

## Viewpoint

## WHO, the Global Fund, and medical malpractice in malaria treatment

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In 1998, WHO launched a new, high profile campaign to Roll Back Malaria, with the stated goal to halve malaria deaths worldwide by 2010.<sup>1</sup> Achieving that goal requires preventive interventions (eg, insecticide-treated bednets, household insecticide spraying), but the main difference between life and death for malaria patients hinges on appropriate treatments. Simply, each malaria case must be promptly and accurately diagnosed, and treated with an effective malaria drug.

However, with nearly half the time to the 2010 deadline now past, progress on effective treatment is so inadequate that Roll Back Malaria is failing to reach its targets. Far from being on track to halve malaria deaths, WHO acknowledges that “RBM [Roll Back Malaria] is acting against a background of increasing malaria burden”.<sup>2</sup>

Of the several reasons that could cause malaria deaths to increase, one stands out most prominently: drug resistance in the deadly species of malaria, *Plasmodium falciparum*. WHO now writes of “global malaria control . . . being threatened on an unprecedented scale” by continued use of outdated drugs such as chloroquine, which is ineffective in most parts of Africa, and sulfadoxine-pyrimethamine, which is becoming so.<sup>3</sup> For example, in East Africa, surveillance and clinical trial data show that up to 64% of patients given chloroquine and 45% given sulfadoxine-pyrimethamine will fail treatment, and those figures are climbing.<sup>4,5</sup>

When treatment failure becomes so frequent, malaria deaths rise greatly, especially in children. In West Africa (Senegal), results of a 12-year community-based study<sup>6</sup> showed that the onset of chloroquine resistance at least

doubled childhood malaria death risk, and in some sites, increased it up to 11-fold in the youngest children. In East and southern Africa, the proportion of children dying from malaria doubled as chloroquine and later sulfadoxine-pyrimethamine resistance took hold from the 1980s to the 1990s, even as deaths from other causes declined.<sup>7</sup> Elsewhere in Africa, chloroquine resistance increased the proportion of admissions to hospital and deaths from malaria by two-fold to four-fold.<sup>8</sup>

These links between drug resistance, treatment failure, and finally death are not controversial. WHO concurs that chloroquine resistance is a “very likely” reason why childhood malaria deaths in Africa are increasing, and that chloroquine “has become useless in most malaria-endemic areas”.<sup>2,9</sup> WHO further agrees that resistance to sulfadoxine-pyrimethamine, which is often the replacement for chloroquine, “is also widespread and its use [too] will soon have to be discontinued”.<sup>9</sup> That is borne out in Kenya, where a decision 5 years ago (1998) to switch from chloroquine to sulfadoxine-pyrimethamine treatment is already faltering because sulfadoxine-pyrimethamine treatment failure quickly reached dangerous levels.<sup>4,10</sup>

The demise of chloroquine and sulfadoxine-pyrimethamine leave artemisinin-class combination therapies (ACT) as the best treatment option. The main reason for treating malaria with combination therapy is the same as for AIDS, tuberculosis, and leprosy, in which it is standard practice: patients given two (or more) robust and highly effective drugs are less likely to encounter drug resistance and fail treatment—which brings both clinical and public-health benefits. These benefits have now been shown in a large meta-analysis<sup>11</sup> of nearly 6000 patients, which shows that combining existing malaria drugs with an artemisinin both reduces patients’ risk of treatment failure (by 75%), while lessening the pool of infectious parasites (gametocytes) that transmit the disease to others. In studies done on nearly every continent,<sup>12–19</sup> ACT successfully treats 90% or more of patients. That level of success can probably be maintained for a very long time, since artemisinins have been used as Chinese traditional medicines for 2000 years, with no observed resistance.<sup>20,21</sup>

The superiority of ACT is now so established that of the five treatments WHO recommends for drug resistant *P falciparum* malaria, four are ACTs (the other is a “short-term solution” for countries that cannot use ACT immediately).<sup>3</sup> ACT is now the preferred policy for WHO and the Roll Back Malaria campaign as a whole:

“Recently WHO has formulated policy that elevates combination drug therapy to preferred first therapy for all malaria infections in areas where *P falciparum* is the predominant infecting species of malaria. Combination therapy (CT) with formulations containing an artemisinin compound (ACT) is the policy standard . . .”<sup>22</sup>

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	Parasitological failure (%)		Clinical failure (%)	
	Chloroquine	Sulfadoxine-pyrimethamine	Chloroquine	Sulfadoxine-pyrimethamine
Ethiopia	88 (82–94)	..	79 (51–93)	..
Kenya	71*	23 (13–38)	64 (32–87)	8 (0–52)
Senegal	42 (24–59)	0	13 (10–16)	..
Uganda	41 (10–96)	17 (0–73)	28 (9–89)	10 (0–25)

Data are median (range). See reference 24 for original data sources and methods, which vary. \*Range not available.

**Parasitological and clinical failure rates for *P falciparum* malaria in some African countries, 1996–2002**

However, WHO violates its own policy standard regularly. Most African countries reluctantly cling to chloroquine, sulfadoxine-pyrimethamine, or the insignificantly better combination of chloroquine and sulfadoxine-pyrimethamine, because ACT is ten times more expensive and, therefore, unaffordable to them.<sup>2,23</sup> When those same countries seek financial aid from the Global Fund for AIDS, Tuberculosis, and Malaria (GFATM) to purchase ACT, they are forcefully pressured out of it by governments such as the USA, whose aid officials say that ACT is too expensive and “not ready for prime time”.<sup>24</sup> WHO acquiesces to this pressure to cut costs, and despite a policy that names ACT as the gold standard of treatment, WHO signs its approval when GFATM funds cheap but ineffective chloroquine or sulfadoxine-pyrimethamine to treat *P falciparum* malaria.

This series of errors is illustrated by several projects currently supported by GFATM. Although GFATM claims it supports only projects that use “proven and effective interventions” and “interventions that work”, in Africa in 2003, it allocated more funds to purchasing of chloroquine and sulfadoxine-pyrimethamine than to ACT.<sup>25</sup> In January, 2003 (funding round 2), Africa was allocated US\$16.1 million for ACT, \$27.7 million for chloroquine, and \$10.8 million for sulfadoxine-pyrimethamine (round 2). The corresponding amounts for October, 2003 (funding round 3), were \$2.2 million, \$2.4 million, and \$0.5 million.<sup>26</sup>

These budgetary differences are not insignificant. The unit price differences between chloroquine (\$0.13), sulfadoxine-pyrimethamine (\$0.14), and ACT (\$1.00–3.00) mean that patients given chloroquine and sulfadoxine-pyrimethamine will outnumber those given ACT by at least ten to one.<sup>2</sup> Since GFATM plans this budget for countries where chloroquine and sulfadoxine-pyrimethamine resistance in *P falciparum* is well advanced (table), many patients with malaria will fail treatment—and sometimes die.<sup>27</sup>

Senegal has switched in 2003 from chloroquine to combination therapy for malaria treatment, but until this change GFATM agreed to continue chloroquine treatment, despite the known increase in child mortality (two-fold to 11-fold) that it causes.<sup>6</sup> In Kenya, GFATM rejected the government’s request to finance ACT, but later agreed to finance sulfadoxine-pyrimethamine, despite evidence that sulfadoxine-pyrimethamine treatment failure exceeds 50% in some districts (eg, Kibwezi).<sup>4,28</sup> In Ethiopia and Uganda, GFATM agreed to finance the combination treatment of chloroquine and sulfadoxine-pyrimethamine—a pairing that WHO describes as “not recommended”—while falsely insisting that its action is “consistent with current treatment guidelines of WHO”.<sup>29,30</sup>

These are very obvious errors of scientific and medical judgment; and although WHO might be expected to spearhead a corrective intervention, the evidence suggests that it instead exacerbated the errors. In Kenya, Ethiopia, and Uganda, WHO’s country representatives reviewed the

funding proposals in which inappropriate drugs were sought—and signed their approval. Those signatures follow a declaration that WHO “has participated throughout the . . . process” of developing the proposal to GFATM, and that it “reviewed the final proposal and [is] happy to support it”.<sup>31–33</sup>

These decisions are indefensible. For WHO and GFATM to provide chloroquine and sulfadoxine-pyrimethamine treatments in the countries we cite as examples at least wastes precious international aid money, and at most, kills patients who have malaria. If one takes the measured increase in childhood malaria mortality that follows *P falciparum* drug resistance (two-fold to 11-fold) and extrapolates it to populations in which GFATM is funding chloroquine or sulfadoxine-pyrimethamine despite resistance (more than 100 million people in the four countries we name), then at least tens of thousands of children die every year as a direct result. Those patients who survive will often become much sicker and require retreatment, at some further expense of time and money. We do not exaggerate to state that, based on the outcomes, there is no ethical or legal difference that separates them from conduct otherwise condemned as medical malpractice (compare the case in which a doctor or pharmacist who, like these institutions, knowingly furnished treatments that failed perhaps 80% of the time, while withholding the alternatives as “too expensive”).

These problems might be discounted as aberrations, but for the evidence that they recur systematically. In addition to the four countries we name here, a WHO memorandum names five others where GFATM funded chloroquine and where, less than 2 years later, governments must already re-evaluate and move toward ACT.<sup>3</sup> Accordingly, there is often a disconnection between official policy, which favours ACT, and the reality created by WHO and GFATM, who routinely approve and finance inferior drugs. It is essential to understand why this has happened to repair the situation.

To begin with, WHO has failed to define the medical norms for malaria treatment. Although there are carefully crafted WHO model treatment guidelines for HIV/AIDS and tuberculosis (the latter are in their third edition), to date for malaria, recommendations are found only in scattered WHO reports, rather than in official, comprehensive WHO malaria treatment guidelines.<sup>34,35</sup> The lack of any such norms handicaps poor countries, who naturally hesitate to change their treatment policies and request funding for ACT when that displeases the powerful donor governments who warn them—usually in private—that ACT is too expensive.<sup>2,24</sup> The same lack of norms also causes WHO to miss opportunities to intervene and recommend ACT. That is probably why WHO country representatives, poorly informed by Geneva, gave approval to GFATM applications for ineffective drugs that violate WHO policy.

In theory, the GFATM’s Technical Review Panel should block proposals like this, but as the evidence shows, it often approves ineffective drugs for funding. For example, the panel approved Uganda’s GFATM proposal with praise for “strategies based on best practices”, when in fact the malaria treatment proposed (chloroquine and sulfadoxine-pyrimethamine) is very plainly “not recommended” by WHO’s experts.<sup>29,36</sup> Such decisions seem puzzling, until one realises that the Technical Review Panel is not actually a “technical” review panel. The four malaria reviewers on the Technical Review Panel are selected by a points-based system, in which “technical knowledge . . . and ability to judge whether proposals are . . . scientifically sound” count for only 22% of that decision.<sup>37</sup> By contrast, “familiarity

with international processes and . . . partnerships” and “familiarity with multisectoral approaches” count for twice as much (44%), even though it is hard to know what those criteria really mean.

The evidence therefore shows that the current practices of WHO and GFATM are not adequate to safeguard the best interests of patients with malaria. We offer several recommendations for improvement.

Above all, WHO should publish malaria treatment guidelines that countries can depend on as authoritative norms. Those guidelines should consolidate and broaden the knowledge in various WHO reports, in a single, systematic presentation that is reviewed every year, and that addresses clinical algorithms, diagnostic methods, malaria case definitions, standard treatment regimens, definitions of cure, and so on.<sup>29,38</sup> WHO can do this for malaria by copying its own actions on HIV/AIDS: first, WHO convened treatment specialists to debate and write the AIDS treatment guidelines, and second, it set the campaign goal of treating 3 million AIDS patients in developing countries by 2005.<sup>34,39</sup> Importantly, that is the opposite sequence to Roll Back Malaria, which, in 2003 still does not have the treatment guidelines to reach the 1998 pledge of halving malaria mortality in this decade.

Next, once they exist, WHO treatment guidelines should be used to judge each proposal for malaria treatment, so that only effective drugs receive GFATM funding. Although this recommendation seems obvious, neither WHO nor GFATM believe it is within their mandate. Both agencies emphasise their roles as mere advisers or funders, while emphasising that selection of malaria treatments is properly done by countries—who, in our experience, are often pressurised by aid donors.<sup>28</sup> The fact that neither agency believes it has the obligation to intervene and ensure that lives and money are not wasted is proof that a new entity is necessary.

We recommend that a new review committee be created, which is composed of independent malaria treatment experts, convened by WHO, and tasked by GFATM to review each proposal seeking finance for malaria drugs. This Green Light Committee (so called because it controls the green light that lets a drug be financed and supplied) has an exact precedent in tuberculosis. In 2000, outside experts created a Green Light Committee, with WHO support, to review countries' proposals to fund drugs for multidrug-resistant tuberculosis.<sup>40</sup> Later, this Green Light Committee and the GFATM integrated their procedures, and today, countries wanting drugs for multidrug-resistant tuberculosis submit applications to both the Green Light Committee and GFATM in a single envelope, so that the technical and financial decisions affecting treatment happen together. The need for a similar malaria Green Light Committee is undeniable, since multidrug resistance in malaria is much more common than in tuberculosis.

Once the WHO treatment guidelines exist and the malaria Green Light Committee is operational, its first task should be to retrospectively review all GFATM-funded countries in view of the guidelines. To let the full (usually 5 year) duration of financing run without updating the standard of care, where justified by the evidence, would be unethical. This retrospective review will be easiest for countries where GFATM funding has been approved but not yet disbursed (eg, Uganda), although it should also be done for countries where disbursement is underway. If a retrospective review finds that a country cannot use chloroquine or sulfadoxine-pyrimethamine safely, and instead requires costlier ACT, then GFATM should entertain a supplemental funding proposal.

Finally, to ensure equally wrong-headed decisions do not affect any intervention or disease again, GFATM should return to its original principles—and make the technical review panel a truly technical entity. Panelists should be selected on the basis of 100% technical and scientific knowledge, not 22%, as is true now.

None of these recommendations imply new implementation challenges for WHO and GFATM. Most have clear precedents in the HIV/AIDS or tuberculosis field, which means that equal treatment for malaria must be possible.

The scientific community must now watch future developments closely, because numerous earlier warnings have been ignored. In 1999, several authors wrote in *The Lancet* to warn of an impending “malaria disaster”, which is now apparent in rising malaria deaths.<sup>20</sup> In 2000, one of the authors (AA) reported that aid agencies were funding ineffective malaria drugs, but the agencies denied that accusation and forcefully opposed a proposal to link technical review to funding decisions.<sup>41,42</sup> Similarly, our recommendation to create a malaria Green Light Committee has not been answered, either affirmatively or negatively, by WHO and GFATM in several months. Rather, WHO has reiterated its earlier policy statements favouring ACT—the same statements that were not heeded through these many errors—and established a new unit responsible for addressing tuberculosis and HIV drug resistance—but not malaria.<sup>3,43</sup>

The weight of evidence leads us to conclude that a crisis exists, characterised by institutional inadequacies that result in good policies for malaria control not being fulfilled. Although the inadequacies are easily rectified, a risk exists that if WHO and GFATM do not act with celerity, the reputations of both will be tainted such that rich governments lose confidence and cease funding them. That would deal a tragic blow not only to malaria treatment, but also to the spectrum of efforts against malaria, tuberculosis, and AIDS, which require and deserve billions of dollars wisely spent. The evidence now proves that money is often unwisely spent—very dangerous evidence indeed—and no delay is tolerable in fixing that.

#### Conflict of interest statement

A Attaran advises Novartis on its not-for-profit partnership with WHO for the joint distribution of ACT (Coartem) in developing countries. K Barnes is a recipient of grants from WHO and GFATM for malaria research, monitoring, and evaluation of ACT in South Africa. C Curtis is the recipient of research grants from WHO in which ACT is used. U d'Alessandro advises GlaxoSmithKline on development and safety of malaria drugs and vaccines. M Galinski is president of Malaria Foundation International, which has received funding for advocacy of Roll Back Malaria. G Kokwaro advises the not-for-profit Medicines for Malaria Venture on development of new drugs, including ACT. S Looareesuwan is coordinator of WHO's SEAMEO TROPED Network, and director for Thailand. T Mutabingwa and W Watkins are Chairman and member of the secretariat, respectively, for the East African Network for Monitoring Antimalarial Treatment, which has effectively supported studies using ACT. W Watkins advises GlaxoSmithKline on development of new malaria drugs, including ACT. Most of the authors have participated in WHO-organised expert consultations or conferences at some time. All authors write in their personal capacity and do not represent the views of any institution or company.

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