

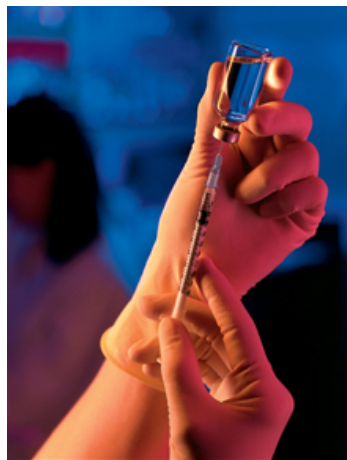
## Vaccines for newest pandemic flu threat to be tested at Emory in national effort

Woodruff Health Sciences Center | Sep. 18, 2013

Physician/researchers at Emory University and Children's Healthcare of Atlanta will begin testing a vaccine designed to protect against H7N9 influenza, the bird flu strain that caused severe illness and death in China last spring.

The National Institute of Allergy and Infectious Diseases of the National Institutes of Health is sponsoring the clinical trial through the Emory Vaccine and Treatment Evaluation Unit (VTEU) and seven other VTEUs around the country. The Emory clinical trial will be conducted at the Emory Vaccine Center's Hope Clinic in nearby Decatur, and at the Emory Children's Center Vaccine Research Clinic.

"This bird flu vaccine trial is extremely important, because humans have not developed any immunity to this newly identified H7N9 virus. By preparing for a potential outbreak through a tested vaccine, we hope to reduce the potentially severe impact of a future pandemic. We also expect to learn more about flu vaccines, how they induce immunity, and the most effective doses in different age groups," says Mark J. Mulligan, MD, professor of medicine in Emory University School of Medicine and executive director of the Hope Clinic.



The new avian influenza strain was first detected in China last spring in 135 people, most of whom had contact with poultry. Most people had severe respiratory infections, and 44 people – or 32 percent of those who were ill – died. While the median age of those stricken with the H7N9 flu was 58, four cases were confirmed in children.

"Although the H7N9 influenza virus has not spread easily between people and has not yet been detected in the United States, there is concern that this could change and potentially it then could develop into a global pandemic," says Paul Spearman, MD, chief research officer for Children's Healthcare of Atlanta and Nahmias-Schinazi Professor and vice chair of research in the Department of Pediatrics, Emory School of Medicine.

The clinical trial will enroll up to 700 healthy adults nationally 19 to 64 years old. At Emory, researchers expect to enroll approximately 175 volunteers at the Hope Clinic and at the Emory Children's Center (ECC), with support from Children's Healthcare of Atlanta through its partnership with Emory if future studies in younger age groups are needed.

Participants will receive different dosages of an investigational vaccine given with an adjuvant – a substance added to a vaccine to increase the body's immune response. Each participant will receive two vaccinations at approximately 21 days apart.

The clinical trial is expected to gather critical information to determine whether the vaccine and adjuvant are safe and effective in inducing protective immune responses.

Several worldwide influenza outbreaks (pandemics) have occurred during the past century, including Spanish flu of 1918, Asian Flu of 1957, Hong Kong Flu of 1968, and H1N1 influenza (swine flu) of 2009. The Spanish Flu pandemic resulted in an estimated 60 million deaths worldwide.

"We certainly hope we will never need to deploy an H7N9 bird flu vaccine for a pandemic. But we must prepare for the worst and be ready, while hoping for the best," says Mulligan, who is serving as the national and local principal investigator for this NIH-funded study.

The Emory VTEU was one of the eight NIH-sponsored sites to test the H1N1 vaccine in 2009 against a pandemic outbreak.

The VTEUs were established in 1962 as a vital research component of the NIAID. The units

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conduct clinical trials for all infectious diseases other than HIV/AIDS. Emory was designated a VTEU site in 2007. The VTEUs have conducted hundreds of clinical studies over the past four decades.

An important strength of the VTEUs is their ability to rapidly enroll large numbers of volunteers into trials and to immunize the volunteers in a safe, effective and efficient manner. This rapid-response capability is especially important for testing vaccines designed to combat pandemic influenza.

In addition to Emory, VTEU sites are Baylor College of Medicine, Houston; Children's Hospital Medical Center, Cincinnati; Group Health Cooperative, Seattle; Saint Louis University, St. Louis; University of Iowa, Iowa City; University of Maryland School of Medicine, Baltimore; and Vanderbilt University, Nashville. Additionally, the University of Texas Medical Branch in Galveston will be conducting the trial as a subcontractor to Baylor College of Medicine.

Further information about the clinical trials can be found at [ClinicalTrials.gov](http://ClinicalTrials.gov) using the identifiers: NCT01938742 and NCT01942265.

For more information about the clinical trial at Emory, please see [www.hopeclinic.emory.edu](http://www.hopeclinic.emory.edu) call 877-424-HOPE, or email [vaccine@emory.edu](mailto:vaccine@emory.edu).

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