Private sector role remains elusive

Provision Ending a free market treatment supply initiative is not universally supported, writes *Andrew Jack*

The US government may be among the strongest defenders of the free market but it has found itself in unusual company in recent months as part of an escalating campaign to undermine programmes supporting private sector involvement in the distribution of malaria treatments.

Late last year, a curious coalition including both the US president's Malaria Initiative and Oxfam, the UK-based development charity, claimed victory with the decision by the Global Fund to Fight Aids, TB and Malaria to wind down its unit overseeing the Affordable Medicines Facility – malaria (AMFm).

The idea behind the AMFm was pragmatic. Even if the best long-term approach to distributing malaria treatments is via the public health system with no direct charge to patients, failures in supply and the long distance to clinics mean many buy drugs from private vendors. By subsidising the high cost of artemisinin in combinating therapies (ACTs), the scheme would make the best drugs available more cheaply than substandard or inappropriate alternatives such as chloroquine.

"Providing drugs should not be restricted solely to the public sector because there will never be enough money," says Prof Barry Bloom at Harvard School of Public Health, who conducted an evaluation of the AMFm and regrets its axing. "Working together with the private sector strikes me as an experiment worth pursuing and not killing."

Since 2009, the programme had subsidised nearly 320m artemisinin-combination treatments in Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania and Uganda, at a cost of more than $460m underwritten by donors including those governments that channelled support through the Global Fund.

To its critics, the AMFm risked undermining public sector provision of healthcare, imposing costs that reduced access for the poorest, draining off supplies of ACTs from public clinics and risking greater abuse of a valuable antimalarial drug by handing its use to non-medically trained people. "Just 40 months away from the Millennium Development Goal deadline . . . progress is being threatened by the support of some donors for the Affordable Medicines Facility–malaria," wrote Oxfam in a report last summer that spelled out its doubts.

Painful reality: a Cambodian boy has his finger pricked for a blood sample during screening Getty

More practically, there were concerns that the subsidy would prove ineffective, with intermediaries profiting from donor subsidies while adding mark-ups to make the final price of ACTs to patients higher and less affordable than less desirable alternative treatments.

Some observers suggest that Oxfam took an ideological stance against involving the private sector, while US opposition – in turn driving ambivalence towards the AMFm by the World Health Organisation, a beneficiary of its support – reflected a reluctance by Washington-based "Beltway bandits" to lose a share of funding and control.

Others retort that there were just as strong beliefs, economic lobbies and individual careers that benefited from the continuation of the AMFm and that the programme's evaluation was restricted in a way that prevented full assessment of its effectiveness. Prof Bloom's evaluation concluded that the AMFm pilot was successful in increasing availability, decreasing retail prices and increasing market share of quality-assured ACTs. It found in five of eight pilot countries, that ACTs were "dramatically" more available and prices for patients were reduced. It did not assess the impact on morbidity and mortality.

The idea of working with the private sector is not yet dead. While the global fund will no longer support the AMFm centrally, it will still permit subsidies by individual recipient countries that choose to use them. Meanwhile, there is little doubt that in the absence of easily accessible and affordable healthcare, the private sector will continue to play a significant role in tackling malaria. The Center for Health Market Innovations, which promotes ways of improving privately delivered health care, is among groups trying to research the role of "informal providers" in more detail.

Hans Ritvield from Novartis, who coordinates access programmes for Coartem, the first and most widely used ACT, says his company is making a loss on sales to the public sector at $1 per treatment. It plans to expand a programme of offering the drug at a range of higher prices between $4 and $12 for Africa's emerging middle class to make the product self sustaining.

More generally, critics and supporters alike agree on one thing. The advent of low-cost, rapid diagnostic tests makes it essential that ACTs are only supplied to those with confirmed cases of malaria. Otherwise, drugs will be misused, supplies wasted and non-malaria illnesses inadequately treated.

The next wave of pilot programmes – including some under way from Unitaid, the Geneva-based donor – will focus on incentives for private vendors to sell medicines and diagnostics responsibly. "We need to look at different options for rapid diagnostic tests," says Rob Newman, head of the WHO's global malaria programme. "It is a false dichotomy to talk about being 100 per cent for or against the private sector. Countries need to decide how important it is, and we all need to work to generate the evidence."

The AMFm may be dead but the search for successors is already under way.

Falling impact shifts focus to politics

Elimination

The need for fresh approaches remains, writes *Andrew Jack*

Richard Feachem brandishes a sheet of paper showing four maps of the world that shift from almost universally bright red in 1900 to green with a more modest central belt of intermittent red in 2025. The colours portray malaria's declining impact.

At the start of the last century, the disease was transmitted in countries from Chile to Sweden and affected almost every nation. Today, it remains present in 99 and, within a decade, he believes the "malaria map" could shrink significantly further.

"Five years ago, talk of elimination was not acceptable," says Sir Richard, head of the global health group of the University of California San Francisco. "Today, it's mainstream."

While global eradication of malaria may be impossible, some specialists argue that its elimination from many more countries is feasible and control at a manageable level is possible in others, provided that resources are sustained and allocated.

Since 2008, Armenia, Morocco, Turkmenistan and the United Arab Emirates have joined a list totalling 111 countries that are malaria-free. A further 34 he classifies as malaria-eliminating, with considerable scope to remove the burden of the disease as soon as 2015.

Progress is not easy. Sir Richard's team estimates that there have been 75 resurgences globally since 1930, as political attention and funding shifted elsewhere.

Today, he worries about the trade-off as the Global Fund to Fight Aids, TB and Malaria focuses on high-incidence countries at the expense of lower incidence ones with greatest potential for elimination. There is also the need for new tools and approaches, as the disease shifts from *Plasmodium falciparum* in children and pregnant women to *Plasmodium vivax* affecting adult males – often migrant groups.

While some parts of the hot and wet tropical areas of Africa present a rate of transmission that

> 'Five years ago, talk of elimination was not acceptable. Today, it is mainstream'

may prove too difficult to eliminate with current technology, he argues that climatic conditions are less of a brake elsewhere.

"Elimination requires a lot of spending, for surveillance and a much better ability to tackle cases and outbreaks," cautions Sylvia Meek, technical director of the Malaria Consortium, a British-based charity.

"It needs much more investment than most countries are willing to provide. The difficulty is how to maintain political commitment when malaria is no longer seen as a problem."

Vaccines Test setbacks demonstrate formidable nature of the adversary

Disappointing results from clinical trials of the leading candidate among antimalarial vaccines have demonstrated once again just how formidable an adversary is the malaria parasite, **writes Charles Batchelor**.

A Phase 3 trial among more than 15,000 six-12-week-olds at 11 sites across seven African countries of the RTS,S vaccine showed lower efficacy than an earlier Phase 2 trial with children aged five-17 months. RTS,S, which targets the parasite in the human liver, is being developed by Glaxo SmithKline in a public-private partnership with the Path Malaria Vaccine Initiative

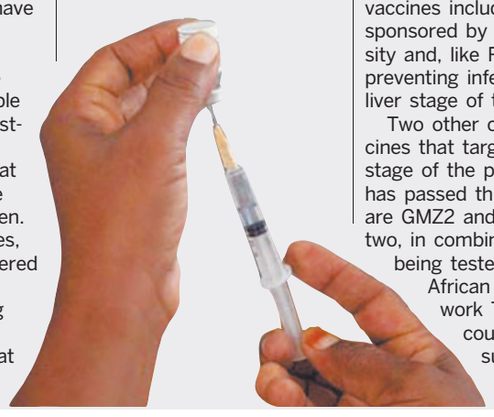
The latest trial showed efficacy rates of 31 per cent against clinical malaria and 37 per cent against severe malaria (involving serious organ failure). This compared with rates of 56 per cent and 47 per cent respectively among the older infants.

"This was a bit of a surprise," said Joe Cohen, adviser to the GSK Malaria Vaccine Project and co-inventor of the vaccine. "We can speculate on the reasons [for lower efficacy]. The infants have more immature immune systems than older children. The vaccine was administered at the same time as routine vaccines for tetanus and polio so there may have been some interference between them."

The latest results have come from a larger sample than the Phase 2 field testing trial among the older infants. "The lesson is that small trials don't give the full picture," said Dr Cohen.

Despite these difficulties, analysis of the data gathered from the Phase 3 trial of RTS,S alone is continuing with researchers drawing comfort from the fact that the side effects appeared to be no different to those experienced after taking the standard vaccines against childhood illness.

"There are currently no licensed malaria vaccines," says Vasee Moorthy, technical officer at the World Health Organisation (WHO). "Clinical testing of RTS,S is at least five to 10 years ahead of other candidate vaccines. WHO will make evidenced-based policy recommendations on RTS,S in 2015 based on the full results of the Phase 3 trial, including site-specific efficacy and the booster dose data."



Three of the other malaria vaccine projects are at the Phase 2 stage while there are also promising approaches earlier in development, according to Dr Moorthy. The three Phase 2 vaccines include ME-TRAP, sponsored by Oxford university and, like RTS,S, aimed at preventing infection at the liver stage of the pathogen.

Two other candidate vaccines that target the blood stage of the pathogen after it has passed through the liver, are GMZ2 and MSP3. These two, in combination, are being tested by the African Malaria Network Trust in four countries in sub-Saharan Africa.

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