

Advancing new vaccines against influenza

Each year, seasonal or annual influenza causes 250,000 to 500,000 deaths and five million cases of severe illness.¹ Epidemics and outbreaks have the potential to cause millions of deaths worldwide. Public health leaders worry that many millions of people could die, mostly in the developing world, if a highly virulent pandemic strain were to emerge in today's interconnected world.²

Vaccination is the best strategy for preventing and controlling the spread of influenza and is routine in much of the industrialized world, but barriers to affordability and availability often make current influenza vaccines inaccessible in the developing world. Alternative vaccine strategies are needed that can break down these barriers and bring effective protection to underserved populations. To this end, PATH is collaborating with public- and private-sector partners to advance the development of promising new influenza vaccines that can be accessible, affordable, and available to people in low-resource countries during influenza outbreaks.

INFLUENZA VACCINE DEVELOPMENT FOR VULNERABLE POPULATIONS

Live-attenuated influenza vaccines (LAIVs), made out of weakened influenza virus, have been used to combat seasonal influenza for decades in some regions. They have the potential to be produced inexpensively, quickly, and in large quantities, which could lead to a more efficient response in influenza outbreaks. They are delivered intranasally, which can reduce reliance on needles and enable non-medical personnel to administer vaccine. Furthermore, they are particularly viable options for young children in low-resource settings. To speed the development of these vaccines, we are partnering with Russia's Institute of Experimental Medicine (IEM), to advance the development of LAIV candidates against influenza strains that have been known to cause severe disease in humans, specifically influenza A(H7N3), A(H5N2), and A(H2N2). These candidates are in varying stages of Phase 1 clinical evaluation in healthy adults. The technologies developed through the partnership with IEM will be made available for use in low-resource countries



PATH/Mike Wang

under the World Health Organization's Global Pandemic Influenza Action Plan to Increase Vaccine Supply.

Novel technologies that can broadly protect across influenza's ever-changing strains could be additional options for cost-effective and efficient influenza prevention. If successful, they could eliminate the need to periodically adjust influenza vaccines to circulating strains, as scientists do today. To support the development of these innovative technologies, we are collaborating with the Icahn School of Medicine at Mount Sinai to advance preclinical research on broad-coverage influenza vaccines that the global population can afford.

OTHER RESEARCH TO ADVANCE THE INFLUENZA VACCINE FIELD

Recognizing that successful vaccine development requires access to a full spectrum of scientific resources, we are also investing beyond the vaccine products in our portfolio to support clinical studies designed to inform future LAIV development efforts and policymakers when deciding on the potential for LAIV use in low-resource countries. Among these are clinical trials designed to generate efficacy and additional safety data for a trivalent LAIV candidate produced by the Serum Institute of India, Ltd. They are evaluating the candidate's ability to prevent disease in children as young as two years of age—

important information given the high burden of influenza illness in this age group. The studies are taking place in Bangladesh in partnership with icddr,b (International Center for Diarrheal Disease Research, Bangladesh) and the Johns Hopkins Bloomberg School of Public Health (JHSPH); and in Senegal in collaboration with Institut de Recherche pour le Développement, Institut Pasteur de Dakar, and the US Centers for Disease Control and Prevention. Previously, we generated additional safety and immunogenicity data to support these studies by partnering with icddr,b/JHSPH on a pediatric Phase 2 study of the LAIV candidate in Bangladesh.

In partnership with JHSPH and the US National Institute of Allergy and Infectious Diseases, we also conducted a clinical study among healthy adults examining the nature of protection provided when priming with H5 and H7 LAIVs and then later boosting with inactivated influenza

H5 vaccines. This study could be an important proof-of-concept that could contribute to global strategies for using H5 influenza vaccines to prepare for and respond to potentially deadly avian influenza outbreaks.

REFERENCES

1. World Health Organization. Influenza (Seasonal) [fact sheet no. 211]. WHO; April 2009. Available at: www.who.int/mediacentre/factsheets/fs211/en/index.html. Accessed August 19, 2013.
2. Murray CJ, Lopez AD, Chin B, et al. Estimation of potential global pandemic influenza mortality on the basis of vital registry data from the 1918-20 pandemic: a quantitative analysis. *The Lancet*. 2006;368(9554):2211-2218.



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MAILING ADDRESS
PO Box 900922
Seattle, WA 98109 USA

info@path.org
www.path.org

STREET ADDRESS
2201 Westlake Avenue
Suite 200
Seattle, WA 98121 USA