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### Ebola Vaccine Called 100% Effective

**December 23, 2016** | By [David Kohn](#)

An experimental Ebola vaccine was highly protective against the deadly virus in a major trial in Guinea, according to a new study that included researchers from the University of Maryland School of Medicine (UMSOM).

Researchers from the [Center for Vaccine Development \(CVD\)](#) at UMSOM and its sister institution, CVD-Mali of Bamako, Mali, took part in the study, which was performed in Guinea, West Africa.

The results were published Dec. 23 in [The Lancet](#). The vaccine is the first to prevent infection from one of the most lethal known pathogens, and the findings add weight to early trial results published last year.

“This hallmark study led by WHO [World Health Organization] assessed the efficacy of an Ebola vaccine under extremely arduous field conditions during the Ebola epidemic in Guinea in 2015. To perform the field trial, it was necessary within just a few weeks to train cadres comprising approximately 250 field investigators in the principles of Good Clinical Practices. Most of these field workers had not previously participated in a vaccine study or in other forms of clinical research.” said [Myron M. Levine, MD, DTPH](#), the Simon and Bessie Grollman Distinguished Professor at the School of Medicine. “We are proud to have contributed to this important work, which involved efforts from many investigators across the globe. The organization and performance of this innovative field trial on short notice in one of the world’s least developed countries with virtually no research infrastructure was an extraordinary *tour de force*.”

The vaccine, called rVSV-ZEBOV, was studied in a trial involving 11,841 people in Guinea during 2015. Among the 5,837 people who received the vaccine, no Ebola cases were recorded 10 days or more after vaccination. In comparison, there were 23 cases 10 days or more after vaccination among those who did not receive the vaccine.

The trial was led by WHO, together with Guinea’s Ministry of Health and other international partners.

“While these compelling results come too late for those who lost their lives during West Africa’s Ebola epidemic, they show that when the next Ebola outbreak hits, we will not be defenseless,” said Marie-Paule Kieny, WHO’s assistant director-general for health systems and innovation, and the study’s lead



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The vaccine's manufacturer, Merck, Sharpe & Dohme, this year received Breakthrough Therapy Designation from the U.S. Food and Drug Administration and PRIME status from the European Medicines Agency, enabling faster regulatory review of the vaccine once it is submitted.

Since the Ebola virus was first identified in 1976, sporadic outbreaks have been reported in Africa. But the 2013-2016 West African Ebola outbreak, which resulted in more than 11,300 deaths, highlighted the need for a vaccine.

The trial took place in the coastal region of Basse-Guinée, the area of Guinea still experiencing new Ebola cases when the trial started in 2015. The trial used an innovative design, a so-called "ring vaccination" approach - the same method used to eradicate smallpox.

When a new Ebola case was diagnosed, the research team traced all people who may have been in contact with that case within the

previous three weeks, such as people who lived in the same household, were visited by the patient, or were in close contact with the patient, their clothes or linen, as well as certain "contacts of contacts." A total of 117 clusters (or "rings") were identified, each made up of an average of 80 people.

Initially, rings were randomized to receive the vaccine either immediately or after a three-week delay, and only adults over 18 years were offered the vaccine. After interim results were published showing the vaccine's efficacy, all rings were offered the vaccine immediately and the trial was also opened to children older than 6 years.

In addition to showing high efficacy among those vaccinated, the trial also shows that unvaccinated people in the rings were indirectly protected from Ebola virus through the ring vaccination approach (so-called "herd immunity"). However, the authors note that the trial was not designed to measure this effect, so more research will be needed.

“Ebola left a devastating legacy in our country. We are proud that we have been able to contribute to developing a vaccine that will prevent other nations from enduring what we endured,” said Keïta Sakoba, coordinator of the Ebola response and director of the National Agency for Health Security in Guinea.

To assess safety, people who received the vaccine were observed for 30 minutes after vaccination, and at repeated home visits up to 12 weeks later. Approximately half reported mild symptoms soon after vaccination, including headache, fatigue and muscle pain but recovered within days without long-term effects. Two serious adverse events were judged to be related to vaccination (a febrile reaction and one anaphylaxis) and one was judged to be possibly related (influenza-like illness). All three recovered without any long-term effects.

It was not possible to collect biological samples from people who received the vaccine in order to analyze their immune response. Other studies are looking at the immune response to the vaccine including one conducted in parallel to the ring trial among front-line Ebola workers in Guinea.

“This both historical and innovative trial was made possible thanks to exemplary international collaboration and coordination, the contribution of many experts worldwide, and strong local involvement,” said John-Arne Røttingen, director of the Division of Infectious Disease Control at the Norwegian Institute of Public Health, and the chair of the study steering group.

In January, GAVI, the Vaccine Alliance provided \$5 million to Merck toward the future procurement of the vaccine once it is approved, prequalified and recommended by WHO. As part of this agreement, Merck committed to ensure that 300,000 doses of the vaccine are available for emergency use in the interim, and to submit the vaccine for licensure by the end of 2017. Merck also has submitted the vaccine to WHO’s Emergency Use and Assessment Listing procedure, a mechanism through which experimental vaccines, medicines, and diagnostics can be made available for use prior to formal licensure.

Additional studies are ongoing to provide more data on the safety of the vaccine in children and other vulnerable populations such as people with HIV. In case of Ebola flare-ups prior to approval, access to the vaccine is being made available through a procedure called “compassionate use” that enables use of the vaccine after informed consent. Merck and WHO’s partners are working to compile data to support license applications.

The rapid development of rVSV-ZEBOV contributed to the development of WHO’s R&D Blueprint, a global strategy to fast-track the development of effective tests, vaccines, and medicines during epidemics.

CVD and CVD-Mali investigators helped train about 250 field workers for the trial. **Moussa Doumbia, MD**, an experienced vaccine clinical researcher at CVD-Mali who was deployed to WHO, served as one of the on-site principal investigators of the Guinea field trial.

The rVSV-ZEBOV trial is funded by WHO, with support from the Wellcome Trust, the United Kingdom Department for International Development, the Norwegian Ministry of Foreign Affairs to the Norwegian Institute of Public Health through the Research Council of Norway, the Canadian government through the Public Health Agency of Canada, Canadian Institutes of Health Research, International Development Research Centre and Department of Foreign Affairs, Trade and Development and Médecins Sans Frontières.

The trial team includes experts from the University of Bern, the University of Florida, the London School of Hygiene and Tropical Medicine, Public Health England, the European Mobile Laboratories among others. The trial was designed by a group of experts including the late Professor Donald A. Henderson of Johns Hopkins University, who led the WHO smallpox eradication effort by using the ring vaccination strategy.

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