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Study confirms Ebola and Marburg Virus DNA Vaccines are Safe and Immunogenic In Africa

Successful execution of first Ebola vaccine study in Africa using early-generation vaccine candidate

Dec. 23, 2014 (SILVER SPRING, Md.) – Results from the first Ebola vaccine clinical trial conducted in Africa (in 2009-2010) reveal a vaccine candidate produces the same immune response seen in the United States in an African setting. Importantly, this vaccine candidate is a precursor to candidates currently under evaluation for potential testing in West Africa. The findings of this 2009-2010 study, published online today in *The Lancet*, describe the successful execution and analysis of a Phase 1 clinical trial of two DNA vaccine candidates, one for the Ebola virus and the other for the closely related Marburg virus. The trial, conducted in Uganda, also demonstrated that the vaccines for the Ebola and Marburg viruses could be combined safely.

“The RV247 study represents the first Ebola vaccine trial conducted in Africa. Since immune responses to vaccines can differ around the world, these findings are encouraging for the development of an effective Ebola vaccine for Africa,” said Merlin Robb, M.D., Director for Clinical Research at the US Military HIV Research Program (MHRP), whose site in Uganda, Makerere University Walter Reed Project (MUWRP), conducted the study. “Given separately and concurrently, both vaccines were safe, well-tolerated, and elicited antigen-specific humoral and cellular immune responses.”

Outbreaks of Ebola and Marburg virus, both filoviruses, have occurred sporadically since their discovery in 1976 and 1967, respectively. The 2014 Ebola outbreak concentrated in three West African nations, is the largest on record and notable for extension into densely populated cities. Finding comparable safety and immunogenicity in U.S. and Ugandan populations provided proof of principle that a protective, multivalent filovirus vaccine is attainable.

The products used in the trial were tested in the U.S. prior to the launch of the study in Uganda and were developed by the Vaccine Research Center (VRC) at the National Institute of Allergy and Infectious Diseases (NIAID). These findings have led to the clinical evaluation of a more potent vaccine developed by the VRC, a Chimpanzee Adenovirus type 3 vector (cAd3) encoding the same wild-type glycoprotein antigen. This vaccine entered clinical trials in September 2014. MUWRP will begin testing this vaccine in early January 2015. As part of this upcoming study, some Ugandan volunteers from the 2009 DNA study

will receive a boost, or additional injection, with the new vaccine candidate to explore a more long lasting effect of vaccination.

MUWRP was selected by the NIAID to conduct RV 247 based on their expertise in conducting HIV vaccine trials. Following a deadly 2007 outbreak of a new strain of Ebola virus in the Bundibugyo region of Uganda, MUWRP developed a strong interest in creating a vaccine that cut across subtypes of the virus. A total of 373 volunteers were screened for eligibility, and 108 volunteers were enrolled into the study between November 2009 and April 2010.

“The Ugandan scientific community and general population were very interested in participating in vaccine research relevant to Ugandan public health, including filovirus vaccine research,” said Hannah Kibuuka, M.D., the principal investigator of the RV 247 Ebola study in Uganda. “Many of the people who volunteered were aware of the impact of Ebola outbreaks in Uganda. Most were educated at the university level.”

MUWRP is part of the [US Military HIV Research Program](#), which has an extensive medical research infrastructure to conduct clinical studies in endemic areas. When it conducted this first Ebola vaccine study, MUWRP already had clinical research experience with vaccines and conducted them in accordance with Good Clinical Practices. They also had established capabilities in data management and community engagement, and laboratory capabilities to measure safety parameters and collect and manage samples so that immune responses could be evaluated.

MHRP, centered at the Walter Reed Army Institute of Research, has other sites in Africa that have also expressed interest in participating in future Ebola vaccine studies. Plans are underway at the MHRP site in Nigeria to participate in a large phase 2 study of the cAd3 Ebola vaccine. “The US Military has partnered with the African scientific and general community for more than 40 years,” according to MHRP director Col. Nelson Michael, M.D., Ph.D. “We have worked on the ground for decades with host nations to build sustainable infrastructure to support infectious diseases research in areas such as HIV, malaria, dengue virus and Ebola. We work closely with NIAID scientists to identify and address key research areas that will help speed progress to develop globally effective vaccines for global public health threats.”

See NIAID statement on this study. The clinicaltrials.gov identifier for this study is [NTC00997607](#)

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About MHRP

The US Military HIV Research Program (MHRP) at the Walter Reed Army Institute of Research conducts research to develop an effective HIV vaccine and integrates prevention, treatment, diagnosis and monitoring as part of a global effort to protect troops and reduce the impact of HIV worldwide. MHRP has developed six state-of-the-art international research sites in the Africa and Asia. In 2009, MHRP announced results of an Army-sponsored clinical trial in Thailand that demonstrated for the first time a modest ability to protect against HIV infection, reducing the number of infections by 31.2 percent. The program successfully collaborates on HIV prevention care and treatment services, funded by the President's Emergency Plan for AIDS Relief (PEPFAR), with African militaries and in the communities where it conducts research. For more information, visit www.hivresearch.org or find MHRP on Facebook, www.facebook.com/hivresearch, and Twitter at @MHRPInfo.

An interview with an RV247 Ebola vaccine trial volunteer is on the MHRP [website](#).

About the Walter Reed Army Institute of Research (WRAIR)

WRAIR is a leader in global efforts against the world's most pervasive and high impact infectious diseases, such as malaria, HIV/AIDS, Ebola, and dengue. Infectious diseases pose a significant and persistent threat to force protection and readiness and while the primary mission of Army medical research is protection of the U.S. Service and their family members, vaccines and treatments developed by Army researchers also benefit global public health.

Around the world, WRAIR infectious disease physicians and scientists work alongside civilian researchers and medical professionals to test and develop products that will ultimately reduce the impact of some of the world's most lethal diseases.

Some of the WRAIR's enduring contributions to global health include:

- Developing some of the most widely used anti-malarial drugs, including chloroquine, primaquine, mefloquine, doxycycline and atovaquone/proguanil
- Advancing major steps forward in the scientific advancement of a first-ever malaria vaccine and took part in Phase III testing overseas (with GlaxoSmithKline)
- Helping develop vaccines to prevent meningitis, Japanese encephalitis, hepatitis A, adenovirus and influenza

For more information on WRAIR, visit: <http://wrair-www.army.mil>

