

Highlights of [GAO-13-374T](#), a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

Influenza—in both its seasonal and pandemic forms—is an ongoing public health concern. In the United States, seasonal influenza has been associated with thousands of deaths each year, according to CDC. In a pandemic, such as the 2009 H1N1 influenza pandemic, the disease causes a global disease outbreak with the potential for many more deaths. HHS has responsibility for coordinating the nation's response to public health emergencies, including an influenza pandemic. Within HHS, CDC makes recommendations on vaccination, tracks the disease, and disseminates public health messages on influenza. This testimony discusses (1) lessons learned from federal responses to prior influenza outbreaks and (2) federal investments to strengthen the U.S. vaccine supply and production capacity.

This testimony is based on prior GAO work on issues related to influenza vaccine supply and distribution; federal investments in domestic vaccine production capacity and production technologies; and the federal response to the 2009 H1N1 pandemic. This prior work includes analyses of information and interviews with officials within HHS, CDC, and FDA, as well as officials from vaccine manufacturers, medical supply distributors, state and local governments, provider groups, and other stakeholders. GAO also obtained updated information from HHS on the severity of the past three seasons, the numbers of vaccine doses distributed, and the status of advanced vaccine technology projects funded by HHS. HHS reviewed updated information and provided technical comments, which are incorporated as appropriate.

View [GAO-13-374T](#). For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

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INFLUENZA

Progress Made in Responding to Seasonal and Pandemic Outbreaks

What GAO Found

GAO's prior work has identified a number of lessons from federal responses to seasonal influenza vaccine shortages and the 2009 H1N1 pandemic that carry implications for future influenza seasons or another influenza pandemic. These lessons include the value of planning that involves the Department of Health and Human Services (HHS); the importance of effective communication among all levels of government and with the public; and the difficulty of matching vaccine supply with the public's demand for it. First, planning is critical to an effective response, and it particularly helped in responding to the H1N1 pandemic. Planning activities, such as exercises and interagency meetings, built relationships that positioned the government to respond effectively. Second, clear and consistent communication, especially regarding the availability of vaccine, is key. The failure to effectively manage public expectations of vaccine availability can undermine government credibility and contribute to individuals' failure to seek or receive an influenza vaccination. Recognizing the importance of sharing updated information, HHS's influenza website includes a vaccine finder for individuals, and the Centers for Disease Control and Prevention's (CDC) website helps providers find vaccine available for purchase. Third, predicting all of the influenza virus strains that will be circulating in a given season and their likely severity is difficult. Finally, matching influenza vaccine supply to demand is challenging, as the supply of and demand for vaccine can vary throughout seasons and across multiple seasons. HHS has taken a number of steps to address these lessons learned; however, the department continues to face challenges, particularly in communicating messages in changing circumstances and in facilitating the matching of available vaccine supply with public demand.

HHS has taken steps to strengthen the U.S. influenza vaccine supply by making investments in the development of vaccine production technologies and by enhancing domestic production capacity. Influenza vaccine has generally been produced in a complex egg-based process that poses limitations in timeliness and the susceptibility of the egg supply to certain influenza viruses. Prompted by these disadvantages, HHS has made investments in alternative vaccine production technologies, including cell-based and recombinant technologies. Since fiscal year 2005, HHS has awarded over \$1 billion in contracts to manufacturers to develop cell-based technology. One of these manufacturers recently received approval from HHS's Food and Drug Administration (FDA) for its cell-based seasonal influenza vaccine, which it intends to produce for the 2013–2014 influenza season. In addition, in fiscal year 2009, HHS entered into a contract worth approximately \$81 million with one manufacturer for the continued development of recombinant technology; that manufacturer's seasonal influenza vaccine made using this technology is expected to be available for the 2013–2014 influenza season. HHS has complemented its investments in vaccine production technologies with its investments in domestic manufacturers' production capacity. Since fiscal year 2005, these investments have contributed to the doubling of the number of domestic influenza vaccine manufacturers and a general increase in the number of influenza vaccine doses produced and distributed.