Evaluating a universal influenza vaccine in U.S. adults

An influenza vaccine candidate designed to protect across multiple strains is currently being studied in healthy U.S. adults in Cincinnati, Ohio, and Durham, North Carolina. The study will evaluate the safety of and immune response prompted by a new vaccine technology that has potential to protect against *all* influenza strains. Currently, there are no licensed universal influenza vaccines; the development of one could eliminate the need to periodically adjust influenza vaccines to circulating strains—as scientists do today—thereby creating a cost-effective and efficient way to protect people around the world.

Influenza is a viral disease that causes mild to severe respiratory illness, and sometimes death. It spreads from person-to-person through coughing and sneezing, and poses a particular risk to the elderly, people with chronic illness, pregnant women, infants, and young children, who are more likely to suffer complications as a result. Influenza viruses are constantly changing into slightly different strains, so infection or vaccination one year does not mean immunity the next.

Globally, seasonal influenza results in three to five million cases of severe illness and up to 500,000 deaths each year. What's more, the virus has the potential to cause millions of deaths worldwide if a highly virulent pandemic strain were to emerge.

The effects of influenza are likely to be greatest in resource-limited countries where people may have underlying nutritional deficiencies, untreated medical issues, and limited access to healthcare. Models estimate that if an influenza pandemic were to occur, 96 percent of deaths would happen in low-resource countries.

PATH, an international nonprofit organization, has partnered with the Icahn School of Medicine at Mount Sinai in New York (ISMMS), Cincinnati Children's Hospital Medical Center (CCHMC), and the Duke Clinical Research Institute (DCRI) to conduct this study.

Photo: PATH/Matthew Dakin

The vaccine candidates are manufactured by Meridian Life Science in Memphis, Tennessee, and GSK Vaccines in Rixensart, Belgium. The Emmes Corporation in Rockville, Maryland is providing study monitoring for the trial.

Several vaccine candidates are being used in this study, but the combination under primary investigation is a chimeric hemagglutinin H8/1N1 live attenuated influenza vaccine, followed by a chimeric hemagglutinin H5/1N1 inactivated influenza vaccine.

Chimeric technology—pioneered by ISMMS—is key to this study. By changing the structure of the influenza virus's hemagglutinin molecule (a protein on the virus's surface that facilitates entry into respiratory tract cells, where the virus replicates) scientists hope to prompt an immune response against the portion of the virus that is similar across strains and across seasons—thereby negating the need for annual vaccination.

The study began in December 2017 at two sites: CCHMC and DCRI. Volunteers were divided between five different study arms to receive two doses of either study vaccine or placebo, and will spend between 15 and 17 months participating.

This study will pave the way for future studies of the vaccine's effectiveness and, eventually, the development of a broadly protective influenza vaccine.