

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases Research Addressing  
the Public Health Threat of Influenza

Testimony before the

House Committee on Energy and Commerce

Subcommittee on Oversight and Investigations

Carole A. Heilman, Ph.D.

Director of the Division of Microbiology and Infectious Diseases

National Institute of Allergy and Infectious Diseases

November 19, 2015

Mr. Chairman, Ranking Member DeGette, and members of the Subcommittee, thank you for the invitation to discuss the National Institutes of Health's (NIH) response to the public health threat posed by influenza. The National Institute of Allergy and Infectious Diseases (NIAID) is the lead NIH institute for research on immunologic, allergic, and infectious diseases, including influenza.

The NIAID mission balances basic, translational, and clinical research addressing current biomedical challenges with the capacity to rapidly respond to new threats from emerging and re-emerging infectious diseases, including seasonal and pandemic influenza. Given the morbidity and mortality of influenza in the United States every year, and the disease's economic burden, we recognize the importance of research to develop new tools to diagnose, treat, and prevent seasonal influenza, as well as prepare for the next influenza pandemic. NIAID's longstanding influenza research program includes efforts to develop a universal influenza vaccine that could provide durable protection against a variety of seasonal and pandemic influenza viruses.

Important to these NIAID efforts are ongoing collaborations with academia, the biotechnology and pharmaceutical industries, and other Federal partners, particularly the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Office of the Assistant Secretary for Preparedness and Response (ASPR), including the Biomedical Advanced Research and Development Authority (BARDA), and the National Vaccine Program Office within the Department of Health and Human Services.

### **Basic Research**

NIAID support for basic research on influenza continues to inform the development of new and improved vaccines, diagnostic tools, and antiviral drugs applicable to both seasonal and pandemic influenza strains. As part of this focus, NIAID supports fundamental research to better

understand the evolution and pathogenesis of influenza viruses in animals and humans. Researchers supported by NIAID's Centers of Excellence for Influenza Research and Surveillance (CEIRS) program are studying the global emergence and spread of novel influenza viruses, critical information that is provided to the World Health Organization (WHO). Influenza virus surveillance and sequencing using next-generation genomic technologies supported by NIH have begun to provide a more detailed picture of the evolution of the influenza virus and insights into controlling the impact of influenza outbreaks. Additionally, further understanding of the way our immune system responds to influenza and influenza vaccines is resulting in new approaches to the development of vaccines that have more breadth in their ability to protect against a variety of influenza viruses.

### **Diagnostics Development**

NIAID supports research aimed at improving influenza diagnostics to make them faster, more accurate, and usable wherever patients seek medical care. In particular, NIAID is funding the development of diagnostic platforms to examine the molecular makeup of influenza viruses to quickly distinguish between seasonal strains and those with pandemic potential. NIAID also supports development of influenza clinical assays to determine viral sensitivity to neuraminidase inhibitors – drugs that both lessen the severity and duration of illness in those infected, and potentially prevent infection in close contacts. To help ensure that patients receive prompt and effective care, NIAID will continue to develop rapid diagnostic tools that distinguish one influenza strain from another and also detect resistance to antiviral drugs.

## **Antiviral Therapies Development**

Antiviral medications are important tools in treating and preventing complications of influenza infection. Three antiviral drugs (neuraminidase inhibitors) currently are recommended for the treatment of influenza in the United States. The emergence of antiviral-resistant influenza strains, however, requires the development of new and better treatment options. NIAID continues to pursue novel influenza therapeutics

influenza A virus during the 2014-2015 influenza season. When genetic changes in

NIAID, in collaboration with BARDA, is continuing to support the development of HA stem-based universal influenza vaccines and other promising universal influenza candidates. NIAID intramural researchers also have developed a ferritin nanoparticle vaccine based on a stabilized HA stem from an H1N1 influenza virus. The vaccine, which lacks the HA head to more effectively

Although we cannot predict when a universal influenza vaccine would be publicly available,

variant strains of H3N2, and H7N9 to assess the immune responses these candidate vaccines induce in humans. Furthermore, NIAID is partnering with BARDA to investigate the safety and immunogenicity of an inactivated H5N8 vaccine with and without two stockpiled adjuvants designed to boost immune responses. H5N8 influenza is a novel strain of highly pathogenic avian influenza that has caused some of the outbreaks of disease in U.S. poultry populations and wild birds that have occurred since late 2014. These studies will inform potential “dose-sparing” strategies to maximize the supply of stockpiled vaccines in the event of a pandemic. In addition, NIAID intramural scientists are conducting clinical studies of prime-boost vaccine regimens for swine (H1) and avian (H7) influenza viruses, and collaborating with industry and BARDA to develop live, attenuated vaccines against potentially pandemic influenza viruses.

### **Other Clinical Research**

NIH scientists are investigating human influenza infection under controlled conditions through clinical research with healthy volunteers challenged with influenza virus. These studies will help scientists more precisely define the timeframe between exposure to influenza virus and viral shedding, and the timing for the onset and duration of influenza symptoms as well as the development of an immune response. The scientists also are searching for factors correlated with protection against influenza. The findings of these studies are informing the design of clinical trials to evaluate candidate influenza countermeasures. For example, building upon NIAID research, an ongoing Phase II trial at the NIH Clinical Center is evaluating the efficacy of a novel monoclonal antibody targeting the stem of the influenza HA protein. In addition, NIAID, through its Vaccine and Treatment Evaluation Units (VTEUs), the Institute’s longstanding clinical trials network for rapid testing of candidate vaccines and therapeutics, recently conducted a Phase II



