

CONSULTATION ON THE ECONOMICS AND FINANCING OF UNIVERSAL ACCESS TO PARASITOLOGICAL CONFIRMATION OF MALARIA

May 31-June 1 2010

Meeting Report

BACKGROUND AND OBJECTIVES

The Global Fund has invested in interventions to prevent malaria—principally insecticide-treated nets and indoor residual spraying—and to treat with effective antimalarial medicines. It is also the main source of funding for rapid diagnostic tests (RDTs). As of 2008, the Global Fund hosts and manages the Affordable Medicines Facility-malaria (AMFm)¹, an innovative financing mechanism for antimalarial drugs. The Global Fund’s spending to expand access to malaria prevention and treatment accounted for about 62 percent of all external funds for malaria control disbursed to malaria-endemic countries between 2000 and 2007.

In the World Malaria Report 2009² and the Guidelines for the Treatment of Malaria 2010³, the Global Malaria Programme (GMP) at the World Health Organization (WHO) recommended prompt parasitological confirmation by microscopy or with RDTs for all patients with suspected malaria, before treatment is started; treatment solely on the basis of clinical suspicion should be considered only when a parasitological diagnosis is not accessible.

In resource-poor settings with weak health infrastructure, most malaria treatment currently is based on presumptive diagnosis and most antimalarial treatments are purchased directly by patients or caregivers in the private sector. In the Democratic Republic of Congo, for example, the private sector dominates the market, selling 85% of all antimalarials taken in the country. In Nigeria, the private sector accounts for an even higher percentage—about 95%—of all antimalarials⁴. These two countries alone accounted for more than one-third of all estimated malaria cases in the WHO Africa Region in 2006.

As a responsible and learning investor in the fight against HIV/AIDS, tuberculosis and malaria, the Global Fund seeks to base its investments on the best evidence and current technical guidelines to achieve the greatest impact in a resource-constrained environment. To this end, the Global Fund and the WHO co-convened a “Consultation on the Economics and Financing of Universal Access to Parasitological Confirmation of Malaria” to consider the economic and financial implications of WHO’s recommendation for universal access to parasitological confirmation of malaria, including potential investments in diagnostics. The consultation included experts in economics, financing, epidemiology,

¹ <http://www.theglobalfund.org/en/amfm/?lang=en>

² http://whqlibdoc.who.int/publications/2009/9789241563901_eng.PDF

³ http://whqlibdoc.who.int/publications/2010/9789241547925_eng.pdf

⁴ <http://www.actwatch.info>

biotechnology, product development and service delivery in resource-poor settings (public and private sectors).

The objectives of the consultation were to examine and discuss the following questions:

- (a) What are the economic implications of expanded (including universal) access to the parasitological confirmation of malaria?
- (b) What are the current costs of RDT use and their probable future evolution, considering the marginal cost of production, packaging and distribution, and the cost of use in terms of provider skills required and costs of alternative actions if the RDT is negative for malaria?
- (c) What are the best options for financing expanded (including universal) access to the parasitological confirmation of malaria?

A summary of the general discussion and recommendations follows, with the main points of individual presentations summarized in Appendix 1. This report is intended to complement the pre-consultation report that was prepared by Professor David Schellenberg and colleagues, which appears as Appendix 2.

GENERAL DISCUSSION

Summary

Fever is an extremely common presenting complaint in patients in many settings and malaria is—or was—the single most important cause of fever in many places. For decades it was considered appropriate to treat fevers presumptively as malaria, given the availability of an inexpensive, safe and effective antimalarial drug, the mortal risk of untreated malaria and the difficulty of accessing a parasitological diagnosis.

But developments in recent years have changed the equation. Resistance to the most affordable antimalarial drugs (chloroquine and sulfadoxine-pyrimethamine) has spread, and their replacements—highly efficacious artemisinin-based combination therapies (ACTs)—are at least ten times more expensive. Malaria is less common than it was because control measures have been effective (mainly insecticide-treated nets, ACTs and in some places, indoor residual spraying) and for other known and unknown reasons. In many places where malaria is presumed and treated as such, only a fraction of people actually have malaria. It is rapid diagnostic tests (RDTs) that have allowed this insight and now afford an unprecedented opportunity to improve both the management of patients with fever and the cost effectiveness of malaria treatment policies.

The 2010 WHO recommendation to do routine, universal diagnosis before treatment provides a clear goal. It is still not well implemented in most malaria endemic countries in sub-Saharan African — where only about 22 percent of suspected cases of malaria are tested, either by microscopy or RDT, before treatment⁵. The proportion tested is higher in some places where parasite-based diagnosis has long been the norm. It is getting from parasitological confirmation of malaria being the *exception* to being the *rule* that focused the attention of this consultation. Financial and economic aspects dominated the discussion, as planned, but in the background was always the knowledge that other factors—not least of them behavioral—were important and could influence the issues on the table.

The two-day Global Fund–WHO consultation did not revisit the recommendation for pre-treatment parasitological confirmation of malaria, the technical issues specific to the tests themselves (e.g., performance and technical aspects), or the details of cost-effectiveness analyses of different approaches to malaria diagnosis.

Each of the questions that guided the agenda was viewed from multiple perspectives, and country and institutional arrangements. Discussions covered mainly *P. falciparum* but included considerations relevant to *P. vivax* malaria. Examination by blood smears with a microscope is established in places, and, when quality of microscopy is ensured, malaria RDTs are not generally expected to replace it in those sites. Because RDTs are feasible in peripheral settings where most patients seek treatment, and where microscopy is not available and not practicable, the discussion at the consultation focused mainly on RDTs.

What emerged from the discussion was a consensus that the WHO recommendation for universal access to pre-treatment diagnosis of malaria should be supported and acted on immediately. Some decisions can be made based on the information available, and information to support further expansion can be

⁵ Based on 18 of 35 countries reporting in 2008. WHO, World Malaria Report 2009.

gathered systematically within a few years through operations research and fed directly into implementation. An agenda for action and practical research—and a need for some ongoing consultation—emerged. Specific recommendations appear at the end of this summary.

The major unresolved issues revolve around:

1. How to create the right incentive structures to increase demand for confirmatory diagnosis from practitioners and consumers, including the use of financial incentives, possible packaging of RDTs with drugs, and enhancing recognition of the importance of appropriate treatment for malaria and non-malaria illnesses;
2. How to manage febrile, RDT-negative patients at all levels of service delivery in the public and private sectors;
3. Defining the full fever management package (including supporting activities to manage the RDT-negative patients), and estimating the cost of universal access to it in the public and private sectors, including the informal sector;
4. The best expansion paths, in terms of benefits to patients and in learning for the remaining expansion, recognizing that universal diagnosis will not be adopted in all endemic areas simultaneously and that introduction will be easier in some countries and settings than others;
5. The architecture of financing that is suitable for the purpose of expansion from the current situation to universal access to RDTs; and
6. Sources of financial support for products and activities.

The key elements of each issue, ideas for moving forward, information gaps and timing concerns are explored in the following sections.

1. Creating an Incentive Structure

The basic question is how to encourage the use of quality-assured RDTs in febrile patients with suspected malaria, and then encourage treatment appropriate to either positive (malaria) or negative (not malaria) results. Affordable prices for RDTs, ACTs and treatment for non-malaria febrile illnesses—with the right *relative* prices—are essential although not sufficient, because demand is influenced by other elements. The financial incentive structure must recognize the essential role of shopkeepers in community healthcare. A universal financing scheme, such as AMFm for antimalarial drugs, was not ruled out, but it is also possible that different structures may be needed for different settings and different types of outlet. A formal analysis of the alternatives and other plausible incentive structures, and of their cost-effectiveness, is needed.

Public Healthcare Sector

Ideally, the cost to the patient of diagnosis and treatment for a febrile illness would be the same whether it were malaria, pneumonia or some other illness. It may be possible to equalize costs in public healthcare systems, but each country will have to work out the details. Governments use different

sources of revenue and payment schedules to finance public healthcare, including taxes, user fees, partial or full cost-recovery for services and insurance, which affect consumer prices for laboratory services and treatment. In most malaria endemic countries, the consumer price of RDTs and ACTs can be reduced using subsidies from international or national funds.

Private Healthcare Sector

Devising a means of regulating prices for diagnosis and treatment of febrile illnesses in the private sector—formal and informal—is more challenging than it is in the public sector. This discussion centers on malaria treatment, but it will not be separated in practice from the issue of the most appropriate management for those who do not have malaria, discussed below.

Without specifying exactly how it would be accomplished, the desired outcome is that the patient is cured of his or her febrile illness, and that diagnosis and treatment for malaria do not cost significantly more than diagnosis and treatment of non-malaria febrile illnesses. From a shopkeeper's perspective, can she or he make the same profit regardless of the outcome of the test result and the treatment given? This means that, in most cases, RDTs should be cheaper than ACTs, and that the price of treatment for non-malaria febrile illness is comparable to the price of an ACT. At their full retail cost, few people currently can afford ACTs anyway, but if and when AMFm is operational, ACTs will cost little more than the cheapest antimalarial now being sold (e.g., chloroquine or sulfadoxine-pyrimethamine).

Information about how the price of RDTs will affect consumer behavior at the interface between patients and sellers of RDTs and ACTs is scarce currently: how people will act cannot be predicted reliably without some more empirical evidence. The results of a recent study in western Kenya presented at the consultation⁶ provided one data point about the effects of RDT prices on the demand for ACTs in the private sector. When offered a voucher for subsidized RDTs, more than 80% of households who visited the drug shop chose to get the patient tested. However, because the majority of people who tested negative went on to purchase ACTs anyway, RDTs only modestly improved targeting. In this study, the availability of vouchers to subsidize RDTs in drug shops increased the fraction of ACT users who are malaria-positive by 11%. In the study area, 32% of people taking ACTs before the study did not have malaria, and in many other places, that proportion is even larger.

Better information, the availability of treatment for non-malaria fevers, and experience are likely to affect people's choices. Learning more about the determinants of consumer behavior, as well as optimal mix of practices and prices for both medicines and diagnostics is a priority.

Government Perspective

Governments will be incentivized to encourage RDT use if they can generate cost savings on ACT procurement that can be used for other purposes. A country that has been using some of its Global Fund grant or has used national funds to purchase ACTs could realize gains from reducing the use of ACTs as a result of decreasing the over-treatment of fevers presumed to be malaria without confirmation.

⁶ See Appendix 1, presentation of Professor Jessica Cohen.

Senegal has demonstrated this, achieving high levels of RDT use within 18 months. The Global Fund, which currently does not grant money to pay for antibiotics to treat fevers caused by bacterial infections, was encouraged to consider this.⁷ The desirability of linking or integrating the management of malaria with IMCI and IMAI was reiterated, both for community-based and facility-based care.

Even before Global Fund financing became available, in 2003, Cambodia began to provide subsidized RDTs and co-packaged ACTs through the public and private sectors, including village malaria workers. The initiative, which has expanded every year, was developed in response to the growing problems of multidrug resistance, inappropriate prescription practices in the private sector, the proliferation of fake antimalarial drugs, and over-treatment of presumed malaria. Subsidized ACTs (Malarine® - \$0.63/blister pack for adults and \$0.30/blister for children [2009 prices]) have been distributed in 17 endemic provinces in Cambodia. RDTs (Malacheck® - \$0.25/test) have now also been distributed widely. In 2009, the ratio of RDTs to ACTs sold was 2:1. The program is the longest-running of its type, and has been successful in establishing the practice of using RDTs for malaria diagnosis, although information is currently lacking on how successful the program is at targeting ACT treatment.

Intervention Packs

The idea of “intervention packages” was raised. Either a “malaria pack,” including an RDT and an ACT or a “fever pack,” including an RDT, an ACT, an antibiotic and an antipyretic, could be developed. On balance, drawbacks (particularly overtreatment with antibiotics, which would encourage antibiotic resistance) were seen to outweigh advantages. If, however, the medicines not dispensed are left with the shopkeeper for a refund, or are reconstituted into a new “fever pack” for the next patient, such a system might work. The rationale for discussing packs has, in part, to do with shopkeeper profits. “Packages” is one way to equalize profit regardless of the outcome of test results. The reality of making less money on patients who need no further treatment is a deterrent to RDT use that has to be factored in, even if shopkeepers are not all “profit maximizers.”

2. When It Isn't Malaria: Management of RDT-Negative Patients

In some settings, a large proportion of people who fall ill in Africa and test negative for malaria, by microscopy or RDTs, are treated with antimalarial medicines anyway. Because diagnosis (mainly microscopy) has been available mainly in formal settings, it is providers who are responsible for this practice much of the time, but the pattern is likely to be similar in informal settings (the study described above, in western Kenya, came to similar conclusions). The question is why. The reasons most often cited are skepticism about the reliability of diagnostic tests (maybe more so for microscopy than for RDTs), entrenched habit (of treating all fevers as malaria) and a lack of appreciation of the causes and appropriate management of non-malaria fevers. Where microscopy has not been available and

⁷The Global Fund will consider providing financing for the management of non-malarial febrile illnesses in its next round of funding, pending the results of ongoing studies examining cost savings from reduction of ACT over-treatment and cost projections on the demand for antibiotic treatment, with RDT deployment.

diagnosis has been based on clinical assessment only, the over-prescription of malaria drugs can be reduced by the introduction of RDTs.⁸

Among the benefits of expanded use of RDTs should be the clinical benefit of treating people for what they *have* and not treating for what they *do not have*. In the face of a negative RDT result, health providers must look for other causes of illness. Unfortunately, there are no rapid tests to differentiate illnesses caused by bacteria—which should be treated—from those caused by viruses, for which no specific treatment is usually required. Tests could be developed for specific (non-malaria) organisms, but these would have limited merit because several pathogens are important in every setting, and the combination of important agents would vary from place to place. An alternative approach is to develop *rapid* tests for markers of disease severity (more specific than elevated temperature, which can be measured easily, but less specific than naming the infecting organism, which cannot) that identify those who need a referral to a healthcare facility or for whom appropriate management can be offered at the testing site. The likely utility of such tests has not been recognized, however, and they are unlikely to be developed soon without encouragement.

Of greatest concern is the possibility that the non-malaria illness is bacterial pneumonia. The IMCI algorithm based on cough, difficult breathing and increased respiratory rate allows a trained healthcare provider to detect most of these cases. As with malaria, especially among infants and young children, delayed treatment can lead to death.

In a formal health facility (public or private), evaluation of the patient by clinical examination supplemented by laboratory tests can guide treatment decisions. IMCI and IMAI guidelines address this situation and are clear about when antibiotics should be used. But in informal settings—mostly unregulated shops managed by untrained shopkeepers—where the majority of people in many endemic countries seek treatment advice and purchase malaria drugs, it is not clear how these guidelines could be implemented. Because these algorithms sacrifice some specificity for high sensitivity, over-treatment with antibiotics could still be a problem, depending on the proportion of RDT negative patients given antibiotics. Resistance to the common relatively inexpensive antibiotics is already widespread in many parts of Africa and Asia. At the same time, untreated bacterial pneumonia kills more infants and children than does malaria.

In an ideal situation, basic health services through accredited sources (trained in IMCI and IMAI, and dispensing RDTs, ACTs, antibiotics and antipyretics), public or private, would be accessible to all, including remote communities. In reality, a large proportion of people (up to 70% in some places) purchase antimalarial drugs in drug shops, managed by vendors with no special training in treating malaria or other fevers. For some patients, no other points of care are accessible. Some people also purchase antimalarials in the private sector because it is more convenient, cheaper, less time-consuming, or because the symptoms do not seem serious enough for them to go to a clinic or hospital.

⁸ Ansah EK, Narh-Bana S, Epokor M et al. (2010). Rapid testing for malaria in settings where microscopy is available and peripheral clinics where only presumptive treatment is available: a randomised controlled trial in Ghana. *BMJ* 2010;340:c930 doi:10.1136/bmj.c930.

Whatever the reason, the private sector is the service delivery point for a lot of people. It is, therefore, important to chart the most feasible pathways to:

- Expanding the use of RDTs, ensuring access for all cases of suspected malaria
- Using ACTs when the RDT is positive
- Avoiding ACT use and ensuring appropriate alternative management options when the RDT is negative. This includes antibiotics as warranted by diagnostic information based on simplified IMCI/IMAI guidelines.

The reach of community health workers is being expanded all over Africa, and can reduce (but not quickly eliminate) the need for access to treatment through the informal private sector. Recent experience in Senegal has shown the feasibility of country-wide implementation of RDTs for malaria, including expansion at the community level. The rapid scale-up of RDT implementation at all levels of the healthcare system in Senegal—from 90,000 RDTs in 2007, the first year of the programme, to 500,000 in 2009—generated a dramatic drop in reported malaria cases. ACT consumption decreased, from 1.6 million courses in 2006 to 174,000 in 2009. Taking 2006 as a baseline, 3.2 million courses of ACTs were “saved” from 2007 through 2009. Assuming an average of US\$1 per ACT treatment course, this translates to a savings of \$3.2 million.⁹

3. A Malaria Diagnosis Package: RDTs and Supporting Activities

The ex-manufacturer price of an RDT is approximately half of the cost of an adult course of ACTs and more than a child’s course. Unlike the cost of treatment, the cost of testing with an RDT is the same for children and adults. As with ACTs, subsidies will be needed to place RDTs in the affordable range for most endemic countries and, certainly, to make them relatively inexpensive compared with ACTs. RDTs themselves must be financed, but that alone will not be enough.

Items to Be Financed and Their Costs

The cost of expanding to universal access to parasitological confirmation of malaria over a relatively short period, as implied by the WHO recommendation and supported by the consultation, includes more than just the procurement costs of RDTs.

Activities to ensure the effective use of RDTs include, at base, training people to use them, periodic monitoring and retraining and public education to enhance demand. A lesson from AMFm is that supporting activities should be included in cost estimates from the outset. The consultation did not

⁹ See Appendix 1, presentation of Dr. Moussa Thior

produce a detailed list¹⁰, but the activities and goods that should be considered as part of a package include:

- Distribution costs for RDTs, including transport and supply management,
- Quality testing of RDTs,
- Training, monitoring and supervising providers at all levels who will be expected to use RDTs,
- Incorporating RDTs and related supplies into systems for procurement, supply chain management and the health information system
- Information campaigns to educate the public about RDTs and other causes of and treatments for fever, and
- Procurement of gloves, sharps and sharps disposal containers

To this RDT-specific list, medicines and supplies for non-malaria fevers must be added.

RDTs can be used by both experienced healthcare workers at different levels and by people with no healthcare training, but RDT-specific training is needed for all people expected to use them. Without training, mistakes in performing the tests, reading results and adhering to test results are more likely to occur.

A realistic estimate of the total resource envelope of a global RDT package can only be derived taking into account: 1) the items included in a complete package and 2) the likely expansion paths to achieve universal coverage. The trajectory of costs over the near term (2-5 years) and the medium term (6-10 years) should be calculated. Some factors to be considered, in addition to the rate and type of expansion of RDT use, include the reduction in the need for ACTs, possible progress towards malaria elimination, and needs for management of non-malaria febrile illnesses.

4. Expanding Access to RDTs toward Universal Access to Parasitological Confirmation of Malaria

Expanding toward universal access to RDTs cannot occur simultaneously everywhere. It must be phased in. The challenge is to find the most advantageous expansion pathways to both provide services to people and generate information that can be used for further expansion. Two lines of expansion were discussed in some detail at the consultation, with the understanding that expanding in one direction would not entirely preclude some expansion in another, but was a matter of emphasis. The discussions centered around 1) phasing-in RDTs *initially* in low transmission vs. high transmission areas, and 2) introducing RDTs *initially* through public health facilities, followed by formal private sector healthcare providers, and then expanding to the informal private sector. The consultation did not address conditions in each country, but clearly the needs of each national malaria control programme and country policy should be considered in the expansion of access to RDTs.

¹⁰ Introducing RDTs into national programs is discussed in *Malaria Rapid Diagnostic Test Performance: Results of WHO product testing of malaria RDTs: Round 1 (2008)* (Annex 6 :Introducing RDT-Based Malaria Diagnosis Into National Programmes).

Whichever expansion path is adopted, actions should be taken to: 1) promote the value of RDTs and the need to manage appropriately all causes of potentially serious febrile illness; and 2) strengthen the supply chain for quality assured RDTs and medicines (ACTs and antibiotics) in both the public and private sectors.

High vs. low transmission environments

One line of argument contends that in the short run, it may be advantageous to expand access to RDTs first in low-transmission areas where the benefit “per RDT” should be higher than it would be in high-transmission areas. This is because a higher proportion of people will test negative and not require ACT treatment. A similar argument could be made for the low transmission season in intensely seasonal malaria settings, though such a strategy would risk causing confusion within any one setting.

The option of concentrating on low-transmission settings was rejected in favor of giving equal priority to all areas where ACT use is common, basing decisions about expansion paths on other factors.

The use of diagnostics for surveillance when countries are engaged in malaria elimination is a special case and not considered further in this discussion

Formal healthcare vs. informal private-sector settings¹¹

It should be easier to introduce or expand the effective use of RDTs in formal healthcare settings (i.e., where a patient interacts with a healthcare practitioner whose main purpose is to diagnose and treat patients) than it is in the informal private sector. The means to manage patients with negative RDT results should also be more available and easier to implement in formal settings, although training and monitoring are required to improve the adherence to test results and treatment by providers and consumers.

The private informal sector is more of a challenge, for obvious reasons. However, the need to improve the management of febrile illness cannot be ignored as the majority of the public in most African countries buys their malaria drugs in the informal private sector. Experience in Cambodia and Brazil point to the feasibility of RDT use in some informal private settings in combination with ACTs, but experience is as yet very limited in sub-Saharan Africa.

Intermediate between formal healthcare facilities and informal shops are registered pharmacies, where a pharmacist with some disease training may diagnose and treat, but whose business depends on selling commodities.

¹¹ This report uses “formal” to refer to all government-provided services (e.g., hospitals, clinics, health posts, community health workers) plus private-sector health care that involves a practitioner or adviser registered with the government. “Informal” settings are all other private sector points of antimalarial drug sale, largely shops that sell only drugs (without a pharmacist) or drugs plus other items. The distinction between public- and private-sector is also important, especially in matters of finance.

A strategy of quickly increasing access in formal healthcare settings (public and private), and a slower pace of expansion in informal settings seemed most feasible and acceptable to the consultation.

5. Financial Architecture

In the current context, financial architecture refers to the *mechanisms and routes* of resource flows to fund the RDT package. Unlike the global subsidy for ACTs, for which a single system (AMFm) was deemed optimal to operate globally,¹² the optimum architecture of financing an expansion of RDTs from the status quo to universal access is unknown. It is not clear if an expansion (of access to RDTs and supporting interventions) is best done through multiple financial support systems, or if a single global pricing and financing mechanism would be required. The consultation brought out the modesty of collective knowledge on this point.

Subsidies will be needed for the RDT commodities themselves, and possibly for the medicines to treat the non-malaria fevers. As with ACTs, supporting activities can be funded in a more standard manner, through the type of grants and other assistance provided by the Global Fund, other multilateral and bilateral agencies or non-governmental organizations.

The AMFm mechanism was needed because access to quality ACTs through the private sector at affordable prices was considered essential. Where a subsidy for RDTs is needed only in the public sector, it can be accomplished relatively easily through existing (non-AMFm) channels. In the case of ACTs, AMFm is designed to allow market forces to do most of the work because co-paid ACTs would simply be substituting for other antimalarial medicines.

The financial architecture can, to a large extent, influence product flows as well as relative prices of RDTs in relation to ACTs and to some extent, to antibiotics. Various models may be considered, e.g., that central medical stores purchase all RDTs needed for the country and that registered private sector vendors could purchase them at subsidized prices (as currently happens in many countries for ACTs and other medicines).

6. Sources of Funding

Funding sources to support the expansion of RDT use were not discussed formally, but the topic arose several times. The consultation assumed a similar array of funding sources as for ACTs and other malaria control measures. A number of modeling and trial based evaluations have found RDTs to be cost-effective in both low and high transmission settings, taking into account the health outcomes of non-malaria febrile illnesses and assuming high compliance with RDT results.¹³ Despite uncertainties over the total amount of funding likely to be available for malaria control in the coming years, it was generally agreed that a persuasive case would be needed to support a comprehensive package of interventions to manage malaria and other febrile illnesses.

¹² Arrow KJ, Panosian CB and Gelband H, eds. *Saving Lives, Buying Time: Economics of Malaria Drugs in an Age of Resistance*. National Academy Press, 2004.

¹³ See Appendix 1, presentation of Dr. Yoel Lubell

The immediate effect of increasing the use of RDTs is that funding requirements for ACTs will be reduced, assuming that other factors remain the same and that people who test negative are not treated for malaria. Money intended for purchasing ACTs should be available for grants to support other interventions. This would apply not only to the Global Fund, but to other international funding sources, to national malaria control programs and possibly to other departments within ministries of health (especially those that purchase antibiotics). It was also recognized that using RDTs can produce public health benefits that are not usually captured in a cost analysis, but do have value. In the case of RDTs, to the extent that ACTs are used less, they reduce drug pressure which is the main determinant of antimalarial drug resistance.

The Global Fund is currently the main source of malaria RDT funding. From Round 4 to Round 9 the Global Fund has approved \$446 million for RDTs, 82 percent in Rounds 7 through 9; 82 percent of funded malaria grants in Round 9 included a malaria RDT component. The Global Fund is likely to be the source of most RDT funding over the years, certainly for public sector distribution. With the exception of a few countries, such as Cambodia, how much the Global Fund support for RDTs is destined for use at the community level and in the private sector is unclear at present. Countries rarely ask the Global Fund to finance technical support, though they could. Countries should be encouraged to ask for such assistance to implement an RDT package.

RECOMMENDATIONS

The recommendations are intended to guide the field from current practice for suspected malaria, which is mainly presumptive treatment—that is, treatment without parasitological diagnosis—to universal access to diagnosis before treatment in as short a period as possible. Three interlocking categories—1) implementation, 2) operations research (including evaluation) and 3) policy analysis—capture the range of activities that will be needed, with activities to begin concurrently in each. The overwhelming sense of the consultation was that expanding access to RDTs would be good for patient management, good for malaria control and good for public health in the affected countries. This change is feasible and the questions that need to be answered are definable and researchable.

Specific recommendations endorsed by the consultation follow. How much or how little can be achieved, and how quickly, will depend on funding and expertise applied to the issue, and the priority it is accorded. The consultation did not discuss which organizations should be responsible either for coordinating, developing detailed plans for, or for carrying out the recommendations of the consultation.

1. IMPLEMENTATION

RDTs (and microscopy) are already established in some settings, so implementation does not open an entirely new chapter.

1. Public and formal private sector: plan for relatively quick deployment of RDTs in as many formal settings as possible. This includes strengthening information systems and taking steps to maximize provider compliance with test results.
2. Informal private sector: expansion of RDT use in the informal private sector, with a phased deployment transitioning from presumptive treatment to pre-treatment diagnosis with RDTs. Implementation of RDT use in the informal private sector is necessary to achieve successful implementation of parasite-based diagnosis and will be informed by further operations research.
3. Funding of non-malarial fever management, particularly involving funding of antibiotics and training in their appropriate use, will be essential to successful implementation of parasite-based diagnosis and should be considered for inclusion in proposals to the Global Fund.

2. OPERATIONS RESEARCH (INCLUDING EVALUATION)

Operations research involves “learning before we go” through pilots and experiments, and “learning as we go” through evaluation.

1. Pilot programs and operations research projects should be designed and executed to inform approaches for appropriate private sector use (both formal and informal settings) of RDTs and effective and appropriate IMCI-type responses to RDT- negative patients. It will be important to build into this deployment strategies to learn quickly how to ensure the best alignment among absolute and relative prices and incentives for optimal use of RDTs, ACTs and other drugs and supplies needed to treat non-malaria fevers.

2. A menu of options should be developed for pilot studies and experiments to assess determinants of use of diagnostics and treatment for managing fever. A plan for choosing among these should be devised, with the aim of creating a portfolio of projects of maximum value for future program design. Pilot studies of financing comprehensive interventions for the management of fever (including decision charts, RDTs, antibiotics, ACTs, antipyretics and all supporting activities), in order to better define the financial requirements, should be included among the options.

3. POLICY ANALYSIS

This analysis and research is focused on questions of direct relevance to eventual implementation of RDTs on a large scale.

1. Analysis of the options for the financial architecture to support large-scale implementation of RDTs and supporting interventions at various levels and in all sectors. Specific analyses include:
 - i. Relative pricing structure for RDTs, ACTs and treatments for non-malaria fevers
 - ii. Analysis of plausible incentive structures and their cost-effectiveness
 - iii. Whether RDTs should be subsidized at the factory gate, as ACTs will be under AMFm, or closer to the point of use
 - iv. The possible effects of public subsidies on private sector prices
2. Research to better understand the epidemiology, burden of disease and approaches to management of non-malaria febrile illnesses (NMFIs) in malarious areas. Specific analyses include:
 - i. The likely effects of introduction of new vaccinations (Hib, pneumococcal) on the detection and management of malaria and non-malaria fevers
3. Identification of major causes of non-malarial febrile illness, and evaluation and market analysis of the usefulness of developing specific RDTs for these and/or for markers of disease severity, to stimulate more investments in the development of such tests. The market analysis should explicitly address how the desirability and feasibility of potential tests are affected by their sensitivity and specificity.
4. Second generation cost-effectiveness analysis of RDT use in different environments, paying particular attention to:
 - i. implications of non-financial (i.e., system capacity) costs on transition to universal access to parasitological confirmation of malaria diagnosis ;
 - ii. the full range of options for the management of RDT negative patients, including assessment of the potential role of markers of disease severity
 - iii. specific requirements for countries with greater prevalence of *P. vivax* , particularly in South and Southeast Asia; and
 - iv. pricing and other instruments that can influence appropriate use

5. Strategies for using RDTs and other diagnostic approaches (e.g., PCR and serological tests) in surveillance and response in low-transmission areas and for use in malaria elimination programmes. This recommendation could be referred to the groups involved in malaria elimination/eradication.

Final List of Participants

Professor Dean Jamison (University of Washington, Seattle) **Chair**
 Professor David Schellenberg (ACT Consortium, LSHTM) **Co-Chair**
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Ms. Patricia Atkinson (Bill & Melinda Gates Foundation, Seattle)
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