

New malaria vaccine is safe and protective in children, scientists find

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A new vaccine to prevent the deadly malaria infection has shown promise to protect the most vulnerable patients — young children — against the disease, according to an international team of researchers led by the University of Maryland School of Medicine's Center for Vaccine Development (CVD) and the Malaria Research and Training Center at the University of Bamako in Mali, West Africa. In a new study of the vaccine in young children in Mali, researchers found it stimulated strong and long-lasting immune responses. In fact, the antibody levels the vaccine produced in the children were as high or even higher than the antibody levels found in adults who have naturally developed protective immune responses to the parasite over lifelong exposure to malaria.

"These findings imply that we may have achieved our goal of using a vaccine to reproduce the natural protective immunity that normally takes years of intense exposure to malaria to develop," says Christopher V. Plowe, M.D., M.P.H., professor and chief of the Malaria Section of the CVD. Dr. Plowe, a lead author of the study to be published online in the Feb. 4 issue of <u>PLoS ONE</u>, the journal of the Public Library of Science, also is an investigator with the Howard Hughes Medical Institute and a Doris Duke Distinguished Clinical Scientist.

In areas of the world such as Africa, where malaria is particularly rampant, the young are most vulnerable to the disease since they have not built up the same natural immunity as adults. A child dies of malaria every 30 seconds, according to the World Health Organization. There are about 300 million malaria cases worldwide each year, resulting in more



than one million deaths, most of them African children.

Malaria is caused by a parasite spread to humans through mosquito bites. There is no approved vaccine to protect against the condition, though using bed nets or killing mosquitoes with insecticides can prevent infection. The parasite is treatable using medications, though <u>drug</u> resistance is a relatively common problem. Eradicating the disease has become a priority for scientists and health officials worldwide. An effective and broadly protective vaccine is a key step toward that goal.

In addition to the Howard Hughes Medical Institute's support of Dr. Plowe's research, the study was sponsored by the U.S. Army and funded by the National Institute of Allergy and Infectious Disease (NIAID), part of the National Institutes of Health, and the United States Agency for International Development (USAID).

The new vaccine, called FMP2.1/AS02A, was developed as part of a longstanding research collaboration between the Walter Reed Army Institute of Research (WRAIR) GlaxoSmithKline Biologicals (GSK). The vaccine consists of a form of the AMA-1 protein, invented and manufactured by WRAIR, and the AS02 Adjuvant System, developed and manufactured by GSK. The Adjuvant System is a compound that boosts the immune response to the vaccine. Previous studies in the U.S. and in Mali already have found the vaccine to be safe and to produce strong immune responses in adults.

The vaccine, based on a single strain of the falciparum malaria parasite — the most common and deadliest form of the parasite found in Africa — targets malaria in the blood stage. The blood stage is the period after the mosquito bite, when the parasite multiplies in the blood, causing disease and death. Other blood stage vaccines have been tested but none has shown the ability to prevent malaria disease.



For the study, the University of Maryland School of Medicine's CVD team collaborated with a group of Malian researchers from the Malaria Research and Training Center, led by Mahamadou Thera, M.D., Ph.D., and Ogobara Doumbo M.D., Ph.D. The study also included collaborators WRAIR, GSK Biologicals, NIAID and USAID.

The scientists tested the vaccine in 100 Malian children ages 1-6 at the Bandiagara Malaria Project in rural Mali. The children were randomly assigned to receive either one of three escalating doses of the malaria vaccine or a control rabies vaccine. All three doses of the vaccine proved to be safe and well tolerated, and all three doses also showed very strong antibody responses that were sustained for at least a year.

Based on the vaccine's apparent success in this early trial, the same international team of U.S., Malian and European investigators now are subjecting it to further study in a much larger trial of 400 Malian children to evaluate its effectiveness against malaria disease. That study also will examine whether the vaccine — though it is based on a single strain of malaria — can protect against the broad array of malaria parasites that exist. The scientists hope the vaccine could be combined with other vaccines to create a multi-component immunization that is highly protective.

"The University of Maryland employs hundreds of researchers worldwide in 23 countries outside of its home campus in Baltimore," says E. Albert Reece, M.D., Ph.D., M.B.A., dean of the School of Medicine, vice president for medical affairs of the University of Maryland and the John Z. and Akiko K. Bowers Distinguished Professor. "Dr. Plowe is a world-leading malaria researcher, and this groundbreaking work is representative of the global impact of the Center for Vaccine Development and the rest of the University of Maryland School of Medicine. I hope this study leads to a lifesaving vaccine for the children of Africa."



Provided by University of Maryland Medical Center

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