees, reputations and customers. World Economic Forum research found that businesses are concerned about malaria and in countries with some malaria, 40% of executives questioned predicted that malaria would impact their company in the next five years [26]. Many businesses in endemic countries already have health education programmes, which are or can be used to educate employees and their families about malaria prevention and treatment.

Bi-P Biliion estimated that malaria cost the company almost US$2.7bn, and joined a public private partnership to help improve the health and economic strength of the region in which they were working, promoting IRS and use of ACTs [26]. ExxonMobil found that investment in malaria prevention and treatment services for employees and contractors pays off, with one such project in Chad and Cameroon saving the company US$3.8 million in project delay costs. Many other companies working in endemic areas have similar experiences of the benefits of tackling malaria amongst employees [26].

2.6.3.4 Corporate social responsibility

Some private-sector companies, though not directly affected by the disease, are involved in tackling malaria through their corporate social responsibility programmes, donating money and resources through NGOs or funds, or helping to raise awareness about the disease. An example of the private sector being involved in tackling malaria whilst not directly affected is the kind contribution of PriceWaterhouseCooper, Speedo and Microsoft in the World Swim for Malaria.

2.6.4 International non-governmental organisations (INGOs)

More INGOs are including malaria control in their activities. These include AMREF, MSF, Oxfam, Save the Children, Merlin and Christian Aid, but very few INGOs focus on malaria or have extensive malaria programming. This is in contrast to HIV/AIDS control, which has attracted major support from INGOs.

2.6.5 Foundations

2.6.5.1 Bill and Melinda Gates Foundation

The Bill and Melinda Gates Foundation, a private philanthropic foundation, is a significant funder of malaria activities. The Gates Foundation has pledged $650,000,000 to the GFATM, more than either the UK or EC have. Their total global health budget from 1994 to date totals $6,644,484,878. Malaria specific grant-making focuses on supporting research into new malaria drugs and vaccines; supporting mosquito control through alternative pesticides, IRS and ITNs; improving malaria treatment through drug development; controlling malaria through developing models to scale up malaria control; prevention and treatment; accelerating access to new drugs and vaccines; and advocating to increase financial support and build commitment and awareness.

2.6.2.3 France and the Air Ticket Solidarity Levy

France has been a major supporter of the GFATM, pledging $1.15 billion, 12% of the total amount pledged to the fund to date. France has also been key in proposing and promoting the financing mechanisms of UNITAID and the Air Ticket Solidarity Levy through which a large proportion of UNITAID’s funds will be generated. These mechanisms will be discussed in section 3.

2.6.2.4 Other bilateral donors

Other bilateral donors such as Germany, Denmark, Japan, Italy, Canada, Norway, Ireland, Netherlands, Spain, Chile, and Brazil also contribute to fighting malaria, through GFATM, bilateral programmes and projects, and other mechanisms, for example Norway, Chile, and Brazil are all supporting UNITAID. Many of these bilateral donors, in particular the members of the G8, could do more to support efforts to fight malaria through increasing resources and participating in innovative financing mechanisms.

2.6.3.1 The private sector and research institutions

Most research and development of new malaria treatment and prevention methods is carried out by the private sector, often in public-private partnerships. Multinational pharmaceutical companies such as GSK and Novartis develop and manufacture antimalarial drugs and diagnostic tools on a not-for-profit basis, often as part of a corporate social responsibility strategy. Smaller private-sector companies also work on research into these areas on a for-profit basis. Pesticides and ITN development is also largely carried out by the private sector.

Universities and other academic institutions in particular play a key role in malaria research, particularly in the areas of new basic knowledge and early stage research. They are also vital partners in many PPPs.

An example of a private sector company working on a not-for-profit basis in malaria prevention is that of Sumitomo Chemical Company, who having developed a LLIN, have transferred this technology to a net manufacturer in Tanzania, leading to a major increase in production. Aventis and Bayer have also distributed insecticides at low cost in endemic countries [26].

Information technology businesses are also working with academics and governments to develop surveillance systems to monitor and map the levels of malaria, and predict epidemics.

2.6.2.1 Other sectors

target countries, through commodities, training and supporting the development of systems to implement these measures. This commitment to tackling malaria represents a significant step towards filling the financing gap for meeting the MDGs on malaria, but other donors need to follow the example of the US in terms of resources committed if this gap is to be filled.
2. Existing Financing

2.7 Multilateral organisations and United Nations (UN) agencies

2.7.1 World Health Organisation (WHO) Global Malaria Programme (GMP)

The World Health Organisation Global Malaria Programme establishes and promotes WHO policies, standards and guidelines for malaria prevention and control. It is responsible for formulating malaria policy and strategy, providing operations support and capacity development, and coordinating WHO’s global efforts to combat malaria.

2.7.2 United Nations Children’s Fund (UNICEF)

UNICEF is involved in funding and implementing projects with partners, including distributing ITNs and IPT, supplying drugs and improving case management across the malaria endemic world. It is an active member of the RBM partnership, and also conducts advocacy and education work to increase understanding of and action against malaria.

2.7.3 Special Programme for Research and Training in Tropical Diseases (TDR)

TDR aims to help coordinate, support and influence global efforts to combat a portfolio of major diseases of the poor and disadvantaged. It is funded through many multilateral and bilateral donors, foundations, and private companies. It works in partnership with research institutes, ministries of health, disease control programmes, industry, academia and non-governmental organisations. Its 2006-7 Operations Budget includes US$15.2 million for malaria R&D, with the majority going into improved case management and combination therapy to prevent drug resistance [27].

2.8 Partnerships

2.8.1 Roll Back Malaria Partnership (RBM)

The RBM Partnership is an alliance of diverse partners (including malaria-endemic countries, bilateral and multilateral donors, civil society, the private sector and academia), launched in 1998 to provide a coordinated global approach to fighting malaria. The Partnership aims to halve the burden of malaria by 2010. RBM partners work together to scale up malaria-control efforts at country level, coordinating activities to avoid duplication and fragmentation. RBM also plays a key role in advocacy for malaria control and research at community, national, regional and global levels [28].

2.8.1.1 Malanias Medicines and Supplies Services (MMSS)

MMSS is an initiative of the RBM partnership to help endemic countries access antimalarial medicines, ITNs, RDTs and insecticides. It works at all levels of the supply chain in collaboration with UN agencies, technical agencies and donor partners to support procurement and supply management for the commodities needed to achieve the MDGs related to malaria. There is currently some uncertainty over the future of MMSS, but there is a need for this role, particularly in relation to forecasting, as discussed in section 3.3.1.

2.8.2 Public Private Partnerships (PPPs)

PPPs are particularly influential in malaria R&D, as section 4.2.1.1 explains.

2.8.2.1 Medicines for Malaria Venture (MMV)

MMV is dedicated to discovering, developing and delivering new antimalarial drugs through public private partnerships. MMV was launched in 1999 following discussion between WHO and the International Federation of Pharmaceutical Manufacturers Association (IFPMA). It brings together partners from the public, private and philanthropic sectors to develop affordable, effective drugs for the treatment and prevention of malaria. The MMV portfolio currently consists of 20 projects, 4 of which are in Phase II development.

2.8.2.2 Malaria Vaccine Initiative (MVI)

MVI is a vaccine development programme, created in 1999 through funding from the Bill and Melinda Gates Foundation. It aims to accelerate the development of promising malaria vaccines and ensure their availability in the developing world. It collaborates with partners from the public and private sectors, and organisations such as the Global Alliance for Vaccines and Immunisation (GAVI). MVI was created to remove the roadblocks to successful malaria vaccine development, and bring together the various parties involved. MVI currently has 10 vaccine development projects, with two currently in the process of field trials in Africa.

2.8.2.3 Global Alliance for Vaccines and Immunisation (GAVI)

GAVI is a PPP focused on increasing access to immunisation for children in developing countries. Whilst GAVI is not directly involved in malaria, as no malaria vaccines currently exist, it is the structure through which IFFim’s funds will be disbursed (see Section 3.12.3), and works to strengthen immunisation systems that could also potentially be used for distributing ITNs and IPT.

2.8.2.4 Drugs for Neglected Diseases (DNDi)

DNDi was established in 2003 as a partnership between public sector research institutions, an NGO, and TDR. DNDi focuses on neglected leishmaniasis, human African trypanosomiasis and Chagas disease, but its portfolio also includes work on developing a new fixed-dose ACT. DNDi is not a traditional PPP as it seeks to take neglected diseases R&D out of the marketplace and encourage greater public sector involvement.

2.8.2.5 Foundation for Innovative New Diagnostics (FIND)

FIND is a not-for-profit organisation that seeks to develop rapid, accurate and affordable diagnostic tests for poverty-related diseases. FIND works with academia, public and private research institutions and industry. FIND has recently been awarded a US$9.8m grant from the Bill and Melinda Gates Foundation to evaluate existing RDTs for malaria.

2.8.3 Multilateral Initiative on Malaria (MIM)

MIM is a multilateral collaboration of agencies, institutes and governments working together to strengthen and sustain, through collaborative research and training, the capability of malaria endemic countries in Africa to carry out the research required to develop and improve malaria-control tools and strengthen the research-control interface. MIM supports research into functional genomics, health policies, systems and services research, pathogenesis, drugs, epidemiology, socioeconomic and behavioural research, evaluation of community-based large scale preventive and therapeutic interventions, and vectors.

Figure 2.8 Levels of the supply chain that MMSS works at

Source: http://www.rbm.who.int/
3. Financing Delivery

Financing the delivery of malaria control interventions requires more than purchasing insecticide-treated nets and drugs for countries in need. Health systems require strengthening, human resources need effective development and mobilisation, and emergency response mechanisms must be in place to deliver the effective preventive, diagnostic and treatment services necessary to reduce the global burden of malaria. Table 3.1 illustrates one way to calculate the additional funding necessary to support health systems in reducing national malaria burdens.

Table 3.1 Estimating overhead/health system costs

<table>
<thead>
<tr>
<th>Scenario</th>
<th>28,135,957</th>
<th>44,170,023</th>
<th>200,081,511</th>
<th>1,742,096,692</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>26,840,334</td>
<td>312,256,916</td>
<td>204,829,767</td>
<td>239,298,996</td>
</tr>
<tr>
<td>2007</td>
<td>23,456,789</td>
<td>267,890,123</td>
<td>195,987,654</td>
<td>228,345,906</td>
</tr>
<tr>
<td>2008</td>
<td>20,234,567</td>
<td>185,557,257</td>
<td>173,456,789</td>
<td>200,987,654</td>
</tr>
<tr>
<td>2009</td>
<td>17,095,678</td>
<td>153,245,678</td>
<td>162,345,678</td>
<td>185,987,654</td>
</tr>
<tr>
<td>2010</td>
<td>14,000,000</td>
<td>130,000,000</td>
<td>142,000,000</td>
<td>166,000,000</td>
</tr>
</tbody>
</table>

3.1 Delivering malaria prevention and treatment

Efforts to halve the malaria burden by 2010 involve a number of interventions, including early diagnosis and treatment, proper use of artemisinin-based combination drugs, intermittent preventive therapy, insecticide-treated nets, and vector control [30]. These evidence-based and cost-effective methods, if brought to scale in malaria-endemic countries, should reduce both malaria-related illness and death. This section summarises these key interventions, indicating current and potential financing mechanisms.

3.1.1 Insecticide treated nets (ITNs)

ITNs can reduce all-cause mortality among children under age five by 20%. This translates into preventing almost half a million deaths each year in sub-Saharan Africa. ITNs protect against anemia in pregnant women and young children, the groups at highest risk from malaria and malarial anemia. In many sub-Saharan African countries, where much of the rural population is exposed to stable intense malaria transmission and systems for large-scale indoor residual spraying (IRS) do not currently exist, ITNs have several advantages [31]. ITNs require less delivery and maintenance infrastructure than other vector control methods. They allow resources to be targeted towards higher risk groups, such as pregnant women, young children, and people living with HIV/AIDS (PLWHA). ITNs can provide longer protection, particularly if long-lasting insecticidal nets (LLIN) are used. See section 4.4.1.1 for more on LLINs.

3.1.1.1 Taxes and tariffs

Though African governments agreed to eliminate taxes and tariffs on ITNs under the Abuja Declaration, this has proven difficult. Most countries apply the “Harmonized Commodity Description and Coding System” introduced by the World Customs Office, to classify products. Nets are currently classified as textiles and customs offices can be reluctant to give exemption for all products covered by the code. Some countries also subscribe to regional agreements on tariffs and taxation rates, which can influence the adoption of policy charge. For example, the West African Economic and Monetary Union requires its eight member states to adhere to the Common External Tariff Resolution, which stipulates fixed import duty rates of 20% and value-added tax (VAT) rates of 18%. Changes in national policy would be greatly facilitated by changes to international agreements [5].

Figure 3.1 indicates that only Kenya and Tanzania had reversed mosquito net tariffs before the Abuja Declaration. Four other countries (Cote d’Ivoire, Nigeria, Uganda, and Zambia) did so by Africa Malaria Day 2001, while another eleven (Benin, Cameroons, Chad, Ghana, Guinea, Kenya, Liberia, Mal, Mozambique, Namibia, and Sudan) had reversed tariffs by the end of 2002.

Table 3.2 Estimated numbers of ITNs and costs assuming 100% ANC and EPI attendance

<table>
<thead>
<tr>
<th>No. NETS NEEDED</th>
<th>COST (at US$7.28/ITN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year</td>
<td>Scenario 1: 100% coverage of vulnerable population</td>
</tr>
<tr>
<td>2006</td>
<td>132,262,874</td>
</tr>
<tr>
<td>2007</td>
<td>124,657,980</td>
</tr>
<tr>
<td>2008</td>
<td>117,890,123</td>
</tr>
<tr>
<td>2009</td>
<td>111,000,000</td>
</tr>
<tr>
<td>2010</td>
<td>104,234,567</td>
</tr>
</tbody>
</table>

NB: Assuming no continuing sources [32]

3.1.1.2 Current financing and delivery mechanisms for ITNs

Some ITN programmes have brought about impressively rapid increases in ITN coverage at national scale (e.g., national immunisation campaigns in Togo and Niger), and others have managed steady progress through more sustained delivery systems. However, the combination of sustained delivery, high coverage, and national scale operation remains elusive, and most young children in Africa and other malaria-prone countries still do not have the protection afforded by ITNs. 330 million of which are needed for full coverage by 2008. Major distribution barriers include shortage of funds, lack of public awareness, and poor infrastructure and logistics. The choice of delivery models has been constrained by a shortage of funding and ITNs, with donor preference for short-term funding and quick results within defined geographic areas. However, an integrated approach to ITN distribution, using a mix of delivery models (e.g., ANC, routine vaccination campaigns, commercial) is needed to achieve complete and sustained coverage, as each model can reach segments of the population not reached by others. For example Ghana, Kenya, Nigeria and Tanzania are planning to combine more than one method of delivering free and/or highly subsidised ITNs with varied private-sector involvement [32]. Table 3.2 indicates the estimated costs of providing ITN coverage for 100% of pregnant women and children under age five in sub-Saharan Africa, using different delivery mechanisms.
3. Financing Delivery

Scenario 1 (Table 3.2) estimates costs of coverage without considering distribution mechanisms. Scenario 2 considers ITN delivery to all pregnant women through routine ANC (with 100% attendance and projected population increase) and to all children under five in the 42 countries planning measles campaigns (assuming ITN delivery could be combined with all campaigns). Scenario 3 estimates additional delivery of an extra ITN through EPI vaccination to children aged 9 months (assuming 100% coverage), which dramatically increases the number of ITNs needed.

As coverage across countries of sub-Saharan Africa (SSA) is currently low, a catch-up period of rapid scale-up is suggested (using combined measles campaigns, national polio immunization days (NIDs), child health days/weeks, and/or re-treatment of nets currently in households) as a complement to a more sustained ‘keep-up’ set of strategies (using ANC, EPI, and/or commercial distribution) [32]. Research suggests that the public-health value of commercial net markets has been underestimated, having contributed more to equitable and sustainable coverage of mosquito nets than the ITNs delivered by public-health projects [35]. However, ITN and LLIN coverage is still concentrated among richer, lower risk groups. A number of organisations distribute ITNs during mass child immunisation campaigns (e.g. case study 3.1).

3.1.2 Indoor residual spraying (IRS)

In areas of unstable or epidemic malaria, indoor residual spraying (IRS) with approved insecticides has several important advantages over other methods. It has rapid, reliable short-term impact and can be targeted to high-risk communities on an annual basis or in response to changing transmission patterns. IRS has been successfully implemented for many years in countries where large populations face unstable malaria transmission (e.g. Mozambique, South Africa, Thailand, India and Afghanistan). However, it is relatively demanding in planning, logistics, skills, and coverage levels [31]. A recent WHO Position Statement endorses the use of IRS for scaling up global malaria control and elimination, stating ‘Effective implementation of IRS with DDT or other recommended insecticides should be a central part of national malaria control strategies where this intervention is appropriate’ [38]. This statement has sparked debate in many countries, sometimes creating tension between agricultural and health sectors over the use of DDT, and fears of the potential impact this could have on trade with the EU (issues that have yet to be resolved). The attention this position statement received may have led to other important malaria interventions, such as effective diagnosis and treatment, and distribution of ITNs to at-risk populations, being overshadowed.

3.1.2.1 Choice of IRS insecticide

There are currently 12 insecticides recommended by WHO for IRS, belonging to four chemical groups (one organochlorine, six pyrethroids, three organophosphates and two carbamates). Selection must be based on insecticide susceptibility and vector behaviour, safety for humans and the environment, and efficacy and cost-effectiveness [39]. Dichloro-diphenyl-trichloroethane (DDT) is again being promoted in the narrow context of disease control, and remains one of the most cost-effective insecticides for use in IRS [40-44].

DDT has the longest residual efficacy against malaria vectors (6–12 months depending on dosage and surface), pyrethroids (4–6 months), organophosphates and carbamates (2–6 months) have shorter effect, and can sometimes require two to four spray cycles per year depending on length of transmission season. However, pyrethroids are cheaper to transport and can be equally cost-effective in epidemic-prone or seasonal transmission areas.

3.1.2.2 Current financing and delivery mechanisms for IRS

Financial costs per person protected are generally quite low for IRS, and often lower than for ITNs (e.g. US$0.86 versus US$1.42–4.21 in a Kenyan study [45]). However, local conditions must be considered in use of IRS and choice of insecticide [39, 46, 47]. Figure 3.3 indicates that IRS ranges from US$1.58 per Disability-Adjusted Life Year (DALY) averted. Most IRS delivery is financed by bilateral aid (e.g. USAID/PMI) and national resources, channelled through government programmes.

3.1.3 Intermittent preventive treatment (IPT)

Intermittent preventive treatment of pregnant women (IPTp), usually with sulfadoxine-pyrimethamine (SP), has been shown to reduce the risk of maternal anemia, placental parasitemia, and low birth weight, in appropriate settings [48]. This is now being integrated into the reproductive health programmes of a number of African countries. Recent research also demonstrated that IPT of infants with SP at 2, 3, and 9 months of age, at the time of routine immunization, reduces malaria incidence by 59%, and episodes of severe anaemia by 50% [49, 50]. IPT may also be beneficial in children [51, 52].

The threat to these strategies of increasing SP resistance is a major concern. Further research is needed to determine suitable drug options, including combinations (e.g. ACTs) and whether similar results can be obtained in other epidemiological settings. See section 4.4.2 for more.

3.1.3.1 Current financing and delivery mechanisms for IPT

In the absence of parasite resistance, IPTp with SP is clearly cost-effective. The cost-effectiveness ratio in very low income countries is between US$4 and US$26 per DALY, and remains below $150 even in higher-income settings. While IPTp remains an ‘attractive’ option even up to 83% SP drug resistance, it is recommended that it not be introduced in areas with more than 50% SP resistance [53, 54].

National vaccination programmes may become a sustainable delivery mechanism for a number of possible interventions (e.g. IPT, ITNs, vitamin A, iron supplementation) against malaria and anaemia.

Case Study 3.1. Distributing ITNs through vaccination programmes

In contrast to low ITN coverage rates, childhood vaccinations delivered through mass campaigns commonly reach more than 90% of the targeted population - children aged 9 months to 14 years. In populations where measles vaccination campaigns are conducted, malaria is frequently the greatest health risk to children. For example, the December 2004 National Integrated Child Health campaign in Togo was the first of its kind to distribute free ITNs nationwide in conjunction with a national immunisation campaign. International and local partners under the Measles Initiative distributed more than 800,000 ITNs along with measles and polio vaccines and de-worming medicine (mebendazole), to cover 95% of Togolese children 9-59 months.

The campaign demonstrated that it is possible to successfully implement multiple health interventions on a national scale.
3. Financing Delivery

3.1.4 Improved access to effective malaria treatment

Combination therapies have long been used to treat tuberculosis and HIV, and now are proving necessary in malaria treatment. Some degree of resistance has been reported to all first-line antimalarial drugs. Multi-drug resistant P. falciparum has been documented extensively and chloroquine-resistant P. vivax has been confirmed in several countries. Artesinimisin derivatives are powerful antimalarials, but no clear resistance has been reported, and are believed to be better tolerated than most antimalarials. However, they only last a short while in the bloodstream, and cannot always clear all parasites by themselves, thus making them most useful in combination with longer acting antimalarials. A number of potential artesunate-based combination therapies (ACTs) have been approved, whilst others are in various stages of the development and approval process [55-57].

3.1.4.1 Diagnosis

Rapid and accurate diagnosis is critical to accurate and effective treatment. Unfortunately, recent progress in the development and distribution of antimalarial compounds has not been matched by the improved capacity of health care workers to diagnose malaria. Microscopy, the traditional gold-standard test, requires significant infrastructure, including specialised supplies and equipment, laboratories, trained staff and quality control mechanisms. In much of the malaria-endemic world, microscopy services are thus unavailable, and patients are diagnosed on the basis of their symptoms. Clinical diagnosis cannot differentiate accurately between malaria and other febrile illnesses, or differentiate between different malaria species, resulting in substantial mistreatment and over-treatment of malaria [51].

The rapid rise of drug-resistant malaria and the introduction of ACTs increase the urgency of providing accurate case detection. Rapid diagnostic tests (RDTs), which can confirm the presence of malaria parasites from a finger-prick blood sample, are an invaluable alternative to microscopy [54]. Though relatively expensive, they do not require special knowledge, equipment or electricity to operate, can give results in minutes, and can be used at community level. The development of these tests is an important landmark in malaria control efforts, and their use has increased markedly with some 30 million RDTs used in 2005. Over 30 malaria RDT manufacturers now exist. The lack of performance data for many of these tests, the variability in published performance of others, and the lack of standardization in testing has generated confusion with regard to test selection and use. Apparent inadequacies in the sensitivity, thermostability, and geographic applicability of existing commercial RDTs has further complicated the introduction of this important new tool for malaria case management. The Foundation for Innovative New Diagnostics (FIND) was recently awarded a combined total of US$1.5 million by the Bill & Melinda Gates Foundation and the Dutch Government to address this critical issue by systematically evaluating existing RDTs in close collaboration with WHOI, identifying deficiencies in current tests, and developing new assays that meet the needs of malaria control programmes.

3.1.4.2 Current financing and delivery mechanisms for malaria diagnosis and treatment

Both ACTs and the necessary blood diagnostics to support their widespread usage cost considerably more than prior ’first-line drugs’ and clinical (symptomatic) diagnosis. ACTs range from US$1-2.30 per dose (compared to chloroquine at US$0.10), while the cheapest RDTs to detect P. falciparum cost US$0.60-0.70 each. Most low-income countries cannot even attempt this transition without the promise of increased and sustainable funding, such as that offered by the GTAM. Malaria affects poor countries with limited purchasing power. While most drugs can be marketed using tiered (differential) pricing there is much less opportunity with malaria treatment to charge above marginal production costs, significantly reducing private sector R&D incentive [58]. Having pressured countries to switch to expensive treatments, a key donor concern must be how financing procurement and distribution can be made predictable and sustainable.

The majority of deaths from severe malaria are caused by the delayed administration of effective treatment. While most ACTs are distributed through public-sector channels, many people initially seek treatment from the private and informal sector (e.g. drug-sellers, traditional healers). Thus improving community-based distribution is important. Training and supervising community drug-sellers to use RDTs and blister-packed ACTs is one delivery model that could increase the number of private and informal-sector patients that receive and complete a full treatment course. This has been piloted in Myanmar and Cambodia, but cost-effectiveness has not been systematically evaluated [59, 60].

3.1.4.3 Proposed global ACT subsidy

Because ACTs cost considerably more than previous first-line malaria treatments, the people that need them most often cannot afford them. To deal with this issue (and to slow down the spread of resistance that would be significantly faster if artesinin and potential partner drugs were used widely in monotherapy), a global subsidy for ACTs has been proposed. The proponents of this idea argue that there is a need for a global strategy to ensure the development of resistance is delayed, as antimalarial effectiveness is a global public good. A subsidy would save lives and lower the burden of malaria, discourage monotherapy by lowering the prices of ACTs, stimulate the ACT market and maintain the impetus to produce new antimalarial drugs [58]. A global subsidy would allow ACTs to flow through both public and private sector channels, increasing access to the subsidised drugs, and has the added advantages of minimising the administrative costs of the subsidy through making exclusion unnecessary and minimising the incentives for counterfeit drugs, diversion and smuggling of ACTs.

The subsidy would operate through a copayment system. The wholesaler/procurement officer places orders for ACTs from manufacturers. The manufacturer supplies the drug, invoicing the buyer for the subsidized price, and invoicing the subsidy operator for the amount of subsidy. Figure 3.2 illustrates how this process would work.

Research into the likely effects of a global subsidy show that delayed introduction of the subsidy would reduce the benefits of it in terms of drug resistance, therefore immediate action is necessary. It is estimated that initially new funds amounting to US$300-500 million per year need to be committed for subsidising ACTs for the entire global market to reduce drug prices to levels comparable to chloroquine [58]. (Recent estimates suggest that funding required will probably be at the lower end of the range due to recent falls in drug prices.)

Work is currently under way in identifying the architecture necessary for the subsidy thanks to financing from the Bill and Melinda Gates Foundation. A Global ACT Subsidy Task Force has been set up within RBM, and a detailed plan for the subsidy is expected by June 2007. It is hoped that the global ACT subsidy will be launched in November 2007. An important initial step is the listing of ACTs as ‘lifesaving drugs,’ enabling endemic countries to procure them more easily.
### 3. Financing Delivery

**Figure 3.2 Potential flow of funds and products with a Global ACT Subsidy**

An assessment of the cost-effectiveness of various interventions indicated that several are cost-effective, though not affordable by most endemic-country governments [54]. As illustrated in figure 3.3, Goodman et al. determined that in a very low-income country, the cost-effectiveness range for insecticide treatment of existing nets was US$4-10 per DALY averted, provision of nets and insecticide treatment was US$19-85, IPTp (two rounds per year) US$12-58, IPTt was US$4-29, and improvement in case management was US$1-85.

Goodman et al. estimated that a very low-income country’s cost-effectiveness range for insecticide treatment of existing nets was US$4-10 per DALY averted, provision of nets and insecticide treatment was US$19-85, IPTp (two rounds per year) US$12-58, IPTt was US$4-29, and improvement in case management was US$1-85.

**Table 3.3 Sample Malaria Essential Service Package**

<table>
<thead>
<tr>
<th>Health staff trained to diagnose/treat congenital malaria</th>
</tr>
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<tr>
<td>ACT</td>
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**Figure 3.3 Cost-effectiveness ranges and means in a very low-income sub-Saharan African country with moderate to high malaria transmission**

3.2 Resource allocation

Tackling malaria remains one of the most cost-effective public health interventions, producing excellent health and economic returns. However, it requires a long-term, scaled-up commitment from both national governments and the international community [11]. A recurring issue is affordability versus sustainability, and who pays in the short versus long term.

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3.3 Health system strengthening

While the wealth of the global community is sufficient to allow for malaria to be tackled, WHO reports that many national health systems remain weak, unresponsive, inequitable, and even unsafe [61]. When signatories of the Abuja Declaration re-dedicated their countries to halving malaria mortality in Africa by 2010, this entailed health system reform [6]. However, while the key cost drivers of malaria control are human resources, drugs, and technology, an overview of plans and policy reports in many endemic countries indicates a major gap between rhetoric and reality [62, 63]. The funding and operationalisation of disease-specific programmes has failed to effectively and sustainably deliver services to those at greatest risk of malaria. Government and donor reliance on purpose-driven vertical programmes has reduced the functionality of primary health care – leaving it lacking integration, effective referral systems, or multi-sectoral operational approaches. To reduce malaria mortality, it is essential to establish systems for ensuring that health facilities have adequate stocks of drugs and supplies, and that staff is trained and supervised in the rapid identification and care of children and adults with malaria [64, 65].

The areas of health system strengthening most relevant to malaria service delivery include corporate-style reform of government services (e.g. decentralisation, forecasting, purchasing private services), enabling and regulating the private sector, and increasing sustainable financing. An important consideration is the repositioning of national malaria control programmes (NMCPs), which have tended to be small, underfunded, politically weak, and low priority within the MOH. Given the rapid and massive expansion in responsibilities of NMCPs, it is essential to ensure they are adequately staffed with skilled people, and that their position and profile within MOH does not involve excessive layers of approval in order to take action.
3.3.1 Forecasting for malaria

Forecasting of both epidemiology and demand/supply is essential to improving access to malaria drugs and lack of accurate and credible information will cost lives. Demand forecasting, as one component of supply chain planning of drugs and products at the international level, is receiving increasing attention. A key driver is the increasing funds being made available for diseases such as malaria. Current mechanisms are poor with funders often separated from the recipients who make purchasing decisions. This leads to critical mistakes, such as expired drugs filing shelves or stock-outs of life-saving drugs and supplies. Some of the key bottlenecks to disbursement of GFATM monies in the early rounds have included forecasting, procurement and supply management. Great efforts have been made to overcome these bottlenecks, but adequate attention needs to be given to protect countries from losing the benefit of GFATM resources because of avoidable poor performance.

3.3.2 ‘Corporatisation’ of government service delivery

‘Corporatisation’ refers to the restructuring of public organisations along private-sector lines (e.g. ‘Corporatisation’ refers to the restructuring of public organisations along private-sector lines) [66]. The current example of epidemiological forecasting is the Malaria Atlas Project (MAP). Researchers at the University of Oxford Wellcome Trust Collaborative Programme are mapping malaria risk worldwide. Using information from orbiting satellites, population censuses, and other electronic data to determine the presence of malaria vectors, MAP has assembled information from 3.126 communities in 79 countries. This open-source database represents the single largest repository of contemporary information on malaria risk. [66]

3.3.3 Purchasing private services

An increasingly popular method of utilising the private sector is through purchasing service delivery. These contracts range from supply of drugs and ITNs to conducting feasibility studies or developing health communications [70]. Social marketing of nets and treatment services has been given some success by governments [71], but this has sometimes been at the cost of commercial sector development.

3.4 Enabling and regulating the private sector

While the private sector could play an increasing role (e.g. delivery of ITNs, treatment), evidence remains mixed on the cost-effectiveness of private-sector delivery in developing countries, while efficiency comparisons across this diverse sector are difficult. Private sector treatment providers range from fully general practitioners, to part-time clinics run by off-hours’ public employees and clinics staffed by unlicensed or unqualified providers. Many people find it easier to go to a local drug seller or private clinic for malaria treatment, but practitioners are largely unregulated and often untrained. While some countries have initiated schemes to train and supervise private and informal practitioners in accurate and timely malaria diagnosis and treatment, few of these pilot programmes have been systematically evaluated [67].

3.4.1 Medical Transparency Alliance (MeTA)

In an attempt to reduce drug prices, DFID has proposed establishing MeTA, an initiative to increase transparency regarding how drug prices are decided, and where price increases between manufacturer and patient are added in. It is hoped that this scheme, which is an extension of DFID’s Extractive Industries Transparency Initiative (EITI), will help to expose corruption, and show where large mark-ups are being imposed. Drug price can rise significantly between manufacturer and patient, with transport and importation costs, mark-ups, taxes, fees and tariffs all being added. This information will be used to help identify, where savings can be made, and help to reduce costs. However, resistance to the scheme is likely, as has been the case with EITI, with only 2 of the 20 countries that signed up to EITI publishing adequate reports on mining revenues.

3.5 Human resources

“A country’s health workforce is made up of health workers who are at many different stages of their working lives... an effective health workforce strategy has to focus on three core challenges: improving recruitment, helping the existing workforce to perform better and slowing the rate at which workers leave…” [61]

Strengthening the health sector requires human resource development, and effective human resources are crucial to the delivery of malaria control interventions [76]. While developing capable, motivated and supported health workers is essential to achieve national and global health goals [61], a number of factors including capacity, supervision and attrition influence the effectiveness of malaria service delivery. For example, the African region has 24% of global disease burden but only 3% of all health workers. The exodus of skilled professionals in the midst of so much unmet health need places Africa at the epicentre of the global health workforce crisis [61].

Case Study 3.3 Essential workforce needed to achieve the MDGs

WHO has identified a threshold in workforce density below which high coverage of essential interventions, including those necessary to meet the health-related Millennium Development Goals (MDGs), is unlikely. There are currently 57 countries with critical shortages, equivalent to a global deficit of 2.4 million doctors, nurses and midwives. The proportional shortfalls are greatest in sub-Saharan Africa. Paradoxically, these inefficiencies often coexist in countries with large numbers of unemployed health professionals. Poverty, imperfect private labour markets, lack of public funding, bureaucratic red tape and political interference produce shortages in the midst of underutilised talent.

Source: [61, 70, 76-78]
3. Financing Delivery

Workforce efficiency depends on the way it is managed. Human resource development is concerned with the necessary functions (e.g. planning, managing, supporting) to put the right people, with the right skills and motivation, in the right place at the right time - and thus retain the agility to respond to crises, meet current gaps, and anticipate the future [61, 76].

3.1 Human resource planning and recruitment

Better integration of human resource forecasting, at sectoral and organisational levels, is crucial to improving service provision for malaria prevention and treatment. This is especially true as skilled human resources become available for malaria. The work achieved in each post, through deployment, utilisation, development, and retention, should contribute to strategic goals. Formal human resource planning (HRP) is more effective than traditional ad-hoc planning methods and can match staff levels to strategic and budgetary needs, overcome skill shortages, and improve working environments [76]. In some countries where favouritism, corruption and discrimination have become virtually institutionalised, systematic approaches to recruitment are particularly necessary (e.g. positive action' approaches encourage a broader applicant pool) [79].

3.2 Managing performance and attrition

Performance management systems, often based on 'management by objectives' (MBO), link goals to individual job contributions, using quantitative and qualitative measurement [80]. Structured performance appraisal plays a central role [76]. It helps define and enhance performance through clarifying job purpose, defining key tasks, deciding required standards, developing improvement plans using Specific, Measurable, Achievable, Realistic and Time-specific (SMART) targets, performance monitoring and appraisal [81]. This is followed with rewards, training, or punitive measures. Over-reliance on structured career paths when public-sector jobs are no longer certain, however, can lead to frustration and unnecessary redundancies. Performance-related pay (PRP), an extension of the performance appraisal process, is one way of providing individuals incentive to work more effectively in meeting organisational goals. Evidence indicates that properly implemented schemes can improve public-sector management [76]. However, they do not necessarily encourage individuals to work towards organisational or sectoral goals [82, 83].

In malaria-endemic countries, major HR retention problems are due to migration. Source countries can do more to adjust training to need and demands while improving local conditions. Receiving countries, such as the UK, can also do more to ensure ethical recruitment policies and support to human resource development in source countries. Additional common reasons for temporary or permanent exit from the health workforce include risk of violence, illness and death, and occupational change [61].

3. Emergencies

More than 80% of current complex emergencies occur in malaria-endemic areas, and malaria control in emergencies (e.g. natural disaster; conflict) requires additional resource considerations [84]. Health crises caused by epidemics, natural disasters and conflict are often sudden, often unexpected but invariably recurring. The quality of response, ultimately depends on workforce preparedness based on local capacity backed by timely international experience. Responding effectively to emergencies requires quick access to funding, and staff trained either in rapid response or emergency readiness. Additionally, this requires coordinated planning based on sound information, rapid mobilization of workers, command and control responses, and intersectoral collaboration between governments, NGOs, military, peacekeepers, and the media. Large-scale funding for emergencies that receive broad media coverage may not be sustained beyond 6-12 months [84].

DFID has proposed the creation of an international emergency response fund that could improve on the current delays in access to funding and lack of cross-sector coordination.

3.7 Monitoring and evaluation (M&E)

One of the main criticisms aimed at the global malaria control community is that it is unable to accurately calculate how much malaria there is either globally or in any particular country. If we do not know how much malaria there is, how can we know if our control efforts are working? Similarly, information on levels of coverage with recommended interventions is limited. One problem in obtaining accurate estimates is that many people with malaria do not use public-sector facilities for treatment but rather rely on private practitioners or shops, and sometimes home remedies or no treatment. Thus, measurement of the burden of disease, death, and coverage of interventions must include community-based as well as facility-based information.

3.7.1 RBM Monitoring and Evaluation Reference Group (MERG)

Good progress has been made in recent years in developing indicators of malaria burden and intervention coverage, which can be measured by standardised household survey tools, open to local adaptation. In 2002, the RBM Monitoring and Evaluation Reference Group (MERG) was established to act as an advisory body for the RBM Partnership Board on monitoring and evaluation of RBM initiatives at international, regional, and national levels. The MERG is guided by the overall commitment of RBM partners to (i) partnership and capacity building; (ii) harmonisation, accountability and transparency in scaling-up actions; and (iii) bridging the gaps between technical and programmatic support needs at the country level. MERG arranged for the development of the Malaria Indicator Survey (MIS), a comprehensive package of tools for providing guidance in carrying out household-level surveys relevant for assessing core malaria indicators. While these standardised tools are an important step in tracking progress towards achieving malaria targets, the process of undertaking these surveys is very costly. A single national survey can cost up to US$1 million. Effective monitoring and evaluation of malaria interventions allows for individual programme strengthening and sharing of lessons learned to benefit other countries and sectors. Despite increasing investment, however, the monitoring and evaluation of malaria programmes is often weak, particularly at national and sub-national levels. This is largely due to limited human resources and equipment, lack of an enabling environment, and weak linkages with other programmes and partners. Additionally, complex and incompatible donor requirements often waste precious human resources and other capacity on repetitive and parallel reporting requirements.

3.7.2 Health Metrics Network (HMN)

The recently established Health Metrics Network (HMN) is a global collaboration designed to deliver long-lasting solutions to health information systems (HIS) development. It is increasingly important that donors harmonise reporting requirements to follow a single national M&E framework. Ideally this framework would be supported by a single national HIS, rather than a number of smaller malaria or management specific systems. A movement is emerging towards developing more integrated and comprehensive health information systems, which can provide better information in the long-term. HMN is based on the premise that poverty is not an excuse for poor countries to have poor health information. It is because they are poor that they cannot afford to be without good health information.

HMN’s goal is to increase the availability and use of timely and accurate health information by catalysing the joint funding and development of core country health information systems. In pursuit of this goal, HMN will lay out a vision and identity strategies for health information systems development and strengthening, support countries in implementing such strategies, and generate new knowledge and global public goods through research, technical innovation, and sharing lessons learned.

Most malaria-endemic countries will require considerable support to develop a comprehensive computerised HIS. Thus, funding and technical support for monitoring and evaluation must be built into programme and health system strengthening at all levels. For example, GFA/T now recommends that 5-10% of grants be spent on M&E.
3. Financing Delivery

3.8 Operational Research

Operational research is often overlooked, yet it is essential for effective delivery that the best ways to deliver interventions are identified and disseminated. Monitoring and evaluation of projects and programmes is part of this. M&E of donor-funded projects is usually required and funded by the donor. However, some areas of operational research need additional attention and funding, particularly operational issues that go beyond the scope of a single project or programme, or that involve new methods or tools. Major donors (including GFATM) should look at ways of supporting operational research to answer questions arising from programme implementation and identify what works and what does not. It is crucial that this information is then shared with those involved in tackling malaria at all levels.

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3.9 Milestones

Aspirational milestones play an important role in directing and assessing progress towards achieving priorities, and identifying areas that need strengthening. The milestones in tables 3.4a, b, c and d were identified by the RBM Partnership as part of its Global Strategic Plan 2005-2015.

<table>
<thead>
<tr>
<th>Priorities</th>
<th>Milestones</th>
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<tbody>
<tr>
<td>Achieve malaria-related Millennium Development Goals</td>
<td>Two-thirds reduction in &lt;5 mortality rate</td>
</tr>
<tr>
<td>Achieve Abuja coverage targets in Africa and increase coverage elsewhere</td>
<td>Malaria related household expenditure is reduced by 75% in comparison with 2005</td>
</tr>
<tr>
<td>System strengthening</td>
<td>Malaria morbidity and mortality is reduced by 75% in comparison with 2005</td>
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<td>Universal and equitable coverage with effective interventions</td>
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<td>Universal and equitable coverage with effective interventions</td>
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<tr>
<th>Priorities</th>
<th>Milestones</th>
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<tbody>
<tr>
<td>Achieve malaria-related Millennium Development Goals</td>
<td>Global (upstream) subsidy in place for ACTs</td>
</tr>
<tr>
<td>Achieve Abuja coverage targets in Africa and increase coverage elsewhere</td>
<td>More ACT products pre-qualified (reduction in monotherapies, increase in raw materials)</td>
</tr>
<tr>
<td>System strengthening</td>
<td>LLIN manufacturers develop viable business plans to attract venture capital</td>
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<td></td>
<td>Increase financial flows to country malaria control programs from all financing sources (including national budgets, global financing sources)</td>
</tr>
<tr>
<td></td>
<td>Enabling environment: reduction in taxes and tariffs</td>
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<tr>
<td></td>
<td>Enabling environment: diversification of commodity production (e.g. production of generics and LLINs in endemic countries)</td>
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<td>Emergency funding mechanism</td>
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<tr>
<th>Priorities</th>
<th>Milestones</th>
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</thead>
<tbody>
<tr>
<td>Achieve malaria-related Millennium Development Goals</td>
<td>Continue to increase and sustain adequate financial flows to global financing mechanisms for RBM (GFATM, bilateral, multilateral, foundations, corporations)</td>
</tr>
<tr>
<td>Achieve Abuja coverage targets in Africa and increase coverage elsewhere</td>
<td>Increased investment in malaria research and development, operational research (implementation)</td>
</tr>
<tr>
<td>System strengthening</td>
<td>Sustained annual global malaria spending of at least US$3 billion</td>
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<td>Emergency funding mechanism</td>
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<th>Priorities</th>
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<tbody>
<tr>
<td>Achieve malaria-related Millennium Development Goals</td>
<td>Medium- and long-term predictability of adequate funding sources to allow stable five-year planning and budgeting to occur</td>
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3.10 Intellectual Property Rights (IPRs)

As technology advances, World Trade Organisation (WTO) regulations and frameworks, such as IPRs, are becoming increasingly relevant to malaria control. Currently, in addition to drug patenting technology for the production of long-lasting insecticide treatment of mosquito nets is maintained by a few private firms.

The WTO Anti-Counterfeiting Trade Agreements, under the World Trade Organization (WTO), are of immediate concern for malaria service delivery. TRIPS prohibits producer countries from exporting inexpensive generic versions of patented drugs, despite potential health needs and/or lack of patent in the importing country. This unfairly disadvantages poor countries without the ability to manufacture their own drugs.
In response to concerns over the effect of TRIPS on access to essential medicines by the world’s poorest people, in November 2001 the Doha Declaration on the TRIPS Agreement and Public Health (2001) was issued by the WTO. This declaration asserts that intellectual property rules should not prevent countries from protecting public health, and gave developing countries the right to ensure safeguards to enable price reductions via compulsory licence (CL) or generic competition 

**3.
Financing Delivery**

It is vital that malaria treatment is accessible to those countries and people that need it. Use of the safeguards within TRIPS and the Doha Declaration may be able to play a part in this. As such, international institutions and donors should fully implement their obligations under the Paragraph 6 Public Health Solution, and give developing countries the technical and legal assistance necessary to use these safeguards. It is also essential that the United States desists from forcing countries into signing TRIPS-plus agreements, which leave countries without the right to put public health before intellectual property rights.

### 3.11 Country-level initiatives to increase sustainable funding

As more international donors are becoming interested in malaria control for poverty reduction, there is increasing recognition of the need for coherent and harmonised support of comprehensive national health financing plans (e.g. ‘Three Ones’ principles). The Roll Back Malaria partnership has an active Harmonisation Working Group, making efforts to ensure that well-meaning support is fully coordinated and follows country leadership, so it does not create excessive burdens on recipient countries. A key element for success is development of sound and clear national strategic plans, to which all partners can contribute.

Country-level initiatives include taxes, risk pooling, and direct payments such as user fees. Evidence shows that in virtually all countries where user fees were introduced or increased there was a consequent decrease in service utilisation, often most significant among the poorest [86]. This is highly inequitable, and will hinder the ability of countries to meet the MDGs on malaria. User fees cannot be considered a way to increase sustainable funding for malaria, as they prevent those who need it most from accessing effective treatment.

Insurance schemes show more long-term promise, but are often difficult to set up, and are less practical in rural areas with high malaria as they rely on risk pooling and the principle of covering uncertain risks (see Section 2.5.1.3). Taxes are a common source of national healthcare financing in developing countries. However, taxes and tariffs on malaria drugs and equipment (e.g. ITNs, microscopes) continue to drain programme resources and reduce effectiveness. Despite Abuja Declaration promises, necessary commodities are still delayed by bureaucracy or import fees (see Section 3.1.1). Additionally, attention must be given to tax evasion, which erodes the tax base of many developing countries reducing available resources. Earmarked remittances inject significant resources into developing countries. These could be more effective if certain issues were addressed globally and nationally (e.g. excessive cost of transfers, scarce geographical coverage, lack of a banking culture in many developing countries), enhancing the impact of remittances on development while respecting their private nature.

### 3.12 Global initiatives to increase sustainable funding

‘A major source of aid inefficiency and ineffectiveness is the lack of coherence among donors regarding objectives and requirements, and a failure to reconcile these with the needs, priorities and preferences of the countries receiving assistance. The sheer multiplicity of donors, with different outlooks, accounting systems and priorities have created a landscape of aid that, at best, can only be described as chaotic’ [87].

The current international aid system suffers from high transaction costs, politicisation, lack of transparency, incoherence, and unpredictability. Current requirements have stretched the administrative capacities of many recipient countries to breaking point, undermining any pretence of local ownership of development programmes [87]. Additionally, while most contributions came from official development assistance (ODA) budgets of donor governments, traditional funding sources do not meet the current financial requirements.

The international community has begun turning its attention to the quality of aid. A new UN report recommends a shift to a multilateral model similar to the Marshall Plan and European Community (EC) regional funds [87]. Donors and advocates have proposed a number of innovative financing mechanisms to ensure a reliable flow of resources necessary to ensure prevention and treatment programmes are sustainable and achieve health results. Some of the more important mechanisms under debate are:

- **Aid Guarantee Facility (AGF)**
- **UNITAID (the International Drug Purchase Facility - IDPF)**
- **International Finance Facility (IFF)**
- **Debt Conversion**
- **Air Ticket Solidarity Levy**

If successful, these mechanisms could contribute significantly to financial predictability and sustainability, though doubt remains as to how well some of these mechanisms may contribute to global funding coherence and collaboration. However, mechanisms such as the air solidarity levy and UNITAID are already well-integrated.

#### 3.12.1 The Aid Guarantee Facility (AGF)

Unpredictability of aid (see Figure 2.5) represents a major problem for recipient countries, particularly in the health sector where sustained investment is essential. The idea of an Aid Guarantee Facility has been suggested to limit the negative affects of aid fluctuations. The main aim of the AGF is to support current financing mechanisms, thus making them more effective. The AGF would provide developing countries with sustainable bridge financing to continue initiatives that might otherwise fail due to delayed or halted funding.

#### 3.12.2 UNITAID (International Drug Purchase Facility)

The French-led UNITAID was launched in September 2006 at the 61st UN General Assembly. A small secretariat is hosted by WHO. Currently, five core funders (France, Norway, UK, Brazil and Chile) use the air ticket solidarity tax and long-term budget commitments to provide bulk purchasing of drugs for poor countries. This sustainable and predictable support would also serve to complement existing financing mechanisms such as the GFATM. It is envisaged...
3. Financing Delivery

that UNITAID will raise between €250-300 million in its first year, with €200 million of that coming from the French Air Solidarity Levy and €20 million from the UK. UNITAID aims to lower the cost of drugs for HIV/AIDS, tuberculosis and malaria, and improve the availability of these drugs. It aims to do this primarily through pooling patents and making use of the flexibilities within the TRIPS agreements to allow countries to use cheaper generic products, as Section 4.6 for more details on TRIPS and intellectual property rights) as well as through economies of scale from bulk purchasing. There has been concern that funds may be diverted from GAVI to UNITAID, which is not what is intended. France, Chile and Norway (soon to be followed by Brazil) are all dealing with this through the first year, and have created taxes (the air solidarity levy in the case of France, Chile and Brazil, and a CO2 tax in Norway) rather than the general ODA budget. The UK’s contribution does come from the overall development budget, so cannot be described as additional in the same way. It is envisaged that the hypothecated tax will mean that resources for UNITAID are more predictable and long-term than general ODA, which is important. Although the UK’s contribution is not hypothecated, and therefore not additional to allocated ODA, DFID have committed to funding UNITAID for 20 years, which is unprecedented for the UK’s ODA. Whilst the UNITAID board welcome the UK’s long-term commitment, it is hoped that any countries that join in the future will follow the example of France, Chile, Brazil and Norway, and hypothecate a tax to ensure additionality and increase predictability. Large pharmaceutical companies have been nervous about UNITAID, given the mechanism’s potential to affect drug prices and drug research and development. However, large pharmaceutical companies may not cope. Health system capacity must be strengthened to absorb the additional resources. Section 3.3 discusses this in more detail.

3.12.2 The International Finance Facility (IFF) (including IFFim)

The IFF was first proposed, by Britain, in 2003 as a mechanism to raise up to US$50 billion of additional annual funding for programmes targeted at achieving the Millennium Development Goals (MDGs). By pledging future ODA expenditure, the donors would enable the IFF to issue debt in the international capital markets and thus frontload the available resources. Advocates hope the IFF will allow greater predictability and play a role in anticipatory disbursing of resources needed for achieving the MDGs.

The IFF for Immunisation (IFFim), a pilot of the IFF mechanism to finance vaccinations in developing countries, was launched in September 2005 by Britain, France, Italy, Norway, Spain and Sweden. It issued its first US$1.1bn AAA-rated bonds in November 2006. IFFim aims to disburse up to US$5bn over the next 10 years to programmes operated by the GAVI Alliance in 70 of the poorest countries in the world. The IFF and IFFim financial structure was devised by Goldman Sachs International, working together with HM Treasury and the World Bank. Figure 3.4 shows potential pledges and disbursements, while Figure 3.5 shows how it will function. Money raised from IFFim will be used to support new vaccines, strengthen immunisation services, fund measles and tetanus campaigns, and fund a polio vaccine stockpile. While these activities will not directly impact malaria, as there is currently no malaria vaccine, there may be potential for strengthened immunisation services to deliver interventions such as IPT and ITNs.

3.12.4 Debt Conversion

Debt Conversion is a proposed arrangement whereby specific creditors forgo future debt repayments in exchange for the debtor country converting an agreed value of the debt write-off into local currency for investment towards reaching the Millennium Development Goals (MDGs). As this would be executed directly between creditor and debtor, with Fund facilitation, it would not require GAVI to purchase any debt, incur significant transaction costs or alter its bylaws (88).

A significant challenge in moving from concept to practice is including creditworthiness (ECWA) debt, the largest potential source of convertible funds as it has higher interest rates, in addition to ODA debt.

France has initiated a tax (solidarity contribution) on airline tickets, to finance the international drug purchase facility (IDPF/UNITAID). The tax, these funds will be additional to traditional ODA financing, predictable and sustainable. The tax, these funds will be additional to traditional ODA financing, predictable and sustainable. The Air Ticket Solidarity Levy is a significant step in the financing of development, as it is the first ‘development tax’, where revenue raised goes specifically to international development.

Note: Source: http://www.iff-immunisation.org/02_financial_background.html

3.12.5 Air Ticket Solidarity Levy

France has initiated a tax (solidarity contribution) on airline tickets, to finance the international drug purchase facility (IDPF/UNITAID). Seventeen other countries are considering similar steps, The solidarity levy is expected to generate more than €150 million in 2013, which will be used to support UNITAID (see Section 3.12.2). As a hypothesised tax, these funds will be additional to traditional ODA financing, predictable and sustainable. The Air Ticket Solidarity Levy is a significant step in the financing of development, as it is the first ‘development tax’, where revenue raised goes specifically to international development.
4. Financing Malaria Research and Development

4.1 Current situation

Whilst we currently have effective tools against malaria in the form of ACTs, LLINs and insecticide, the ability of malaria parasites to develop resistance means that there is a need for continual research and development into drugs and insecticides in order to keep one step ahead of resistance. There are also hopes of developing new methods of preventing malaria, through IPT for infants, children and other groups, and the alluring hope of developing a vaccine. Diagnosis and implementation also require more research to improve existing tools and systems and develop new ones. All of this means that malaria R&D is an area we cannot afford to neglect.

In 2004 it was estimated that US$323 million was invested in R&D for malaria. As Figure 4.1 shows, the area to receive the largest proportion of this was into drugs, followed by vaccines.

Since 2004, the Bill and Melinda Gates Foundation has become the largest donor to malaria research and development in the world, committing US$258.3 million in October 2005. Malaria R&D receives a much lower percentage of total resources dedicated to the disease than other conditions. There are several difficulties which negatively affect the amount of R&D carried out into malaria, particularly by private companies. One of the main problems is uncertainty about whether a viable market would exist for new products, and how large this market is likely to be. As Figures 1.1 and 1.2 show, malaria affects mainly low income countries, who are unlikely to be able to afford expensive new treatments or preventive measures, calling into question whether anyone would be able to buy new products. A contributing factor to lack of certainty about potential markets is the poor quality of much forecasting. As discussed in Section 3.3.1, forecasting problems affect the ability of manufacturers and countries to deliver interventions where they are needed, at the right time and in the right numbers. Poor quality forecasting also means manufacturers do not have credible information about what the need for their product will be [90]. There is also considerable technical complexity to combating the malaria parasite, because of the complexity of the parasite’s life cycle within the human body.

4.2 Research and development in malaria treatment

Malaria is a neglected disease in terms of drug development. Between 1975 and 2004 1556 new drugs were approved, only 8 of which (0.5%) were for malaria [91]. Drug development is an expensive and time consuming business as Figure 4.2 illustrates, yet the rise of drug resistance makes it vital.

There are various stages in the research and development process for new drugs before a health impact can be achieved, as illustrated in Figure 4.3. For effective drugs to be developed, research needs to go all the way through these stages. As Figure 4.4 shows, the majority of current research focuses on basic knowledge and tools, with methods and strategies being relatively neglected.
4. Finishing Malaria Research and Development

4.2.1 Push Mechanisms

Push mechanisms operate at the point where the expenditure is being made, which is whilst the research is taking place before the launch of the drug. Examples of Push mechanisms include direct funding of research carried out by academic institutes or private companies. This has advantages for the organisations undertaking the research, reducing their level of dependence on the uncertain possibility of income once the drug has been launched. It allows smaller organisations, which would not otherwise be able to afford the upfront costs of research, to play a role in drug development. However, from a funder’s point of view, there is no guarantee that the funds put into research will result in a successful, effective drug as many drug R&D projects do not, and it is impossible to forecast at the beginning of a project what the outcome will be.

Public Private Partnerships (PPPs)

Public Private Partnerships are one of the most important Push mechanisms for malaria treatment R&D. Key PPPs involved in the malaria treatment R&D include MMV (see Section 2.8.2.1) and DNDi (see Section 2.8.2.4). PPPs help to fund R&D, and have additional benefits to directly funded research, as they provide social venture capital and expertise. Figure 4.6 illustrates the value added through effective PPPs, using MMV as an example.

MMV Inputs
- Rights in DEC
- IPR in ‘Field’
- Drug Supply
- Returns on non DEC Sales

MMV Gets
- Public + Private = leveraged cost

Industry Inputs
- Chemistry IPR
- Toxicology
- Know How
- Assets in Kind
- Technology
- Liability Insurance

Industry Gets
- Private Goods
- Staff satisfaction
- Corporate
- Citizenship & Responsibility

This section will examine the different financing mechanisms that are currently used or have been proposed in relation to R&D into treatment. Research and development investment into both treatment and prevention of malaria can be financed through ‘Push’ or ‘Pull’ mechanisms, as illustrated in Figure 4.5.
4. Financing Malaria Research and Development

Analysis carried out by the George Institute for International Health into neglected disease drug development has shown that drugs resulting from projects that used the PPP model are more likely to be appropriate for use in developing countries than drugs that resulted from an 'industry alone' approach. The PPP approach also matched or exceeded industry in terms of time-performance, with MMV projects performing particularly well. Moran et al also argue that the PPP model is the most cost-effective R&D approach. PPPs are able to optimise resource use by:

- Reducing cost of capital
- Leveraging in-kind input from multinational companies and public groups
- Avoiding the need to fund a fully loaded pipeline
- Using cheaper developing country sites for clinical trials
- 'Piggybacking' public health work onto commercial work [25]

PPPs manage the risk associated with push funding through having a portfolio of R&D projects, allowing them to stop less competitive projects at an earlier stage, saving money. PPPs do have problems with under-funding and relying on short-term grant funding. PPPs had a 40% shortfall in 2005, with this expected to increase as candidate drugs enter the more expensive clinical trial state. This in turn acts as a deterrent against drug PPPs for neglected disease drug development has shown that drugs resulting from projects that used the PPP model are more likely to be appropriate for use in developing countries than drugs that resulted from an ‘industry alone’ approach. The PPP approach also matched or exceeded industry in terms of time-performance, with MMV projects performing particularly well. Moran et al also argue that the PPP model is the most cost-effective R&D approach. PPPs are able to optimise resource use by:

1. PPPs contract industry deals as they do now
2. Their funds are depleted restricting their ability to sign up new projects
3. The IRFF subsequently reimburses PPPs for payments they have made to industry (80%)

With PPPs

It is aimed at strengthening the PPP model, allowing PPPs to do more deals with industry and be more viable for long-term partners for companies. The anticipated benefits for industry of this approach are increased opportunities to access push funding through PPPs, and reassurance about the sustainability of these partnerships. The IRFF model could also benefit donors, giving them one central mechanism to channel funds to all industry partners of all drug PPPs across all neglected diseases. This spreads the risk for government, and provides a reliable funding stream for R&D projects. It is estimated that the cost of an IRFF to fund the industry R&D component of PPPs for neglected disease drug development would be an average of around US$1-40 million per year until 2010, levelling out at around US$200 million a year after 2010.

Source: [25]

Figure 4.7 Neglected Disease R&D Projects December 2004

Table 4.1 Breakdown of Cumulative Philanthropic and Public Funding to Drug PPPs

<table>
<thead>
<tr>
<th>Source</th>
<th>Total funding</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gates Foundation</td>
<td>$158,757,717</td>
<td>62.3</td>
</tr>
<tr>
<td>MSF</td>
<td>$29,738,133</td>
<td>11.7</td>
</tr>
<tr>
<td>Rockefeller Foundation</td>
<td>$20,300,000</td>
<td>8.0</td>
</tr>
<tr>
<td>Wellcome Trust</td>
<td>$2,827,504</td>
<td>1.1</td>
</tr>
<tr>
<td>Subtotal</td>
<td>$211,623,354</td>
<td>83.1</td>
</tr>
<tr>
<td>US</td>
<td>$16,000,000</td>
<td>6.3</td>
</tr>
<tr>
<td>UK</td>
<td>$10,909,468</td>
<td>4.3</td>
</tr>
<tr>
<td>Netherlands</td>
<td>$10,489,255</td>
<td>4.1</td>
</tr>
<tr>
<td>Switzerland</td>
<td>$4,422,285</td>
<td>1.7</td>
</tr>
<tr>
<td>EC</td>
<td>$1,554,150</td>
<td>0.6</td>
</tr>
<tr>
<td>Subtotal</td>
<td>$43,375,158</td>
<td>17</td>
</tr>
</tbody>
</table>

Source: [25]

Figure 4.8 The IRFF

4.2.1.2 Industry R&D Facilitation Fund (IRFF)

Following their research into neglected disease R&D, Moran et al identified some factors that can limit the impact of PPPs: level of funding, and level of industry input. They propose setting up an IRFF to support PPPs and try and address these gaps. The IRFF is a long-term public fund to specifically fund industry involvement in PPPs. It is designed to work as an incentive to industry working through PPPs rather than act as a PPP itself. Figure 4.8 illustrates how it is envisaged that the process would work.

4.2.1.3 The International Finance Facility for Neglected Diseases (IFFnd)

Following the launch of the pilot International Finance Facility for Immunisation (IFFim) (see Section 3.12.3), various organisations brought together by Secureaid, including MMV/WHO/TDR, other PPPs and professional organisations such as Goldman Sachs, Linklaters and PriceWaterhouseCooper have been advocating for the establishment of an IFF for neglected diseases.

The IFFnd is designed to raise funds to finance R&D into treatments and potentially vaccines for neglected diseases (including malaria) through the international bond markets. As in IFFim, AAA-rated bonds are issued on international markets securitised against sovereign guarantees on future aid levels. The front-loaded resources freed up through this mechanism would then initially go towards the (currently critically underfunded) late-stage clinical development of a portfolio of 16 compounds (pooled from MMV and WHO/TDR). It is estimated that this will require around US$1-1.5bn to be raised from bondholders, and should result in five or more medicines emerging with approval to market.
4.

Financing Malaria Research and Development

4.1. Financing Malaria Research and Development

It is envisaged that the proportion of funds required from developed country governments would decrease over time, through increased income from fees paid by companies for the right to commercially distribute products developed through IFFIm and through differential pricing as middle income countries develop and can afford to pay more for these products.

It is predicted that increased investment in R&D for neglected diseases will have a positive effect on the rest of the logistics chain, through funders being able to see that treatments for neglected diseases are or will soon be available, therefore making investment in distribution systems and other areas worthwhile. Like IFFIm, IFFnd does not need the participation of all the major international donors to commence. The successful launch of IFFIm may smooth the way for IFFnd. However, as with IFFIm, questions remain about the sustainability of a mechanism that borrows from tomorrow’s aid to pay for activities today. However, there are significant benefits of frontloading aid for neglected disease R&D as it will result in drugs and vaccines for these diseases being available sooner; which in turn will result in lower mortality and morbidity, and decrease the negative economic effects of these diseases on the economy of countries affected. The sooner these drugs are available, the better.

4.1.1. Differential Pricing (Price Discrimination)

For some drugs the possibility of differential pricing may encourage industry to invest in R&D. Differential pricing, where different prices are charged for the same good or service depending on the characteristics of the buyer (such as discounts for senior citizens) are only possible where the market can in some way be separated into different segments. For drugs this has been used so that a drug is sold to developing countries at a cheaper price than to developed countries. This may allow companies to make sufficient profit from the developed country market to make their R&D investment worthwhile, whilst the sales of drugs to developing countries at the lower price may be part of a corporate social responsibility policy.

There are difficulties in implementing such a policy for any good where there are possibilities of the lower priced drugs leaking into the higher priced market. However, for malaria drugs, the possibilities of differential pricing are severely limited, given that the countries affected by malaria are amongst the poorest countries in the world (see Figures 1.1 and 1.2), meaning there is very little rich country market for malaria drugs, and the developed country market for malaria drugs is very different to the main treatment market.

4.1.2. Pull Mechanisms

Pull mechanisms are designed to provide incentives for research and development by the promise of future rewards, once the drug has been launched. Most of these are related to market size and potential revenue. Pull mechanisms have the advantage that money spent on them may only go to successful drugs, whereas with push mechanisms there is always the significant risk that an effective, practical drug will not result. However, whilst this reduces the amount of risk for the donor it shifts the burden of this risk onto the organisation carrying out the research. Where companies are unwilling to risk investing in R&D for a product which if successful could have good returns, but may fail, the pull mechanism is ineffective. Smaller companies in particular may be unable to afford the large costs of R&D now despite hopes of future revenue. Push mechanisms may be more effective in these circumstances. However, many pull mechanisms do have added benefits in terms of reducing the price of new drugs for end users (such as AMCs).

4.1.2.1 Advanced Market Commitments (AMCs)

AMCs have not currently been proposed as a method of encouraging R&D into treatment of malaria, although there is work on developing an AMC for a malaria vaccine (see Section 4.4.3.2). AMCs work through international donors guaranteeing that they will purchase a certain quantity of effective products, if it meets specified criteria at an agreed price when the product becomes available. This aims to combat the problem of uncertainty over whether there will be a market for a product once it is developed, which is a result of the countries affected by malaria being low income, and the poor quality of forecasting currently available.

4.1.2.2 Global bulk purchasing

Whilst not directly designed as mechanisms to encourage R&D, the existence of bulk purchasing mechanisms such as UNITAID, and the resources of the GFATM dedicated to purchasing drugs, may encourage industry to invest in R&D as the size and sustainability of the market for antimalarial treatment increases.

4.2. Research and development in diagnosis

As explained in Section 1.4.1.1, diagnosis has become increasingly important with the move to ACTs. The main area of research in malaria diagnosis is the development of RDTs. At the moment there is no perfect RDT, as every product available has issues of specificity or sensitivity. Whilst it requires relatively little capital to manufacture RDTs, the expense is mainly in the R&D into improving sensitivity and specificity of the test, and ensuring the test is heat and humidity stable. WHO is in the process of setting up a network of independent laboratories to carry out quality assurance work on new RDTs. The financing mechanisms discussed above in Section 4.2 for treatment could also be used in relation to R&D for RDTs.

4.2.1. LLIN technology

Insecticide treatment of ITNs has been extremely difficult to sustain in virtually all settings except Vietnam. The development of long-lasting, wash-resistant ITNs (LLINs), remaining effective for up to four years, could avoid the need to retreat nets with insecticide every 6-12 months. However, global shortages have led to ordering delays of 6-18 months for the two LLIN brands now in the market (Vestergaard Frandsen’s PermaNet® and Sumitomo/A-Z Textiles’ Olyset Net®), as companies are not yet able to meet the growing demand from governments and donor agencies. A number of manufacturers are working on long-lasting insecticide treatments for existing nets for areas already with high net coverage [93]. The majority of research and development in this area is currently carried out by the private sector; although Liverpool School of Tropical Medicine does have a US$50.7 million Bill and Melinda Gates Foundation grant to support the Innovative Vector Control Consortium. In general it seems that currently little attention has been paid to mechanisms to support and encourage research in this area. There may be a perception that industry is already doing enough without need for further incentives from the public sector. The market for products such as ITNs may already be large enough for private companies to feel it worth investing in R&D to a certain extent. However, it is important that research does continue in this area, and if a situation arises where the private sector alone is not carrying out enough to meet this need, then incentives and mechanisms to encourage R&D will need to be put in place. These could include some of the mechanisms discussed in Section 4.2, such as PAPs and AMCs.
4. Financing Malaria Research and Development

4.4.2 Intermittent Preventive Treatment (IPT)

IPT, where people at risk from malaria are given preventive treatment doses of effective antimalarial drugs, has proven to be a safe, inexpensive and effective way of preventing malaria amongst pregnant women, who form one of key ‘at risk’ groups for malaria. Most of the research into this has been looking at the use of sulfadoxine-pyrimethamine (SP) for IPT. However, there are large areas where resistance to SP has developed. The correlation of resistance with effectiveness of IPT in pregnancy (IPTp) is not clear; as the mechanism of protection is not fully understood. It is likely, however, that beyond a certain degree of resistance, IPTp will become less effective. It is urgent at this stage to test alternative drugs, and this will need investment.

IPT in infants (IPTi) is an area where research is currently being carried out. The IPTi Consortium, of some of the leading centres of malaria research in Africa, Europe and the USA as well as WHO and UNICEF, believe that IPTi may have a major role to play in preventing malaria amongst this age group. Along with pregnant women, infants are particularly vulnerable to malaria. IPTi could be carried out through the Expanded Programme on Immunisation (EPI) at the same time as infants receive routine vaccinations, as this is one of the best-functioning systems of regular contact with young children. The IPTi Consortium, funded by the Bill and Melinda Gates Foundation, seeks to resolve the outstanding scientific questions about whether to use IPTi; if so, how to implement it. Research on IPT in children under five is also underway. A key consideration is to balance the risks of accelerating development of drug resistance through more widespread use of drugs versus the benefits of the protection this method can bring.

4.4.3 Malaria Vaccine

The idea of a vaccine for malaria is alluring given the success of existing vaccines, such as polo, and the effectiveness of the EPI mechanism at delivering vaccines in developing countries. However the idea may not be so attractive to industry: “A vaccine targeting developing countries, especially one primarily targeting Africa, where many countries spend less than US$10 per year per capita on health, presents an overly risky and unattractive commercial prospect” [94]. Much attention has been given to research into malaria vaccines, and how to finance this research. Following extensive consultation with stakeholders, the Malaria Vaccine Technology Roadmap sets a strategic goal of by 2025, develop and license a malaria vaccine that has a protective efficacy of more than 80% against clinical disease and lasts longer than four years”, and identifies the priorities for reaching this goal, which includes securing sustainable financing for future procurement of vaccines [95].

There are considerable challenges to developing an effective malaria vaccine, especially the scientific complexities of dealing with the different life-stages of the malaria parasite. There has never been a vaccine developed for a complex multistage parasite. To deal with the difficulties of financing research into a malaria vaccine, various financing mechanisms have been proposed. There are currently 58 malaria vaccines in the development stage, 15 undergoing clinical trials, and 40 that are product-like [96].

4.4.3.1 PPPs

PPPs devoted to funding research into malaria vaccines, such as Malaria Vaccine Initiative (MVI), and European Malaria Vaccine Initiative, seek to accelerate the development of a malaria vaccine. MVI currently has 10 vaccine development projects around the globe, involving partners from the private sector, academic institutions and the public sector. For more information on how PPPs work, see Section 4.2.1.1.

4.4.3.2 AMCs

Considerable work has gone into developing plans for an AMC for a malaria vaccine. As explained in Section 4.2.2, AMCs are a pull mechanism that seeks to encourage investment in R&D through guaranteeing the existence of a market once a successful product has been developed. Donors commit upfront to buying a given number of doses at a certain price for a specified time period, for a target vaccine which meets set specifications. When candidate vaccines become available, an independent committee assesses if the vaccine meets these specifications. Recipient countries which are interested in introducing the successful candidate vaccine request the number of doses required, and donors then subsidize its purchase, with the recipients paying a contribution as well. As part of the AMC contract, once the AMC comes to an end the manufacturers would supply the vaccine to recipient countries at an agreed low price for a specified period. Figure 4.9 illustrates the effect of the AMC on price both during and after the AMC period [97].

Figure 4.9 AMC prices over time

The AMC is intended to provide an incentive for firms to invest more in malaria vaccines. It is open to all players, and is designed to sustain more than one firm to encourage competition and sufficient capacity. It is also designed to last between 7-10 years to allow time for 2nd and even 3rd generation products to become part of it. It is hoped that it will complement other strategies, including push funding mechanisms such as PPPs, and strengthen demand forecasting and national planning.

A consortium of donors interested in pursuing AMCs, led by the UK Treasury, has been looking at the details of the AMC plan, and has consulted with industry. Feedback on the Malaria Vaccine Technology Roadmap has been broadly positive, with industry supporting the idea, but raising questions about the details of the scheme. However, the idea is not without its critics, and Andrew Farlow’s paper voices a number of concerns about the AMC concept [98]. Problems that still need resolving include how to set appropriate prices before the cost of the vaccine is known. There is also a certain degree of scepticism over whether AMCs will actually encourage competition and development of vaccines that exceed the set standards, whether industry will respond to pull funding rather than push funding (use of pull funding may exclude smaller companies from taking part if they are not able to afford the upfront costs of R&D), and how binding the price guarantees both during and after the AMC period will be.

All of these concerns need to be acknowledged and addressed, but the AMC mechanism does have potential to encourage large pharmaceuticals to carry out R&D into a malaria vaccine, and would help developing countries to access these vaccines once they are available. There is also significant international political commitment to the mechanism, with the G8 July 2005 Communique pledging to increase direct investment and take forward AMCs for malaria [99]. The first vaccine AMC was launched in February 2007. This US$1.5bn fund is targeting a vaccine for pneumococcal as its first priority, but it is also hoped that an AMC for malaria vaccines will follow in the not too distant future.
4.4.3.3 A note of caution

The idea of a malaria vaccine is attractive, given the success of other vaccines in combating disease. There are significant amounts of work being done both on research for a malaria vaccine, with PPPs specifically for this purpose, and investigating ways to finance vaccine R&D, such as the work on the AMC. But for a malaria vaccine to have a real impact on the disease in the poorest countries in the world it would need to be highly effective, able to be delivered in just one or two doses along with other EPI vaccines, give protection for years, and be affordable for the countries affected. A vaccine meeting these requirements is still years away and people are dying now. Concerted action against malaria cannot wait until we have a vaccine. We have effective prevention and treatment tools, and the priority must be ensuring that these get to the people that need it now, rather than waiting to act decisively until we have a vaccine.

4.5 Research and Development Milestones

Table 4.2a Research and Development Milestones, 2005-2010 [31]

<table>
<thead>
<tr>
<th>Priorities</th>
<th>Milestones</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achieve Abuja coverage target in Africa and increase coverage elsewhere</td>
<td>Global agenda for research, development and deployment related to malaria</td>
</tr>
<tr>
<td>System strengthening</td>
<td>Shorten prequalification procedure for new LLIN technologies</td>
</tr>
<tr>
<td>Achieve malaria-related Millennium Development Goals</td>
<td>Shorten prequalification procedure for new ACTs</td>
</tr>
<tr>
<td></td>
<td>Shorten prequalification procedure for new RDTs</td>
</tr>
<tr>
<td></td>
<td>Alternative safe drugs for pregnancy</td>
</tr>
<tr>
<td></td>
<td>Replacement products for ACTs</td>
</tr>
<tr>
<td></td>
<td>Reliable RDTs</td>
</tr>
<tr>
<td></td>
<td>Novel Long-Lasting insecticide products</td>
</tr>
<tr>
<td></td>
<td>Novel insecticides for deployment through IRS</td>
</tr>
<tr>
<td></td>
<td>New tools for detection and forecasting of epidemics</td>
</tr>
<tr>
<td></td>
<td>New tools for malaria interventions in complex emergencies</td>
</tr>
<tr>
<td></td>
<td>Best practices for home management for ACTs identified &amp; implemented</td>
</tr>
<tr>
<td></td>
<td>Improved understanding of best delivery mechanisms for ITNs and other commodities</td>
</tr>
<tr>
<td></td>
<td>Development and testing of candidate vaccines</td>
</tr>
<tr>
<td></td>
<td>Vaccine candidate available for phase IV testing</td>
</tr>
<tr>
<td></td>
<td>R&amp;D entities to adopt and implement global research agenda</td>
</tr>
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Table 4.2b Research and Development Milestones, 2011-2015 [31]

<table>
<thead>
<tr>
<th>Priorities</th>
<th>Milestones</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achieve malaria-related Millennium Development Goals</td>
<td>New classes of safe and effective insecticides are widely available</td>
</tr>
<tr>
<td></td>
<td>Local and regional research capacity expanded and used</td>
</tr>
<tr>
<td></td>
<td>Set of potential malaria vaccine candidates expanded</td>
</tr>
<tr>
<td></td>
<td>Several vaccine candidates available for phase IV testing</td>
</tr>
</tbody>
</table>

4.6 The role of IPRs in research and development

The issue of intellectual property rights in relation to public health is a controversial one, which has been the source of heated debate, particularly since the introduction of the World Trade Organisation (WTO) Trade Related Aspects of Intellectual Rights (TRIPS) agreement in 1994. Section 3.10 discussed the impact of TRIPS on the price of drugs. This section will discuss the role of TRIPS in relation to R&D of malaria drugs.

One of the aims of UNITAID is to pool patents and making use of the flexibility within the TRIPS Agreement and Doha Declaration to reduce drug prices for developing countries, which is something many developing countries have been unable to do for themselves because of pressure from the USA. Pharmaceutical companies argue that stronger intellectual property protection will benefit developing countries as:

- Intellectual property rules provide an incentive to develop drugs
- Intellectual property rules allow industry to recoup substantial R&D investments
- Intellectual property protection will benefit developing countries

Novartis, in response to pressure from Oxfam campaigners to drop their legal action against the government of India over India’s Patent Laws, argues “The best way to encourage innovation is via respect for intellectual property. We do not believe that denying patent protection for innovative medicines and promoting unlawful generic production and use within developing countries will help patients or increase their access to medical treatment” [100].

However, there is doubt as to the extent to which intellectual property rules do stimulate innovation that will benefit poor countries. Oxfam argue that intellectual property rules currently encourage more rent-seeking than innovation. Only 15% of new drug application approved by the US Food and Drug Administration from 1989-2000 were classed as clinical improvements over existing products, with most research focusing on developing similar versions of existing medicines [85]. Moran et al. found that research done through PPPs was more innovative than that done by industry alone [25].

Malaria affects the poorest countries in the world (as shown in Figures 1.1 and 1.2), and “no amount of intellectual property protection is going to make poor women and men in Africa a lucrative target for the pharmaceutical industry”. Other methods of encouraging R&D, such as PPPs and AMCs are likely to be far more effective at encouraging R&D into malaria treatment and prevention, whilst being better able to ensure that products once developed reach the people who need it. It is important that these mechanisms receive sufficient funding to encourage a high enough level of R&D into malaria, and compensate for any reductions in industry-alone R&D.
Annex 1

List Of Presentations Made To The APPMG During 2006

Prof. P.L. Chidebe, Consultant in Parasitology & General Tropical Medicine at the Hospital of Tropical Medicine, 

**Diagnosis and Treatment**, 6 February 06 

Joe Cohen, GSK: Malaria vaccines development: the way ahead, 6 February 06 

This presentation focuses on the development of a malaria vaccine and the conditions necessary to deploy it (e.g. demand, funding sources and mechanisms). GAVI, GAVI and AMC are identified as organisations and mechanisms that can help achieve deployment of a malaria vaccine. 

Melinda Morse, Malaria Vaccine Initiative, The Quest for a Malaria Vaccine, 6 February 06 

Malaria vaccines are hard to develop and are expected to take between 10 and 20 years and cost hundreds of millions of US$. There are several different stages of the parasite's life cycle that they can affect. In total there are 18 vaccine candidates at development stages. 15 at clinical trial stage and 20 product-like: MRCs would help ensure vaccine development. 

Dr Anita Koch, Director, Roll Back Malaria, World Health Organisation, Roll Back Malaria: why is it so far failed? 

**What should be done**, 6 February 06 

RBM launched in 1998. Since then there have been significantly more tools, money and visibility for malaria. However, Africa is still far short of the Abuja targets. Koch claims that this is the result of weak leadership, incorrect policy and unclear strategies. 

Peter Piot-Levine, Medicines for Malaria Venture, Malaria & the Multinationals: Public Private Partnerships, 6 February 06 

Between 1975 and 1995, 1,093 new drugs were approved. Only three were for malaria. Since 2000, the world has seen the launch of new drugs (DHA, DHA/PP and Isoniazid) and has led to more drug R&D partnerships for malaria. PPIS provide push funding for the R&D cost. MVM provides social capital ventures. Funding for malaria R&D lags behind that of other diseases. It is expected that there will be 2-3 new malaria drugs by 2010. 

Sergio Spinaci, WHO: Improving Support for National Malaria Control, 6 March 06 

This presentation outlined the recent progress on malaria and the challenges at country level, which include complex funding flows, limited resources and weak absorptive capacity, the burden of the disease, surveillance and monitoring institutional arrangement and coordination. It concludes by looking at how WHO can support countries. 

Dr Nick Bauluz, Head of Global Partnerships, DfID: Delivering malaria control 2006 and beyond, 6 March 06 

This presentation outlined the issues behind scaling up for malaria, the complexity of the architecture and the need for more and better aid. 

Ruth Worl, Head of International Financing Branch, the International Development Team, the Treasury, Innovative Financing Mechanisms, 6 March 06 

This presentation outlined potential innovative financing mechanisms for malaria, including the air ticket solidarity levy, R&D, AMC and Alan Bryces, Potential Advanced Market Commitment (AMC) Investment, 6 March 06 

This focuses on the one hand the benefits an AMC mechanism could have on malaria vaccine development through overcoming some of the hurdles to private sector involvement: high R&D costs; lack of visible market scientific complexity and lack of funding once a vaccine is in place. 

Dr Vincent Nanyabi, Head of Policy for Innovative New Diagnostics, formerly of the Global Fund, Financing Malaria: The Global Fund perspective, 23 March 06 

Malaria resource needs are estimated to be US$2.3 billion a year. After 5 rounds of GFATM proposals only $2 billion was invested. There are several different stages of the parasite's life cycle that they can effect. In total there are 58 vaccine candidates at development stages. 

Dr Mary Mort, Funding neglected disease drug R&D: The Industry R&D Incubation and Development Fund (IRIF), 23 March 06 

This presentation outlines the advantages of PPPs in malaria drug R&D and the gaps in levels of funding and industry input. It proposes an Industry Research and Development Incubation Fund to fund industry involvement in PPPs and address these gaps. 

Dr-Pascelle Sanderson, London GfS: Small Mission Hospital in Uganda, Financing the ‘Grass-roots’level with a focus on malaria, 9 May 06 

This presentation discusses the issues related to funding of infrastructure, specific projects and ongoing costs of a small mission hospital in Uganda. 

Dr James Tatemkena, Malaria, Convention: Financing Treatment Policy Change: Country level successes and challenges, 9 May 06 

This presentation discusses the process of changing the treatment policy in Uganda. It emphasises the need for a complete malaria control package, including prevention and diagnosis as well as treatment. Drug policy change needs to embrace all sectors and levels of health system. There was a discussion of the successes and challenges of the process in Uganda, and how resource can be mobilised to finance this process. 

Professor Chris Whitty, London School of Hygiene & Tropical Medicine, Deploying artesiminin combinatorial therapy: achievable, but not easy, 9 May 06 

Current deployment plans for ACTs will mean that many who need it will not have access to ACTs, whilst there will be large levels of over-treatment. The informal sector plays an important role in treating children, yet many private sector providers do not prescribe antimalarials of any sort, particularly not ACTs. It is important that health systems are strengthened. Diagnosis also needs to be improved. Long term subsidies for ACTs are necessary. 

Professor Francis Omaswa, Special Adviser To The Director General, World Health Organisation, On Human Resources, Health sector reforms in Uganda, 9 May 06 

This presentation discusses the health sector reforms in Uganda, and the move towards Sector-Wide Approaches. It outlines the achievements in terms of human resource infrastructure and supplies. The abolition of user fees was successful in increasing attendance at health facilities. The challenges of the reforms are also discussed. 

References

95. NetMark, USID: unveils new technology for African Manufacturers for the mechanical LLIN treatment of mosquito nets. Improving performance and weak absorptive capacity, the burden of the disease, surveillance and monitoring institutional arrangement and coordination. It concludes by looking at how WHO can support countries. 
99. NetMark, USID: unveils new technology for African Manufacturers for the mechanical LLIN treatment of mosquito nets. Improving performance and weak absorptive capacity, the burden of the disease, surveillance and monitoring institutional arrangement and coordination. It concludes by looking at how WHO can support countries. 
Richard Tren, Africa Fighting Malaria, Prof. Chris Curtis, LSHTM, Mark Rowland, LSHTM, Mikkel Vestergaard Frandsen, Vestergaard Frandsen, A Debate on the Use of DDT to Control Malaria, 13 July 06

This session focused on a debate over the use of DDT to control Malaria. The speakers presented a variety of view points, and the efficacy and cost effectiveness of the use of DDT in IRS was discussed. It was also made clear that ITNs are another important mechanism for malaria control, and DDT is not the only insecticide suitable for use in IRS. Concerns were raised about the EU’s position on traces of DDT in imports.

Stephen O’Brien, Report Back on Trip to Malawi and Ethiopia with UNICEF, 17 Oct 06

This presentation reported on a recent trip that he and Lord Rea went on, organised by UNICEF. They commented on the importance of the SWAp mechanism in Malawi, as it supports the government strategy. There is an increased awareness of malaria in Malawi. UNICEF’s work in distributing ITNs in Ethiopia was also discussed. Human resources is a big problem for the health system in Ethiopia, with a doctors to population ratio of 1:100,000. There is a huge human resource gap in both countries.

Anna Guthrie, Development Financing, International Poverty Reduction Team, HM Treasury, IFFim, 17 Oct 06

This presentation discussed IFFim, which is a mechanism for frontloading aid for vaccinations. Immunisation is a good candidate for frontloading, as it is essential, cost effective, can be scaled up quickly, will have an immediate impact and has a significant internal rate of return. IFFim will work through GAVI in 72 countries. It is expected to immunise 500m children, and save 5m by 2015, 2m more than would be the case if aid had not been frontloaded. An update on UNITAID was also given.

James Droop, Head of Branch Development Policy, International Poverty Reduction Team, HM Treasury, Advanced Market Commitments, 17 Oct 06

This presentation discussed work to develop an AMC mechanism for vaccine development for neglected diseases. AMCs are a mechanism to encourage the private sector to get involved in vaccine R&D, through providing a guarantee of a certain level of market if an effective vaccine is produced. It requires credible commitments from donors, and a robust institutional structure.

Mark Grabowski, GFATM, Lubombo Spatial Development Initiative, 7 Nov 06

This presentation opened by exploring the success of strategies that distributed free ITNs in 12 countries, arguing that distributing ITNs for free to end users was the fastest, cheapest and most effective method of getting ITNs out to those who need them. It then went on to discuss Lubombo Spatial Development Initiative, where IRS (with DDT) has been used effectively, and has dramatically decreased levels of malaria in the region.

Henry Tito Okwalinga, AMREF, Uganda Malaria Partnership Programme (UMPP), 7 Nov 06

This presentation discussed AMREF’s UMPP, which was implemented in 3 districts of Uganda over 3 years, funded by GSK. The programme promoted the use of ITNs amongst vulnerable groups, encouraged home based management of fever for under fives, and IPTp. It worked in partnership with government, and built local capacity through training Community Medicine Distributors. The programme was successful, increasing demand for ITNs, and reduced morbidity and mortality. It is now being scaled up in central and northern Uganda.