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VSV-EBOV Ebola Vaccine Appears Safe and Generates Immune Response

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An experimental Ebola vaccine called VSV-EBOV appears safe and elicited a robust immune response in a small phase 1 clinical trial, according to findings to be published in the *New England Journal of Medicine* on April 2, 2015.

Two independent but coordinated studies, performed at the Walter Reed Army Institute of Research (WRAIR) and the National Institute of Allergy and Infectious Diseases (NIAID), explored the safety and immunogenicity of the investigational vaccine when administered at different dosages.

“These pivotal early studies helped inform dose selection for testing of VSV-EBOV vaccine in a large-scale clinical trial in West Africa,” noted Lt. Col. Jason Regules at WRAIR, one of two co-lead authors of the paper. “We were gratified to see that the vaccine was not associated with significant adverse effects in this very carefully monitored study,” Regules added.

Scientists at the Public Health Agency of Canada’s National Microbiology Laboratory originally developed the VSV-EBOV vaccine candidate, one of two Ebola vaccines currently in large scale testing in West Africa. It has been licensed to NewLink Genetics Corp. in collaboration with Merck Sharp & Dohme Corp (Merck). The Ebola virus genetic material is delivered by a carrier virus (recombinant Vesicular Stomatitis Virus, or rVSV). The candidate vaccine does not contain Ebola virus and cannot cause Ebola virus disease.

The trials collectively enrolled 52 volunteers who received either the vaccine candidate or a placebo. Those volunteers given the vaccine received one of two different doses and volunteers were assessed on days 1, 3, 7, 14, and 28 to see if they developed anti-Ebola antibodies.

Twenty-six of 28 volunteers (93%) in the vaccine group showed the intended Ebola glycoprotein antibody response within two weeks of vaccination, and all of the volunteers had antibodies within 28 days of receiving the vaccine. Researchers saw a higher antibody response in the vaccine recipients who received the higher vaccine dose.

“We saw a robust immune response following a single dose of the vaccine, which could be particularly useful in outbreak interventions,” said Col. Stephen Thomas, WRAIR’s Deputy Commander and senior author on the paper. NIAID researchers are also looking at effects of an extra boost of the vaccine at day 28; results are expected later this year.

This clinical trial began in October during the peak of the devastating Ebola outbreak in West Africa. The combined experience of WRAIR and NIAID with Ebola, other infectious diseases research, and the conduct of human clinical trials enabled an agile shift in resources towards prioritizing the Ebola vaccine trial in just 11 weeks. All partners took part in developing the necessary assays to characterize vaccine safety and immune response. Critical support was provided by the Army

Medical Research Institute of Infectious Diseases (USAMRIID) and the DoD Chemical Biological Defense Program.

“This is an example of the whole of government working at its best to address a public health issue,” said Col. Thomas. “We were able to leverage the WRAIR’s experience in conducting ethical and safe clinical research experiments to meet a global need.”

About VSV-EBOV Ebola vaccine

VSV-EBOV is based in part on a genetically engineered version of vesicular stomatitis virus, which primarily affects rodents, cattle, swine and horses. Human VSV infections are rare and mild. In the VSV-EBOV investigational vaccine, the gene for the outer protein of VSV replaces the same gene segment of the Zaire Ebola virus species. Receiving the VSV-EBOV vaccine cannot cause an individual to become infected with Ebola.

The vaccine candidate, VSV-EBOV, is also referred to as VSV-ZEBOV, rVSV-ZEBOV, rVSVΔG-ZEBOV-GP, or BPSC1001. For more information on these studies, see ClinicalTrials.gov numbers NCT02269423 and NCT02280408.

About the Walter Reed Army Institute of Research (WRAIR)

Established in 1893, WRAIR is the oldest, largest and most programmatically diverse military research institute of the US Army Medical Research and Materiel Command and Department of Defense. WRAIR has an extensive international research network that includes sites in Africa, Thailand and elsewhere in Southeast Asia, Germany, and Georgia. The Institute is comprised of the Center for Infectious Disease Research and the Center for Military Psychiatry and Neuroscience.

For more information visit websites for [WRAIR](#) or its [Clinical Trials Center](#).



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