



Know What to Do About the Flu

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Vaccines, Vaccine Allocation and Vaccine Research

Next Steps Toward an H1N1 Influenza Vaccine

HHS Secretary Kathleen Sebelius is directing nearly \$1.1 billion in existing preparedness funds to manufacture two important parts of a vaccine for the Strategic National Stockpile, to produce small amount of potential vaccine for research, and to perform clinical research over the summer. [Press Release](#)

- [Vaccines Overview](#)
- [CDC Advisors Make Recommendations for Use of Vaccine Against Novel H1N1 - video press conference \(CDC\)](#)
- [Preparing for Vaccination with Novel H1N1 Vaccine \(CDC\)](#)
- [Questions and Answers about the Clinical Trials of 2009 H1N1 Influenza Vaccines](#)
- [HHS Purchases Additional H1N1 Vaccine Ingredients](#)
- [HHS Announces Advanced Development Contract for New Way to Make Flu Vaccine](#)
- [HHS 2009 H1N1 Vaccine Development Activities](#)
- [HHS 2009 H1N1 Vaccine Development Next Steps: Questions and Answers](#)
- [U.S. 2009 H1N1 Vaccine Strategy \(PDF - 580KB\)](#)
- [Vaccine Allocation \(PDF - 1.83 MB\)](#)
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- [Strategic National Stockpile \(SNS\) \(CDC\)](#)
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Overview

Vaccination is one of the most effective ways to minimize suffering and death from influenza. The U.S. Government is working to expand domestic flu vaccine production capacity to be able to produce pandemic influenza vaccines for the entire population within six months of a pandemic declaration. However, at the beginning of a pandemic, the scarcity of pre-pandemic and pandemic influenza vaccine will require that the limited supply be allocated or prioritized for distribution and administration.

The government has developed [Guidance on Allocating and Targeting Pandemic Influenza Vaccine \(PDF - 1.83 MB\)](#) which provides strong guidance to states, territories, and tribes for the allocation of limited supply of vaccine, and describes the scientific and ethical framework for how this guidance was developed.

A tiered allocation for vaccines in severe pandemics is recommended with the following objectives considered the most important:

- Protect those who are essential to the pandemic response and provide care for persons who are ill;
- Protect those who maintain essential community services;
- Protect children;
- Protect workers who are at greater risk of infection as a result of their job, and
- Protect those who maintain homeland and national security.

Because there will likely be a limited supply of vaccine, research is underway to develop adjuvants. An adjuvant is a substance that is added to a vaccine to improve the immune system's production of antibodies which is the desired response to vaccines. The successful addition of an adjuvant means that a given supply of vaccine can be used to treat more people.

H1N1 (Swine) Flu

- [Pandemic Influenza Vaccine Manufacturing Process and Timeline](#) (World Health Organization)
Read about the process and time required to produce a new vaccine.
- [WHO Safety of Pandemic Vaccines](#) (World Health Organization)
Learn about the regulatory procedures in place for the licensing of pandemic vaccines, including international procedures for expediting regulatory approval.
- [Questions and Answers about the Clinical Trials of 2009 H1N1 Influenza Vaccines](#) (National Institute of Allergy and Infectious Diseases)
- [NIAID Set to Launch Clinical Trials to Test 2009 H1N1 Influenza Vaccine Candidates](#) (National Institute of Allergy and Infectious Diseases)
Scientists in a network of medical research institutions across the United States are set to begin a series of clinical trials to gather critical data about influenza vaccines, including two candidate H1N1 flu vaccines.
- [WHO recommendations on pandemic \(H1N1\) 2009 vaccines](#) (World Health Organization)
Three key objectives that countries could adopt as part of the pandemic vaccination strategy are identified, and recommendations are made on vaccine prioritization and development.
- [HHS Purchases Additional H1N1 Vaccine Ingredients](#) (U.S. Department of Health and Human Services)
\$884 million is committed to the purchase of H1N1 antigens and adjuvants, two key ingredients for the potential H1N1 vaccine.
- [Interim guidance for use of 23-valent pneumococcal polysaccharide vaccine during novel influenza A \(H1N1\) outbreak](#) (Centers for Disease Control and Prevention)
Provides guidance on which groups should be vaccinated with the 23-valent pneumococcal polysaccharide vaccine.
- [HHS Announces Advanced Development Contract for New Way to Make Flu Vaccine](#) (U.S. Department of Health and Human Services)
Using new recombinant influenza vaccine technology, vaccine candidates, clinical investigational lots, an commercial-scale vaccine production may be available faster than by using traditional vaccine production methods
- [First Batch of a Swine Flu Vaccine Produced](#) (Voice of America)
The Swiss pharmaceutical company Novartis says it has produced a first batch of a vaccine, weeks ahead of expectations by using cell-based production.
- [HHS 2009 H1N1 Vaccine Development Activities](#) (U.S. Department of Health and Human Services)
Overview of vaccine development activities for a 2009 H1N1 vaccine.
- [HHS 2009 H1N1 Vaccine Development Next Steps: Questions and Answers](#) (U.S. Department of Health and Human Services)
Questions and answers in related to the development of H1N1 influenza vaccine
- [U.S. 2009 H1N1 Vaccine Strategy \[PDF - 580KB\]](#) (U.S. Department of Health and Human Services)
Graphical depiction of the predicted waves of the outbreak and the expected timeframes for vaccine development, manufacturing, and distribution and administration.
- [HHS Takes Additional Steps Toward Development of Vaccine for the Novel Influenza A \(H1N1\)](#) (U.S. Department of Health and Human Services)
Learn how parts of an H1N1 vaccine will be produced, stored, and used in clinical studies.
- [Vaccines for the Influenza A \(H1N1\)](#) (World Health Organization)
Read questions and answers about vaccine development for H1N1 flu (swine flu).

H1N1 (Swine Flu) Immunization Campaign

Are you planning a novel H1N1 flu vaccination program here in the U.S.?

Yes, we are preparing for an H1N1 vaccination campaign. Working with Congress, governors, mayors, state and local health departments, the medical community and our private sector partners, the administration has been actively preparing for a range of H1N1 virus outbreak scenarios that may develop over the next few months and will prepare action plans based on the best scientific information available to help our nation respond aggressively to H1N1.

As we prepare for the fall flu season, we will be working closely with our partners in the medical community to develop, test, purchase and distribute vaccines as well as medicines to treat those who may contract the H1N1 virus.

We are making every effort to have a safe and effective H1N1 vaccine available for distribution as soon as mid-October, but it is possible, even probable, that epidemics may begin in different parts of the country before then. This makes prevention even more critical.

Over the course of the next few months, with the assistance of our partners in the private and public sector

and at every level of government, we will move aggressively to prepare the nation for the possibility of a more severe outbreak of the H1N1 virus. We will do all we can to plan for different scenarios. We ask the American people to become actively engaged with their own preparation and prevention. It's a responsibility we all share.

Who will be recommended as priority groups to receive the novel H1N1 vaccine?

On July 29, 2009, the Advisory Committee on Immunization Practices (ACIP)—an advisory committee to CDC—recommended that novel H1N1 flu vaccine be made available first to the following five groups:

- Pregnant women
- Health care workers and emergency medical responders
- People caring for infants under 6 months of age
- Children and young adults from 6 months to 24 years
- People aged 25 to 64 years with underlying medical conditions (e.g. asthma, diabetes)
- Combined, these groups would equal approximately 159 million individuals.

Why are these priority groups different than those listed in your previous pandemic plans?

Our pandemic plans developed over the past several years were just that—plans. Our previous planning guidance was intended to provide strong advice to support planning an effective and consistent pandemic response by States and communities. Nevertheless, it is important that plans are flexible as the guidance may need to be modified based on the status of vaccine technology, the characteristics of pandemic illness, and risk groups for severe disease – factors that will remain unknown until a pandemic actually occurs. It is recognized that the supply of the novel H1N1 vaccine will not be available all at once, but rather, be produced at a rate that depends on both efficiency of production and manufacturing capacity. Given that the novel H1N1 influenza vaccine supply will continue to be available over time, allocation decisions needed to be made.

The priority groups identified during that planning process were based on what we projected might occur with a hypothetical virus in a future influenza pandemic. Now that an actual flu pandemic has arrived, we must be flexible and adjust our response based on the nature of the actual virus that has emerged, is circulating and causing disease around the world. Based on what we know now about the novel H1N1 virus and the most vulnerable groups that are being affected most by this virus and those most likely to encounter it—younger people, pregnant women, healthcare personnel, and people who have underlying health conditions—it is necessary to revise and refine our vaccine prioritization guidance based on real world events.

Where will the vaccine be available?

Every state is developing a vaccine delivery plan. Vaccine will be available in a combination of settings such as vaccination clinics organized by local health departments, healthcare provider offices, schools, and other private settings, such as pharmacies and workplaces.

How are you going to vaccinate everyone in this country and how are we going to pay for it?

The President and the Congress are committed to doing everything we can to keep the American people safe and have allocated funding that can be used to produce vaccine components necessary to protect Americans. To date, HHS has already invested more than \$1 billion to produce a bulk supply of vaccine and to prepare pilot lots of potential vaccine for use in clinical studies.

In addition Congress passed and President Obama recently signed a supplemental appropriation for \$7.5 billion to cover the costs of preparing for H1N1 including a vaccination campaign.

As we prepare for the fall flu season, we will be working closely with our partners in the medical community to develop, test, distribute and produce flu vaccines for prevention and anti-virals administer an H1N1 flu vaccine and to distribute and dispense antiviral medications for those who may require treatment.

We will make every effort to have a safe and effective H1N1 vaccine available for distribution to those who are identified as target audiences as soon as possible, but our current estimate is that a vaccine for H1N1 won't be ready for distribution until mid-October. This fact makes prevention even more critical.

The process of making and testing a vaccine is already underway and decisions regarding vaccine formulation and dosing will be informed by the clinical studies that will start later this summer. Not everyone in the country may need an H1N1 vaccine. We will know more once the clinical trials are complete.

Will HHS be providing liability protection for vaccine manufacturers? And will HHS compensate eligible individuals who might be injured by a vaccine?

On June 15, 2009, HHS Secretary Sebelius signed a declaration under the Public Readiness and Emergency Preparedness (PREP) Act to extend liability immunity against tort claims (except for willful misconduct) to individuals and entities involved in all stages of 2009 H1N1 influenza vaccine development, testing, manufacture, distribution, prescribing, administration, and use. Liability immunity means that there is no legal tort claim that can be pursued in state or federal court. Individuals and entities that receive liability immunity under the declaration include manufacturers, distributors, States, locals, Tribes, and other entities that supervise or administer a vaccination program, and healthcare professionals or others authorized under State law to prescribe, administer, and dispense vaccines, when they are carrying out activities in accordance with the conditions stated in the declaration. One condition of the declaration is that the vaccination activities must relate to a present or future federal contract, grant, cooperative agreement, interagency agreement, or memorandum of understanding. Vaccines procured by the federal government for distribution are included. PREP Act declarations are intended to encourage manufactures to produce vaccine, and other entities to participate in distribution, dispensing, administration, and use of the vaccine.

The PREP Act also authorizes the Department to establish a compensation program when a declaration is issued under the Act. Funds for a compensation program were provided under the June 24 Supplemental

Appropriations Act. The Department is currently working on developing a compensation program for eligible individuals who sustain covered injuries following vaccination.

H5N1 Flu (Avian Flu)

Research efforts have led to the development of a vaccine for one of the two known strains of the H5N1 influenza virus in humans.

Vaccines

- [HHS Awards \\$487 Million Contract to Build First U.S. Manufacturing Facility for Cell-Based Influenza Vaccine](#) (U.S. Department of Health and Human Services)
The development of the first cell-based vaccine manufacturing facility in the United States is expected to increase the nation's capacity to make pandemic influenza vaccine by at least 25 percent. The cell-based influenza vaccine can be produced faster and in greater quantities than the traditional egg-based vaccine.
 - [Availability of a New Recombinant H5N1 Vaccine Virus](#) (World Health Organization)
A new H5N1 recombinant vaccine virus has been developed and is available for distribution, under a Material Transfer Agreement (MTA), to institutions, companies and others interested in pandemic vaccine development.
- [Questions and Answers on Pandemic Influenza Vaccine](#) (World Health Organization)
- Learn the difference between seasonal influenza vaccines, "pre-pandemic" vaccines, and pandemic vaccines. Vaccine development, vaccine production, and universal access to pandemic influenza vaccine are also discussed
- [FDA Approves the First U.S. Vaccine for Humans Against H5N1 Virus](#) (Food and Drug Administration)
- The vaccine was obtained from a human strain and is intended for immunizing people 18 through 64 years of age who could be at increased risk of exposure to the H5N1 influenza virus contained in the vaccine.
- [Vaccine Production in Cells](#)
Provides background on a new method of producing vaccines and current efforts to develop cell-based vaccines for influenza.

Vaccine Allocation

- [Guidance on Allocating and Targeting Pandemic Influenza Vaccine](#) (PDF - 1.83 MB), July 23, 2008
The guidance provides a planning framework to help state, tribal, local and community leaders ensure that vaccine allocation and use will reduce the impact of a pandemic on health and minimize its disruption to society and the economy.
- [Citizen Voices on Pandemic Flu Choices -- A Report of the Public Engagement Pilot Project on Pandemic Influenza](#), December 2005
This report describes the convening of a representative group of stakeholders and citizens-at-large, the structure and process of stakeholder and citizen dialogues and deliberations, and the decisions made and recommendations that were developed.
 - [Preface & Executive Summary](#) (PDF - 298.92 KB)
 - [Full Report](#) (PDF - 1.11 MB)
 - [Attachments](#) (PDF - 1.27 MB)

Vaccine Research

- [Guidance on Vaccine Product Development and Approval](#) (U.S. Food and Drug Administration) View draft guidance, publications, and other information from the FDA about vaccine development and the product approval process.
- [Questions and Answers: H5N1 Avian Flu Vaccine Trials](#) (National Institute of Allergy and Infectious Diseases)
Questions and answers about testing and evaluating potential avian flu vaccines for people.
- [Antiviral Response in Pandemic Influenza Viruses](#) (Centers for Disease Control and Prevention)
Read about viral proteins and their possible role in human pandemics.
- [Initiative for Vaccine Research](#) (World Health Organization)
Read about WHO's actions to guide, support, and facilitate the development, clinical evaluation, and world-wide access to safe, effective and affordable vaccines against infectious diseases.
- [Draft Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Starting Materials Used in the Production of Viral Vaccines for the Prevention and Treatment of Infectious Diseases](#) (U.S. Food and Drug Administration)
Read draft guidance from the FDA to facilitate manufacturers in the development and availability of safe

and effective vaccines, including those to address emerging and pandemic threats.

Clinical Trials

[Avian Influenza Clinical Trials \(ClinicalTrials.gov\)](#)

Learn about current avian flu clinical trials.

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