

September 2005

# INFLUENZA VACCINE

## Shortages in 2004–05 Season Underscore Need for Better Preparation



G A O  
Accountability · Integrity · Reliability

# Highlights

Highlights of [GAO-05-984](#), a report to the Committee on Government Reform, House of Representatives, and the Committee on Homeland Security and Governmental Affairs, U.S. Senate

## Why GAO Did This Study

In early October 2004, the nation lost about half its expected influenza vaccine supply when one of two major manufacturers announced it would not release any vaccine for the 2004–05 season because of potential contamination. The Centers for Disease Control and Prevention (CDC) had earlier recommended vaccination for 188 million individuals, including those at high risk of severe complications from influenza (such as seniors and those with chronic conditions), and other groups (such as their close contacts). Although health officials took actions to distribute the limited supply of influenza vaccine, reports persisted of high-risk individuals and others in priority groups who could not find a vaccination, including those who were turned away and never returned when supplies became available. Such reports raised questions about the adequacy of U.S. preparedness to respond to significant vaccine shortages.

GAO was asked to examine actions taken at federal, state, and local levels to ensure that high-risk individuals had access to influenza vaccine during the shortage, including any lessons learned.

[www.gao.gov/cgi-bin/getrpt?GAO-05-984](http://www.gao.gov/cgi-bin/getrpt?GAO-05-984).

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119 or [crossem@gao.gov](mailto:crossem@gao.gov).

# INFLUENZA VACCINE

## Shortages in 2004–05 Season Underscore Need for Better Preparation

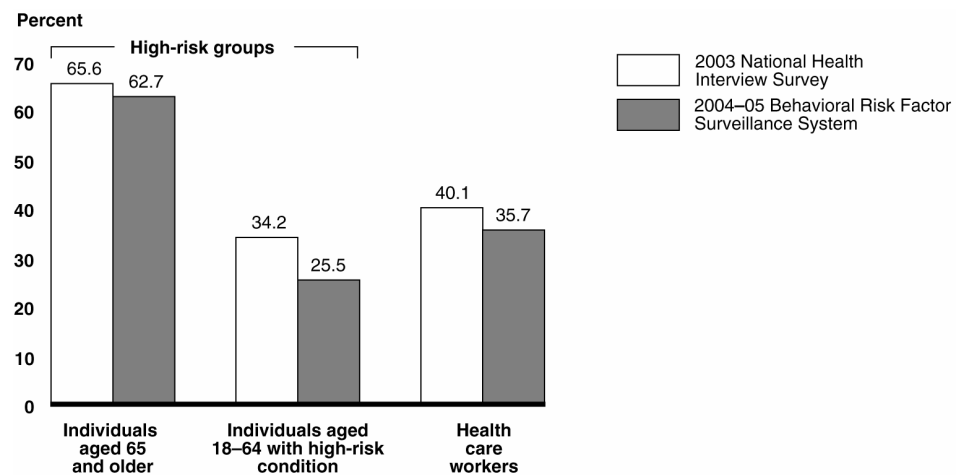
### What GAO Found

Federal, state, and local health officials took several actions beginning in October 2004 to help ensure that individuals at high risk of severe complications from influenza had access to vaccine. Federal officials, for example, quickly revised vaccination recommendations to target available vaccine to high-risk individuals and to other priority groups. Additional actions were aimed to distribute vaccine expeditiously and to communicate with providers and the public as events unfolded and vaccine supplies changed. Beginning in mid-December, health officials took steps to distribute additional vaccine, broadening recommendations on who should be vaccinated.

Although these actions helped achieve vaccination rates approaching past levels for certain priority groups, such as those aged 65 years and older, several lessons emerged, including some that could help with future shortages. First, unless planning for problems is already in place, action is delayed. CDC's lack of a contingency plan contributed to delays and uncertainty about how to ensure that high-risk individuals had access to vaccine. Second, when actions occur late in the influenza season, they are likely to have little effect. Third, effective response requires communication that is both clear and consistent. CDC has taken a number of steps, including issuing interim guidelines in August 2005, to respond to possible future shortages. It is too early, however, to assess the effectiveness of these efforts in coordinating actions of federal, state, and local health agencies and others.

In commenting on a draft of this report, HHS concurred with GAO's finding that contingency planning would improve response efforts, and the agency indicated that additional preparations were under way.

**Influenza Vaccination Rates for Selected Priority Groups**



Source: CDC.

---

# Contents

---

|                             |   |    |
|-----------------------------|---|----|
| <b>Letter</b>               |   | 1  |
|                             | Results in Brief  | 3  |
|                             | Background  | 5  |
|                             | Health Officials Took Steps to Vaccinate High-Risk Individuals and<br>Others in Priority Groups           | 10 |
|                             | Planning, Timely Action, and Communication Are Key to an<br>Effective Response                            | 23 |
|                             | Concluding Observations   | 32 |
|                             | Agency Comments   | 33 |
| <b>Appendix I</b>           | <b>Comments from the Department of Health and Human<br/>Services</b>                                      | 35 |
| <b>Appendix II</b>          | <b>GAO Contact and Staff Acknowledgments</b>  | 37 |
| <b>Related GAO Products</b> |   | 38 |
| <b>Tables</b>               |   |    |
|                             | Table 1: Groups Recommended for Influenza Vaccination, Before<br>and After October 5, 2004                | 13 |
|                             | Table 2: Phase I of CDC's Influenza Vaccine Distribution Plan   | 16 |
|                             | Table 3: Communication Methods Used by Various Health<br>Departments to Disseminate Influenza Information | 21 |
| <b>Figures</b>              |   |    |
|                             | Figure 1: Influenza Vaccine Cycle   | 6  |
|                             | Figure 2: Influenza Vaccine Production and Distribution   | 8  |
|                             | Figure 3: Timeline of the 2004–05 Influenza Vaccine Shortage  | 11 |
|                             | Figure 4: Phase II of CDC's Influenza Vaccine Distribution Plan   | 17 |
|                             | Figure 5: Influenza Vaccination Rates for Selected Priority Groups  | 24 |

---

---

## **Abbreviations**

|      |  |
|------|--|
| ACIP | Advisory Committee on Immunization Practices |
| CDC  | Centers for Disease Control and Prevention   |
| FDA  | Food and Drug Administration                 |
| HHS  | Department of Health and Human Services      |

This is a work of the U.S. government and is not subject to copyright protection in the United States. It may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.



United States Government Accountability Office  
Washington, DC 20548

September 30, 2005

The Honorable Tom Davis  
Chairman  
The Honorable Henry A. Waxman  
Ranking Minority Member  
Committee on Government Reform  
House of Representatives

The Honorable Susan M. Collins  
Chairman  
Committee on Homeland Security and Governmental Affairs  
United States Senate

As the traditional influenza vaccination period started in fall 2004, the nation faced the unexpected loss of nearly half its projected vaccine supply. One of the two major manufacturers of influenza vaccine for the United States warned in late August 2004 that deliveries would be delayed because a small quantity of its vaccine failed sterility tests. On October 5, 2004, the manufacturer announced that because of potential contamination, it would be unable to release any vaccine for the U.S. market. The Department of Health and Human Services (HHS) had expected that this manufacturer would produce about 47 million doses—close to half of the 100 million doses estimated for the 2004–05 influenza season.<sup>1</sup> Before the October 5 announcement, HHS’s Centers for Disease Control and Prevention (CDC) and its Advisory Committee on Immunization Practices (ACIP) had recommended that those at high risk of severe complications from influenza and those in other priority groups—such as health care workers and those aged 50–64 years—receive an influenza vaccination.<sup>2</sup> After the announcement, with no other U.S.-

---

<sup>1</sup>See Centers for Disease Control and Prevention, “Supplemental Recommendations about Timing of Influenza Vaccination, 2004–05 Season,” *Morbidity and Mortality Weekly Report*, vol. 53, no. 37 (2004): 878–879.

<sup>2</sup>ACIP makes recommendations to CDC, and CDC generally adopts them; we refer to such recommendations as CDC recommendations. Although CDC estimates published in October 2004 show about 188 million people in high-risk and other priority groups, not everyone in these groups receives a vaccination each year. According to CDC, the prior maximum number of doses distributed was approximately 83.1 million. Thus CDC estimated that an expected 100 million doses of vaccine would be sufficient to meet demand for the 2004–05 influenza season.

---

licensed manufacturers able to replace the large amount of lost vaccine on such short notice, concerns arose about the effects of the loss, especially on those most vulnerable to complications from influenza.

Media reports of long lines of seniors waiting hours for a chance at a vaccination, of others at high risk who could not find a vaccination, and of individuals turned away who never returned when supplies became available fueled worries that the nation was not adequately prepared to respond to the significant vaccine shortage or to an influenza pandemic (a widespread or worldwide influenza epidemic). Notwithstanding these concerns, CDC's postseason data indicate that 2004–05 vaccination rates among certain high-risk groups such as seniors approached historical rates.<sup>3</sup>

You observed that the 2004–05 influenza vaccine shortage was the most severe in recent history and that lessons learned from this season would enable the nation to better deal with a similar situation in the future. This report examines the response to the 2004–05 shortage and identifies the lessons. We address the following questions:

1. What actions were taken at federal, state, and local levels to ensure that high-risk individuals had access to influenza vaccine during the 2004–05 shortage?
2. What were the lessons learned from the strategies implemented at the federal, state, and local levels to ensure that high-risk individuals had access to influenza vaccine?

To address these objectives, we reviewed documents and interviewed officials from (1) CDC and HHS's National Vaccine Program Office; (2) national organizations, including the Association of State and Territorial Health Officials, the Association of Immunization Managers,

---

<sup>3</sup>See Centers for Disease Control and Prevention, "Estimated Influenza Vaccination Coverage among Adults and Children, United States, September 1, 2004–January 31, 2005," *Morbidity and Mortality Weekly Report*, vol. 54, no. 12 (2005): 304–307.

---

and the National Association of County and City Health Officials;<sup>4</sup> (3) organizations that conduct mass immunization clinics; (4) sanofi pasteur,<sup>5</sup> the remaining major manufacturer of influenza vaccine available for people at high risk of influenza-related complications; and (5) Kaiser Permanente, a health system that is a large purchaser of influenza vaccine. We also conducted site visits to a judgmental sample of states (California, Florida, Maine, Minnesota, and Washington) and localities (San Diego and San Francisco, California; Miami–Dade County, Florida; Portland, Maine; Stearns County, Minnesota; and Seattle–King County, Washington). We selected these states and localities to reflect a mix of geographic locations, population size, and vaccination success rates.<sup>6</sup> In each state, we reviewed documents and interviewed officials from public health agencies, professional associations, and provider organizations. We also interviewed local representatives of home health organizations that conduct mass immunizations and representatives of the Minnesota Multistate Contracting Alliance for Pharmacy, which arranges purchase of vaccines for use in 43 states. We conducted our work in accordance with generally accepted government auditing standards from March through September 2005.

---

## Results in Brief

Upon learning that nearly one-half of the projected vaccine supply would be unavailable for the 2004–05 influenza season, federal, state, and local health officials took several actions to help ensure that those at high risk of severe influenza-related complications had access to available vaccine. These efforts prompted federal revision of the recommendations on who should be vaccinated, so that vaccine could be directed to those at high risk and to other priority groups. Federal, state, and local actions also focused on distributing vaccine to priority groups, using a number of

---

<sup>4</sup>Members of the Association of State and Territorial Health Officials include the chief health officials representing state and territorial public health agencies. Members of the Association of Immunization Managers include immunization program directors from state health departments, U.S. territories, and selected cities. Members of the National Association of County and City Health Officials include representatives from local public health agencies. In addition to officials from these associations, we interviewed some association members.

<sup>5</sup>Aventis Pasteur became sanofi pasteur (spelled without capital letters) in January 2005.

<sup>6</sup>We selected our sites on the basis of CDC’s Behavioral Risk Factor Surveillance System survey data (state-level data) on the percentage of adults in priority groups for 2004–05 who reported receiving an influenza vaccination during the traditional fall vaccination period (September–November 2004).

---

communication strategies to keep providers and the public informed about the shortage. CDC, for example, developed and implemented a complex plan to distribute vaccine to providers serving priority groups across the states. Late in the influenza vaccination period—from mid-December through January—health officials took various actions to increase vaccine availability and attempted to distribute vaccine across the wider population by broadening recommendations on who should be vaccinated.

A number of lessons emerged from federal, state, and local responses to the 2004–05 influenza vaccine shortage, some specific to that season’s shortage, others with wider ramifications for potential future shortages or a public health emergency. The primary lessons fall into three broad, interrelated categories: planning, timely action, and communication.

- **Limited contingency planning slows response.** At the start of the traditional fall vaccination period, CDC did not have a contingency plan specifically designed to respond to a severe influenza vaccine shortage. The lack of such a plan led to delays and uncertainty on the part of many state and local entities on how best to ensure access to vaccine during the shortage by individuals at high risk and others in priority groups. Nevertheless, some state and local entities used strategies that enabled them to respond relatively efficiently. For example, a number of states used existing emergency preparedness plans and issued emergency health directives to improve priority groups’ access to vaccine during the shortage. Some public health departments also facilitated the administration of vaccine in an orderly fashion when demand was highest, including scheduling vaccinations by appointment and holding lotteries.
- **Unless expedited, actions to boost available supply may have little effect.** Although federal agencies attempted to boost influenza vaccine supply, their efforts came too late in what turned out to be a relatively moderate influenza season. For example, HHS officials purchased vaccine that was not licensed for the U.S. market, but the purchases occurred in December 2004 and January 2005, by which time demand had already waned. Similarly, state officials reported that CDC’s attempt to expand availability to other children and to adults of the vaccine purchased for its Vaccines for Children program came after demand for vaccine had dropped.
- **Effective response requires communication that is both clear and consistent.** Although CDC quickly communicated with nonfederal agencies, providers, and the public throughout the changing environment of the 2004–05 influenza season, communication was not always coordinated among these entities, and inconsistent messages did occur, contributing to delays and confusion and ultimately resulting in a late-season vaccine surplus. For example, in California, state officials in mid-



---

December were advising vaccinations for those aged 50 years and older, while CDC was simultaneously recommending vaccinations only for those aged 65 years and older. In addition, although a national campaign communicated the early-season messages to step aside in favor of those in priority groups, the campaign did not include a message to come back later when more vaccine became available. In certain locations, individuals seeking vaccination found themselves in a communication loop if they tried to follow CDC's advice to contact their local public health department for vaccine availability: when they did so, they were told to call their primary care provider, but when they called their primary care provider, they were told to call their local public health department. Furthermore, public education about the various forms of vaccine fell short. For example, despite the availability of a nasal spray vaccine for healthy individuals aged 5–49 years who were not pregnant, inadequate education about the vaccine contributed to the reluctance of some individuals to use it.

After the 2004–05 influenza season, CDC reviewed its response to the vaccine shortage and took a number of steps, including issuing interim guidelines in August 2005 to assist in responding to possible future shortages.

We provided a draft of this report to HHS, and pertinent sections to the states and localities we visited and to sanofi pasteur, for their review. HHS concurred with our finding that contingency planning is important and indicated that further actions, such as approval of additional influenza vaccines for the U.S. market, were under way. HHS, states, localities, and sanofi pasteur provided technical comments, which we incorporated as appropriate. HHS's written comments appear in appendix I.

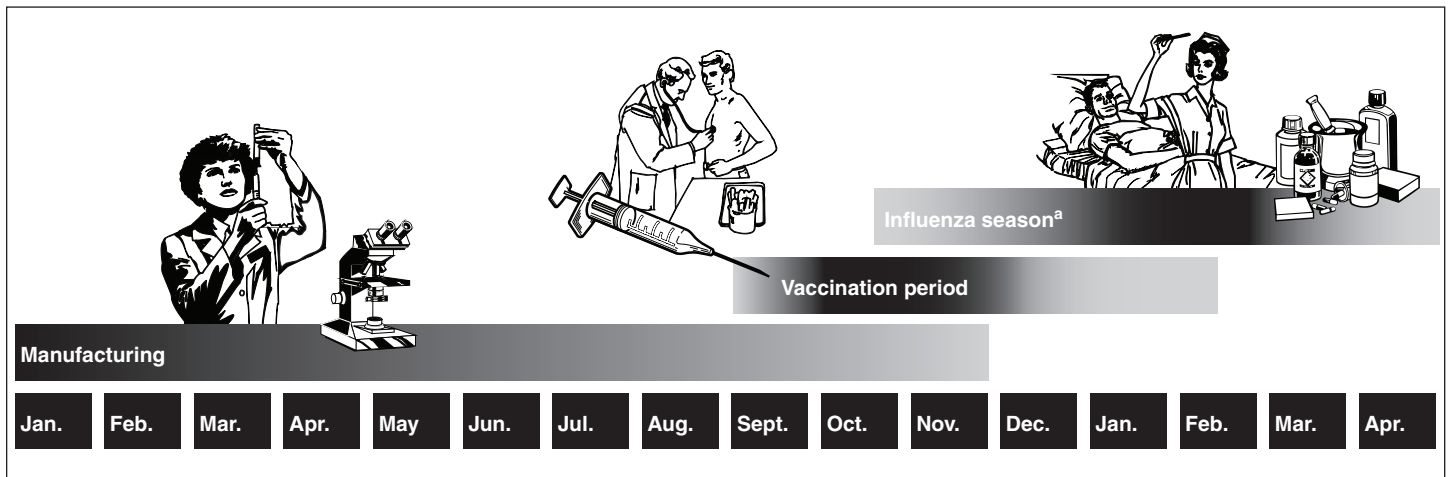
---

## Background

Influenza is characterized by cough, fever, headache, and other symptoms and is more severe than some viral respiratory infections, such as the common cold. Most people who contract influenza recover completely in 1 to 2 weeks, but some develop serious and potentially life-threatening medical complications, such as pneumonia. On average each year in the United States, more than 36,000 individuals die and more than 200,000 are hospitalized from influenza and related complications. People aged 65 years and older, people of any age with chronic medical conditions, children younger than 2 years of age, and pregnant women are generally more likely than others to develop severe influenza-related complications.

Vaccination is the primary method for preventing influenza and its more severe complications. Produced in a complex process that involves growing viruses in millions of fertilized chicken eggs, influenza vaccine is administered annually to provide protection against particular influenza strains expected to be prevalent that year. Experience has shown that vaccine production generally takes 6 or more months after a virus strain has been identified, and vaccines for certain influenza strains have been difficult to mass-produce. After vaccination, the body takes about 2 weeks to produce the antibodies that protect against infection. According to CDC, the optimal time for vaccination is October through November, because the annual influenza season typically does not peak until January or February. Thus in most years, vaccination in December or later can still be beneficial (see fig. 1). If supplies permit, CDC recommends a vaccination for anyone who wants one. Because circulating influenza strains change, a new vaccine is created each year. For this reason, and because immunity declines over time, CDC recommends a new influenza vaccination every year for high-risk individuals and other priority groups, including close contacts of those at high risk.

**Figure 1: Influenza Vaccine Cycle**



Source: GAO (analysis), Art Explosion (clip art).

<sup>a</sup>The influenza season varies from year to year, generally beginning in late October and peaking in January or February.

---

Two types of vaccine are recommended for protection against influenza in the United States: (1) an inactivated virus vaccine injected into muscle and (2) a live virus vaccine administered as a nasal spray. The injectable vaccine—which represents the large majority (over 95 percent) of influenza vaccine administered in this country—can be used to immunize healthy individuals and those at high risk of severe complications, including those with chronic illness and those aged 65 years and older. The nasal spray vaccine, in contrast, is currently approved for use only among healthy individuals aged 5–49 years who are not pregnant. Although vaccination is the primary strategy for protecting individuals who are at greatest risk of serious complications and death from influenza, antiviral drugs can also contribute to the treatment and prevention of the disease.<sup>7</sup>

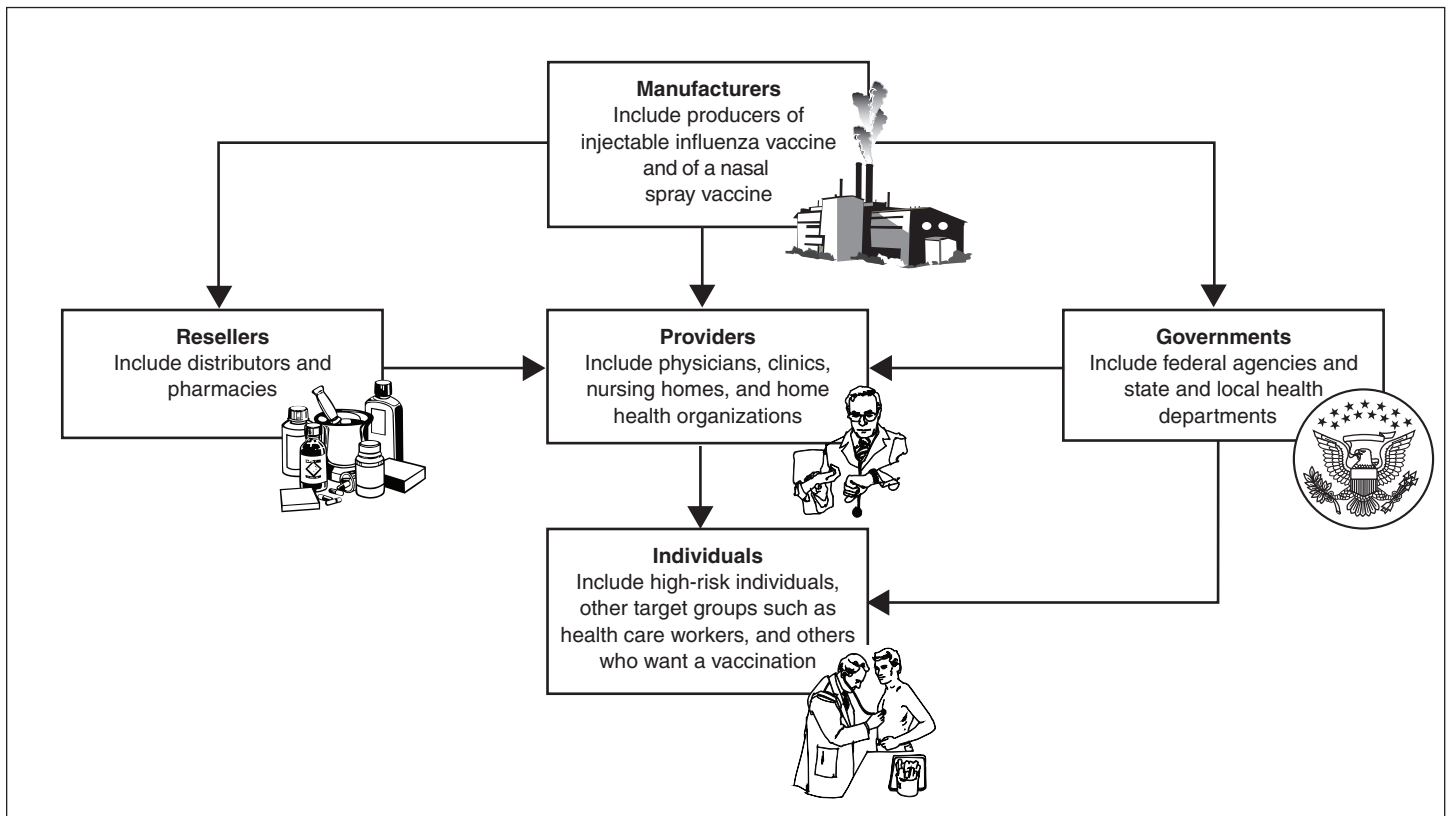
In a typical year, manufacturers make influenza vaccine available before the optimal fall vaccination season. For the 2003–04 influenza season, two manufacturers—one with production facilities in the United States (sanofi pasteur) and one with production facilities in the United Kingdom (Chiron)—produced about 83 million doses of injectable vaccine, which represented about 96 percent of the U.S. vaccine supply. A third U.S. manufacturer (MedImmune) produced the nasal spray vaccine. According to CDC, MedImmune produced about 3 million doses of the nasal spray vaccine, or about 4 percent of the overall influenza vaccine supply, for the 2003–04 season.

Influenza vaccine production and distribution are largely private-sector activities. Manufacturers sell influenza vaccine to resellers (such as medical supply distributors and pharmacies), to federal agencies and state and local public health departments, or directly to providers (see fig. 2). Individuals can obtain an influenza vaccination at a number of places, including physicians' offices, public health clinics, nursing homes, and nonmedical locations such as workplaces or retail outlets. Millions of individuals receive influenza vaccinations through mass immunization campaigns in these nonmedical settings, where organizations such as visiting nurse agencies under contract administer the vaccine.

---

<sup>7</sup>Four antiviral drugs have been approved for treatment. If taken within 2 days of illness, these drugs can reduce symptoms and make someone with influenza less contagious to others.

**Figure 2: Influenza Vaccine Production and Distribution**



Source: GAO (analysis), Art Explosion (clip art).

HHS has limited authority to control vaccine production and distribution directly; influenza vaccine supply and marketing are largely in the hands of the private sector.<sup>8</sup> In the event that the Secretary of HHS determines and declares a public health emergency, the Public Health Service Act

<sup>8</sup>FDA has limited authority to prohibit the resale of prescription drugs, including influenza vaccine that has been purchased by health care entities such as public or private hospitals. This authority does not extend to resale of the vaccine for emergency medical reasons. The term "health care entity" does not include wholesale distributors.

---

authorizes the Secretary to “take such action as may be appropriate” to respond.<sup>9</sup>

Within HHS, CDC is one of the agencies that help protect the nation’s health and safety. CDC’s activities include efforts to prevent and control diseases and to respond to public health emergencies. ACIP, after consulting with CDC, makes recommendations on which population groups should be targeted for vaccination. CDC also administers a number of programs to help make vaccines, including influenza vaccine, affordable for low-income and other populations. For example, under CDC’s Vaccines for Children program, vaccines are provided free of charge for certain children 18 years of age or younger, including those who are Medicaid-eligible, uninsured, or underinsured (that is, their insurance does not include vaccinations). CDC also reserves stockpiles of certain vaccines. For the 2004–05 influenza season, CDC contracted with vaccine manufacturers to supply influenza vaccine for a national stockpile for the first time. The agency originally contracted for 4.5 million doses, including 2 million doses from Chiron, which were therefore not available. CDC also maintains stockpiles of antiviral medications that can alleviate influenza symptoms and reduce contagion in those who contract the disease.

Other organizations within HHS that are involved with immunization activities include the National Vaccine Program Office, which is responsible for coordinating and ensuring collaboration among the many federal agencies involved in vaccine and immunization activities, and the Food and Drug Administration (FDA), which in approving and regulating the use of vaccines and drugs, including antiviral medications, is responsible for ensuring that they are safe and effective. In addition to federal agencies, state and local health departments are often the first responders in situations affecting public health.

Initially for the 2004–05 influenza season, CDC in May 2004 recommended that about 188 million Americans receive a vaccination—about 85 million at high risk of severe complications and about 103 million in other priority groups, such as people in close contact with high-risk individuals, healthy

---

<sup>9</sup>According to the act, to declare a public health emergency, the Secretary must determine that (1) a disease or disorder presents a public health emergency, or (2) a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists. Public Health Improvement Act, Pub. L. No. 106-505, § 102, 114 Stat. 2314, 2315 (2002) (adding §319 to the Public Health Service Act) (codified at 42 U.S.C. § 247d).

---

people aged 50–64 years, and health care workers.<sup>10</sup> CDC also suggested that, depending on the availability of vaccine, other individuals who should receive a vaccination include (1) any person who wished to reduce the likelihood of contracting influenza, (2) individuals who provide essential community services, and (3) students and others in institutional settings. Although Chiron had announced that it was experiencing production problems in August 2004, according to CDC, the manufacturer had assured the agency that the production issues were being resolved. Subsequently, on September 24, 2004, CDC reiterated its recommendation that 188 million individuals in high-risk and other groups be vaccinated as vaccine became available. CDC also recommended that anyone wanting to reduce the risk of contracting influenza be vaccinated. Not everyone in these high-risk and priority groups, however, receives a vaccination each year. Among health care workers, for example, about 40 percent received a vaccination in the 2002–03 and 2003–04 seasons, according to one CDC survey. Similarly, about 66 percent of individuals aged 65 years and older reported receiving influenza vaccination in the 2002–03 and 2003–04 influenza seasons, according to CDC estimates.<sup>11</sup>

---

## Health Officials Took Steps to Vaccinate High-Risk Individuals and Others in Priority Groups

After the October 5, 2004, announcement of the sharp reduction in expected influenza vaccine supply, federal, state, and local health officials took steps to help ensure that those at high risk of severe complications from infection had access to influenza vaccine. For example, health officials quickly revised vaccination recommendations so that the remaining supply could be targeted to those in priority groups comprising those at high risk, certain health care workers, and household contacts of children younger than 6 months of age. Other efforts focused on distributing vaccine to priority groups and on keeping providers and the public updated as to vaccine availability. Finally, late in the influenza vaccination period—from mid-December through January—health officials’ actions focused on further augmenting the vaccine supply and,

---

<sup>10</sup>CDC recommended vaccination for people aged 50–64 years to raise the low vaccination rates among people with high-risk conditions in this age group. Further, people in this age group without high-risk conditions also benefit from lower influenza rates, fewer medical visits, and less medication. See Centers for Disease Control and Prevention, “Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices,” *Morbidity and Mortality Weekly Report*, vol. 53, RR-6 (2004): 1–40.

<sup>11</sup>See Centers for Disease Control and Prevention, “Estimated Influenza Vaccination Coverage among Adults and Children, United States, September 1, 2004–January 31, 2005,” *Morbidity and Mortality Weekly Report*, vol. 54, no. 12 (2005): 304–307.

once supply increased, on encouraging vaccination for anyone remaining in the priority groups and for others who had earlier deferred vaccination (see fig. 3).

**Figure 3: Timeline of the 2004–05 Influenza Vaccine Shortage**

| May  | August   | September   | October  | November  | December   | January  |
|--|--|---|--|---|--|--|
| <p><b>May 28, 2004</b><br/>CDC recommends that 188 million Americans, including about 85 million people at high risk of severe complications, be vaccinated for influenza.</p> | <p><b>August 26</b><br/>CDC says Chiron's vaccine may be delayed because of production problems.</p> | <p><b>September 24</b><br/>CDC recommends that influenza vaccination proceed as soon as influenza vaccine is available, as it recommended in May.</p> | <p><b>October 5</b><br/>Chiron's license is suspended by the United Kingdom, cutting the U.S. supply in half. CDC issues a revised list of priority groups it recommends for vaccination and asks others to defer vaccination.</p> <p><b>October 12</b><br/>CDC begins phase I of a distribution plan, to ship about 13 million doses to providers serving high-risk individuals.</p> <p><b>October 14</b><br/>HHS urges all state attorneys general to investigate and prosecute anyone engaging in price gouging of influenza vaccine.</p> | <p><b>November 17</b><br/>CDC begins phase II of a distribution plan, where states order vaccine through CDC to fill their estimated unmet needs for vaccinating priority groups.</p> | <p><b>December 7</b><br/>HHS agrees to purchase from Europe influenza vaccine not licensed for use in the United States.</p> <p><b>December 15</b><br/>Nine states have begun offering influenza vaccine to people aged 50 years and older and to household contacts of high-risk individuals.</p> | <p><b>January 3, 2005</b><br/>CDC broadens vaccine recommendations to those aged 50 years and older and to household contacts of high-risk individuals.<sup>a</sup></p> <p><b>January 27</b><br/>CDC advises anyone wanting an influenza vaccination to seek one and makes available late-season doses previously reserved for the federal vaccine stockpile or Vaccines for Children program.<sup>a</sup></p> |

Source: GAO.

<sup>a</sup>CDC actions broadening recommendations on who should be vaccinated applied only in locations where state and local health officials judged vaccine supply to be adequate.

## Federal and State Officials Took Quick Actions

Several responses by public health officials took place within hours or days of the public announcement that a severe shortage of influenza vaccine was imminent.

- Federal and state health officials redefined priority groups for influenza vaccination.** CDC immediately redefined the groups recommended to receive vaccine in 2004–05 for protection against influenza and its complications and issued revised recommendations on October 5, 2004. These revised recommendations focused on priority groups that included high-risk individuals, health care workers involved in

---

direct patient care, and household contacts of children younger than 6 months of age. CDC's revised recommendations decreased the number of people in groups recommended for vaccination from about 188 million to about 98 million (see table 1).<sup>12</sup> At the same time, CDC also asked people not in these priority groups to forgo or defer vaccination. State and local health officials we met with reported having quickly adopted CDC's revised recommendations. Some health departments, however, found that they did not have enough vaccine to cover everyone in CDC's priority groups and therefore subdivided CDC's priority groups. For example, in Maine, all health care workers were initially excluded from the state's priority groups, although later, Maine health officials recommended vaccination for particular types of health care workers, such as those working in intensive care units and emergency departments, if local vaccine supply allowed.

---

<sup>12</sup>On October 5, 2004, CDC issued interim recommendations for influenza vaccination during the 2004–05 season, which took precedence over earlier recommendations. The season's priority groups for vaccination with injectable influenza vaccine were considered to be of equal importance. See Centers for Disease Control and Prevention, "Interim Influenza Vaccination Recommendations, 2004–05 Influenza Season," *Morbidity and Mortality Weekly Report*, vol. 53, no. 39 (2004): 923–924.



**Table 1: Groups Recommended for Influenza Vaccination, Before and After October 5, 2004**

|  | Population (millions) <sup>a</sup> | May 2004 <sup>b,c</sup> | October 5, 2004 <sup>c</sup> |
|--|------------------------------------|-------------------------|------------------------------|
| <b>High-risk groups</b>  |                                    |                         |                              |
| People aged 65 years and older   | 35.6                               | ✓                       | ✓                            |
| Adults and children with chronic illness   | 39.4                               | ✓                       | ✓                            |
| Pregnant women   | 4.0                                | ✓                       | ✓                            |
| All children aged 6–23 months  | 5.9                                | ✓                       | ✓                            |
| <b>Other priority groups</b>   |                                    |                         |                              |
| Health care workers aged 64 years and younger  | 7.0                                | ✓                       | ✓                            |
| People aged 2–64 years who are household contacts of high-risk individuals <sup>d</sup>          | 69.5                               | ✓                       |                              |
| People aged 2–64 years who are household contacts of children younger than 6 months <sup>d</sup> | 6.3                                | ✓                       | ✓                            |
| Healthy people aged 50–64 years who are not household contacts of high-risk individuals          | 20.1                               | ✓                       |                              |
| <b>Totals</b>  |                                    | <b>187.8</b>            | <b>98.2</b>                  |

Source: CDC.

Note: Check marks denote priority groups recommended by CDC, at the time shown, for vaccination.

<sup>a</sup>Based on July 1, 2002, population estimates, U.S. Census Bureau.

<sup>b</sup>CDC suggested that, depending on vaccine availability, anyone wishing to reduce the likelihood of contracting influenza, individuals who provide essential community services, and students and others in institutional settings also be vaccinated.

<sup>c</sup>CDC suggested that residents of nursing homes and long-term-care facilities, and children 6 months–18 years old receiving chronic aspirin therapy, also be vaccinated.

<sup>d</sup>These groups belonged to a single category in CDC’s May 2004 recommendations.

- HHS collaborated with manufacturers to temporarily halt further distribution of injectable influenza vaccine and to ramp up production of nasal spray vaccine.** At the request of CDC, sanofi pasteur, the sole remaining manufacturer of injectable influenza vaccine for the U.S. market, voluntarily suspended further distribution of the approximately 25 million doses it had not yet shipped on October 5, 2004, until the week of October 11, 2004, when CDC completed its assessment of the situation. Distribution was temporarily halted because CDC needed time to devise a plan to better target vaccine distribution to providers serving individuals in the priority groups. HHS officials also worked with MedImmune, the maker of the nasal spray vaccine, to increase its production for the 2004–05 influenza season from about 1 million doses to a total of 3 million doses.

- 
- **Federal officials evaluated foreign sources of influenza vaccine and assessed the federal stockpile of antiviral medications.** On October 11, 2004, HHS convened an interagency team, comprising officials from HHS's Office of the Secretary, CDC, FDA, and others, to devise a plan to import influenza vaccine not licensed for the U.S. market from foreign manufacturers; this vaccine could be administered in the United States under an investigational new drug protocol.<sup>13</sup> Around the same time, FDA quickly authorized the redistribution of vaccine among hospitals and other health entities to alleviate shortages.<sup>14</sup> HHS also assessed its stockpile of antiviral medications that could be used to prevent or treat influenza and began the process of purchasing more. According to HHS officials, by December 2004 the federal government purchased and stockpiled enough antiviral medicines to treat more than 7 million people.
  - **State and local health departments used existing emergency plans and incident command systems.** Some state and local health departments used their emergency preparedness plans and incident command systems (the organizational systems set up specifically to handle the coordinated response to emergency situations) during the influenza vaccine shortage. The five state health departments and two of the local health departments we visited used their incident command systems to help manage shortage-related activities, and three of the state health departments reported using their emergency plans. In addition, officials from the Florida Health Care Association, an organization representing long-term-care providers in that state, reported using certain elements in their disaster planning guide, which includes plans for disasters like hurricanes or bioterrorism.
  - **Federal and state officials took measures against price gouging.** Around the time (October 13, 2004) that one Florida-based distributor was sued by that state for selling influenza vaccine at significantly inflated prices,<sup>15</sup> several states began issuing warnings that all suspected cases of

---

<sup>13</sup>FDA requires the submission of an investigational new drug application before the initial entry of an unapproved drug—including vaccines licensed for use in other countries—into human studies in the United States. This investigational new drug application includes a description of the vaccine and its method of manufacture, and results of previously conducted quality control and toxicology testing.

<sup>14</sup>Section 503(c)(3)(B)(iv) of the Food, Drug, and Cosmetic Act allows such entities to sell, purchase, or trade a drug or vaccine or offer to sell, purchase, or trade a drug or vaccine for emergency medical reasons. On October 9, 2004, CDC issued a statement noting that “anticipated shortages of influenza vaccine this influenza season constitute emergency medical reasons.”

<sup>15</sup>Florida v. ASAP Meds. Inc., No. 04-16032(09) (Fla. Cir. Ct. filed Oct. 13, 2004) (settlement agreement filed May 19, 2005).

---

price gouging by vaccine distributors and providers would be reported to the states' attorneys general for further investigation and possible prosecution. In support of states' efforts to curtail the overpricing of limited influenza vaccine, CDC began collecting reports of price gouging and shared the information with the National Association of Attorneys General and state prosecutors. On October 14, 2004, the Secretary of HHS sent a letter to the attorney general of each state, urging thorough investigation of reports of price gouging, and on October 22, 2004, HHS filed a "friend of the court" brief in support of the Florida lawsuit.

---

### Public Health Officials Acted to Distribute Remaining Vaccine

Beginning in mid-October, federal, state, and local public health officials acted to distribute the remaining 25 million doses of injectable influenza vaccine across the states and directed the limited amount of available injectable vaccine to those in priority groups. State and local public health departments also took steps to help ensure that vaccine was distributed to those within their jurisdictions who were in priority groups.

### CDC Devised a Plan to Distribute the Limited Supply of Influenza to High-Risk Individuals and to Others in Priority Groups

In October and November, working with representatives from national public health organizations and sanofi pasteur, CDC developed a plan to distribute sanofi pasteur's unshipped vaccine. The plan consisted of two overlapping phases and was aided by the manufacturer's voluntary sharing of proprietary information to help identify geographic areas in greatest need of vaccine.

Phase I, which began the week of October 11, 2004, consisted of filling orders that were clearly identifiable as public-sector orders and orders, such as those from long-term-care facilities, that had been placed with sanofi pasteur. Orders selected for full or partial filling included those that could be immediately identified as placed by the Department of Veterans Affairs, the Indian Health Service, long-term-care facilities and hospitals, and others (see table 2). Filling these orders distributed approximately 13 million doses of vaccine over a 6–8 week period.

---

---

**Table 2: Phase I of CDC's Influenza Vaccine Distribution Plan**

| <b>Provider type</b>  | <b>Percentage of orders filled</b> |
|---|------------------------------------|
| Department of Veterans Affairs  | 100                                |
| Indian Health Service   | 100                                |
| Long-term-care facilities and hospitals   | 100                                |
| Providers who care for children (Vaccines for Children program providers, office-based pediatricians) | 100                                |
| Community immunization providers  | 75                                 |
| Visiting Nurses Association of America  | 50                                 |
| Department of Defense   | 50                                 |
| Office-based primary care providers   | 50                                 |
| State and local public health departments   | 50                                 |

Source: CDC.

Phase II, which was announced by CDC on November 9, 2004, consisted of distributing approximately 12 million doses: about 3 million doses for some of the remaining public-sector orders from phase I and about 9 million doses across the states according to a formula based on each state's percentage of the estimated nationwide unmet need.<sup>16</sup> CDC calculated a state's unmet need by taking the total estimated number of individuals in priority groups in the state and subtracting the total number of doses that had been delivered before and during phase I. To help state health officials identify the regions within their states needing vaccine from phase II distribution, CDC developed an Internet-based program called the Flu Vaccine Finder on its secure data network.<sup>17</sup> The program allowed state health officials to view, county by county, a list of vaccine orders shipped by sanofi pasteur to various types of customers, such as pediatricians and hospitals. Officials could then allocate vaccine available to their state under phase II to providers within their state that needed, but had not yet received, vaccine (see fig. 4). According to CDC officials, the agency understood that not all of the phase II doses would be ready to ship to states at once, so orders were partially filled and shipped in waves.

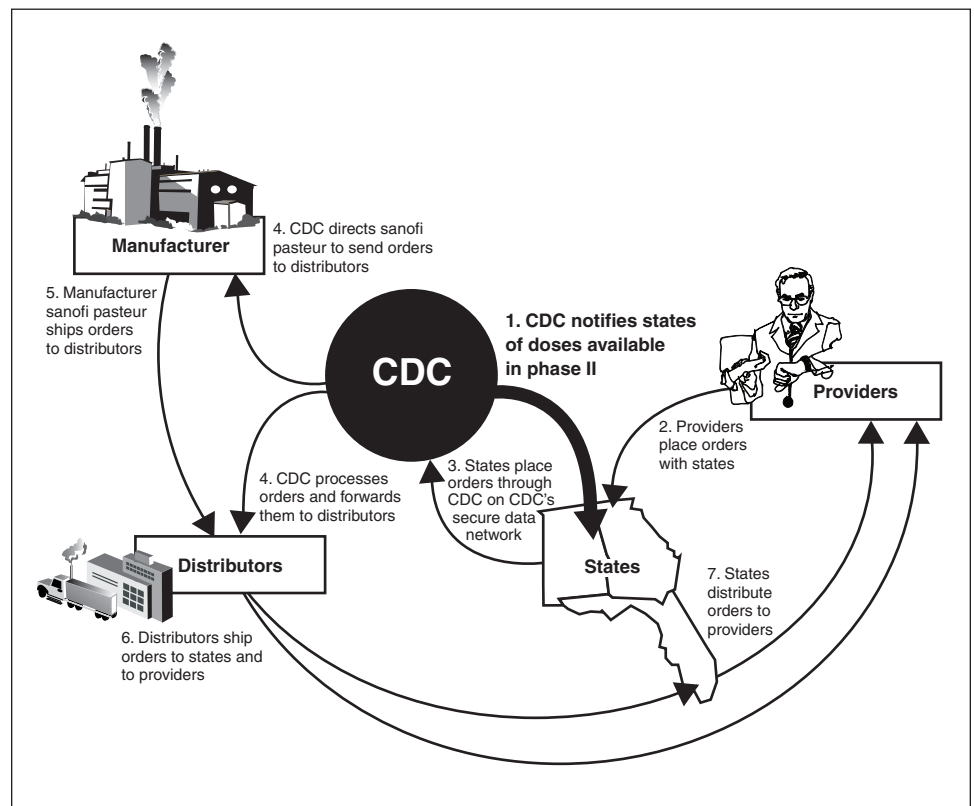
---

<sup>16</sup>To determine the number of individuals in priority groups in each state, CDC used U.S. Census data and available data from the National Health Interview Survey for each of the groups.

<sup>17</sup>The secure data network is an ongoing project sponsored by CDC that allows CDC field staff, researchers, and public health partners to securely exchange confidential, proprietary, or sensitive data over the Internet.

Furthermore, the formula for determining each state's allocation was imperfect, according to CDC, resulting in some states' having more vaccine than needed to cover demand from those in priority groups and other states' having too little. In response, CDC reallocated vaccine available for ordering by states in December 2004. In addition, some states found it necessary to redistribute vaccine within their own borders, or they attempted to purchase or sell vaccine to other states to best align supply and demand at local levels. States could begin ordering their vaccine allotments through the secure data network on November 17, 2004, and ordering continued through mid-January.

**Figure 4: Phase II of CDC's Influenza Vaccine Distribution Plan**



Source: GAO (analysis), Art Explosion (clip art).

Note: Not all states (for example, Minnesota and Maine) chose to order vaccine through phase II of CDC's influenza vaccine distribution plan.

---

Federal, State, and Local  
Actions Limited Vaccine to  
High-Risk Individuals and  
Others in Priority Groups

Public health officials at all levels implemented various strategies to help ensure that their vaccine supplies were targeted to high-risk individuals and others in priority groups.

- **Emergency directives issued.** To help support providers in vaccinating only those individuals in CDC's priority groups, a number of states, such as California and Florida, issued emergency public health directives requiring health care providers to limit influenza vaccination to people in priority groups and to refrain from vaccinating individuals not in CDC's priority groups.<sup>18</sup> Some of these directives, including those of the District of Columbia and Michigan, explicitly stated that providers failing to comply with these directives could face penalties, such as fines or imprisonment. But some states chose not to issue emergency directives. For example, Minnesota state health officials reported that they had such strong voluntary compliance and cooperation from the state's provider community that they decided it was not necessary to post a directive mandating compliance.
- **Surveys conducted of providers and long-term-care facilities.** During mid-October, working with national professional organizations, CDC conducted a survey of long-term-care facilities to identify those that had placed orders with Chiron. A number of health departments, including six we visited, had also surveyed long-term-care facilities, and at least two, Minnesota and Seattle–King County in Washington State, completed their surveys before CDC began administering its version. In addition, many state health departments, including three we visited, surveyed providers about vaccine availability and the need for covering those in priority groups. In an effort to assess the degree of the vaccine supply shortage, for example, Minnesota public health officials developed and administered a survey to identify how much influenza vaccine was available in each of its 92 local public health jurisdictions, not knowing before the shortage which providers had ordered vaccine from Chiron or which ones had ordered from sanofi pasteur.
- **Vaccine transferred among states.** Because CDC's distribution plan was based in part on estimated need for vaccine, some states received more than enough to cover demand from their priority groups, and some states received too little. To redistribute vaccine to locations that needed vaccine to meet demand from priority groups, a state could attempt to sell its available vaccine to another state. According to the Association of State and Territorial Officials, Nebraska shipped some vaccine to other states

---

<sup>18</sup>During the 2004–05 influenza season, the Association of State and Territorial Health Officials reported that 15 states and the District of Columbia issued emergency public health directives.

---

when its own demand was met. Minnesota state health officials also reported offering to sell available vaccine to other states. At the same time, states without enough vaccine, such as Maryland, tried to obtain it from another.

- **Partnerships established with the private sector.** To augment state and local vaccine supply, public health departments looked to the private sector for help. A number of state and local health departments we talked with reported facilitating redistribution or acting as brokers for donations of vaccine that had been purchased by large employers for employee vaccination campaigns before the shortage. According to health officials in Washington, for example, one large employer donated about 700 doses of influenza vaccine to the health department in Seattle–King County, which was then able to supply local nursing homes. Certain states and localities partnered with for-profit and not-for-profit home health organizations, which held mass immunization clinics and set up clinics in providers’ offices to help administer the vaccine quickly. For example, the Visiting Nurses Association of Southern Maine held a mass immunization clinic on a local college campus. These organizations followed CDC’s recommendations for vaccinating priority groups by screening potential vaccine recipients.
- **Crowding alleviated through appointments and lotteries.** In an effort to control crowding, health officials in some localities created vaccination appointments for individuals who were at high risk or in another priority group. When available supplies were insufficient to cover every qualified person who wanted a vaccination, some health departments held lotteries for available vaccine. The local public health department in Portland, Maine, for example, held a lottery for the small amount of vaccine it had received before the shortage plus the several hundred doses donated by an area medical center and the state department of health. To register for the lottery, people had to show they belonged to a priority group by supplying a note from their provider.

---

### Public Health Officials Used Multiple Communication Strategies to Impart Key Information

Throughout the 2004–05 influenza vaccine shortage, federal, state, and local health officials used a variety of communication mechanisms to keep health officials, providers, and the public updated about vaccine availability and about the various strategies for distribution to providers and the public. At the federal level, CDC held frequent press conferences beginning in early October 2004. At these events, the agency updated the public on current efforts and recommendations, and it asked people who did not belong to a priority group to step aside and defer vaccination so that those in the priority groups would have access. CDC also conducted biweekly conference calls with representatives from various national health organizations to update them and obtain their feedback on

---

distribution efforts.<sup>19</sup> According to CDC officials, state and local health officials could generally access the minutes from these discussions the following day on CDC's Health Alert Network.<sup>20</sup> CDC also used this network to send advisories and updates on the influenza vaccine situation, beginning on October 5, 2004, and continuing through the end of January. The majority of the state health officials we met with reported receiving key information about the shortage from this network; the information was then forwarded to local health officials, hospitals, and medical associations that, in turn, passed the information on to providers.

State and local health officials we met with also reported using various communication methods to relay national guidance, along with state and local guidance, and information about vaccine availability. These communication methods included mass e-mails and faxes; public education campaigns for influenza prevention; the media, including television, radio, and newspapers; telephone hotlines; and Web sites (see table 3).

---

<sup>19</sup>National health organizations included the Association of State and Territorial Health Officials, National Association of County and City Health Officials, Council of State and Territorial Epidemiologists, and Association of Public Health Laboratories.

<sup>20</sup>The Health Alert Network is an early-warning and response system operated by CDC, which is designed to ensure that state and local health departments, as well as other federal agencies and departments, have timely access to emerging health information.



**Table 3: Communication Methods Used by Various Health Departments to Disseminate Influenza Information**

|                     | Mass e-mails, faxes | Health Alert Network | Provider education campaign | Public education campaign (posters, flyers) | Media publicity | Telephone hotline | Web site |
|---------------------|---------------------|----------------------|-----------------------------|---|-----------------|-------------------|----------|
| <b>California</b>   |                     |                      |                             |   |                 |                   |          |
| State health agency | ✓                   | ✓                    | ✓                           | ✓   | ✓               | ✓                 | ✓        |
| San Diego           | ✓                   |                      | ✓                           | ✓   | ✓               | ✓                 | ✓        |
| San Francisco       | ✓                   | ✓                    | ✓                           | ✓   |                 | ✓                 | ✓        |
| <b>Florida</b>      |                     |                      |                             |   |                 |                   |          |
| State health agency | ✓                   | ✓                    | ✓                           | ✓   | ✓               | ✓                 | ✓        |
| Miami–Dade County   | ✓                   | ✓                    | ✓                           | ✓   | ✓               | ✓                 | ✓        |
| <b>Maine</b>        |                     |                      |                             |   |                 |                   |          |
| State health agency | ✓                   | ✓                    | ✓                           | ✓   | ✓               | ✓                 | ✓        |
| Portland            |                     |                      |                             |   | ✓               | ✓                 | ✓        |
| <b>Minnesota</b>    |                     |                      |                             |   |                 |                   |          |
| State health agency | ✓                   | ✓                    | ✓                           | ✓   | ✓               | ✓                 | ✓        |
| Stearns County      |                     | ✓                    | ✓                           | ✓   | ✓               |                   | ✓        |
| <b>Washington</b>   |                     |                      |                             |   |                 |                   |          |
| State health agency | ✓                   | ✓                    | ✓                           | ✓   | ✓               |                   | ✓        |
| Seattle–King County | ✓                   |                      |                             |   |                 | ✓                 | ✓        |

Source: GAO.

### Late-Season Actions Aimed to Boost Supply and Demand

At the latest part of the influenza vaccination period, from mid-December 2004 through January 2005, federal and state health officials took several actions intended to further augment the vaccine supply and make vaccine more accessible. Four areas were addressed: broadened recommendations for groups to be vaccinated, modifications to the Vaccines for Children program, purchase of foreign-made vaccine, and release of the federal stockpile of influenza vaccine.

- CDC and states broadened the priority groups for influenza vaccination.** On December 17, 2004, CDC announced broadened vaccination recommendations to include those aged 50–64 years and household contacts of high-risk individuals in locations where state and local health officials judged vaccine supply to be adequate. CDC’s broadened recommendations became effective January 3, 2005, allowing extra time for vaccination of individuals in the original priority groups and time for state and local health departments to prepare for increased

---

requests for vaccine.<sup>21</sup> As of January 3, 2005, however, according to information from the Association of State and Territorial Health Officials, 20 states had already expanded vaccination recommendations: 13 specified the additional groups identified by CDC, and 7 lifted all vaccination restrictions, allowing anyone wanting a vaccination to get one.<sup>22</sup> On January 27, 2005, CDC endorsed states' efforts to broaden vaccination recommendations to include all people wanting influenza immunization in states and localities where vaccine supply was sufficient to do so. Before that date, according to association officials, 27 states had already expanded recommendations to include everyone, although a few states waited longer to expand recommendations.

- **CDC made vaccine from the Vaccines for Children program more widely available.**<sup>23</sup> CDC's ACIP passed a resolution for CDC's Vaccines for Children program, effective December 17, 2004, that expanded the groups of children eligible to receive the program's influenza vaccine to include program-eligible children outside of CDC's priority groups who were household contacts of people in high-risk groups. Later, on January 27, 2005, CDC authorized limited amounts of influenza vaccine from the Vaccines for Children program and held by the states to be transferred to state health departments for nonprogram use where the demand among program-eligible children had already been met. Public providers that had a reserve of program vaccine after vaccinating their program-eligible children could then use this vaccine for adults and children who were not eligible for the Vaccines for Children program.
- **HHS purchased foreign-manufactured influenza vaccine for the U.S. market.** After efforts initiated in early October to develop a plan to obtain foreign-made influenza vaccine that was not licensed for the U.S. market and make it available under an investigational new drug protocol, HHS in December 2004 purchased about 1.2 million doses from one manufacturer in Germany and, in January 2005, purchased about 250,000 doses from another manufacturer in Switzerland. CDC could then make this vaccine available to those states and localities wanting additional vaccine to

---

<sup>21</sup>See Centers for Disease Control and Prevention, "Updated Interim Influenza Vaccination Recommendations, 2004–05 Influenza Season," *Morbidity and Mortality Weekly Report*, vol. 53, no. 50 (2004): 1183–1184.

<sup>22</sup>By December 15, 2004, nine states had begun offering influenza vaccine to people aged 50 years and older and to household contacts of high-risk individuals.

<sup>23</sup>In November 2004, CDC provided guidance for providers to borrow influenza vaccine from the Vaccines for Children program, to immunize children ineligible for the program, if, among other things, the providers anticipated being able to replace the borrowed doses in the near term.

---

alleviate shortages. According to HHS officials, however, none of the additional doses were used in the 2004–05 influenza season.

- **CDC made stockpiled vaccine available to providers.** On January 27, 2005, after the production of 3.1 million late-season doses designated for CDC's stockpile of influenza vaccine,<sup>24</sup> CDC announced that it would make this vaccine available to sanofi pasteur, which, in turn, could market and sell the vaccine to public and private providers and then replenish CDC's stockpile. This strategy allowed providers to order influenza vaccine directly from the manufacturer or a distributor, rather than go through state or local health departments. Providers who purchased these stockpiled doses would also be allowed to return unused vaccine for a credit and would have to pay only shipping costs for returned vaccine.

---

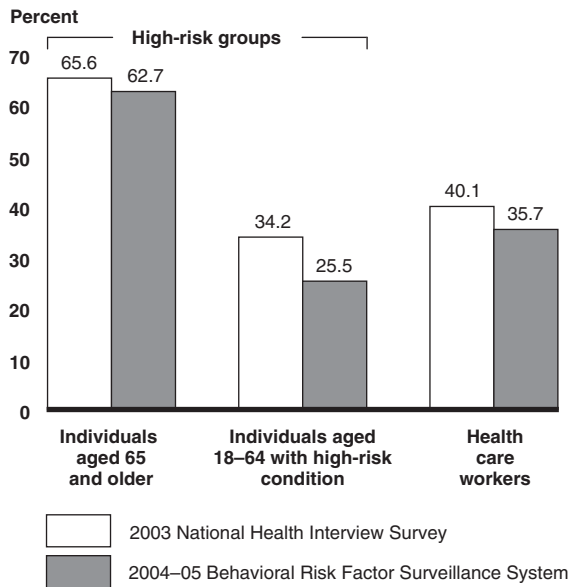
## Planning, Timely Action, and Communication Are Key to an Effective Response

Although the actions taken to address the influenza vaccine shortage helped achieve vaccination rates approaching past levels for certain priority groups (see fig. 5), a number of lessons emerged from federal, state, and local responses to the 2004–05 influenza shortage. Some lessons were specific to that season's shortage, and others have wider ramifications for potential future shortages or a pandemic. The primary lessons can be grouped into three broad, interrelated categories: planning, timely action, and communication.

---

<sup>24</sup>Before Chiron's announcement, CDC had planned to establish a stockpile of approximately 4.5 million doses of injectable influenza vaccine purchased from both Chiron and sanofi pasteur. The primary purpose of the planned stockpile was to meet late-season, unmet pediatric demand.

**Figure 5: Influenza Vaccination Rates for Selected Priority Groups**



Source: CDC.

### Lesson Learned: Limited Contingency Planning Slows Response

Before October 5, 2004, CDC lacked a contingency plan specifically designed to respond to a scenario involving a severe influenza vaccine shortage at the start of the traditional fall vaccination period; the absence of a plan led to a delay in response. Faced with the unanticipated shortfall in the amount of influenza vaccine expected to be available for the 2004-05 influenza season, CDC revised recommendations and worked with sanofi pasteur to begin assessing available supply and to create a distribution plan for the remaining vaccine. Developing and implementing this plan took time and led to delays in response and some confusion at the state and local levels, particularly right after Chiron's October 5, 2004, announcement. Public health officials in all five states we visited remarked that although phase I of CDC's redistribution plan quickly and effectively distributed some vaccine to public and private providers serving priority groups, the vaccine available in phase II of CDC's redistribution plan was too much, too late. Phase II ordering began on November 17, 2004, and continued into January 2005, but several weeks could elapse after orders were placed until vaccine was delivered. According to state and local public health officials we interviewed, by the time the vaccine was delivered through a cumbersome distribution process, demand for the vaccine had substantially waned, and public and private providers were left to redistribute the excess. The phase II distribution problem was

---

compounded for state and local health officials because CDC restricted access to its secure data network to two people per state. This narrow restriction left several state and local public health officials, according to those we interviewed, without vital information about the supply or demand for vaccine.

Our work showed that four areas of planning are particularly important for enhancing preparedness before a similar situation in the future:

(1) defining the responsibilities of federal, state, and local officials; (2) using emergency preparedness plans and emergency health directives; (3) distinguishing between demand and need; and (4) identifying mechanisms for distributing and administering vaccine.

- **Better defining responsibilities of federal, state, and local officials can minimize confusion.** During the 2004–05 vaccine shortage, CDC worked with national organizations representing states and localities to coordinate roles and responsibilities. Several public health officials we spoke with reported that CDC effectively worked with sanofi pasteur and national organizations representing state and local health officials to coordinate responsibilities shortly after Chiron’s announcement. Despite these efforts, however, problems occurred. For example, to identify national demand for vaccine, federal, state, and local health officials surveyed providers in states and localities to assess existing supply and additional need. CDC worked with national professional associations to survey long-term-care providers throughout the country to determine if seniors had adequate access to vaccine. Maine and other states, however, also surveyed their long-term-care providers to make the identical determination. This duplication of effort expended additional resources, burdened some long-term-care providers in the states, and created confusion.
- **Emergency preparedness plans and emergency health directives help coordinate local response.** State and local health officials in several locations we visited reported that using existing emergency plans or incident command centers helped coordinate effective local response to the vaccine shortage. For example, public health officials from Seattle–King County said that using the county’s incident command system played a vital role in coordinating an effective and timely local response and in communicating a clear message to the public and providers. In addition, according to public health officials, emergency public health directives helped ensure access to vaccine by supporting providers in enforcing CDC’s recommendations and in helping to prevent price gouging in those states whose directives addressed price gouging. Certain officials we spoke with, however, reported that although plans and directives helped, improvements were still needed. Some health officials indicated that as a

---

result of the past influenza season, they were revising state and local preparedness plans or modifying command center protocols to prepare for future emergency situations. For example, in Maine, after experiences during the 2004–05 influenza season, state officials recognized the need to speed completion of their pandemic influenza preparedness plan. In addition, they said the vaccine shortage experience helped identify which officials should attend which meetings during a crisis to ensure the right people have the right information.

- **Distinguishing between demand and need for vaccine can improve distribution.** In discussing the adequacy of vaccine supplies, public health officials make a distinction between demand and need for vaccine by a high-risk group. In this context, demand is the number of high-risk individuals who want to receive an influenza vaccination, and need is the total number of high-risk individuals in an area or region, regardless of whether they want to receive a vaccination. Because some individuals in high-risk groups are unlikely to be vaccinated, estimating vaccine amounts on the basis of total need, rather than demand, can overstate the amount that will likely be used in any given location. Differentiating between demand and need would have helped states avoid substantially over- or underordering vaccine from CDC or a manufacturer. California state officials said that differentiating between demand and need earlier in the season could have reduced delays and confusion during the shortage. Certain states and localities we visited had taken time before the season to address contingencies for vaccine supply fluctuations. For example, Minnesota state officials used experiences in previous influenza seasons to build a state influenza plan that educated providers and local public health officials about the difference between demand and need. According to state officials, communicating this difference to local providers and health officials helped more accurately identify how much vaccine was in demand throughout the state.
- **The distribution and administration of vaccine can be facilitated.** One mechanism used in a majority of the states and localities we visited was building partnerships between public and private sectors. This mechanism was effective in both the distribution and the administration of vaccine. In San Diego County, California, for example, local health officials worked with a coalition of partners in public health, private businesses, and nonprofit groups throughout the county. In addition, several states and localities also partnered with other organizations, including home health organizations, to increase their capacity to administer vaccine to large numbers of people. For example, public health officials, including those in California and Florida, worked with national home health organizations to quickly immunize those in high-risk and other priority groups by holding mass immunization clinics. Other mechanisms we identified, aimed mainly at addressing the challenge of

---

administering a limited amount of vaccine, included scheduling appointments and holding lotteries. In Stearns County, Minnesota, for example, public health officials worked with private providers to implement a system of vaccination by appointment. Rather than standing in long lines for vaccination, individuals with appointments went to a clinic during a given time slot. Public health officials in Portland, Maine, emphasized the effectiveness of holding a lottery as a way to equitably administer limited amounts of vaccine to people and as an alternative to having large crowds show up for a limited number of doses.

After the 2004–05 influenza season, CDC officials developed lessons learned from their experiences, including lessons on the importance of contingency planning and defining which groups have higher priority in the event of a vaccine shortage. In August 2005, CDC issued interim guidelines to assist state and other immunization programs in planning for and dealing with an influenza vaccine shortage during the 2005–06 season.<sup>25</sup> Also in August 2005, CDC published potential priority groups for vaccination in the event of a shortage. Because the total vaccine supply for the 2005–06 influenza season was not then known, however, CDC did not recommend setting priorities for injectable vaccine at that time.<sup>26</sup> On September 2, 2005, CDC published priority recommendations for use of injectable vaccine through October 24, 2005.<sup>27</sup>

---

**Lesson Learned: Unless Expedited, Actions to Boost Supply Are Likely to Have Little Effect**

During the 2004–05 influenza vaccine shortage, federal, state, and local officials needed to continually adapt to changing vaccine supply and demand, to make decisions, and to take action quickly. The actions they took after the traditional fall vaccination period, however, came too late to boost supply while demand was still high. These actions included making available foreign-manufactured vaccine that was not licensed for the U.S.

---

<sup>25</sup>CDC indicated that it had assembled a team in December 2004 to begin contingency planning for the 2005–06 influenza season. See Centers for Disease Control and Prevention, “Interim Guideline: Planning for a Possible U.S. Influenza Vaccine Shortage, 2005–06 Season,” August 4, 2005, <http://www.cdc.gov/flu/professionals/vaccination/pdf/vaccshortguide.pdf> (downloaded on Aug. 24, 2005).

<sup>26</sup>See Centers for Disease Control and Prevention, “Tiered Use of Inactivated Influenza Vaccine in the Event of a Vaccine Shortage,” *Morbidity and Mortality Weekly Report*, vol. 54, no. 30 (2005): 749–750.

<sup>27</sup>See Centers for Disease Control and Prevention, “Update: Influenza Vaccine Supply and Recommendations for Prioritization during 2005–06 Influenza Season,” *Morbidity and Mortality Weekly Report*, vol. 54, no. 34 (2005): 850.

---

market, expanding availability of vaccine from the Vaccines for Children program, and releasing vaccine reserved for the federal stockpile.

HHS's decision to purchase influenza vaccine not licensed for the U.S. market and to make it available under an investigational new drug protocol was too late to mitigate the shortage's effects because of when such vaccines became available and because of cumbersome administrative requirements. Soon after Chiron's October 5, 2005, announcement, HHS started looking into foreign vaccine that was licensed for use in other countries but not in the United States. Nonetheless, by the time HHS purchased this vaccine in December 2004 and January 2005, there was little demand for it. CDC officials acknowledged that one lesson learned from experience in 2004–05 was that use of foreign-licensed vaccine under an investigational new drug protocol during the influenza season requires that vaccine be shipped no later than the beginning of October. Further, recipients of such vaccines may be required to sign a consent form and follow up with a health care worker after vaccination—steps that, according to health officials we interviewed in several states, would be too cumbersome to administer and could dampen public enthusiasm for being vaccinated. Although about 1.5 million doses of this vaccine became available, none were used because demand had fallen, and injectable vaccine licensed for the U.S. market was still available.

CDC's December 2004 and January 2005 implementation of decisions to make vaccine from the Vaccines for Children program more widely available was not timely and lacked flexibility. CDC explored options to use program vaccine to vaccinate three groups of people—children eligible for the Vaccines for Children program but not in a priority group, children not eligible for the program, and adults—but only in geographic areas where the needs of eligible children in high-risk groups had been met.<sup>28</sup> But by the time CDC determined that demand from eligible children had been met and announced that it was taking steps to make more program vaccine available for others, many states' demand for additional vaccine had dropped. Because vaccine purchased under the Vaccines for Children program became available for nonprogram use so late, some states reported they were unable to vaccinate all their state's children in CDC's priority groups. In other states, vaccine purchased under the

---

<sup>28</sup>CDC indicated that because the Vaccines for Children program is an entitlement, moving too rapidly to release vaccine to ineligible people may risk denying vaccine to children for whom the law requires availability.



---

program remained unused after all program-eligible children were vaccinated, but completing the process to transfer the unused vaccine delayed some states from administering the remaining vaccine to individuals not eligible for Vaccines for Children. Since CDC expanded program vaccine availability too late, vaccine purchased under the Vaccines for Children program ultimately went unused. As a result, CDC is surveying epidemiologists, state health officials, and immunization managers on lessons learned to connect activities to outcomes, such as releasing program vaccine to increase immunization rates. Further, state health officials we interviewed reported that administrative difficulties in making vaccine available to a broader population hindered its ready use during the shortage. According to state health officials in California and Washington, if broadening Vaccines for Children eligibility had been more flexible and allowed more efficient transfer of vaccine to those not in the program, vaccine could have been made available sooner and more widely to people in priority groups.

CDC's decision to release influenza vaccine produced for its national stockpile was also ineffective because the action came too late. The majority of doses reserved for the stockpile were not delivered until January 2005 because CDC wanted doses produced earlier in the season to be available to fill state orders. By the time the stockpiled doses were released back to the manufacturer for purchase by providers and others in January, national demand had shrunk. Of the 3.1 million doses of injectable vaccine released from the stockpile in January 2005, only approximately 115,000 were ordered. Without exception, state health officials in the five states we visited reported that this vaccine became available too late in the season to be useful.

Finally, certain states faced barriers when trying to buy available influenza vaccine from other states, preventing timely redistribution. During the 2004–05 shortage, some state health officials reported problems with their ability—both in paying for vaccine and in administering the transfer process—to purchase influenza vaccine. For example, Minnesota tried to sell its available vaccine to other states seeking additional vaccine for their high-risk populations. According to federal and state health officials, however, certain states lacked the funding or flexibility under state law to purchase the vaccine when Minnesota offered it. In response to problems encountered during the 2004–05 shortage, the Association of Immunization Managers proposed in 2005 that federal funds be set aside for emergency purchase of vaccine by public health agencies, eliminating cost as a barrier in acquiring vaccine to distribute to the public.

---

Lesson Learned: Effective Response Requires Communication to Be Both Clear and Consistent

While part of the lesson learned about communication was positive, some aspects of this lesson pointed to need for improvement. Positives can be seen, for example, in the extent of CDC's communication. During the 2004–05 shortage, CDC communicated regularly through a variety of media as the situation evolved. Officials from most states and localities we talked with reported that CDC played an active role in communicating information despite a changing environment. Several state and local officials we spoke with said that biweekly conference calls were effective in providing updates and coordinating responsibilities. The state health officer from Alabama, for instance, noted the frequency and quality of the communications that CDC put forth during the influenza season.

Despite these positives, when examining the 2004–05 influenza season, state and local officials identified areas of communication to improve for future seasons. During our visits to states and localities, we found four particularly important communication issues. These issues included maintaining consistency of communications to avert confusion, understanding the importance of changing messages under changing circumstances, using diverse media to reach diverse audiences, and educating providers and the public about prevention alternatives.

- **Consistency among federal, state, and local communications is critical for averting confusion.** Health officials in Minnesota, for example, reported that some confusion resulted when the state determined that the influenza vaccine supply was sufficient to meet demand and therefore made vaccine available to other groups, such as healthy individuals aged 50–64 years, earlier than recommended by CDC. Similarly, health officials in California reported that in mid-December, local radio stations in the state were running two public service announcements—one from CDC advising those aged 65 years and older to be vaccinated, and one from the California Department of Health Services advising those aged 50 years and older to be vaccinated. They emphasized that these mixed messages created confusion. In addition, some individuals seeking influenza vaccine in other regions could have found themselves in a communication loop that provided no answers. For example, CDC advised people seeking influenza vaccine to contact their local public health department; in some cases, however, individuals calling the local public health department were told to call their primary care provider, and when they called their primary care provider, they were told to call their local public health department. This inconsistency in information from authoritative sources led to confusion and possibly to

---

high-risk individuals' giving up and not receiving an influenza vaccination.<sup>29</sup>

- **Modifying messages to respond to changing circumstances can prevent unintended consequences.** Beginning in October, CDC communicated a message asking individuals who were not in a high-risk group or another priority group to forgo or defer vaccination, or to step aside, so that those in priority groups could have access to available vaccine. According to CDC, this message resulted in an estimated 17.5 million individuals who specifically deferred vaccination to save vaccine for those in the priority groups. Public health officials we interviewed, however, lamented the fact that this nationwide effort did not also include a message to individuals who did step aside to check back with their providers or to seek an influenza vaccination later in the season. State and local officials suggested that CDC should have had a message to step aside until a certain estimated date, when more vaccine would be available and demand from individuals in the narrowed CDC priority groups would ease. These officials noted that many people in priority groups, including those aged 65 years and older who should have been vaccinated, stepped aside. These officials also said that they were concerned about other individuals, particularly those aged 50–64 years, who were not vaccinated during the moderate 2004–05 influenza season and, as a result, might think vaccination was not important enough to seek in future seasons.
- **Using diverse media helps reach diverse audiences.** During the 2004–05 influenza season, public health officials reported the importance of using a variety of communication methods to help ensure that messages reached as many individuals as possible. For example, officials from the health department in Seattle–King County, Washington, reported that it was important to have a telephone hotline as well as information posted on a Web site, because some seniors calling Seattle–King County's hotline reported that they did not have access to the Internet. Further, public health officials in Miami–Dade County in Florida said that bilingual radio advertisements promoting influenza vaccine for those in priority groups helped increase the effectiveness of local efforts to raise vaccination rates.

---

<sup>29</sup>According to data collected during December 1–11, 2004, on self-reported vaccination during September 1 through November 30, 2004, among adults in priority groups who had not yet received influenza vaccine, about 23 percent reported that they attempted to obtain a vaccination but could not. See Centers for Disease Control and Prevention, "Estimated Influenza Vaccination Coverage among Adults and Children—United States, September 1–November 30, 2004," *Morbidity and Mortality Weekly Report*, vol. 53, no. 49 (2004): 1147–1150.

- 
- **Education is important in alerting providers and the public about prevention alternatives.** Educating health care providers and the public about all available influenza vaccines and forms of prevention may increase the number of vaccinated individuals and also reduce the spread of influenza. Experience with the nasal spray vaccine in 2004–05 illustrates the importance of education. Approximately 3 million doses of nasal spray vaccine were ultimately available during the season for vaccinating healthy individuals.<sup>30</sup> According to public health officials we interviewed, however, some individuals were reluctant to use this vaccine because they feared that the vaccine was too new and untested or that the live virus in the nasal spray could be transmitted to others. State health officials in Maine, for example, reported that the state purchased about 1,500 doses of the nasal spray vaccine for their emergency medical service personnel and health care workers, yet 500 doses were administered. Further, public health officials we interviewed said that education about all available forms of prevention, including the use of antiviral medications and good hygiene practices, can help reduce the spread of influenza.<sup>31</sup>

According to CDC officials, as part of preparations for the 2005–06 influenza season, the agency developed a draft communication plan—separate from the interim guidelines issued to states—from lessons learned, which includes messages for responding to the fluctuations in supply and demand anticipated throughout the season. As of August 2005, CDC officials said that this plan will remain in draft form because tactics will be changed and updated as circumstances change.

---

## Concluding Observations

Aided by a relatively moderate influenza season, efforts to mitigate the sudden and unexpected shortage of influenza vaccine for the 2004–05 season were largely successful, although the season was not without problems. Lacking a preseason plan to address a significant shortfall after the beginning of the traditional fall vaccination period, the federal government reacted to the shortage and its aftereffects as they unfolded

---

<sup>30</sup>The nasal spray vaccine was recommended for individuals aged 5–49 years who were not pregnant, including some individuals, such as health care workers in this age group and household contacts of children younger than 6 months, in the priority groups defined by CDC.

<sup>31</sup>CDC posted guidance on its Web site in October 2004 about use of antiviral medications and other ways to prevent the spread of influenza, including covering the mouth when coughing, hand washing, and staying home from work when ill. See <http://www.cdc.gov/flu/protect/preventing.htm> (downloaded on Aug. 8, 2005).

---

throughout the season. This lack of preseason planning created confusion and delays during the optimal fall influenza vaccination window, when state and local public health agencies and health care providers most needed vaccine to protect individuals at high risk of severe complications. Conversely, federal efforts to boost supply late in the season had little effect, because demand fell off sharply in December and January, and vaccine became available too late. In some instances, uncoordinated communication from federal to state and local jurisdictions, and to providers and the general public, contributed to confusion, frustration, and individuals' failure to seek or receive an influenza vaccination. Drawing from experiences during the 2004–05 shortage, CDC has taken a number of steps, including issuing interim guidelines in August 2005, to assist in responding to possible future shortages. It is too early, however, to assess the effectiveness of these efforts in coordinating actions of federal, state, and local health agencies and others who play a part in the annual influenza vaccination process.

---

## Agency Comments

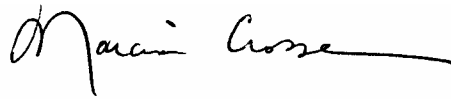
In commenting on a draft of this report, HHS noted that the draft summarized in detail the activities undertaken by CDC and its public- and private-sector partners to deal with the influenza vaccine shortage of 2004–05, and the agency concurred with our finding that contingency planning will greatly improve response efforts. The agency also provided details on other actions, such as approval of additional influenza vaccines for the U.S. market, that were under way. HHS also agreed that adjustments to vaccination recommendations and vaccine supply ideally should occur earlier in the influenza season, but such adjustments cannot always be implemented in a shortage year. HHS's written comments appear in appendix I.

---

As arranged with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days after its issue date. At that time, we will send copies of this report to the Secretary of HHS, the Directors of CDC and the National Vaccine Program Office, and other interested parties. We will also make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

---

If you or your staff members have any questions, please contact me at (202) 512-7119 or [crossem@gao.gov](mailto:crossem@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff members who made major contributions to this report are listed in appendix II.

A handwritten signature in black ink that reads "Marcia Crosse". The signature is written in a cursive style with a long horizontal stroke at the end.

Marcia Crosse  
Director, Health Care

# Appendix I: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

SEP 19 2005

Ms. Marcia Crosse  
Director, Health Care  
U.S. Government Accountability Office  
Washington, DC 20548

Dear Ms. Crosse:

Enclosed are the Department's comments on the U.S. Government Accountability Office's (GAO's) draft report entitled, "INFLUENZA VACCINE: Shortages in 2004-05 Season Underscore Need for Better Preparation" (GAO-05-984). These comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department provided several technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Daniel R. Levinson".

Daniel R. Levinson  
Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for U.S. Government Accountability Office reports. OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

**COMMENTS OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED, "INFLUENZA VACCINE: SHORTAGES IN 2004-05 SEASON UNDERSCORE NEED FOR BETTER PREPARATION" (GAO-05-984)**

**General Comments**

The Department of Health and Human Services (HHS) appreciates the U.S. Government Accountability Office's (GAO's) detailed summary of activities undertaken by the Centers for Disease Control and Prevention (CDC) and its public and private sector partners in dealing with the influenza vaccine shortage of 2004. HHS concurs with GAO's finding that contingency planning for such events achieved in advance will greatly improve response efforts. As noted in the draft report, CDC has issued guidelines for State and local public health jurisdictions for any subsequent influenza vaccine supply disruptions. In addition, CDC has worked closely with a planning group of public and private sector partners to develop options for response to another vaccine shortage. Part of this work has included communicating the recommendations of the Advisory Committee on Immunization Practices (ACIP) for prioritization and sub-prioritization, if necessary, of groups who should receive initial supplies of influenza vaccine in the 2005-06 season. These recommendations were published in CDC's Morbidity and Mortality Weekly Report (MMWR) on September 2, 2005.

In the longer term, HHS is encouraged that influenza vaccine supply will improve as a result of additional vaccine companies such as GlaxoSmithKline (GSK) selling influenza vaccine in the U.S. GSK's Fluarix vaccine was licensed on August 31, 2005, and ID Biomedical has stated that it will submit its influenza vaccine license application soon. Also, there are additional vaccine factories in the U.S., such as the one in Pennsylvania purchased by GSK.

HHS also agrees that adjustments in influenza vaccine recommendations and supply should ideally occur before November; however, such adjustments cannot always be implemented in a vaccine shortage year. Indeed, approximately 20 percent of influenza vaccine administered in 2004-05 occurred in December and later, demonstrating that significant vaccine delivery can occur following later recommendations.



---

# Appendix II: GAO Contact and Staff Acknowledgments

---

## GAO Contact

Marcia Crosse, (202) 512-7119 or [crossem@gao.gov](mailto:crossem@gao.gov)

---

## Acknowledgments

In addition to the contact named above, Kim Yamane, Assistant Director; George Bogart; Ellen W. Chu; Nicholas Larson; Jennifer Major; Terry Saiki; and Stan Stenersen made key contributions to this report.

---

# Related GAO Products

---

*Influenza Pandemic: Challenges in Preparedness and Response.* [GAO-05-863T](#). Washington, D.C.: June 30, 2005.

*Influenza Pandemic: Challenges Remain in Preparedness.* [GAO-05-760T](#). Washington, D.C.: May 26, 2005.

*Flu Vaccine: Recent Supply Shortages Underscore Ongoing Challenges.* [GAO-05-177T](#). Washington, D.C.: November 18, 2004.

*Infectious Disease Preparedness: Federal Challenges in Responding to Influenza Outbreaks.* [GAO-04-1100T](#). Washington, D.C.: September 28, 2004.

*Public Health Preparedness: Response Capacity Improving, but Much Remains to Be Accomplished.* [GAO-04-458T](#). Washington, D.C.: February 12, 2004.

*Infectious Disease Outbreaks: Bioterrorism Preparedness Efforts Have Improved Public Health Response Capacity, but Gaps Remain.* [GAO-03-654T](#). Washington, D.C.: April 9, 2003.

*Bioterrorism: Preparedness Varied across State and Local Jurisdictions.* [GAO-03-373](#). Washington, D.C.: April 7, 2003.

*Flu Vaccine: Steps Are Needed to Better Prepare for Possible Future Shortages.* [GAO-01-786T](#). Washington, D.C.: May 30, 2001.

*Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People.* [GAO-01-624](#). Washington, D.C.: May 15, 2001.

*Flu Pandemic: Plan Needed for Federal and State Response.* [GAO-01-4](#). Washington, D.C.: October 27, 2000.

---

## GAO's Mission

The Government Accountability Office, the audit, evaluation and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

---

## Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site ([www.gao.gov](http://www.gao.gov)). Each weekday, GAO posts newly released reports, testimony, and correspondence on its Web site. To have GAO e-mail you a list of newly posted products every afternoon, go to [www.gao.gov](http://www.gao.gov) and select "Subscribe to Updates."

---

## Order by Mail or Phone

The first copy of each printed report is free. Additional copies are \$2 each. A check or money order should be made out to the Superintendent of Documents. GAO also accepts VISA and Mastercard. Orders for 100 or more copies mailed to a single address are discounted 25 percent. Orders should be sent to:

U.S. Government Accountability Office  
441 G Street NW, Room LM  
Washington, D.C. 20548

To order by Phone: Voice: (202) 512-6000  
TDD: (202) 512-2537  
Fax: (202) 512-6061

---

## To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: [www.gao.gov/fraudnet/fraudnet.htm](http://www.gao.gov/fraudnet/fraudnet.htm)

E-mail: [fraudnet@gao.gov](mailto:fraudnet@gao.gov)

Automated answering system: (800) 424-5454 or (202) 512-7470

---

## Congressional Relations

Gloria Jarmon, Managing Director, [JarmonG@gao.gov](mailto:JarmonG@gao.gov) (202) 512-4400  
U.S. Government Accountability Office, 441 G Street NW, Room 7125  
Washington, D.C. 20548

---

## Public Affairs

Paul Anderson, Managing Director, [AndersonP1@gao.gov](mailto:AndersonP1@gao.gov) (202) 512-4800  
U.S. Government Accountability Office, 441 G Street NW, Room 7149  
Washington, D.C. 20548