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Researchers present inner workings of Ebola vaccine trial

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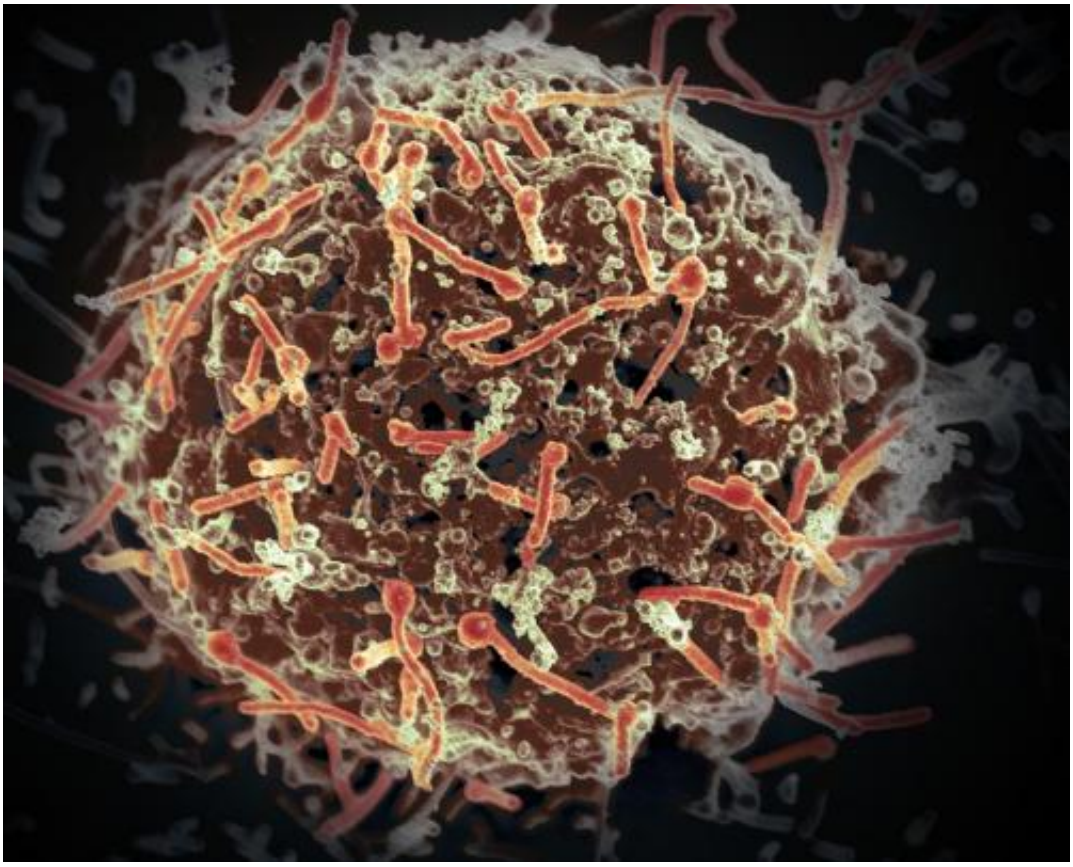

The Ebola virus, isolated in November 2014 from patient blood samples obtained in Mali. The virus was isolated on Vero cells in a BSL-4 suite at Rocky Mountain Laboratories. Credit: NIAID

An experimental vaccine combined with an innovative way of vaccinating people has resulted in an estimated 100 percent efficacy of

the vaccine against the Ebola virus in West Africa—and the approach could establish a new way of responding to outbreaks of emerging pathogens, including the Zika virus.

This is according to two researchers who will discuss their experimental Ebola vaccine trial during the American Association for the Advancement of Science's annual meeting today (Friday, Feb. 12, 2016).

Their discussion will focus on interim results of a study published in *The Lancet* in July. The study examined an experimental Ebola vaccine as well as a way of deploying the vaccine. The strategy includes vaccinating people who had contact with people who contracted Ebola and also the close contacts of people who had that contact—an approach known as ring vaccination.

Ring vaccination was first used in the 1970s to eradicate smallpox. University of Florida researcher Ira Longini, Ph.D., one of the study's authors, and lead author Ana Maria Henao Restrepo, M.D., a medical officer for the World Health Organization, expect the vaccination strategy could be used to combat other emerging pathogens. It works off the concept of surveillance and containment, and can be designed for interventions other than vaccination, including disease prevention and treatment.

"This type of analysis is a very robust design. It worked for the Ebola vaccine, and could work for the Zika vaccine, or any other emerging threat we might see," Longini said. "Now, we want to make the point that we can almost certainly contain future Ebola outbreaks, and that we will probably have a new paradigm and tool for dealing with new outbreaks of whatever emerges in the future."

Longini, a biostatistics professor in the UF colleges of Public Health and Health Professions and Medicine and director of the UF Center for

Statistics and Quantitative Infectious Diseases, will highlight the study's unique design and results of the trial. Because researchers were working in an emergency situation, conducting a standard randomized controlled trial—a trial in which study participants are randomly divided into two groups, one who receives the drug being tested and one who receives a placebo—could have been unethical.

"When you're studying a vaccine for Food and Drug Administration licensure, you would normally like to run the vaccine through a double-blind, randomized placebo-controlled trial," said Longini, also a member of the UF Emerging Pathogens Institute. "To use a placebo in a situation like this Ebola epidemic, in which the probability of someone falling ill and dying is high, could be unethical."

For the researchers' interim results, the study included 7,651 people, more than 3,500 of whom were vaccinated. Researchers found the vaccine 100 percent effective in preventing Ebola illness in vaccinated people and 75 percent effective in reducing the risk of Ebola illness in rings where about half of the people had been vaccinated.

The researchers plan to publish their final paper examining the trial soon, but the trial is still ongoing to deliver ring vaccination for any new clusters of Ebola, including a current cluster in Sierra Leone. The researchers also plan to study how long a vaccinated person's immunity to Ebola lasts.

Provided by University of Florida