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**Nigeria**  
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steps into his shoes

**Kenya**  
Hunt for malaria vaccine  
kicks up a storm!

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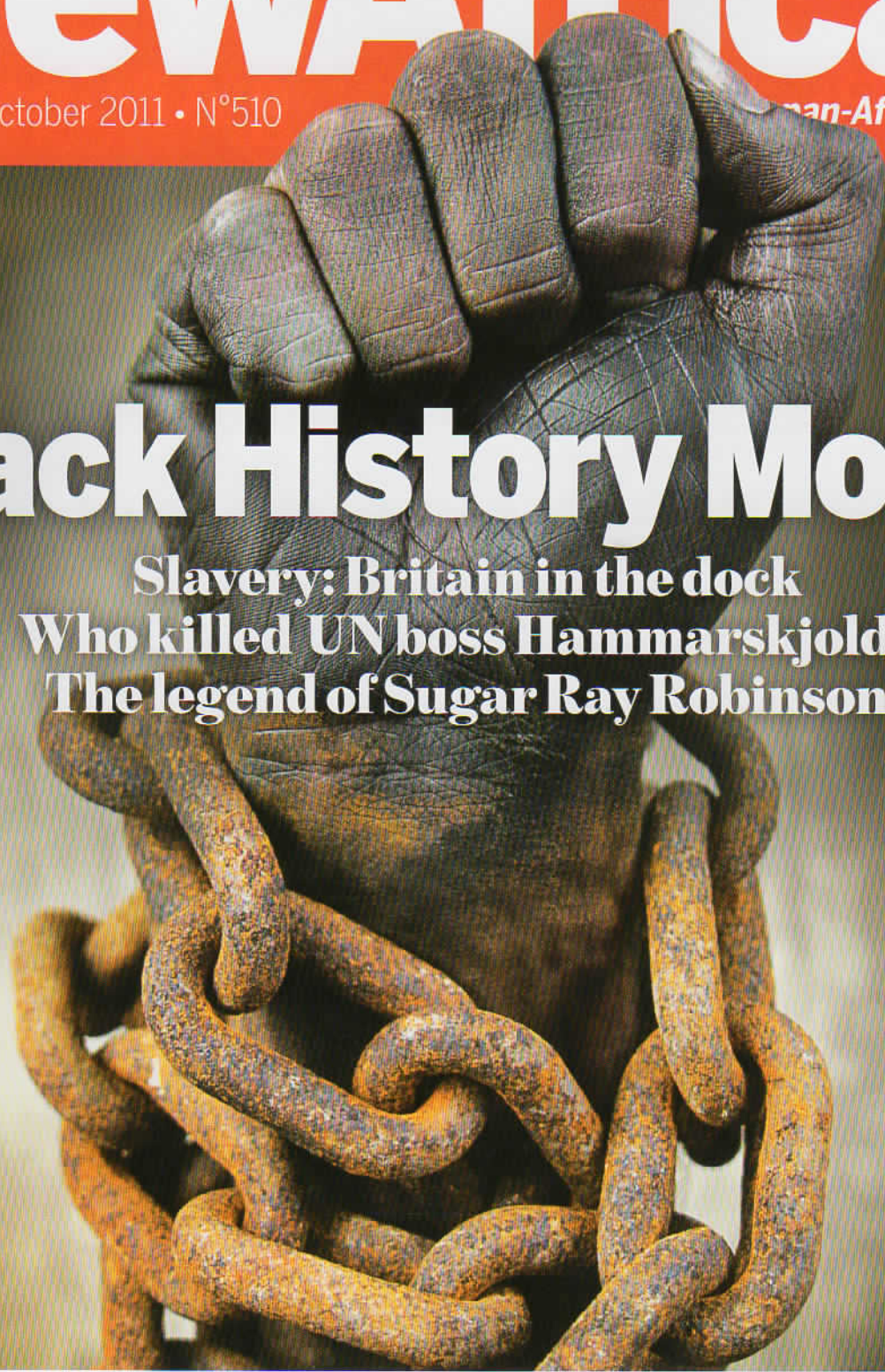
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Malaria kills more people in Africa than HIV-Aids. Therefore attempts to produce a vaccine against the disease should normally be received with joy. But no. The trial stages of a new vaccine, RTS,S, have raised a storm in Africa. Our Kenyan correspondent, **Wanjohi Kabukuru**, went to find out.

## Hunt for malaria vaccine raises a storm

**P**INGILIKANI IS A SMALL VILLAGE in Chonyi, deep in Kilifi County, in Kenya's coastal region. Just like its Swahili name suggests, it is a place of stunning rolling hills and steep undulating knolls.

It is at Pingilikani that Felicia Dzombo's daughter took part in history-making. Dzombo's daughter is among 15,460 infants and children drawn from seven African countries who have been enrolled in the testing of a potential malaria vaccine, called RTS,S. According to the World Health Organisation (WHO), over one million people die annually from malaria, the majority of them in 30 sub-Saharan African countries. Malaria is also the leading cause of death for children under five.

The annual economic cost of the disease currently stands at \$12bn. Over the years, Dzombo has seen several trials within her immediate family and community but she does not know what happens after the tests.

At the Pingilikani Health Dispensary, three heavyweight institutions – GlaxoSmithKline Biologicals (GSK Biologicals), PATH Malaria Vaccine Initiative (PATH-MVI), and the Kenya Medical Research Institute (KEMRI), the country's principal medical research agency, among other partners – have set up a malaria vaccine trial site.

Pingilikani is one of 11 such trial sites spread across seven African countries. The others are in Nanoro (Burkina Faso), Lam-

**Joe Cohen, GlaxoSmithKline's vice-president of Research and Development in charge of Emerging Diseases and HIV, and co-inventor of the potential new malaria vaccine, RTS,S**

barene (Gabon), Kintampo and Kumasi (Ghana), Lilongwe, (Malawi), Manhica (Mozambique), Bagamoyo and Korogwe (Tanzania) and Siaya, Kombewa and Kilifi (Kenya). The trial sites were strategically picked as they “represented diverse malaria transmission settings”. In the words of GSK Biologicals and PATH-MVI, the sites “were chosen for their track record of world class clinical research, strong community relations and commitment to meeting the highest international ethical, medical, clinical and regulatory standards.”

The malaria vaccine is a story that goes back to 1987, when GSK Biologicals (the Belgium-based vaccine division of the global pharmaceutical giant, GSK – headquartered in London) in collaboration with the US Army's Walter Reed Army Institute of Research (WRAIR) developed RTS,S as a vaccine candidate.

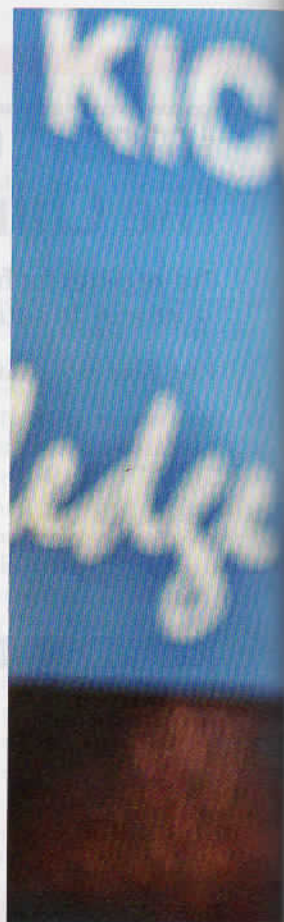
Dr Joe Cohen, who is currently GSK's vice president of Research and Development in charge of Emerging Diseases and HIV, is the co-inventor of RTS,S.

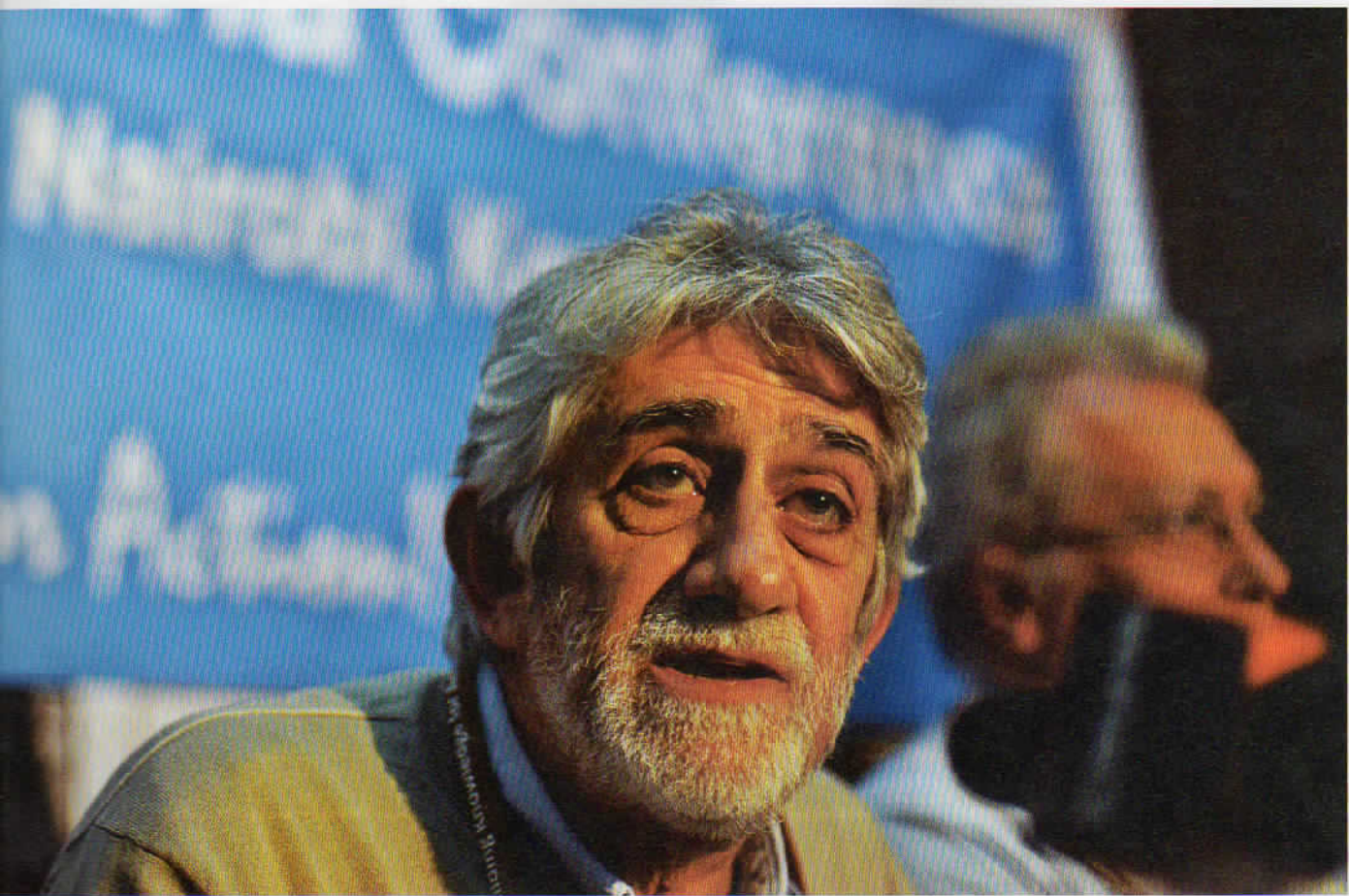
GSK Biologicals is the world's leading vaccine manufacturer. In 2008, it

distributed 1.1 billion doses of vaccines to 176 countries across the globe. The company reveals that RTS,S was first tested in healthy adults in Belgium and the USA. It took 11 years of research before the vaccine was developed. “Phase One trials”, however, were conducted among adults in The Gambia. In January 2001, with financial support from the Bill and Melinda Gates Foundation, GSK and the Programme for Appropriate Technology in Health-Malaria Vaccine Initiative (PATH-MVI) entered into a public-private partnership agreement to develop RTS,S for children in Africa.

Phase two trials commenced in 2002 in Mozambique with 2,000 children in the study. The WHO notes that there are several malaria vaccines being studied but they “are at least five to ten years behind RTS,S in their development.”

In 2008, 16,000 children and infants in Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique and Tanzania were earmarked for a massive vaccine trial. By January this year, according to PATH-MVI, the entire project had enrolled 15,460 infants (between 6-12 weeks) and





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## “The WHO notes there are several malaria vaccines being studied, but they ‘are at least five to ten years behind RTS,S’s development’.”

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children between 5-17 months old.

In November 2009, the RTS,S third phase trials were launched officially in Nairobi, Kenya.

Though the main stakeholders of RTS,S are GSK Biologicals and PATH-MVI, there are another 12 partners and 14 affiliate partners involved, mostly academic institutions.

It is important to note that the malaria vaccine research and development story involves a financial grail of immense proportions. “*Staying the Course? Malaria Research and Development in a Time of Economic Uncertainty*,” a report written by Policy Cures, and released in London in June this year, notes that the annual funding for malaria research and development increased from US\$121m in 1993 to US\$612m in 2009.

PATH-MVI has so far spent more than \$200m and GSK has spent \$300m on RTS,S

and is hoping to splurge another \$100m.

“The Gates Foundation has invested \$635m in malaria vaccine research and development since 1998,” Colleen McCabe of the Gates Foundation says.

At a donors’ meeting organised by the Global Alliance for Vaccines and Immunisation (GAVI) in London in mid-June this year, some \$4.3bn was pledged.

Though hailed by many medical researchers as a milestone in the fight against malaria, the RTS,S trials are now raising a storm within the scientific community over the effectiveness of the vaccine, its side-effects and the overall results, not to mention ethical concerns.

Indeed the RTS,S saga is not the first one for GSK. Over the past year, GSK has been in the news for the wrong reasons.

In October last year, a US Federal Court

in Boston fined the company \$750m for “selling substandard and tainted drugs”. In that same year, a US Senate Committee found that GSK had misrepresented medical data and attempted to intimidate independent scientists who had raised concerns over its diabetes drug, Avandia, which had been linked to heart attacks.

In mid-July 2011, Hong Kong’s Department of Health joined the long list of countries to order GSK to withdraw its bacterial antibiotic “Augmentin” after it was found to contain unhealthy levels of plasticisers.

### Medical concerns

Dr Mae-Wan Ho and Professor Joe Cummins of the London-based Institute of Science in Society (ISIS) first raised safety and ethical concerns over the RTS,S trials some two years ago.

The two scientists aver that “clinical trials of malaria vaccines on infants raise serious concerns over the safety of multiple vaccinations of the very young”. They contend that “effective implementation of existing measures have eradicated malaria from many countries without using vaccines.”

Prof Cummins adds: "We have criticised this vaccine based on the unacceptably high adverse impacts on infants and children during previous clinical trials and the low effectiveness of the vaccine."

The two scientists criticised GSK, the seven participating governments in Africa, and the Bill and Melinda Gates Foundation. "Misguided governments and mega-foundations such as the Bill and Melinda Gates Foundation," Ho and Cummins say, "are complicit in the promotion of these and other even more aggressive vaccines in the pipeline that are of dubious benefit to the countries whose infants are being recruited for clinical trials."

In a report published in 2009, Cummins and Ho commented: "The RTS,S vaccine is the [nearest] to clinical use. It gave satisfactory but short-lived protection of adults who had never been exposed to malaria. An efficacy of more than 70 per cent was reported in 250 male Gambian adults during the first two months of follow-up, but falling to zero per cent in the last 6 weeks.

"This vaccine has since been tried on children and infants. Studies with infants and children are considered important because they are the most sensitive group for malaria infection." The two scholars still assert that RTS,S has adverse effects even though it has been passed as "safe, well tolerated, and immunogenic in young infants".

GSK defends itself by saying "to stimulate an immune response to the malaria parasite, the RTS,S antigen fuses a critical circumsporozoite protein – the surface protein that helps the parasite to invade human liver cells – with a protein found in GSK Biologicals hepatitis B vaccine. The addition of GSK's proprietary Adjuvant Systems (AS) strengthens the immune response even further."

But other authorities have criticised the vaccine. They say the recent trials of malaria vaccines on infants in Africa raise serious concerns over safety, especially as vaccines are administered in large numbers to the young and very young, whose brains may not yet be properly formed.

From 1990 to the end of 2002, according to critics, the Vaccine Adverse Events Reporting System (VAERS), set up by the US Centers for Disease Control and Prevention, and the US Food and Drug Administration, received reports of 9,520 serious adverse events in children under one year



of age after one dose of hepatitis B vaccine, either alone or with other vaccines; among these were 627 deaths. In the same period, there were 38,600 serious adverse events and 753 deaths over all ages for the hepatitis B vaccine. Clearly, deaths among infants less than one year old after hepatitis B vaccination were much higher than those in adults and older children.

It is alleged that in the malaria vaccine

trials, serious adverse events of 10 to 20 per cent or more and even deaths in both trial and control groups are routinely dismissed as "unrelated to vaccination", and hence did not even enter into the VAERS statistics.

Dr Patricia Njuguna, the RTS,S principal investigator at KEMRI Kilifi, however, reckons that all laid-down guidelines have been followed to the letter and no adverse effects have been recorded in Kenya.



**A lab technician prepares blood samples from volunteers in the malaria vaccine trials at Bagamoyo in Tanzania; and below, a sample is taken from an infant**

## “Clinical trials of malaria vaccines on infants raise serious concerns over the safety of multiple vaccinations of the very young.”

“All our trials have been properly monitored. Everything is documented for peer review by independent groups,” Njuguna said. “We have an Independent Data Monitoring and Safety Board which reviews all data and advices accordingly.”

According to Njuguna: “As far as we know and from all the trials we have conducted so far, there are no untoward side effects. Even before we began Phase 2 of the

trials, the vaccine had gone through proper testing and it is safe. Up to this point, just in case new information comes out and RTS,S is deemed to be unsafe, the trials will be stopped, but so far nothing alarming has been spotted.”

GSK’s spokesperson, Didier Lapiere, who is also the vice president in charge of Malaria Clinical Development at GSK, refutes the allegations of unethical practice by the pharmaceutical giant and echoes Dr Njuguna’s sentiments.

“GSK-sponsored clinical trials, including those for RTS,S, are conducted to the same ethical standards irrespective of where they take place in the world,” Lapiere says. “The RTS,S studies are conducted according to the highest international standards for safety, ethics, and clinical practices.

“The trials are reviewed by national regulatory authorities, national and international ethical bodies, and local institutional and ethical review boards. In addition, an independent data monitoring committee (IDMC) oversees the trials, supported by local safety monitors (LSM) at each of the research centres. The main objectives of the IDMC and the LSM are to oversee the safety data and data collection processes.”

### Cummins speaks

*New African* managed to trace Cummins and asked him if it was ethical to involve infants in the RTS,S vaccine trials?

“By participating in the vaccine trials, the children may have been denied effective protection from insecticidal bed nets and treatment with effective drugs that are proven to reduce the impact of malaria. The ethics of the trials on children bears careful review,” Cummins said.

On whether he stands by what he and Dr Ho wrote two years ago and if there has been any change since ISIS published their report, Cummins said: “There does not appear to have been major efforts to improve those important considerations.

“There have been several scientific reports on the results of RTS,S clinical trials and most of those were authored by individuals who were employed by the vaccine manufacturer and many of those owned

stock in the company. It is inescapable that the studies cannot be presumed to be free of conflict of interest. There should have been conflict-of-interest-free adjudicators of the experiments.”

Defending the RTS,S trials, Dr Ally Olotu, a research clinician involved in the trials, who has also published extensively in international scientific journals on the trial findings, says that the vaccine passed all the rigorous procedures required before testing was allowed.

“There are mechanisms and protocols all dealing with safety to ensure that the highest safety standards of participants in any clinical trials are maintained. So far no safety concerns have been raised. It is pretty much clear that up until now the RTS,S vaccine is safe,” Olotu said.

The RTS,S latest findings were published in the July 2011 edition of the *Journal for Infectious Diseases* which was authored by Dr Njuguna, Dr Olotu and the RTS,S co-inventor, Dr Cohen, among others. Prof Cummins describes the report as “perplexing”, particularly the paragraph that notes: “Vaccination with RTS,S/AS01E reduces exposure to blood-stage parasites and, thus, reduces antimerozoite antigen antibody concentrations.” According to Cummins: “The vaccination of children in Africa leads to effects that are difficult to interpret.”

### Phase 3

Should the Phase 3 trials progress as expected, RTS,S will be submitted for regulatory review in 2012. The results of the over-two-decades’ research will be submitted to the European Medicines Agency (EMA) for assessment. After this, RTS,S will be open to review by the WHO and national drug regulatory agencies in Africa. WHO has already indicated that a policy recommendation for RTS,S is possible by 2015. This does not surprise Cummins who says “WHO prequalification may be accelerated following extensive efforts by GSK.”

Andrew Witty, GSK’s CEO, promises a fair price for the vaccines. “We have committed to price RTS,S responsibly and will seek to ensure that the price will not be a barrier to access. We will set a price which covers our costs and generates a small return of around 5% which will be reinvested in the development of the next generation malaria vaccines or for other products for diseases of the developing world.” ■ NA