

Researchers studying vaccine to prevent potential bird flu pandemic

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Scientists at the University of Maryland School of Medicine's Center for Vaccine Development are part of nationwide vaccine research aimed at protecting adults from a new and virulent strain of avian (bird) influenza (flu) virus. The virus, called H7N9 influenza virus, emerged in China last spring. As of mid-August, 135 confirmed human cases, including 44 deaths, have been reported by the World Health Organization. The study, sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), will help prepare for the possibility of a global pandemic.

This <u>bird flu virus</u>, first seen in people who came in contact with poultry, has not been reported outside of China and is not easily transmitted from person to person. Nevertheless, changes in the virus may already be underway that could lead to a global H7N9 pandemic, according to the University of Maryland's co-principal investigator, James D. Campbell, M.D., M.S., who says, "There's <u>genetic evidence</u> this virus is mutating toward the possibility of sustained human-to-<u>human transmission</u>."

This is a strain of influenza that has not been seen previously in humans. "Immunity is not built up the way it is with most human-type <u>flu viruses</u> circulating around the globe. More people get sick, and get sicker than usual with new viruses," says Dr. Campbell, associate professor of pediatrics at the University of Maryland School of Medicine and infectious disease specialist. "This one is totally different from any previous flu virus we know, at least from the early 1900s."



The strength of this strain is another cause for alarm. "If H7N9 stays that pathogenic, but then becomes transmissible, it has the potential to cause a bigger impact than typical seasonal flu," says Dr. Campbell.

The study's principal investigator, Karen L. Kotloff, M.D., says "It's impossible to know with any certainty whether this virus will cause widespread illness as in previous <u>pandemics</u>, but we need to be prepared for the possibility." Dr. Kotloff, professor of pediatrics and medicine, is head of infectious disease and tropical pediatrics at the University of Maryland School of Medicine.

The last pandemic occurred in 2009 with the spread of H1N1 influenza, which originated in pigs and spread to people.

The clinical trial is designed to gather critical information about the safety and effectiveness of the vaccine and immune system responses it induces at different dosages, with and without adjuvants—substances designed to boost the body's immune response to vaccination.

Two concurrent Phase II clinical trials will enroll healthy adults, ages 19 to 64 years old, to evaluate an investigational H7N9 vaccine. The candidate vaccine is made from inactivated H7N9 virus isolated in Shanghai, China, in 2013. Adjuvants are being tested with the investigational vaccine because previous <u>vaccine research</u> involving other H7 influenza viruses has suggested that vaccine without an adjuvant may not induce an adequate protective immune response.

A panel of independent experts will closely monitor participant safety data at regular intervals throughout the study.

"Whether or not an H7N9 pandemic materializes, vaccine studies such as this provide important experience in ongoing efforts to protect the public against sometimes-deadly influenza viruses," says E. Albert Reece,



M.D., Ph.D., M.B.A., vice president for medical affairs at the University of Maryland and the John Z. and Akiko K. Bowers Distinguished Professor and Dean of the University of Maryland School of Medicine. "University of Maryland School of Medicine faculty researchers have been part of every similar vaccine study in the last few decades, making significant contributions to preparing the nation for emerging public health threats."

The University of Maryland is one of eight NIAID-funded Vaccine and Treatment Evaluation Units (VTEUs) studying the H7N9 candidate vaccine. In addition to the University of Maryland, 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; Emory University, Atlanta; 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.

Provided by University of Maryland

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