

**PENNSYLVANIA'S ROLE  
IN INFLUENZA  
PREVENTION AND CONTROL**

**SEPTEMBER 2004**



General Assembly of the Commonwealth of Pennsylvania  
JOINT STATE GOVERNMENT COMMISSION  
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The release of this report should not be interpreted as an endorsement by the members of the Executive Committee of the Joint State Government Commission of all the findings, recommendations or conclusions contained in this report.

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The Joint State Government Commission was created by the act of July 1, 1937 (P.L.2460, No.459) as amended, as a continuing agency for the development of facts and recommendations on all phases of government for the use of the General Assembly.

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TO THE MEMBERS OF THE GENERAL ASSEMBLY:

The Joint State Government Commission is pleased to present this staff report, "Pennsylvania's Role in Influenza Prevention and Control," pursuant to 2004 House Resolution 598 (P.N. 3436). The report describes the threats posed by influenza viruses and the public health infrastructure designed to prevent and control outbreaks. It concludes with recommendations that could improve Pennsylvania's capacity to protect the public health from future influenza epidemics.

The Commission recognizes with gratitude the Pennsylvania Departments of Health, Aging, and Welfare. Their guidance and assistance was indispensable in the publication of this report.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Roger A. Madigan".

Roger A. Madigan  
Chair



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## **EXECUTIVE SUMMARY**

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Influenza pandemics were responsible for millions of deaths in the 20<sup>th</sup> Century. Most notable among the outbreaks was the pandemic of 1918, which caused an estimated 20-40 million deaths worldwide and 500,000 in the U.S. Even in years when no epidemic is declared, the U.S. suffers approximately 36,000 influenza deaths annually. With mounting concern about the emergence of more virulent strains, and with the recently isolated Avian Flu establishing a presence in Southeast Asia, world public health organizations are redoubling their efforts to prevent future epidemics from occurring.

This report is the culmination of research efforts authorized by House Resolution 598 (Pr. No. 3436) of 2004, which directed the Joint State Government Commission to make recommendations on how Pennsylvania could best prepare for an influenza epidemic and ensure an adequate vaccine supply.

It must be noted that flu vaccines are produced and distributed by the private pharmaceutical market. While governmental agencies at the state and local level routinely purchase doses from the Centers for Disease Control and Prevention (CDC), the CDC purchases its supply through private contractors.

The market for vaccines fluctuates as any market does: periods following supply shortages are likely to be oversupplied, while periods of excess supply are likely to see reduced numbers of vaccines brought to market. Shortages are punctuated by dramatic price increases while abundance leads to lowered prices.

The vast majority of vaccines are administered through the private sector, in such places as doctors' offices, hospitals, and, more recently, retail stores. Relatively few immunizations are administered through public sector outreach programs. Thus, the most advantageous roles for governments to assume are those of planning for and coordinating influenza control, and in educating both providers and the public.

## **SUMMARY OF RECOMMENDATIONS**

This report makes the following recommendations:

- Pennsylvania Department of Health (PADOH) should continue to take full advantage of its partnership with the CDC to prepare for outbreaks, purchase vaccines, and successfully stanch an epidemic should one establish itself.
- PADOH should encourage employers and schools to implement influenza education programs that highlight the dangers of flu and encourage immunizations.
- Healthcare workers should be strongly encouraged to get annual vaccinations. In order to accomplish this goal, it is recommended that they be educated about the dangers posed by not being immunized. Further, it is recommended that their employers reduce or remove barriers, such as cost or inconvenience that may discourage immunization.
- PADOH should continue its partnerships with local and private entities in providing immunizations at shelters, churches, community centers and low-income housing sites. Further, it should continue to investigate including daycare centers as potential vaccination venues.
- PADOH should continue its innovative use of the Pennsylvania Health Alert Network (PA-HAN), the Vaccine Management Information System (VACMAN), and the State Immunization Information System (SIIS) to monitor and coordinate the redistribution of vaccines when necessary.

## INTRODUCTION

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House Resolution 598 of 2004 (Pr. No. 3436) directed the Joint State Government Commission to study ways in which the Commonwealth could best prevent or control an influenza epidemic. This report provides a comprehensive description of the influenza virus and its effects, as both a health hazard for individuals and as a threat to public health. Epidemic prevention and outbreak control mechanisms are discussed at length, including descriptions of vaccine production, supply and distribution, and existing government immunization programs.

Approximately 36,000 people die in the U.S. every year from influenza, and thousands more are affected by it. It can be a grave danger to children, the elderly, and others at high-risk. Especially vulnerable to flu and its consequences are persons whose health is compromised by preexisting medical conditions, such as HIV/AIDS or lung disease.

Influenza's propensity to evolve into new forms and for new strains to emerge makes it a difficult target for public health organizations. In the interest of protecting the public health, worldwide influenza surveillance networks have been established to track the disease. The surveillance data is gathered and analyzed by laboratories scattered around the world so that safe and effective vaccines can be developed for the flu viruses in circulation each year.

In the U.S. there are several federal agencies dedicated to influenza surveillance, prevention and control. These federal agencies, in turn, provide coordination, support, and resources to state and local agencies. The various government agencies, their relationships to one another and their functions are presented in detail in this report. Data that show influenza activity, deaths, and immunization rates, and program funding information at the national and Pennsylvania levels are also included.

The report concludes with recommendations.



## INFLUENZA BACKGROUND

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In the United States, influenza affects around ten to twenty percent of the people and is responsible for approximately 36,000 deaths and 114,000 hospitalizations every year.<sup>1</sup> According the National Institute of Allergy and Infectious Diseases (NIAID), “[i]nfluenza, or flu, is a respiratory infection caused by a variety of flu viruses.”<sup>2</sup> Influenza is most commonly seen from November through March.<sup>3</sup> The symptoms of the flu include headache, chills, dry cough, body aches, fever, stuffy nose, and sore throat and usually begin about one to four days after one is infected by the flu virus.<sup>4</sup> In healthy individuals, influenza symptoms usually begin to dissipate after a few days, although malaise and cough can continue for a time period greater than two weeks.<sup>5</sup> For others,

...influenza can exacerbate underlying medical conditions (e.g., pulmonary or cardiac disease), lead to secondary bacterial pneumonia or primary influenza viral pneumonia, or occur as part of a coinfection with other viral or bacterial pathogens. Young children with influenza infection can have initial symptoms mimicking bacterial sepsis with high fevers, and  $\leq 20\%$  of children hospitalized with influenza can have febrile seizures. Influenza infection has also been associated with encephalopathy, transverse myelitis, Reye syndrome, myositis, myocarditis, and pericarditis.<sup>6</sup>

The primary way influenza is “spread is from person to person in respiratory droplets of coughs and sneezes. ... This can happen when droplets from a cough or sneeze of an infected person are propelled ... through the air and deposited on the mouth or nose of people nearby.”<sup>7</sup> The virus can also “... be

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<sup>1</sup> U.S. Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), *The Influenza (Flu) Viruses*, January 15, 2004 <http://www.cdc.gov/flu/about/fluviruses.htm> (07/16/2004).

<sup>2</sup> HHS, National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID), *Health Matters: Flu*, April 2004, <http://www.niaid.nih.gov/factsheets/flu.htm> (07/06/2004).

<sup>3</sup> HHS, CDC, *Influenza: The Disease*, December 30, 2003, <http://www.cdc.gov/flu/about/disease.htm> (07/06/2004).

<sup>4</sup> HHS, NIH, NIAID, *supra* note 2.

<sup>5</sup> HHS, CDC, “Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP),” *MMWR: Recommendations and Reports*, 53 (RR06), (May 28, 2004), <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5306a1.htm> (07/16/2004).

<sup>6</sup> *Ibid.*

<sup>7</sup> HHS, CDC, *supra* note 3.

spread when a person touches respiratory droplets on another person or an object and then touches their own mouth or nose (or someone else's mouth or nose) before washing their hands.”<sup>8</sup> Adults who contract the influenza virus are normally contagious from one day prior to the onset of symptoms to three to seven days after the symptoms begin; however, children are generally contagious for a period longer than seven days.<sup>9</sup>

### INFLUENZA DEFINED

According to the CDC, there are three main types of influenza viruses – types A, B, and C.<sup>10</sup> As stated earlier, influenza affects ten to twenty percent of the U.S. population each year and is responsible for approximately 36,000 deaths and 114,000 hospitalizations.<sup>11</sup> Influenza viruses A and B are responsible for these illnesses; type C influenza can cause mild respiratory illness, and it is not thought to cause the epidemics associated with type A and B influenza viruses.<sup>12</sup>

Influenza type A viruses are divided into subtypes based on two surface antigens: hemagglutinin (H) and neuraminidase (N).<sup>13</sup> To date, fifteen H subtypes and nine N subtypes have been classified. Since 1977 the primary influenza viruses globally circulating included influenza A(H1N1), influenza A(H3N2), and influenza B viruses.<sup>14</sup>

[However, o]n February 6, 2002, the World Health Organization (WHO) and the Public Health Laboratory Service (PHLS) in the United Kingdom reported the recent identification of a new influenza virus strain, influenza A(H1N2), isolated from humans in England, Israel, and Egypt. In addition to the viruses reported by PHLS, the ... [CDC] has identified influenza A(H1N2) virus from patient specimens collected during the 2001-02 and 2002-03 seasons. Influenza A(H1N2) viruses have been identified in the past. Between December 1988 and March 1989, 19 influenza A(H1N2) viruses were identified in 6 cities in China, but the virus did not spread further. ... The new H1N2 strain appears to have resulted from the reassortment of the genes on the currently circulating influenza A(H1N1) and A(H3N2) subtypes.

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<sup>8</sup> Ibid.

<sup>9</sup> Ibid.

<sup>10</sup> HHS, CDC, *supra* note 1.

<sup>11</sup> Ibid.

<sup>12</sup> Ibid.

<sup>13</sup> HHS, CDC, *supra* note 5.

<sup>14</sup> Ibid.



... No unusual levels of disease have been associated with this virus and at this time, it is uncertain if the A(H1N2) virus will persist and circulate widely.<sup>15</sup>

Even with thousands of deaths and hospitalizations every year, influenza is still a highly preventable illness. The most effective way to avoid the flu, regardless of virus subtype, is an annual vaccination. Specific ways to prevent and treat influenza will be discussed later in this report.

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<sup>15</sup> HHS, CDC, *Influenza A(H1N2) Viruses*, December 5, 2003, <http://www.cdc.gov/flu/about/h1n2.htm> (07/06/2004).



# HISTORY OF INFLUENZA PANDEMICS AND EPIDEMICS

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This chapter defines and explains the differences between influenza pandemics and epidemics including how a pandemic begins, what the necessary steps are for an influenza outbreak to be called a pandemic, and a brief summary of the various pandemics and pandemic scares that have occurred since the beginning of the 20<sup>th</sup> century. Most of this chapter's information was found at the United States Department of Health and Human Services (HHS), the National Vaccine Program Office's (NVPO) website.<sup>16</sup> More information, including links to other sources, regarding influenza pandemics is available there.

## PANDEMICS AND EPIDEMICS DEFINED

When describing an influenza outbreak sometimes the terms influenza epidemic and pandemic seem to be used interchangeably. While their definitions are similar, they are not synonymous. An epidemic is commonly defined as "affecting or tending to affect a disproportionately large number of individuals within a population, community, or region at the same time," whereas a pandemic is defined as "occurring over a wide geographic area and affecting an exceptionally high proportion of the population."<sup>17</sup> In the simplest terms, both an epidemic and a pandemic affect a large number of individuals; however, a pandemic is something that affects a much larger geographical region than an epidemic. For example, an influenza epidemic may occur with a community or state, whereas an influenza pandemic is most often thought of when it affects an entire country or the world.

## INFLUENZA PANDEMICS

Almost every year influenza epidemics occur in different regions of the United States. Pandemics, on the other hand occur much less frequently. In fact, during the 20<sup>th</sup> century, there have been only been three pandemics, the 1918 Spanish flu, the 1957 Asian flu, and the 1968 Hong Kong flu and several

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<sup>16</sup> HHS, National Vaccine Program Office (NVPO), February 12, 2004, <http://www.hhs.gov/nvpo/pandemics/fluprint.htm> (07/06/2004).

<sup>17</sup> Frederick C. Mish, ed., *Merriam-Webster's Collegiate Dictionary, Tenth Edition*, (Springfield, Mass.: Merriam-Webster, Inc., 2001), pages 389 and 836.

pandemic scares, the 1976 Swine flu, the 1977 Russian flu, and the 1997 and 1999 Avian flu.<sup>18</sup> Before detailing the past few pandemics and pandemic scares, it is helpful to understand how a pandemic begins and what steps are necessary for an influenza outbreak to be considered an influenza pandemic.

### ***How a Pandemic Begins***

Of the three types of influenza (A, B, and C), only type A influenza viruses have been associated with causing pandemics.<sup>19</sup> Recall that [i]nfluenza A viruses are divided into subtypes, based on differences in two surface proteins: hemagglutinin (H) and neuraminidase (N). [An influenza] pandemic is possible when an influenza A virus makes a dramatic change (i.e., “shift”) and acquires a new H or H+N. This shift results in a new or “novel” virus to which the general population has no immunity.<sup>20</sup>

Additionally, in order for a novel virus to cause a pandemic, it must also spread easily from person to person and cause serious disease.

### ***Steps in a Pandemic***

In order to be better prepared for a pandemic, the WHO has developed a series of phases that planners can use to determine their response to a potentially developing pandemic. These phases are discussed in detail in the *Influenza Pandemic Plan. The Role of WHO and Guidelines for National and Regional Planning*.<sup>21</sup> Below is a summary of these phases taken directly from the HHS, NVPO’s website.<sup>22</sup>

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<sup>18</sup> HHS, NVPO, *Pandemics and Pandemic Scares in the 20th Century*, February 12, 2004, <http://www.hhs.gov/nvpo/pandemics/fluprint.htm> (07/06/2004).

<sup>19</sup> “Influenza C causes only mild disease and has not been associated with widespread outbreaks. ... Influenza B viruses do not undergo shift and do not cause influenza pandemics.” HHS, NVPO, *Influenza Pandemics: How They Start, How They Spread, and Their Potential Impact*, February 12, 2004, <http://www.hhs.gov/nvpo/pandemics/fluprint.htm> (07/06/2004).

<sup>20</sup> “Since, by definition, a novel virus is a virus that has never previously infected humans, or hasn’t infected humans for a long time, it’s likely that almost no one will have immunity, or antibody to protect them against the novel virus.” HHS, NVPO, *Influenza Pandemics: How They Start, How They Spread, and Their Potential Impact*, February 12, 2004, <http://www.hhs.gov/nvpo/pandemics/fluprint.htm> (07/06/2004).

<sup>21</sup> World Health Organization (WHO), Department of Communicable Disease Surveillance and Response, *Influenza Pandemic Plan--The Role of WHO and Guidelines for National and Regional Planning*, April 1999 (Geneve, Switzerland: WHO), <http://www.who.int/csr/resources/publications/influenza/en/whocdscsredc991.pdf> (07/06/2004).

<sup>22</sup> HHS, NVPO, *Influenza Pandemics: How They Start, How They Spread, and Their Potential Impact*, February 12, 2004, <http://www.hhs.gov/nvpo/pandemics/fluprint.htm> (07/06/2004).

To help prepare and respond to a pandemic, WHO has developed a series of descriptive “phases” that can be used by planners.

- Phase 0, Preparedness Level 0 (Inter-Pandemic Period)

Every year, there are three or four strains of influenza viruses moving around the world and causing illness. In a normal year (the pre-pandemic period), all of these viruses will be previously identified strains and will be similar to other strains recently circulating. A vaccine, that covers the strains most likely to circulate during the influenza season, is developed each year. Vaccine is usually administered between October and December each year in the U.S.

- Phase 0, Preparedness Level 1 (Initial Report of a New Strain in Humans)

Occasionally there are reports of isolation of a novel virus from humans without clear evidence of spread from person to person or of outbreak activity. Each report of a novel virus is investigated and, depending on what is learned, we may or may not advance to the next stage of the model.

- Phase 0, Preparedness Level 2 (Novel Virus Alert – Human Infection Confirmed)

A Novel Virus Alert occurs when two or more human infections (with a novel virus) have been confirmed. The ability of the virus to spread from human to human and cause serious disease, however, is still questionable. Human infections with novel viruses have often been seen in Asia first, but a novel virus can be found anywhere. For example, the 1976 novel virus, known as swine flu, originated in Fort Dix, New Jersey.

- Phase 0, Preparedness Level 3 (Human Transmission Confirmed)

This Preparedness Level will exist when human transmission of the new virus sub-type has been confirmed through clear evidence of person-to-person spread in the general population, such as secondary cases resulting from contact with an index case, with at least one outbreak lasting

over a minimum two week period in one country. Identification of the new virus sub-type in several countries, with no explanation other than contact among infected people, may also be used as evidence for significant human transmission.

- Phase 1 (Confirmation of Onset of Pandemic)

To progress from a Novel Virus Alert to Pandemic Imminent, a novel virus must be able to spread efficiently from one person to another. In this phase, the virus is causing several outbreaks in at least one country; it has spread to other countries and disease patterns indicate that severe morbidity and mortality (sickness and death) are likely in at least one segment of the population. The 1997 avian flu virus never efficiently spread from one person to another, so Pandemic Imminent was never declared.

- Phase 2 (Regional and Multi-Regional Epidemics)

The Pandemic phase occurs when the novel virus is causing outbreaks and epidemics in multiple countries around the world. If a community has not prepared itself well before this phase, it may be suddenly facing some very serious public health, social, and economic problems. Fortunately, it is extremely rare for a novel virus to progress to the Pandemic phase. It hasn't happened since the Hong Kong flu of 1968.

- Phase 3 (End of First Pandemic Wave)

Influenza activity in initially affected countries/regions has stopped while outbreaks of the new viruses are continuing elsewhere. During the "downtime," it is important to maintain enthusiasm for the pandemic response by continuing vaccination campaigns and other response efforts. This may be the time when we have a chance to "catch up" to the virus.

- Phase 4 (Second or Later Waves of the Pandemic)

Based on past experiences, at least a second wave of outbreaks caused by the novel virus would be expected to occur within 3-9 months of the initial epidemic in a particular country or region.

- Phase 5 (End of the Pandemic – Back to Phase 0)

The pandemic is declared “over” when the infection rate of influenza returns to pre-pandemic levels, and no more large-scale “wave” of illness are expected. Based on history, it could take two years for this to happen. Once it happens, the cycle begins again.<sup>23</sup>

The duration of each of these phases depends on how contagious the virus is and how prepared the world is to handle such a virus. Additionally, these phases can only be looked at as a guide because a novel virus may not be discovered until it has caused widespread disease.<sup>24</sup>

## **HISTORY OF INFLUENZA PANDEMICS AND PANDEMIC SCARES**

There have been three pandemics and several pandemic scares since the beginning of the 20<sup>th</sup> century. The three pandemics are referred to as the 1918 Spanish flu, 1957 Asian flu, and the 1968 Hong Kong flu. The 1976 Swine flu, 1977 Russian flu, and the 1997 and 1999 Avian flu are the most recent, pandemic scares of note.<sup>25</sup>

The Spanish flu of 1918 was the first influenza pandemic in the 20<sup>th</sup> Century. During this flu outbreak, approximately 20 to 40 percent of the worldwide population became ill and over 20 million people died.<sup>26</sup> Between September 1918 and April 1919 approximately 500,000 deaths occurred in the U.S. alone.<sup>27</sup> This figure is higher than all the Americans killed in all the wars during the 20<sup>th</sup> century.<sup>28</sup> Worldwide, it is estimated that 20 million deaths could be attributed to the Spanish flu of 1918.<sup>29</sup> “One of the most unusual aspects of the Spanish flu was its ability to kill young adults. ... The attack rate and mortality was highest among adults 20 to 50 years old.”<sup>30</sup>

Following the Spanish flu of 1918, the next influenza pandemic occurred in 1957 and was called the Asian flu. Fortunately, because of advances in technology, the 1957 virus was quickly identified and a limited supply of vaccine

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<sup>23</sup> Ibid.

<sup>24</sup> Ibid.

<sup>25</sup> HHS, NVPO, *supra* note 18.

<sup>26</sup> Ibid.

<sup>27</sup> Ibid.

<sup>28</sup> HHS, NVPO, *supra* note 22.

<sup>29</sup> HHS, NVPO, *supra* note 18.

<sup>30</sup> Ibid.

was produced and available by August 1957.<sup>31</sup> Within the U.S., small outbreaks of the virus occurred during the summer of 1957; however, once the U.S. schools opened their doors in the fall, the disease quickly spread among the children who, in turn, brought it home to their families.<sup>32</sup> By October 1957, the infection rates were highest among children, young adults, and pregnant women.<sup>33</sup> However, from September 1957 through March 1958, the elderly had the highest rates of death of any age group.<sup>34</sup> In the United States, about 68,000 people died as a result of the Asian flu of 1957.<sup>35</sup>

The most recent flu pandemic occurred in 1968 and was named the Hong Kong flu because the virus was first detected in Hong Kong.<sup>36</sup> The virus appeared in the U.S. in September of 1968 and became widespread by December.<sup>37</sup> Between September 1968 and March 1969, 33,800 people in the U.S. died from contracting the virus.<sup>38</sup> There are at least three reasons the Hong Kong flu was not more deadly than it was:

First, .... [e]arlier infections by the Asian flu virus might have provided some immunity against the Hong Kong flu virus. ... Second, ... this pandemic did not gain momentum until near the school holidays in December. Since children were at home and did not infect one another at school, the rate of influenza illness among schoolchildren and their families declined. Third, improved medical care and antibiotics that are more effective from secondary bacterial infections were available for those who became ill.<sup>39</sup>

Since the Hong Kong flu of 1968, there have been no influenza pandemics. That being said, there have been several influenza pandemic scares including the 1976 Swine flu scare, the 1977 Russian flu scare, and the 1997 and 1999 Avian flu scare.<sup>40</sup>

The 1976 Swine flu scare was first identified at Fort Dix and was labeled as the “killer flu” because it was thought to be related to the Spanish flu of 1918.<sup>41</sup> Although this claim was later determined to be incorrect, the initial concern over another major pandemic similar to the 1918 pandemic led to a mass vaccination

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<sup>31</sup> Ibid.

<sup>32</sup> Ibid.

<sup>33</sup> Ibid.

<sup>34</sup> Ibid.

<sup>35</sup> Ibid.

<sup>36</sup> Ibid.

<sup>37</sup> Ibid.

<sup>38</sup> Ibid.

<sup>39</sup> Ibid.

<sup>40</sup> Ibid.

<sup>41</sup> Ibid.



campaign throughout the United States.<sup>42</sup> The virus was later named the “swine flu” and never actually moved out of the Fort Dix area.<sup>43</sup>

In 1977, an influenza A(H1N1) virus similar to one that circulated prior to 1957 and named the 1977 Russian flu, resurfaced in northern China and quickly spread worldwide in individuals younger than 23 years old.<sup>44</sup> Because the virus was very similar to viruses that had appeared prior to 1957, many over the age of 23 years had some immunity against the virus.<sup>45</sup> Because most of the illnesses occurred in children, and not in the entire population as a whole, this influenza outbreak was not considered a true pandemic.<sup>46</sup>

The two most recent influenza pandemic scares occurred in 1997 and 1999. In 1997 a few hundred people became infected with the avian A(H5N1) influenza virus in Hong Kong.<sup>47</sup> Eighteen people were hospitalized, and six died as a result of the virus.<sup>48</sup> The most alarming feature of this virus was that this particular virus seemed to occur most severely in young adults.<sup>49</sup> However, the good news was that the virus spread only from chickens to people and did not spread easily from person to person.<sup>50</sup> In order to prevent the spread of the virus all chickens in Hong Kong were slaughtered; once the slaughter was complete no new human infections were found.<sup>51</sup>

In 1999, another avian flu virus, A(H9N2) caused illnesses in two Hong Kong children.<sup>52</sup> While this virus and the avian A(H5N1) present in 1997 have not caused any pandemics, “their continued presence in birds, their ability to infect humans, and the ability of influenza viruses to change and become more transmissible among people is an ongoing concern.”<sup>53</sup>

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<sup>42</sup> Ibid.

<sup>43</sup> Ibid.

<sup>44</sup> Ibid.

<sup>45</sup> Ibid.

<sup>46</sup> Ibid.

<sup>47</sup> Ibid.

<sup>48</sup> Ibid.

<sup>49</sup> Ibid.

<sup>50</sup> Ibid.

<sup>51</sup> Ibid.

<sup>52</sup> Ibid.

<sup>53</sup> Ibid.



## **WAYS TO PREVENT AND TREAT INFLUENZA**

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There are a number of ways that individuals can prevent and be treated for influenza. Although annual vaccination is the most effective way to prevent influenza, there are several healthy habits people can have in order to prevent influenza. Also, there are antiviral medications that can be taken after infection occurs. This section provides a brief overview of two annual vaccination methods, the various antiviral medications available, and a list of healthy habits individuals can have to prevent influenza. This section also outlines the various options available to individuals if they have contracted influenza and what can be done to ease the symptoms of the virus.

### **ANNUAL VACCINATION**

#### ***Inactivated Influenza Vaccine (The Flu Shot)***

The primary way to prevent the flu is to get an annual flu vaccine. Prior to 2003, there was only one kind of flu vaccine widely available, an inactivated influenza vaccine commonly called the flu shot.<sup>54</sup> The flu shot contains three “killed” virus strains including one A (H3N2) virus, one A (H1N1) virus, and one B virus.<sup>55</sup> The three viruses selected to be a part of the vaccine are the virus strains the WHO, the CDC, and the U.S. Food and Drug Administration (FDA) believe are most likely to circulate in the United States in the upcoming season.<sup>56</sup>

While almost everyone over the age of 6 months (who does not have an anaphylactic hypersensitivity to eggs or to other components of the influenza vaccine)<sup>57</sup> can get the flu shot, vaccination with inactivated influenza vaccine is recommended for the following persons who are at increased risk for complications from influenza:

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<sup>54</sup> HHS, CDC, *Questions & Answers: Flu Vaccine*, December 10, 2003, <http://www.cdc.gov/flu/about/qa/flu vaccine.htm> (07/06/2004).

<sup>55</sup> *Ibid.*

<sup>56</sup> HHS, NVPO, *Ongoing Influenza Defense Tactics*, February 12, 2004, <http://www.hhs.gov/nvpo/pandemics/fluprint.htm> (07/06/2004).

<sup>57</sup> Since influenza viruses are grown in embryonated hens' eggs, the vaccine may contain limited amounts of residual egg protein. HHS, CDC, *supra* note 5.

- persons aged  $\geq 65$  years;
- residents of nursing homes and other chronic-care facilities that house persons of any age who have chronic medical conditions;
- adults and children who have chronic disorders of the pulmonary or cardiovascular systems, including asthma;
- adults and children who have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus [HIV]);
- children and adolescents (aged 6 months--18 years) who are receiving long-term aspirin therapy and, therefore, might be at risk for experiencing Reye syndrome after influenza infection;
- women who will be in the second or third trimester of pregnancy during the influenza season; and
- Children aged 6--23 months.<sup>58</sup>

In addition to these high-risk individuals, persons who have frequent contact with any one of these high-risk groups should be vaccinated yearly, including:

- physicians, nurses, and other personnel in both hospital and outpatient-care settings, including medical emergency response workers (e.g., paramedics and emergency medical technicians);
- employees of nursing homes and chronic-care facilities who have contact with patients or residents;
- employees of assisted living and other residences for persons in groups at high risk;

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<sup>58</sup> HHS, CDC, *supra* note 5.

- persons who provide home care to persons in groups at high risk; and
- those who have household contact (including children) with persons at high risk.

Because children aged 0--23 months are at increased risk for influenza-related hospitalization, vaccination is recommended for household contacts and out-of-home caregivers, particularly for contacts of children aged 0--5 months, because influenza vaccines have not been approved by [the] FDA for use among children aged <6 months.<sup>59</sup>

### ***Live Attenuated Influenza Vaccine (FluMist Nasal Spray)***

In 2003 the FDA approved a Live Attenuated Influenza Vaccine (LAIV) administered through a nasal spray, called FluMist.<sup>60</sup> In contrast to the flu shot, this vaccine is administered by a nasal-spray that contains attenuated, or weakened, live viruses instead of the “killed” virus strains used in the flu shot.<sup>61</sup> However, the live viruses contained in the nasal-spray are the same viruses found in the flu shot, namely one A (H3N2) virus, one A (H1N1) virus, and one B virus.<sup>62</sup>

Unfortunately, FluMist is generally more expensive than inactivated influenza vaccines and is only approved for healthy individuals ages 5 to 49 years.<sup>63</sup> People who should not use FluMist include those who:

- have certain lung conditions, including asthma, or health conditions
- have metabolic disorders such as diabetes or renal dysfunction
- have an immunodeficiency disease or are on immunosuppressive treatment
- have had Guillain-Barré syndrome

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<sup>59</sup> Ibid.

<sup>60</sup> HHS, HIN, NIAID, *supra* note 2.

<sup>61</sup> HHS, CDC, *supra* note 54.

<sup>62</sup> Ibid.

<sup>63</sup> HHS, CDC, *supra* note 54.

- are pregnant
- have a history of allergy or hypersensitivity, including anaphylaxis, to any of the parts of FluMist or to eggs

[Additionally, c]hildren or teenagers who regularly take aspirin or products containing aspirin also should not take FluMist.<sup>64</sup>

The Advisory Committee on Immunization Practices (ACIP) also recommends that if at all possible, the inactivated influenza vaccine (or the flu shot) instead of the LAIV (or the nasal spray) be used “for vaccinating household members, healthcare workers, and others who have close contact with severely immunosuppressed persons during periods when such persons require care in a protected environment.”<sup>65</sup>

### ***Timing of the Vaccination***

Since the United States flu season often begins in October or November, the ACIP states that “[t]he optimal time to receive [the] influenza vaccine is usually October -- November.”<sup>66</sup>

### ***Side Affects of Inactivated Influenza Vaccination***

The most frequent side effect of flu vaccination is soreness near the vaccination site that usually lasts less than 2 days.<sup>67</sup> In some cases, [f]ever, malaise, myalgia, and other systemic symptoms can occur after vaccination with inactivated vaccine and most often affect persons who have had no prior exposure to the influenza virus antigens in the vaccine (e.g., young children). These reaction begin 6--12 hours after vaccination and can persist for 1--2 days.

[In some rare cases, i]mmediate -- presumably allergic -- reactions (e.g., hives, angioedema, allergic asthma, and systemic anaphylaxis) ... occur after influenza vaccination. These reactions probably result from hypersensitivity to certain vaccine components; the majority of reactions probably are caused by residual egg protein. Although current influenza vaccines contain

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<sup>64</sup> HHS, NIH, NIAID, *supra* note 2.

<sup>65</sup> HHS, CDC, *supra* note 5.

<sup>66</sup> *Ibid.*

<sup>67</sup> *Ibid.*

only a limited quantity of egg protein, this protein can induce immediate hypersensitivity reactions among persons who have severe egg allergy.<sup>68</sup>

### *Side Effects of LAIV*

Like the flu shot, LAIV also does have some notable side effects. In various placebo-controlled studies testing the safety of LAIV, approximately 20,000 subjects were administered the vaccine.<sup>69</sup> In children (over the age of 5 years), runny nose or nasal congestion, headache, fever, vomiting, abdominal pain, and myalgias were reported more frequently among vaccine recipients than placebo recipients.<sup>70</sup> In adults (age 18-49 years), runny nose or nasal congestions, headache, and sore throat were reported more among those who were administered that vaccine versus those who were just given the placebo.<sup>71</sup>

### *Effectiveness of the Inactivated Influenza Vaccination*

Though the flu vaccine is the best known method for preventing the flu, it is not 100 percent effective. There are a number of factors that influence how effective the vaccine is in any particular person.

The effectiveness of inactivated influenza vaccine depends primarily on the age and immunocompetence of the vaccine recipient and the degree of similarity between the viruses in the vaccine and those in circulation.... When the vaccine and circulating viruses are antigenically similar, influenza vaccine prevents influenza illness among approximately 70%--90% of health adults age <65 years. ...

In a randomized study among children aged 1--15 years, inactivated influenza vaccine was 77%--91% effective against influenza respiratory illness and was 44%--49%, 74%--76%, and 70%--81% effective against influenza seroconversion among children aged 1--5, 6--10, and 11--15 years respectively. ...

Among elderly persons not living in nursing homes or similar chronic-care facilities, influenza vaccine is 30%--70% effective in preventing hospitalization for pneumonia and influenza. Among older persons who do reside in nursing homes,

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<sup>68</sup> Ibid.

<sup>69</sup> Ibid.

<sup>70</sup> Ibid.

<sup>71</sup> Ibid.

influenza vaccine is most effective in preventing severe illness, secondary complication, and deaths. Among this population, the vaccine can be 50%--60% effective in preventing hospitalization or pneumonia and 80% effective in preventing death, although the effectiveness in preventing influenza illness often ranges from 30% to 40%.<sup>72</sup>

### *Effectiveness of the LAIV*

Various studies have tested the effectiveness of the LAIV. In May 2004 the ACIP summarized the effectiveness of the LAIV as described here:

[Effectiveness of LAIV in Healthy Children:] A randomized, double-blind, placebo-controlled trial among 1,602 healthy children initially aged 15--71 months assessed the efficacy of trivalent LAIV against culture-confirmed influenza during two seasons. This trial included subsets of 238 healthy children (163 vaccinees and 75 placebo recipients) aged 60--71 months who received 2 doses and 74 children (54 vaccinees and 20 placebo recipients) aged 60--71 months who received a single dose during season one, and a subset of 544 children (375 vaccinees and 169 placebo recipients) aged 60--84 months during season two. Children who continued from season one to season two remained in the same study group. In season one, when vaccine and circulating virus strains were well-matched, efficacy was 93% for all participants, regardless of age, among person receiving 2 doses of LAIV. Efficacy was 87% in the 60--71 month subset for those who received 2 doses, and was 91% in the subset for those who received 1 or 2 doses. In season two, when A (H3N2) component was not well-matched between vaccine and circulating virus strains, efficacy was 86% overall and 87% among those aged 60--84 months. The vaccine was 92% efficacious in preventing culture-confirmed influenza during the two-season study. Other results included a 27% reduction in febrile otitis media and a 28% reduction in otitis media with concomitant antibiotic use. Receipt of LAIV also resulted in decreased fever and otitis media among vaccine recipients who experienced influenza.

[Effectiveness of LAIV in Healthy Adults:] ... A randomized, double-blind, placebo-controlled trial among 4,561 healthy working adults aged 18--64 years assessed multiple

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<sup>72</sup> Ibid.



endpoints, including reductions in illness, absenteeism, health-care visits, and medication use during peak and total influenza outbreak periods. The study was conducted during the 1997--98 influenza season, when the vaccine and circulating A (H3N2) strains were not well-matched. The study did not include testing of viruses by a laboratory. During peak outbreak periods, no difference was identified between LAIV and placebo recipients experiencing any febrile episodes. However, vaccination was associated with reductions in severe febrile illnesses of 19% and febrile upper respiratory tract illnesses of 24%. Vaccination also was associated with fewer days of illness, fewer days of work lost, fewer days with health-care provider visits, and reduced use of prescription antibiotics and over-the-counter medications.

Among the subset of 3,637 healthy adults aged 18--49 years, LAIV recipients (n=2,411) had 26% fewer febrile upper-respiratory illness episodes; 27% fewer lost work days as a result of febrile upper respiratory illness; and 18%--37% fewer days of health-care provider visits caused by febrile illness, compared with placebo recipients (n=1,226). Days of antibiotic use were reduced by 40%--45% in this age subset.

Another randomized, double-blind, placebo-controlled challenge study among 92 healthy adults (LAIV, n=29; placebo, n=31; inactivated influenza vaccine, n=32) aged 18--41 years assessed the efficacy of both LAIV and inactivated vaccine. The overall efficacy of LAIV and inactivated influenza vaccine in preventing laboratory-documented influenza from all three influenza strains combined was 85% and 71%, respectively, on the basis of experimental challenge by viruses to which study participants were susceptible before vaccination. The difference between the two vaccines was not statistically significant.<sup>73</sup>

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<sup>73</sup> Ibid.

## ANTIVIRAL DRUGS

Although not a substitute for the influenza vaccine, there are three general antiviral drugs, amantadine, rimantadine, and oseltamivir, that can be used to prevent and treat influenza, and one, zanamivir, that is approved to treat only influenza.

Both amantadine and rimantadine are antiviral drugs known as adamantanes and are approved to prevent and treat influenza A viruses.<sup>74</sup> These drugs work by preventing the illness while permitting the development of protective antibodies against the current circulating influenza viruses.<sup>75</sup> Amantadine was originally approved in 1966 to prevent influenza A(H2N2) infection. However, in 1976, amantadine was further approved to treat and prevent influenza A viruses among adults and children  $\geq 1$  year.<sup>76</sup> In 1993, rimantadine was approved to treat and prevent influenza A infection among adults, and to prevent influenza A infection in children.<sup>77</sup> Although rimantadine is only approved to prevent influenza A infection in children, some specialists have considered it appropriate to use the drug to treat influenza A infections among children as well.<sup>78</sup>

In addition to amantadine and rimantadine, there are two other antiviral drugs, zanamivir and oseltamivir, known as neuraminidase inhibitors that can be used for treatment of influenza infections.<sup>79</sup> In 1999, both of these drugs were approved to treat influenza A and B viruses.<sup>80</sup> Zanamivir was approved to treat persons age  $\geq 7$  years, while oseltamivir was approved to treat persons age  $\geq 1$  year.<sup>81</sup> Additionally, in 2000, oseltamivir was approved to prevent influenza among persons age  $\geq 13$  years.<sup>82</sup>

### *Effectiveness of Antiviral Drugs to Prevent and Treat Influenza*

In various studies all four antiviral drugs (amantadine, rimantadine, zanamivir, and oseltamivir) have been shown to reduce the duration of uncomplicated influenza A virus symptoms by about 1 day compared to a placebo.<sup>83</sup> Additionally, zanamivir and oseltamivir have been shown to have the

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<sup>74</sup> Ibid.

<sup>75</sup> Ibid.

<sup>76</sup> Ibid.

<sup>77</sup> Ibid.

<sup>78</sup> Ibid.

<sup>79</sup> Ibid.

<sup>80</sup> Ibid.

<sup>81</sup> Ibid.

<sup>82</sup> Ibid.

<sup>83</sup> Ibid.

same result with uncomplicated influenza B virus symptoms.<sup>84</sup> Unfortunately, there are very few, if any, studies indicating how effective these four antiviral drugs are at preventing serious, influenza-related complications such as pneumonia or exacerbation of various chronic diseases.<sup>85</sup> In addition, few, if any, studies have been completed showing the effectiveness of the antiviral drugs for treatment of influenza among people who are at high risk for serious complications of influenza.<sup>86</sup>

Both amantadine and rimantadine are about 70 percent to 90 percent effective at preventing influenza A infection.<sup>87</sup> Oseltamivir has been found to be about 82 percent effective at preventing febrile, laboratory-confirmed influenza illness.<sup>88</sup> Although zanamivir has not yet been approved to prevent influenza, data has shown that it is about 84 percent effective at preventing febrile, laboratory-confirmed influenza illness as well.<sup>89</sup> Unfortunately, data are currently not available regarding the effectiveness of the four antiviral in preventing influenza among severely immunocompromised people.<sup>90</sup>

### ***Timing of Administering Antiviral Drugs***

When and how long individuals should take antiviral medications for prevention of influenza depends on a number of things, including the cost, compliance, and potential side effects of the drug.<sup>91</sup> For antiviral medication to be fully effective, they must be taken each day during the duration of community's influenza activity.<sup>92</sup> However, according to one study, taking amantadine or rimantadine for the prevention of influenza during a community's period of peak influenza activity was found to be the most cost-effective approach to administering the two antiviral drugs.<sup>93</sup>

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<sup>84</sup> Ibid.

<sup>85</sup> Ibid.

<sup>86</sup> Ibid.

<sup>87</sup> Ibid.

<sup>88</sup> Ibid.

<sup>89</sup> Ibid.

<sup>90</sup> Ibid.

<sup>91</sup> Ibid.

<sup>92</sup> Ibid.

<sup>93</sup> Ibid.

### ***Who Should Take Antiviral Drugs***

Once an individual has influenza, antiviral drugs must be administered within 48 hours after the onset of symptoms to ease these symptoms.<sup>94</sup> However, each of the four antiviral drugs (oseltamivir, zanamivir, rimantadine, and amantadine) have different benefits and side effects; therefore, individuals and health care providers should discuss the various side effects and benefits to each drug before selecting one to treat the symptoms of influenza.

In addition to being used to treat influenza, ACIP's May 2004 Report states the following groups of individuals should consider using antiviral drugs for prevention of influenza:

- Any persons at high risk for influenza complications who are vaccinated after an influenza outbreak has begun should consider using antiviral drugs.<sup>95</sup> This group should consider using antiviral drugs until the development of antibodies has occurred as a result of getting vaccinated.<sup>96</sup> In adults, this process can take approximately two weeks from vaccination.<sup>97</sup> In children under the age of nine receiving their first influenza vaccine, this process can take up to six weeks from vaccination.<sup>98</sup>
- Any person who provides care for those at high risk for influenza complications should consider using an antiviral drug during a community or institutional outbreak.<sup>99</sup> These persons include "...employees of hospitals, clinics, and chronic-care facilities, household members [of high risk individuals,] visiting nurses, and volunteer workers."<sup>100</sup> Even if persons in these groups have been vaccinated for influenza, the outbreak may be caused by a variant strain of influenza that the vaccine may not offer adequate protection against.<sup>101</sup>
- Any person who has immune deficiencies, such as those with HIV, can consider using antiviral drugs during an influenza outbreak.<sup>102</sup> However, these individuals should be monitored closely if antiviral drugs are administered because there is little (if any) data available

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<sup>94</sup> HHS, NIH, NIAID, *supra* note 2.

<sup>95</sup> *Ibid.*

<sup>96</sup> *Ibid.*

<sup>97</sup> HHS, CDC, *supra* note 5.

<sup>98</sup> *Ibid.*

<sup>99</sup> *Ibid.*

<sup>100</sup> *Ibid.*

<sup>101</sup> *Ibid.*

<sup>102</sup> *Ibid.*

concerning possible interactions between the antiviral drugs and other drugs used to manage HIV.<sup>103</sup>

- Finally, any person who should not be vaccinated (due to an allergy to the vaccine or other reason), but wishes to avoid influenza during an influenza outbreak may benefit from taking antiviral drugs.<sup>104</sup> However, the decision to take the antiviral drugs should be left to the patient and the patient's health care providers.<sup>105</sup>

### ***Side Effects of Amantadine and Rimantadine***

Amantadine and rimantadine side effects can include nervousness, anxiety, difficulty concentrating, lightheadedness, nausea, and loss of appetite.<sup>106</sup> Nervousness, anxiety, difficulty concentrating, and lightheadedness occur more often in people taking amantadine than people taking rimantadine.<sup>107</sup> Additionally, more serious side effects such as delirium, hallucinations, agitation, and seizures can sometimes occur in people with long-term illnesses.<sup>108</sup> Fortunately, side effects usually diminish after about one week.<sup>109</sup>

### ***Side Effects of Zanamivir***

Since zanamivir is inhaled, its side effects include decreased respiratory function and bronchospasm, especially in people with asthma or other chronic long diseases. For this reason, zanamivir is usually not recommended for use in people with these types of diseases. Additionally, less than 5% of people given zanamivir reported side effects such as diarrhea, nausea, sinusitis, nasal infections, bronchitis, cough, headache, and dizziness.

### ***Side Effects of Oseltamivir***

Oseltamivir's side effects are mostly gastrointestinal, such as nausea and vomiting. However, if oseltamivir is taken with food these side effects are less severe.

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<sup>103</sup> Ibid.

<sup>104</sup> Ibid.

<sup>105</sup> Ibid.

<sup>106</sup> HHS, CDC, *Antiviral Drugs: Summary of Side Effects*, Undated, <http://www.cdc.gov/flu/protect/antiviral/sideeffects.htm> (07/06/2004).

<sup>107</sup> Ibid.

<sup>108</sup> Ibid.

<sup>109</sup> Ibid.

## OTHER WAYS TO PREVENT AND TREAT INFLUENZA

In addition to getting an annual flu shot and talking to healthcare providers about the use of antiviral drugs, individuals can engage in healthy habit approaches to preventing the spread of influenza. According to the CDC's website,

[t]he following steps may help prevent the spread of respiratory illnesses like flu:

- Avoid close contact  
Avoid close contact with people who are sick. When you are sick, keep your distance from others to protect them from getting sick too.
- Stay home when you are sick  
If possible, stay home from work, school, and errands when you are sick. You will help prevent others from catching your illness.
- Cover your mouth and nose  
Cover your mouth and nose with a tissue when coughing or sneezing. It may prevent those around you from getting sick.
- Clean your hands  
Washing your hands often will help protect you from germs.
- Avoid touching your eyes, nose or mouth  
Germs are often spread when a person touches something that is contaminated with germs and then touches his or her eyes, nose, or mouth.<sup>110</sup>

Despite all efforts to prevent influenza from spreading, each year thousands of Pennsylvania and United States residents contract influenza. The CDC's website provides general steps to follow if an individual develops flu-like symptoms. The following is an excerpt from the CDC's website.

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<sup>110</sup> HHS, CDC, *Key Facts About the Flu: Overview*, January 13, 2004, <http://www.cdc.gov/flu/keyfacts.htm> (07/06/2004).

If you develop flu-like symptoms, and you are not at high risk for complications from the flu:

- Get plenty of rest;
- Drink a lot of liquids;
- Avoid using alcohol and tobacco;
- Consider taking over-the-counter medications to relieve the symptoms of flu (but never give aspirin to children or teenagers who have flu-like symptoms);
- Stay home and avoid contact with other people to protect them from catching your illness;
- Cover your nose and mouth with a tissue when you cough or sneeze to protect others from your germs.

Look Out for [the following] Emergency Warning Signs. ...

In children, some emergency warning signs that need urgent medical attention include:

- High or prolonged fever
- Fast breathing or trouble breathing
- Bluish skin color
- Not drinking enough fluids
- Changes in mental status, such as not waking up or not interacting; being so irritable that the child does not want to be held; or seizures
- Flu-like symptoms improve but then return with fever and worse cough
- Worsening or underlying chronic medical conditions (for example, heart or lung disease, diabetes)

In adults, some emergency warning signs that need urgent medical attention include:

- High or prolonged fever
- Difficulty breathing or shortness of breath
- Pain or pressure in the chest
- Near-fainting or fainting
- Confusion
- Severe or persistent vomiting

Seek medical care immediately, either by calling your doctor or going to an emergency room, if you or someone you know is experiencing any of the signs described above or other unusually severe symptoms. When you arrive, tell the receptionist or nurse about your symptoms. You may be asked to wear a mask and/or sit in a separate area to protect others from getting sick.

... [Additionally, s]ome people are at increased risk to develop complication of flu. This group includes:

- People 65 years of age and older
- Children 6-23 months of age<sup>111</sup>
- People of any age with chronic medical conditions (for example, heart or lung disease, asthma, diabetes, or HIV infection)
- Pregnant women

If you are in a group that is considered to be at high risk for complications from the flu and you get flu-like symptoms, you should consult your health-care provider when your symptoms begin.

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<sup>111</sup> “Children 6-23 months of age are at increased risk for influenza-related hospitalization.” HHS, CDC, *What to do if you get sick: overview (interim guidance)*, January 15, 2004, <http://www.cdc.gov/flu/protect/sick.htm> (07/06/2004).



Some of the complications caused by flu include bacterial pneumonia, dehydration, and worsening of chronic medical conditions, such as congestive heart failure, asthma, or diabetes. Children also may get sinus and ear infections.

... Persons infected with influenza are sometimes at higher risk for developing secondary infections, such as pneumonia.<sup>112</sup>

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<sup>112</sup> HHS, CDC, *What to do if you get sick: overview (interim guidance)*, January 15, 2004, <http://www.cdc.gov/flu/protect/sick.htm> (07/06/2004).



# DATA AND DATA ANALYSIS: PENNSYLVANIA AND UNITED STATES INFLUENZA

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## INFLUENZA IMMUNIZATION

Immunization data is collected by the CDC's Behavioral Risk Factor Surveillance System (BRFSS). Through the use of a telephone survey, data is gathered from a random sample of adults.<sup>113</sup> Participants are asked the following "yes" or "no" question: "During the past 12 months, have you had a flu shot?" Results are processed by the CDC and weighted to population characteristics. The flu question was only a core component (which is defined as a standard set of questions asked by all states) on the questionnaire for 1995, 1997, 1999, 2001, and 2002. Therefore, results are only shown for those five years.

The percentages of "yes" responses are presented in Table 1. Total immunization percentages for Pennsylvania and the United States have been steadily increasing over time. However, Pennsylvania is increasing at a faster rate than the United States as a whole. Demographic categories of sex and race/ethnicity have similar percentages of immunized people throughout the years. However, groups with the lowest education levels and income tend to have higher percentages of their population immunized. The largest differences are within the age category. Percentages gradually increase through the early ages and then drastically increase for the 55-64 and the 65+ age groups. In 2002, Pennsylvanians 65 and older were the highest group immunized at 70.5 percent. Nonetheless, this is still below the goals established in Healthy People 2010 for adult vaccinations. Goals 14-29a and 14-29e of the plan aim at having 90 percent of adults aged 65 years and older vaccinated for influenza.<sup>114</sup>

It is important for individuals who regularly have contact with the sick and elderly to receive the influenza vaccine every year. Alarming, less than 40 percent of healthcare workers are immunized annually.<sup>115</sup> Unvaccinated workers expose high-risk patients to influenza, which can lead to serious complications or even death.

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<sup>113</sup> HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, *Behavioral Risk Factor Surveillance System Technical Information and Data*, [http://www.cdc.gov/brfss/technical\\_infodata/usersguide.htm](http://www.cdc.gov/brfss/technical_infodata/usersguide.htm) (06/29/2004).

<sup>114</sup> HHS, *Healthy People 2010*, <http://www.healthypeople.gov/> (06/30/2004).

<sup>115</sup> HHS, CDC, *supra* note 5.

## INFLUENZA ACTIVITY

The Influenza Branch at the CDC collects and reports information on influenza activity in the United States. An influenza season summary, consisting of each week from October through May, is available with regional and nationwide data. Tables focus on the Mid-Atlantic region, which includes New Jersey, New York City, Pennsylvania, and Upstate New York.<sup>116</sup> Results should be used to determine if influenza activity is increasing or decreasing, but should not be used to conclude how many people may have become infected with influenza in a particular season.

Respiratory specimens are tested for the influenza virus and reported by WHO labs in the U.S., and National Respiratory and Enteric Virus Surveillance System (NREVSS) collaborating laboratories. Positive influenza tested respiratory specimens are shown by the week they were found and virus type for the 2002-2003 and 2003-2004 influenza seasons.

When comparing flu seasons in Table 2 and Figure 1, it should be noted that 9,184 respiratory specimens were tested in 2002-2003 and 14,280 (or 55.5 percent more) were tested in 2003-2004. In the 2002-2003 season, positive specimens reached a high in week 7 (mid February). However, in the 2003-2004 season, positive specimens reached a high in week 51 (late December). Many of the reporting laboratories could not determine the specific influenza subtype based on their method of testing. Therefore, virus type A(Unknown) was the most common type found during both flu seasons. This type exceeded all the other types combined. Also, no specimens were found containing virus types A(H1N1) and A(H1N2) during the entire 2003-2004 season.

Patient visits for influenza-like illness (ILI) is another way to measure influenza activity. ILI is defined as a temperature of >100.0 Fahrenheit and either a cough or sore throat in the absence of a known cause.<sup>117</sup> Approximately 900 sentinel providers throughout the United States report patient visits for ILI on a weekly basis. In Table 3, patient visits for ILI are shown by the week they visited and the age of the patient for the 2002-2003 and 2003-2004 influenza seasons. When comparing flu seasons in Table 3 and Figure 2, it should be noted that ILI was reported from 703,517 total patient visits in 2002-2003 and 918,057 (30.5 percent more) total patient visits in 2003-2004. Like the positive influenza respiratory specimens, patient visits for ILI peaked during week 7 and week 51 for the 2002-2003 and 2003-2004 influenza seasons, respectively. Of the age groups, most visits were among those between 5 and 24 years old during each season. Nearly 70 percent of the visits were from patients under the age of 24.

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<sup>116</sup> HHS, CDC, *Flu Activity*, <http://www.cdc.gov/flu/weekly/fluactivity.htm> (06/03/2004).

<sup>117</sup> *Ibid.*

TABLE 1  
 PERCENTAGE OF PEOPLE IMMUNIZED FOR INFLUENZA<sup>1</sup>  
 BY SEX, AGE, RACE/ETHNICITY, INCOME, AND EDUCATION  
 FOR PENNSYLVANIA AND THE UNITED STATES 1995-2002

	Year									
	1995		1997		1999		2001		2002	
	PA	U.S.	PA	U.S.	PA	U.S.	PA	U.S.	PA	U.S.
<b>Sex</b>										
Male	24.1%	24.6%	28.0%	28.7%	31.5%	31.2%	27.0%	30.6%	31.5%	30.5%
Female	25.7	26.1	29.9	30.3	31.3	32.5	32.1	32.1	35.0	33.1
<b>Age</b>										
18-24	13.5	14.9	18.6	16.6	19.8	18.3	20.9	20.0	18.7	18.2
25-34	9.4	12.5	12.2	15.3	16.2	16.4	10.2	16.5	13.8	17.1
35-44	14.5	14.6	17.6	18.4	19.4	20.5	16.4	19.5	18.9	20.2
45-54	19.3	21.1	21.7	25.9	23.3	28.2	23.4	27.7	28.0	28.9
55-64	29.2	33.1	30.1	38.0	38.5	40.8	37.7	40.1	43.0	42.8
65+	58.6	60.0	65.8	65.9	63.1	67.4	63.8	66.1	70.5	68.4
<b>Race/Ethnicity</b>										
White	25.1	26.2	29.6	30.6	31.4	33.1	30.4	33.5	33.6	33.7
Black	23.9	20.9	27.3	24.8	33.7	27.0	33.3	26.6	32.0	27.7
Hispanic	24.3	20.6	19.5	24.4	29.6	24.0	14.1	26.2	32.0	26.7
Other	24.9	20.6	23.7	27.4	15.3	27.8	14.2	29.0	30.1	28.9
Multiracial	nd	nd	nd	nd	nd	nd	37.0	26.8	38.0	26.2
<b>Income</b>										
Less than \$15,000	36.6	28.9	35.0	32.8	34.0	33.8	31.1	31.8	38.9	32.7
\$15,000-24,999	28.6	28.8	35.4	31.9	35.3	32.8	36.7	32.6	39.5	33.3
\$25,000-34,999	22.0	25.1	26.1	29.1	29.6	30.6	31.2	30.5	31.4	32.4
\$35,000-49,999	19.0	21.5	21.2	26.4	28.9	29.1	28.4	28.6	29.2	30.3
More than \$50,000	19.4	21.4	23.2	26.7	25.4	30.1	23.1	29.0	29.3	30.5
<b>Education</b>										
Less than H.S.	35.7	32.8	39.1	35.5	35.5	34.7	35.8	32.9	39.8	33.4
H.S. or G.E.D.	22.9	24.6	29.0	28.8	30.5	30.7	29.6	30.0	33.7	30.3
Some post-H.S.	24.4	23.7	27.2	27.3	30.2	30.2	28.2	29.7	29.6	30.0
College graduate	22.6	25.3	25.7	30.4	31.7	33.2	29.0	32.6	33.6	34.2
Total	25.0	25.3	29.0	29.6	31.3	31.3	29.7	31.8	33.4	32.1

1. Percentage of "yes" responses to the question: During the past 12 months, have you had a flu shot?

SOURCE: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, *Behavioral Risk Factor Surveillance System Survey Data*, <http://apps.nccd.cdc.gov/brfss/> (06/02/2004).

TABLE 2  
NUMBER OF POSITIVE INFLUENZA TESTED RESPIRATORY SPECIMENS<sup>1</sup>  
BY TYPE FOR THE MID-ATLANTIC REGION<sup>2</sup>  
2002-2003 AND 2003-2004 INFLUENZA SEASONS

Week	Type									
	A(H1N1) & A(H1N2)		A(H3N2)		A(Unknown)		B		Total	
	02-03	03-04	02-03	03-04	02-03	03-04	02-03	03-04	02-03	03-04
40	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	1	1	1	0	2	1
42	0	0	0	0	0	2	0	0	0	2
43	0	0	0	0	0	0	0	1	0	1
44	0	0	0	6	0	0	0	0	0	6
45	0	0	1	7	0	2	0	0	1	9
46	0	0	0	10	0	9	0	0	0	19
47	0	0	0	33	0	16	0	0	0	49
48	0	0	0	21	1	33	0	0	1	54
49	1	0	0	63	1	77	0	0	2	140
50	1	0	0	81	0	228	0	0	1	309
51	4	0	0	37	3	301	0	1	7	339
52	7	0	0	39	3	208	1	1	11	248
53	--	0	--	19	--	280	--	2	--	301
01	3	0	0	14	8	130	2	2	13	146
02	7	0	0	5	15	63	0	2	22	70
03	7	0	1	3	16	37	2	0	26	40
04	11	0	0	1	28	11	1	0	40	12
05	16	0	1	2	32	10	15	0	64	12
06	18	0	2	0	59	13	8	2	87	15
07	16	0	0	0	80	7	4	1	100	8
08	8	0	3	0	45	2	7	0	63	2
09	7	0	1	0	23	0	7	2	38	2
10	8	0	4	0	9	2	3	3	24	5
11	1	0	2	0	5	1	10	0	18	1
12	1	0	1	1	7	0	8	9	17	10
13	0	0	0	1	4	1	2	7	6	9
14	1	0	1	0	4	0	6	3	12	3
15	1	0	1	0	2	0	0	5	4	5
16	1	0	0	0	4	8	3	3	8	11
17	1	0	4	0	1	1	1	3	7	4
18	2	0	0	0	2	0	0	1	4	1
19	0	0	1	0	1	0	1	1	3	1
20	0	0	0	0	0	0	0	0	0	0
Total	122	0	23	343	354	1,443	82	49	581	1,835

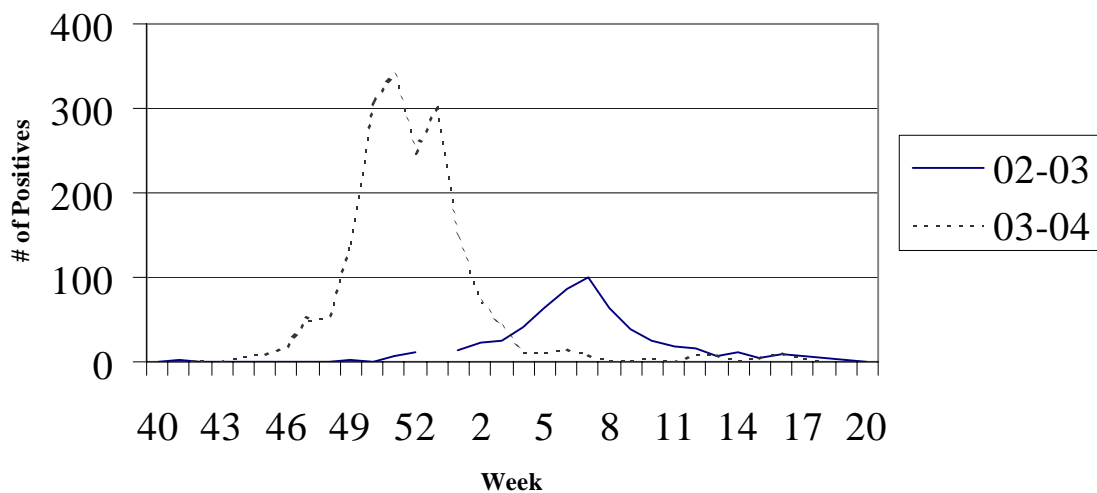
1. Respiratory specimens testing positive for influenza are reported by WHO and NREVSS collaborating laboratories.

2. The Mid-Atlantic includes New Jersey, New York City, Pennsylvania, and Upstate New York.

Note: The 2002-03 influenza season does not have week 53.

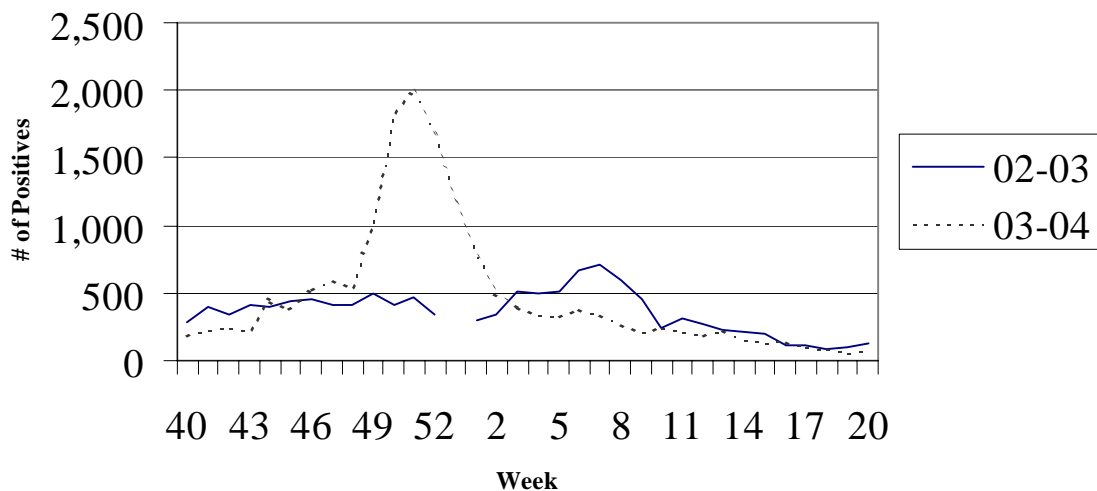
SOURCE: HHS, CDC, *Flu Activity*, <http://www.cdc.gov/flu/weekly/fluactivity.htm> (06/03/2004).

**FIGURE 1**  
**TOTAL POSITIVE INFLUENZA TESTED RESPIRATORY SPECIMENS FOR**  
**THE MID-ATLANTIC REGION**  
**2002-2003 AND 2003-2004 INFLUENZA SEASONS**



SOURCE: HHS, CDC, *Flu Activity*, <http://www.cdc.gov/flu/weekly/fluactivity.htm> (06/03/2004).

**FIGURE 2**  
**TOTAL NUMBER OF PATIENT VISITS FOR INFLUENZA-LIKE ILLNESS**  
**FOR THE MID-ATLANTIC REGION**  
**2002-2003 AND 2003-2004 INFLUENZA SEASONS**



SOURCE: HHS, CDC, *Flu Activity*, <http://www.cdc.gov/flu/weekly/fluactivity.htm> (06/03/2004).

TABLE 3  
NUMBER OF PATIENT VISITS FOR INFLUENZA-LIKE ILLNESS BY AGE<sup>1</sup>  
FOR THE MID-ATLANTIC REGION<sup>2</sup>  
2002-2003 AND 2003-2004 INFLUENZA SEASONS

Week	Age									
	0-4		5-24		25-64		Over 64		Total	
	02-03	03-04	02-03	03-04	02-03	03-04	02-03	03-04	02-03	03-04
40	74	56	95	68	83	38	29	17	281	179
41	121	60	130	93	107	45	33	35	391	233
42	142	61	113	98	63	54	24	23	342	236
43	152	48	134	109	89	47	32	24	407	228
44	153	95	138	204	83	89	17	49	391	437
45	164	90	145	153	98	94	38	41	445	378
46	154	140	156	255	112	100	27	29	449	524
47	140	129	147	308	95	120	33	42	415	599
48	168	184	110	217	96	97	33	40	407	538
49	168	252	155	500	130	200	41	68	494	1,020
50	133	495	125	926	117	344	35	73	410	1,838
51	146	447	164	1,057	112	396	48	83	470	1,983
52	108	546	84	659	112	346	31	121	335	1,672
53	--	346	--	359	--	329	--	135	--	1,169
01	98	192	94	266	90	232	16	75	298	765
02	117	133	116	201	86	127	21	43	340	504
03	167	104	198	156	109	97	42	44	516	401
04	148	84	215	148	115	76	22	38	500	346
05	119	54	275	147	93	89	21	33	508	323
06	107	92	436	151	106	98	15	48	664	389
07	131	78	385	145	154	88	41	33	711	344
08	137	61	301	117	125	65	36	23	599	266
09	113	46	192	90	113	46	32	33	450	215
10	65	38	88	105	60	72	30	26	243	241
11	47	34	136	92	69	58	56	33	308	217
12	64	47	126	77	67	32	19	35	276	191
13	61	54	88	93	63	42	20	36	232	225
14	48	45	102	58	48	29	13	22	211	154
15	47	29	91	47	50	30	15	27	203	133
16	34	40	34	60	31	23	15	19	114	142
17	33	10	30	20	27	38	19	31	109	99
18	27	14	30	28	19	24	13	17	89	83
19	25	15	29	13	25	22	15	7	94	57
20	42	12	53	20	17	21	13	22	125	75
Total	3,453	4,131	4,715	7,040	2,764	3,608	895	1,425	11,827	16,204

1. ILI is reported by U.S. sentinel physicians and defined as a temperature of >100.0 F (>37.8 C) and either a cough or sore throat in the absence of a known cause.

2. The Mid-Atlantic includes New Jersey, New York City, Pennsylvania, and Upstate New York.

Note: The 2002-03 influenza season does not have week 53.

SOURCE: HHS, CDC, *Flu Activity*, <http://www.cdc.gov/flu/weekly/fluactivity.htm> (06/03/2004).



According to flu activity data, the 2003-2004 influenza season was more severe than the 2002-2003 season. Even though the 2003-2004 data were reported from a larger number of tested specimens, positive influenza specimens, expressed as a percentage of all tested specimens, was still higher in 2003-2004 than in 2002-2003. Additionally, patient visits for ILI as a percentage of total patient visits was also higher in 2003-2004 than in 2002-2003.

## INFLUENZA DEATHS

Crude death rates are calculated using population data and resident deaths.<sup>118</sup> To keep rates comparable, the table begins with 1999 because that is the first year International Classification of Diseases (ICD) Tenth Revision was implemented. Influenza related deaths consist of ICD-10 codes J10 (Influenza due to identified influenza virus) and J11 (Influenza, virus not identified). Rates have to be considered with caution because deaths are based on a physician's diagnosis rather than a viral culture. Without a culture, influenza deaths may be incorrectly diagnosed as other respiratory disorders, or vice versa.

In table 4, the crude influenza death rate was 0.41 and 0.45 per 100,000 people in 1999 and 2000, respectively. Subsequently the rates fell to 0.07 and 0.18 in 2001 and 2002, respectively. The decrease from 2000 to 2001 was over 80 percent. Within the demographics, females had a higher death rate than males in every year except 2002. Also, whites had a higher rate than any other race except in 1999. The crude death rate was consistently 0.14 for children four years of age and younger. Rates were low for the ages of five through 64, with more than half of the groups being zero. In the age groups from 65 and above rates increase significantly.

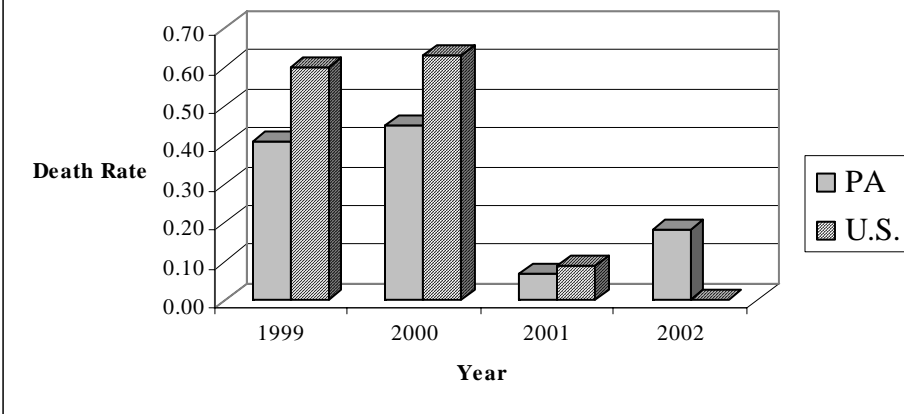
In Figure 3, the total crude death rate for Pennsylvania is compared to the United States.<sup>119</sup> Because U.S. resident deaths were not available for 2002, a rate is only shown for Pennsylvania. The U.S. had a higher crude influenza death rate than Pennsylvania each year. Like Pennsylvania, the U.S. experienced a similar decrease in rates from 2000 to 2001.

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<sup>118</sup> Crude rates are calculated with the following formula: (Resident Deaths/Population) x 100,000.

<sup>119</sup> Figure 3 uses the same population source as table 4 with the addition of U.S. deaths from--U.S. HHS, CDC, National Center for Health Statistics, *Total deaths for each cause by 5-year age groups, United States, 1999-2001*, <http://www.cdc.gov/nchs/datawh/statab/unpubd/mortabs/gmwki10.htm> (06/10/2004).

**FIGURE 3**  
**INFLUENZA DEATH RATES PER 100,000 PEOPLE**  
**FOR PENNSYLVANIA AND THE UNITED STATES 1999-2002**



Note: Because U.S. resident deaths were not available for 2002, only Pennsylvania's rate is shown.

SOURCE: PA Deaths-- PADOH, Bureau of Health Statistics and Research, *Birth and Death Statistics*, <http://www.dsf.health.state.pa.us/health/cwp/view.asp?a=175&Q=201652> (06/10/2004). U.S. Deaths-- HHS, CDC, National Center for Health Statistics, *Total deaths for each cause by 5-year age groups, United States, 1999-2001*, <http://www.cdc.gov/nchs/datawh/statab/unpubd/mortabs/gmwki10.htm> (06/10/2004). Population--Bureau of the Census, *Statistical Abstract of the United States 2000-2003*, <http://www.census.gov/prod/www/statistical-abstract-03.html> (06/14/2004).

TABLE 4  
 INFLUENZA DEATH RATES PER 100,000 PEOPLE  
 BY SEX, RACE, AND AGE  
 FOR PENNSYLVANIA 1999-2002

	Year			
	1999	2000	2001	2002
Sex <sup>1</sup>				
Male	0.24	0.40	0.05	0.27
Female	0.56	0.49	0.09	0.09
Race <sup>2</sup>				
White	0.44	0.52	0.09	0.20
Black	0.09	0.08	0.00	0.08
Other	0.45	0.00	0.00	0.00
Age <sup>2</sup>				
0-4	0.14	0.14	0.14	0.14
5-24	0.06	0.00	0.00	0.03
25-34	0.00	0.00	0.00	0.07
35-44	0.05	0.00	0.00	0.00
45-54	0.12	0.00	0.00	0.06
55-64	0.00	0.35	0.09	0.00
65-74	0.21	0.52	0.11	0.11
75-84	2.30	2.81	0.14	0.96
85+	10.78	10.50	2.01	3.86
Total	0.41	0.45	0.07	0.18

1. 2001 and 2002 death rates are calculated with 2000 population.

2. 2001 death rates are calculated with the average population of 2000 and 2002.

Note: The PADOH specifically disclaims responsibility for any analyses, interpretations or conclusions.

SOURCE: Deaths-- PADOH, Bureau of Health Statistics and Research, *Birth and Death Statistics*, <http://www.dsf.health.state.pa.us/health/cwp/view.asp?a=175&Q=201652> (June 10, 2004). Population-- Bureau of the Census, *Statistical Abstract of the United States 2000-2003*, <http://www.census.gov/prod/www/statistical-abstract-03.html> (06/14/2004).



## **PRODUCING INFLUENZA VACCINES**

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### **VIRUS SELECTION**

In the early part of each calendar year, the FDA's Vaccines and Biological Products Advisory Committee selects three strains of influenza that are most likely to be prevalent in the United States during the coming flu season. The selections are based on information received from the surveillance laboratory networks of such agencies as the WHO, the CDC, and the Department of Defense (DOD). There are a number of considerations that go into the selection, including: which new strains are emerging around the world; whether or not the current vaccines provide the necessary antibody response; and whether or not the candidate strains are suitable for manufacturing vaccines.<sup>120</sup>

As stated previously, influenza viruses are classified by three different types: A, B, or C, based on their antigen composition. There are two noteworthy antigens in flu viruses. The antigen hemagglutinin (H) allows the virus to adhere to a cell and initiate infection. The antigen neuraminidase (N) enables the newly formed viruses to exit the host cell.

Type A viruses are found in many kinds of animals, including fowl, pigs, whales and humans. Type B viruses are widely circulated among humans. Type C virus is common to humans, pigs and dogs, and while it causes mild respiratory infections it does not lead to epidemics.

The most dangerous of A, B, and C is type A. It is believed that Type A was responsible for the pandemics of 1918, 1957, and 1968. This strain is subdivided into groups based on the two surface antigens, H and N. Fifteen H subtypes and nine N subtypes have been classified. The Type A subtypes are classified according to a protocol that includes the location where the strain was first found, a lab identification number, the year the type was discovered and, in parenthesis, the type of H and N it possesses. For example, A/Hong Kong/156/97(H5N1) is the classification for a subtype of A, first discovered in Hong Kong at lab 156 in 1997. The antigens are identified as H5 and N1.

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<sup>120</sup> Telephone conversation of July 6, 2004 with Dr. Roland Levandowski, FDA, Center for Biologics Evaluation and Research, Division of Viral Products, and Joint State Government Commission staff.

At the CDC, wild strains and known, laboratory strains are injected into eggs. After the wild and known genes naturally reassort themselves, the researchers sift through the 256 possible combinations of viruses to find the one that has the desired H and N antigens and will grow inside an egg.<sup>121</sup> The CDC provides the strains of the seed viruses to the FDA's Center for Biologics Evolution and Research (CBER). At the conclusion of a comprehensive review process, the CBER distributes virus reference material to the manufacturers, which then develop the seed viruses.

For the 2004-05 flu season, the vaccine strains are: A/Fujian/411/2002 (H3N2)-like, A/New Caledonia/20/99 (H1N1)-like, and B/Shanghai/361/2002-like antigens. For the A/Fujian/411/2002 (H3N2)-like antigen, manufacturers may use the antigenically equivalent A/Wyoming/3/2003 (H3N2) virus, and for the B/Shanghai/361/2002-like antigen, manufacturers may use the antigenically equivalent B/Jilin/20/2003 or B/Jiansu/10/2003 virus.<sup>122</sup>

## **PRODUCTION BEGINS**

Each of the three strains of flu are injected into separate fertilized chicken eggs. In order to produce the approximately 90 million doses of trivalent flu vaccine in a given year, 270 million eggs are required (90 million doses x 3 eggs per dose). The eggs are incubated, allowing the viruses to multiply. After the viruses have propagated in sufficient numbers, the eggs' allantoic fluid (egg white) is removed. Chemical purification filters out egg-related proteins leaving the virus. Chemical treatments are applied that inactivate the virus and split the viruses into component pieces. Children experience fewer side effects from viruses that have been split during vaccine production. The fragmented viruses are then recombined to form a vaccine that includes all three flu strains.

During the months of June and July, the vaccines are checked by both the manufacturer and the FDA for purity and potency. Upon satisfactory completion of all tests, the FDA licenses the vaccines for sale and distribution. In August, approximately eight months after the identification and manufacturing process began, the vaccine is filled into vials and syringes and packaged for distribution.

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<sup>121</sup> HHS, NIH, NIAID, *Focus on the Flu: Reverse Genetics: Building Flu Vaccines Piece by Piece*, undated, [http://www2.niaid.nih.gov/Newsroom/FocusOn/Flu04/reverse\\_genetics.htm](http://www2.niaid.nih.gov/Newsroom/FocusOn/Flu04/reverse_genetics.htm) (06/23/2004).

<sup>122</sup> "These viruses can currently "...be used because of their growth properties and because they are representative of influenza viruses likely to circulate in the United States during the 2004--05 influenza season." HHS, CDC, *supra* note 5.

The manufacture and distribution is by lot process, through which the FDA and manufacturer can closely monitor the safety and efficacy of each lot of vaccine.

Vaccines are shipped from the manufacturers in September. Vaccination begins in October or November and continues throughout the flu season.

## EXPERIMENTAL VACCINES

There are approaches to producing vaccines that might be faster and more efficient than the process of injecting viral strains into eggs. Researchers are investigating the use of microcarriers, reverse genetics, and particle-mediated epidermal delivery (PMED) devices.

### *Microcarriers*

Small beads, called microcarriers, can lead to a faster, more cost effective approach to manufacturing flu vaccines. With the microcarrier approach, mammalian cells, such as kidney cells (VERO cells) of African green monkeys, are injected with the flu virus strains. The VERO cells are anchored to the microbeads and stirred in a growth medium in biological reactors.

The microcarrier method is considered to be superior to traditional egg-based manufacturing. The microcarrier technology requires less space than egg-based manufacturing.<sup>123</sup> The microbeads provide a relatively large surface area for the VERO cells to thrive and reproduce. The VERO cells reproduce much more rapidly than chickens can lay eggs. Flu strains that are toxic to eggs, and therefore cannot be reproduced in egg-based manufacturing, can be reproduced by using VERO cells. The VERO cells also provide a flu vaccine for people who are allergic to eggs and egg products. The microcarrier process accelerates the production of vaccines, which allows for increased volume and also permits a quicker response when new viruses are discovered.

### *Reverse Genetics*

In using the methodology of reverse genetics to manufacture vaccines, researchers are trying to discover ways to produce flu vaccines by working backwards from what any particular vaccine will look like.<sup>124</sup> Reverse genetics

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<sup>123</sup> HHS, NIH, NIAID, *Scrambling for an Egg Alternative*, undated, [http://www2.niaid.nih.gov/Newsroom/FocusOn/Flu04/egg\\_alternative.htm](http://www2.niaid.nih.gov/Newsroom/FocusOn/Flu04/egg_alternative.htm) (06/23/2004).

<sup>124</sup> HHS, NIH, NIAID, *supra* note 121.

flu vaccines are custom-made by assembling virus genes that code for the desired features. The genes that represent the desired H and N proteins are combined with six genes that come from a virus that has been proven to propagate well inside an egg. The newly assembled DNA code is then inserted into animal cells; the code makes new copies of the desired virus. The virus is then injected into eggs using traditional manufacturing methods. Vaccine researchers hope reverse genetics will prove a quick and effective way to develop a suitable vaccine in the event of a pandemic.

An advantage of reverse genetics is that genes that make a particular virus toxic to eggs can be removed, leaving behind the segments necessary to produce the desired vaccine.

### ***Particle-mediated Epidermal Delivery***

An experimental alternative to traditional vaccines administered by needle is the use of a PMED device.<sup>125</sup> A PMED DNA vaccine delivers the antigen-producing genetic material of the virus directly into a person's skin cells. The dangerous, disease causing elements of the virus are left out of the vaccine. Certain cells that receive the DNA produce the antigen on their surfaces, which signals the body to produce antibodies and other immune responses.

PMED DNA vaccines are considered safe because they do not introduce the virus into the recipient. They can be developed quickly because the manufacturing process does not require the use of fertilized eggs, takes fewer than the usual six months between strain identification and vaccine readiness. Importantly, the body responds as if it were exposed to a live virus, which provides a more robust immune reaction.

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<sup>125</sup> HHS, NIH, NIAID, *Taking Aim Against Possible Flu Pandemic*, undated, [http://www2.niaid.nih.gov/Newsroom/FocusOn/Flu04/taking\\_aim.htm](http://www2.niaid.nih.gov/Newsroom/FocusOn/Flu04/taking_aim.htm) (06/23/2004).



## VACCINE DISTRIBUTION

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Influenza vaccines are similar to other types of pharmaceuticals in that they are distributed through multiple channels in the private sector, a process that meets the specific needs of different types of purchasers. Manufacturers, medical supply and pharmaceutical distributors, and other resellers are included among those who sell and distribute the vaccines. The General Accounting Office (GAO) report *Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People* states that about half of flu vaccines are purchased by providers directly from manufacturers and half from distributors and resellers.<sup>126</sup>

### DIVERSE DISTRIBUTION SYSTEM

Most of the planned production of vaccines is pre-ordered from the manufacturers in May or June. Large volume purchasers, such as distributors and resellers, and public health agencies purchase their vaccine supply by this schedule, thus assuring that they will receive the most favorable prices. Typically, smaller volume purchasers, such as doctors' offices, purchase their supply later in the year from distributors. This offers the smaller volume purchasers the opportunity to place their vaccine orders along with orders for other medical supplies. According to experts interviewed for the GAO report, the varied distribution channels allows for an efficient and effective delivery of a large volume of vaccines in time for the annual fall vaccination period.<sup>127</sup>

Vaccine providers are as diverse as are the distributors, going beyond traditional doctors' offices, clinics, and hospitals. Pharmacies, grocery and convenience stores, workplaces and other venues have begun to offer vaccinations to the public.

#### *Role of Pharmacists*

The Pennsylvania General Assembly, realizing the importance of increasing overall immunization rates, amended the State's Pharmacy Act to allow pharmacists to administer vaccines, including those for influenza. The act

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<sup>126</sup> GAO, *Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People*, May 2001, (Washington, D.C.: GPO), page 12.

<sup>127</sup> *Ibid.*

of June 29, 2002 (P.L. 673, No. 102) amended the act of September 27, 1961 (P.L. 1700, No. 699) by adding Section 9.2, which authorizes pharmacists to administer injectable medications, biologicals, and immunizations to persons 18 years of age and older. The State Board of Pharmacy is required to establish education and training standards and practice guidelines. As part of the legislation, pharmacists must dedicate a minimum of two of the 30 hours of continuing education to this practice and maintain certification in cardiopulmonary resuscitation (CPR).

***Increasing Immunization Rates***

It is believed that the increasing availability of the vaccines contributed to large increases in immunization rates, including the five-fold increase for individuals aged 18-49 between the years 1989 and 1999.<sup>128</sup> See Table 5.

TABLE 5  
PERCENTAGE OF POPULATION RECEIVING  
INFLUENZA VACCINATION

Age group	Percent vaccinated in various years <sup>1</sup>		
	1989	1995	1999
18-49 years	3.4%	13.1%	18.8%
50-64 years	10.6	27.0	35.8
65 years and older	30.4	58.2	66.9

1. Some numbers were based on preliminary data.

SOURCE: CDC's 1989 and 1995 National Health Interview Surveys and 1999 BRFSS data.

The distribution system and the wide variety of venues available to individuals seeking immunization is an efficient way to ensure that a large number of people are vaccinated. There are drawbacks to this system, however. Some physicians and health officials regard it as less than ideal for ensuring that vaccines are made available to high-risk individuals, especially in times of vaccine shortages.

<sup>128</sup> Ibid.

## VACCINE SHORTAGES

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As mentioned in the preceding section, varied distribution and administration systems efficiently deliver vaccines to a large portion of the U.S. population. However, there are instances when the systems are unable to optimally serve the interests of public health. Production shortages of vaccines in recent years illustrated weaknesses of the distribution system and thus raised concerns about the readiness of the healthcare system to prevent and respond to an influenza pandemic.

Shortages arise from several different situations. A shortage may occur when a particular strain is slow growing, which slows the process of manufacturing doses of the vaccine. Slow growing strains led to vaccine shortages in 2001.<sup>129</sup> Early in the 2001 season, manufacturers experienced decreased production yields because of the slow growth of one of the selected strains. To address this situation, the FDA permitted changes in the manufacturing process that allowed for increased production. Also during that time, the FDA had taken regulatory action against two of the manufacturers licensed to distribute influenza vaccine in the U.S.<sup>130</sup> One of the manufacturers made arrangements with the FDA to continue distributing its vaccine while the other elected to withdraw from the market in 2000.<sup>131</sup> As a result of the altered manufacturing processes, approximately 87 million vaccines were released for the 2001-02 season, which was the highest number of vaccines produced in any year up to that time.<sup>132</sup>

ACIP delayed implementation of a recommendation to increase the range of people who should be vaccinated during the 2000-2001 season because manufacturers would have been unable to meet production demands.<sup>133</sup> Instead, the CDC and ACIP issued recommendations to delay implementation of organized influenza vaccination campaigns. Healthcare providers, health

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<sup>129</sup> HHS, CDC, "FDA's Role in Maintaining the Supply of Childhood Vaccines," *Testimony Before the Committee on Governmental Affairs United States Senate: Statement of Lester M. Crawford, D.V.M., Ph.D., Deputy Commissioner, Food and Drug Administration (FDA), Department of Health and Human Services (DHHS), United States Senate*, June 12, 2002, <http://www.cdc.gov/nip/news/testimonies/vac-shortages-FDA-6-12-2002.htm> (08/02/2004).

<sup>130</sup> HHS, CDC, *Questions and Answers for the Public Influenza Supply: 2000-2001 Season*, undated, [http://wdhfs.state.wy.us/epiid/flu\\_vaccine.PDF](http://wdhfs.state.wy.us/epiid/flu_vaccine.PDF) (07/08/2004).

<sup>131</sup> HHS, CDC, *supra* note 129.

<sup>132</sup> *Ibid.*

<sup>133</sup> *Ibid.*

organizations, commercial companies, and other organizations planning organized influenza vaccination campaigns for the 2000-01 influenza season were asked to postpone those initiatives until mid-November. The purpose of the recommendation was to minimize cancellations of vaccine campaigns and wastage of vaccine doses resulting from delays in vaccine delivery.<sup>134</sup> The U.S. GAO reported that there was a six to eight week delay in shipping times, which resulted in a temporary price spike. According to the GAO report, the peak vaccination months of October and November saw prices of \$7 per dose, whereas orders placed before the end of June 2000 were less than \$3 per dose.<sup>135</sup> See Table 6.

TABLE 6  
PRICES PAID FOR INFLUENZA VACCINE  
BY PHYSICIAN GROUPS SURVEYED BY GAO

Date order was placed	Range of price per dose	Average price per dose
June 2000 and earlier	\$1.90 to \$6.35	\$2.90
July through September 2000	\$2.27 to \$4.90	\$4.01
October and November 2000	\$2.50 to \$12.80	\$6.98
December 2000 and later	\$1.50 to \$10.80	\$3.48

Note: The 58 physician group practices we [the GAO] surveyed purchased a total of 89,245 doses of flu vaccine during the 2000-01 season. This table is based on prices the groups paid for nearly 77,000 doses of vaccine received in multidose vials. (The groups received a total of 77,240 doses of vaccine in vials, but 350 doses were provided at no cost by a state health department and for 200 doses the price was not known.) The physician groups also received 12,005 doses of vaccine in prefilled syringes, which are excluded from this table because vaccine in prefilled syringes costs roughly double the price per dose of vaccine sold in vials.

SOURCE: GAO, *Report to Congressional Requesters, Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People*, May 2001, (Washington, D.C.: GPO).

To deal with the delays and potential shortages during the 2000-01 season, CDC undertook a number of activities. The agency contracted with one manufacturer to extend its production period and produce up to 9 million additional doses of additional influenza vaccine. The additional doses were available in December 2000. With the increased supply available on the market, prices began to slide and settled around \$3.50 per dose, above the June average but about half the price of orders placed in October and November.<sup>136</sup> The drop in price not only reflected the increase in production but also a decrease in

<sup>134</sup> HHS, CDC, "Notice to Readers: Delayed Supply of Influenza Vaccine and Adjunct ACIP Influenza Vaccine Recommendations for the 2000-01 Influenza Season," *MMR Weekly*, 49/27, July 14, 2000, pages 619-622, <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/mm4927a4.htm> (07/09/2004).

<sup>135</sup> GAO, *supra* note 126, page 2.

<sup>136</sup> *Ibid.*, page 10.

demand. According to manufacturers and distributors, it is difficult to sell vaccines after November, and the 2000-01 season was unusually light. Despite the early shortages, the final supply of influenza vaccine approximated what was distributed in the previous year. In addition to the CDC's contracting for the production of additional doses, the agency:

- recommended that vaccine be administered to high-risk individuals first;
- provided an internet-based system to facilitate the exchange and redistribution of vaccine;
- conducted promotional campaigns to encourage vaccination of high risk persons;
- communicated with healthcare providers and partners to keep them informed of events; and
- encouraged states to develop plans to help manage and direct vaccine supplies in their jurisdictions.

The CDC's influenza education and media campaign encouraged people at high risk of complications from influenza to seek a flu shot; the campaign also encouraged healthy people 50-64 to seek flu shots in December and early January. The distribution system may have led to problems in implementing these recommendations. Because vaccine shortages had been relatively rare occurrences, there was little need for distributors to develop the capability to identify high-risk individuals and devise the means to deliver vaccines to them. The CDC and ACIP had, at the time of the 2000-01 shortage, not provided guidance as to how to effectively deliver influenza vaccinations to high risk individuals.

The degree of delay experienced by individual providers varied greatly, depending on the vaccine manufacturer, distributor, and when vaccine was ordered. The GAO acknowledged that the purchase, distribution, and administration of influenza vaccine are mainly private-sector responsibilities.

In retrospect, the 2000-2001 vaccine shortage is now regarded as “severe and unusual.”<sup>137</sup> The GAO report notes that, “In a typical year, enough vaccine is

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<sup>137</sup> HHS, CDC, *Testimony of Keiji Fukuda, M.D. Chief, Epidemiology and Surveillance Section Influenza Branch, Division of Viral and Rickettsial Diseases CDC's National Center for Infectious Diseases Before the Special Committee on Aging U.S. Senate*, May 30, 2001, <http://www.cdc.gov/washington/testimony/im053001.htm> (07/09/2004).

available in the fall to meet total demand, both from high-risk individuals and from others who simply want to avoid the flu.”<sup>138</sup>

In response to the shortages and delays experienced during the 2000-01 season, the HHS implemented four initiatives:<sup>139</sup>

- The National Institutes of Health (NIH), FDA, and CDC conducted clinical trials to determine the effectiveness of half-dose of vaccine administered to healthy individuals ages 18-49. Preliminary results showed an acceptable level of protection.
- Opened discussions with private distributors and public health agencies to improve the distribution system when supplies are delayed.
- Recommended that state and local governments draft contingency plans to maximize vaccinations in the event of a delay or shortage.
- Revised guidelines to extend the optimal time for vaccination beyond mid-November.

Shortages can also result when increased public awareness prompts greater numbers of people to get vaccinated. Consumer demand that is stronger than expected can stress the supply and distribution network. The number of doses produced by manufacturers is determined by the amount pre-booked by immunization providers in the beginning of the year, plus an allowance for unexpected demand. In 2001, the entire U.S. supply of influenza vaccine was pre-booked before the end of May.<sup>140</sup> For the 2002-03 season, manufacturers produced a record 95 million doses of flu vaccine, but 12 million went unused and were destroyed.<sup>141</sup>

The 2003-04 season saw 86.9 million doses available but shortages occurred, partly because of an earlier than normal start to the flu season and fears that a previously unidentified strain would cause outbreaks.<sup>142</sup> In fact, a variant cluster of strains was identified in January or early February 2003.<sup>143</sup> Most of the

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<sup>138</sup> GAO, *supra* note 126, page 3.

<sup>139</sup> *Ibid.*, page 18.

<sup>140</sup> Immunization Action Coalition (IAC), IAC Express, no. 300, March 11, 2003, <http://www.immunize.org/genr.d/issue300.htm#n2>, (07/08/2004).

<sup>141</sup> Eric Berger, “Next Season’s Flu Shot Recipe to be Set Today,” *HoustonChronicle.com*, March 17, 2004, <http://www.HoustonChronicle.com>.

<sup>142</sup> Daniel Yee, “100M Doses of Flu Shots to Be Available,” *The Associated Press*, MSNBC Wire Services, June 23, 2004.

<sup>143</sup> CDC, NIP, Record of The Meeting of The Advisory Committee on Immunization Practices February 24-25, 2004.

variants were inhibited by the vaccines that were being produced, but some strains were poorly inhibited. Because the variants emerged after the vaccine manufacturing process was underway, it was difficult to produce vaccines for the new strains. Vaccine manufacturers did not have the appropriate genetic materials and growth media available until June 2003. By that time, the new variant began to predominate and reports of associated morbidity significantly increased demand for the new vaccine.<sup>144</sup>

In an effort to combat the shortages, health officials urged healthy people to opt for the inhaled vaccine FluMist, leaving traditional vaccines available for the elderly and children.<sup>145,146</sup>

When there are vaccine shortages the state and federal governments are able to redistribute their supplies to meet local needs. During the 2003-2004 vaccine shortage, PADOH was able to alleviate shortages by tracking vaccine inventories through the Vaccine Management information system (VACMAN) and coordinating redistribution with providers through the Pennsylvania Health Alert Network (PA-HAN). These two systems are discussed more fully later in this report.

The CDC, for its part, is stockpiling 100 million doses of vaccine for the 2004-05 influenza season, 4.5 million of which are to be held in reserve for children.<sup>147</sup>

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<sup>144</sup> Ibid.

<sup>145</sup> Daniel Yee, *supra* note 142.

<sup>146</sup> FluMist has been approved for use in adults to age 49 and children ages 5 and up. Safety tests on other age groups are not complete. HHS, NIH, NIAID, *A Nasal Spray Flu Vaccine*, June 18, 2003, <http://www2.niaid.nih.gov/Newsroom/FocusOn/Flu04/flumist.htm> (06/23/2004).

<sup>147</sup> Daniel Yee, *supra* note 142.





## **FEDERAL IMMUNIZATION PROGRAMS**

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While many of the prevention and treatment decisions ultimately come down to the individual level, local, state and federal governments play a very important role in influenza prevention and treatment. Federal agencies must work together to determine what three influenza virus strains will be included in the upcoming year's flu vaccine. The HHS, Pennsylvania Department of Health (PADOH), and other state and local agencies need to make sure the vaccine supply is adequate to meet demand and that the vaccine is properly distributed across the country. Local, state, and federal agencies need to make sure the general public is aware of all of the influenza prevention and treatment methods available. Additionally, these agencies need to provide avenues for those who are financially unable to afford the influenza vaccine to ensure that they can still get vaccinated annually.

There are several federal agencies and offices under the direction of the HHS that are responsible for protecting the public against influenza. Among them are the CDC, the NVPO, and the ACIP. Additionally, the Center for Biologics Evaluation and Research (CBER), which plays a vital role in approving influenza vaccines, is under the direction of the FDA.

### **UNITED STATES CENTERS FOR DISEASE CONTROL AND PREVENTION**

The CDC is the federal agency primarily responsible for protecting the public's health. Some of the CDC's critical responsibilities are related to the prevention and treatment of infectious diseases. It accomplishes these tasks through its own research, public health programs and advocacy and also by funding public health programs at the state and local levels. A number of operating components within the structure of the CDC are directly involved in the fight against influenza are the National Center for Infectious Diseases (NCID), and the National Immunization Program (NIP).

#### ***National Immunization Program***

The NIP is the CDC's primary agency for the planning, coordination, and implementation of immunization activities nationwide. The agency provides

consultation, statistical, educational, and epidemiological services to assist health departments in planning, developing, and implementing immunization programs. Importantly, it helps state and local health departments establish contracts for purchasing vaccines from suppliers. NIP is the agency responsible for nationwide surveillance of vaccine preventable diseases, such as influenza, and operates the previously mentioned VACMAN system.

NIP published a strategic plan for the years 2000-2005.<sup>148</sup> The plan's goals specifically related to influenza are:

- Increase to 90 percent the proportion of adults 65 years of age and older in the U.S. who are vaccinated annually against influenza and ever vaccinated against pneumococcal disease.
- Increase to 60 percent the proportion of high-risk adults aged 18 to 64 years of age in the U.S. who are vaccinated annually against influenza and ever vaccinated against pneumococcal disease.

These goals mirror Objectives 14-29a. and 14-29c. in *Healthy People 2010*, which state that 90 percent of adults age 65 years and older, and high risk adults ages 18-64 should be immunized against influenza by 2010.<sup>149</sup>

### **NATIONAL VACCINE PROGRAM OFFICE**

The NVPO was created by Congress in P.L. 99-660 and has responsibility for coordinating the federal agencies involved in vaccine and immunization activities.<sup>150</sup> The NVPO works to accomplish the goals of the National Vaccine Plan, which provides a framework of goals, objectives, and strategies for preventing infectious diseases through immunizations. The National Vaccine Plan has four specific goals, which are:

- Develop new and improved vaccines;
- Ensure optimal safety and effectiveness of vaccines and immunization;

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<sup>148</sup> HHS, CDC, NIP, *A Blueprint for Sustained Success, National Immunization Program Strategic Plan 2000-2005*, undated, <http://www.cdc.gov/nip/webutil/about/strategic-plan.pdf> (07/16/2004).

<sup>149</sup> HHS, CDC, *Healthy People 2010*, undated, <http://www.healthypeople.gov/document/html/objectives/14-29.htm> (08/02/2004).

<sup>150</sup> HHS Public Health Service, NVPO, *U.S. National Vaccine Plan Executive Summary*, March 1994, [http://www.hhs.gov/nvpo/vacc\\_plan/](http://www.hhs.gov/nvpo/vacc_plan/) (07/26/2004).

- Better educate the public and members of the health professions on the benefits of immunizations; and
- Achieve better use of existing vaccines to prevent disease, disability, and death.<sup>151</sup>

Among the agencies that are coordinated through the NVPO are the NIH, CDC, FDA, U.S. Health Resources and Services Administration (HRSA), Department of Defense (DOD), and U.S. Agency for International Development (USAID).

The National Vaccine Advisory Committee (NVAC) is an advisory board to the NVPO Director. The 15 members of the NVAC are appointed by the NVPO Director. The NVAC recommends to the NVPO Director research priorities and ways to ensure adequate and safe vaccine supplies for the states.

### **ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES**

The ACIP consists of 15 experts in fields associated with immunization who have been selected by the Secretary of HHS to provide advice and guidance to the Secretary and the CDC on the most effective means to prevent vaccine-preventable diseases. Each year ACIP reports its findings and regarding the upcoming flu season and recommends which flu strains should be targeted by vaccines.<sup>152</sup>

ACIP develops written recommendations for the routine administration of vaccines to the pediatric and adult populations, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines. ACIP is the only entity in the federal government which makes such recommendations.

### **CENTER FOR BIOLOGICS EVALUATION AND RESEARCH**

CBER is an agency of the FDA. It is responsible for ensuring the safety and efficacy of vaccines, among other things. As such, it is the CBER that gives approval for each of the vaccine types that are manufactured each year.

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<sup>151</sup> Ibid.

<sup>152</sup> The latest available influenza recommendations from ACIP can be found at: HHS, CDC, *supra* note 5.



## **COMMONWEALTH IMMUNIZATION PROGRAMS**

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The Commonwealth operates influenza programs as part of its broad mandate to protect the public health. These programs are funded and administered through several executive departments. The Departments of Health, Aging, and Welfare and Insurance all play important roles in preventing and containing flu outbreaks.

### **ELDERLY IMMUNIZATION ACT**

The General Assembly recently passed the Elderly Immunization Act, (Senate Bill 769 of 2003 (P.N. 1654)), which requires that hospitals offer influenza and pneumococcal vaccines to persons 65 and older if those persons are in the institutions' care for 24 hours or longer. The bill was approved by the Governor on July 15, 2004 and signed into law as Act 85 of 2004.

The bill also requires physician offices, public health clinics, hemodialysis centers, hospital specialty care clinics, and outpatient rehabilitation programs to offer a vaccination for the influenza virus to the extent possible as determined by the facility. If the facility determines it is not possible to provide the vaccine, information is to be provided on other options for obtaining the vaccine. Influenza vaccines are to be offered during the months of October and November and possibly longer depending on the overall availability of the vaccines.

It is estimated that Act 85 will cost the state approximately \$50,000 annually for PADOH to develop and distribute information and educational materials to eligible persons.<sup>153</sup> It is anticipated that there will be an increase in medical assistance expenditures because of the expected increase in immunizations among medical assistance eligible persons; however, the amount of the increase had not been determined at the time of this report.

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<sup>153</sup> Commonwealth of Pennsylvania, House of Representatives, House Committee on Appropriations, "Fiscal Note, Senate Bill 769, Printers No. 1654, Prime Sponsor: Corman," June 21, 2004.

## **PENNSYLVANIA DEPARTMENT OF HEALTH**

All State immunization programs are funded by federal appropriations and grants. The PADOH purchases vaccines through CDC grants, which specify, as part of the award conditions, that the grant recipient meet criteria established by the CDC. During 2003 the department grant amounted to \$34.2 million which was used to purchase 149,000 doses and \$7.1 million for infrastructure support.<sup>154</sup>

The PADOH operates several bureaus and divisions that are responsible for immunization programs, namely the Bureau of Community Health Systems, the Bureau of Communicable Diseases, and the Division of Immunization.

### ***The Bureau of Community Health Systems***

The Bureau of Community Health Systems operates 57 clinical offices and employs approximately 350 nurses and physicians. The bureau provides funding and technical assistance to six county health departments and six municipal health departments. The bureau is responsible for public education and outreach initiatives targeted to both vaccine providers and the general public. The bureau oversees funding for approximately 10 private contractors who administer flu vaccines through Participating Provider Agreements. The agency provides funding for about 50 percent of municipal health departments' clinical staff that administers vaccines. Flu shots are made available to the public through a partnership of state, local and private providers at shelters, churches, community centers and low income housing sites.

### ***The Division of Immunization***

The Division of Immunization is responsible for development and implementation of policies targeting infectious diseases and is charged with regulation and enforcement of those policies. The Division focuses on the reduction or elimination of vaccine-preventable diseases, and as such is the Commonwealth's primary purchaser and distributor of publicly funded flu vaccines. The Division provides flu vaccines to Medicaid eligible children, adolescents and adults, making vaccines available through both public and private healthcare providers. In addition to providing vaccines, the Division offers educational programs, on-going disease surveillance systems, enforcement of school immunization regulations, disease investigations, assessment of immunization coverage, immunization registry and tracking systems, and outbreak control interventions.

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<sup>154</sup> Meeting of PADOH and Commission staff on July 14, 2004.

The Commonwealth does not fund influenza prevention and control activities through line item appropriations. Rather, infrastructure, staff and the administration of the vaccines are paid for from the Commonwealth's general fund.

All doses of influenza vaccine that are purchased by PADOH are done so through the CDC, and each year nearly all doses are administered. The department is able to closely track the distribution and administration of the vaccine doses through two information networks, the Vaccine Management Information System (VACMAN) and the Statewide Immunization Information System (SIIS).

### ***Information and Communication Systems***

Vaccine Management Information System: VACMAN is a database management system operated by NIP and used by 59 state, city, and territorial government immunization programs, including Pennsylvania. VACMAN is used by the CDC to track inventory in a detailed fashion. The number of doses issued to providers can be compared with the number of doses the provider has administered for any given date. Records are compiled that detail the populations served, especially those vaccines provided through the federal Vaccines For Children<sup>155</sup> (VFC) program. These data are used by the CDC to determine the amounts of vaccines participating providers are eligible to receive.

PADOH uses VACMAN to place electronic orders for bulk purchases of influenza vaccines. After they have been ordered, the vaccines may be sent to designated storage facilities or directly to the local health agencies or facilities that will administer the doses.

VACMAN is also a valuable asset in PADOH's initiatives to combat influenza outbreaks. The data provide the department with current inventory information. Importantly, the data are used to show where there are pockets of need, allowing the department to redistribute vaccines to those areas.

Statewide Immunization Information System: SIIS is under development in Pennsylvania.<sup>156</sup> SIIS will track people from birth, recording and monitoring all immunizations they receive. The data will be accessible to approved healthcare providers for purposes of monitoring public health.

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<sup>155</sup> The PA VFC provides free routine childhood vaccines for patients from birth through age 18 for children enrolled in Medical Assistance, uninsured, American Indian, or Alaskan Native. HHS, CDC, NIP, VFC Program, <http://www.cdc.gov/nip/vfc/default.htm> (07/15/2004).

<sup>156</sup> PADOH, *supra* note 154.

There are several advantages to SIIS. It will allow the PADOH, as well as certain health care providers, the ability to measure and monitor the immunization status of children who are enrolled in the system. The system, because it includes most of the health care providers who administer vaccines, will give the PADOH the ability to monitor specific geographic areas and thereby identify pockets of need. Not only will such information assist PADOH's efforts to quickly and efficiently redistribute vaccines, but it will also provide guidance to public education and outreach. Healthcare providers will benefit by having easily accessible immunization records for incoming patients.<sup>157</sup>

Pennsylvania Health Alert Network: In addition to VACMAN and SIIS, the PADOH operates the Pennsylvania Health Alert Network (PA-HAN). PA-HAN is a federally funded communication network that allows the Commonwealth to provide notification of emerging health issues to the general public, public and private healthcare agencies and providers, and emergency management officials.

The information provided on the PA-HAN website is based upon recommendations from the CDC and other health organizations. There are three levels of notification that are broadcast through PA-HAN (in increasing levels of urgency): Health Updates, Health Advisories, and Health Alerts. Health Updates provide information about an incident or situation that does not require immediate action. Health Advisories are similar, but may require the recipient to take immediate action. Health Alerts convey the highest level of urgency and require immediate action. For an example of an influenza-related Health Alert, see Appendix C.

During the 2003-2004 flu season, PADOH accomplished the redistribution of vaccines by utilizing PA-HAN. Healthcare providers who had excess doses were requested to send their overstock to prearranged sites. Providers who were in need of vaccines were able to obtain necessary doses from those depots. It is worth noting that the excess vaccines, most of which came from institutional providers, were donated for redistribution--no money changed hands.<sup>158</sup>

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<sup>157</sup> Pennsylvania Chapter, American Academy of Pediatrics, *Immunization Education Program*, April 10, 2003, <http://www.paaap.org/immunize/states/pa/siis.html> (07/15/2004).

<sup>158</sup> PADOH, *supra* note 154.



## PENNSYLVANIA DEPARTMENT OF AGING (PDA)<sup>159</sup>

The PDA is an important partner in the Commonwealth's fight against influenza.<sup>160</sup> The Prime Time Health program, which is funded through PDA block grants, serves to educate Pennsylvania's seniors about the dangers of influenza and administers vaccinations through PDA's Area Agencies on Aging (AAA).

There are 52 AAA offices, serving all 67 counties, staffed with caseworkers skilled in such areas as geriatrics, social work and community resources.<sup>161</sup> The AAAs developed educational modules on influenza to inform both the public and professionals about the dangers of influenza and the benefits of immunization.<sup>162</sup> The public education and outreach campaigns utilize, for the most part, volunteers and resources local to their communities. A few have received small grants to cover special outreach programs for cultural groups and low income seniors. PADOH has provided some grant money for supplies, brochures, vaccines and public relations. An example of educational material is found in Appendix D.

All adults 50 years of age and older are eligible to receive flu vaccinations at AAAs. Vaccinations are subsidized by Medicare and Medicaid. Seniors who are not covered by those two health insurance programs are charged approximately \$15. Immunizations are administered by a combination of AAA qualified staff, PADOH nurses, visiting nurses, home healthcare professionals and local hospitals. In 2003, 64,359 individuals were vaccinated at AAAs.

## PENNSYLVANIA DEPARTMENT OF WELFARE (DPW)

DPW administers the federal Medicaid program in Pennsylvania.<sup>163</sup> The Commonwealth's Medical Assistance (MA) program reimburses enrolled providers \$10.00 for each influenza vaccine provided to MA enrolled patients. At present, MA covers influenza vaccines for eligible children under the age of 19. DPW expects that the Vaccines for Children (VFC) program will soon assume the responsibility of providing vaccines for children under age

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<sup>159</sup> Unless otherwise noted, information in this section provided by PDA PrimeTime Health program via email to Commission Staff, August 6, 2004.

<sup>160</sup> PADOH, *supra* note 154.

<sup>161</sup> PDA, *Area Agencies on Aging*, November 2, 2001, <http://www.aging.state.pa.us/aging/cwp/view.asp?a=275&Q=177124> (07/20/2004).

<sup>162</sup> PDA, *Prime Time Health Program*, June 28, 2004, [http://www.aging.state.pa.us/aging/CWP/view.asp?A=282&QUESTION\\_ID=173883](http://www.aging.state.pa.us/aging/CWP/view.asp?A=282&QUESTION_ID=173883) (07/20/2004).

<sup>163</sup> Telephone conference between DPW and Commission staff, August 25, 2004.

19, at which time MA will no longer include flu vaccines as a reimbursable expense although it will continue to reimburse the \$10.00 administration expense.

There are two financing approaches that are used to provide vaccines to eligible persons. One financing approach has Managed Care agencies, such as health maintenance organizations, develop provider networks and handle billing and administrative functions of MA on behalf of DPW. In the other financing approach, DPW directly handles the billing and administrative functions of delivering vaccines to eligible MA recipients.

Under the MA program, no vaccination copayments are required of children under the age of 18. Enrollees, regardless of age, who receive their vaccines from a physician are also exempt from copayments, with the exception of General Assistance enrollees aged 21 to 65 years.<sup>164</sup> Copayments for General Assistance enrollees are set at \$2 for medical fees between \$10.01 and \$25,<sup>165</sup> a range which would typically include the cost of influenza vaccination.

Between 57,000 and 97,000 people have received influenza vaccines through the MA program in each of the last five years. These figures show that between 4.3 percent and 6.8 percent of the eligible MA enrollees received influenza vaccinations. Approximately \$1 million have been paid out from the MA program in providing these vaccinations. See Table 7.

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<sup>164</sup> 55 Pa. Code §1101.63(3)(i).

<sup>165</sup> Ibid., (6)(iv)(B).

TABLE 7  
 MEDICAL ASSISTANCE PROGRAM  
 INFLUENZA VACCINE RECIPIENTS<sup>1</sup>  
 BY HEALTHCARE FINANCING APPROACH  
 FOR PENNSYLVANIA, 1999-2003

	Year				
	1999	2000	2001	2002	2003
<b>Managed Care</b>					
Recipients	nd	31,619	46,686	71,862	46,779
Average number of eligible enrollees	978,791	1,020,239	1,049,167	1,141,253	1,204,833
Amount paid	nd	\$626,419	\$446,576	\$724,989	\$545,031
<b>Fee for Service</b>					
Recipients	16,668	25,794	35,391	25,560	34,089
Average number of eligible enrollees	326,358	313,958	320,419	282,555	281,979
Amount paid	\$156,634	\$336,783	\$491,804	\$346,089	\$491,249
<b>Statewide total</b>					
Recipients	nd	57,413	82,077	97,422	80,868
Average number of eligible enrollees	1,305,149	1,334,197	1,369,586	1,423,808	1,486,812
Percentage of enrollees vaccinated	--	4.3%	6.0%	6.8%	5.4%
Amount paid	nd	\$963,202	\$938,380	\$1,071,078	\$1,036,280

1. Includes all age groups.  
 nd. No data.

SOURCE: Data provided by DPW, August 2004.



## PUBLIC FUNDING OF IMMUNIZATION PROGRAMS

Grants and appropriations are made by the federal government, primarily through the CDC, to healthcare entities in Pennsylvania, including PADOH, county and local health departments, universities, and other public and private agencies. Federal funding specifically appropriated for PADOH health centers has increased from 2000-01 through 2002-03, from \$6.1 million to \$7.9 million. The total immunization funds awarded to all healthcare entities in Pennsylvania increased from \$34.5 million in 2000-01 to \$42.2 million in 2001-02. Data for Federal funding awarded to all healthcare entities are not yet available for years 2002-03, 2003-04 and 2004-05. PADOH requested \$9.3 million and \$10.4 million for its state healthcare centers for years 2003-04 and 2004-05 respectively. See Table 8.

TABLE 8  
FEDERAL IMMUNIZATION FUNDING  
IN PENNSYLVANIA  
2000-01 THROUGH 2004-05

Year	Federal funds for disease control immunization within the state healthcare centers <sup>1</sup>	CDC funds for immunization <sup>2</sup>
2000-01	\$6,111,000	\$34,539,793
2001-02	6,559,000	42,239,368
2002-03	7,900,000	nd
2003-04	9,280,000	nd
2004-05	10,411,000	nd

1. 2000-01, 2001-02, 2002-03 are "Actual" amounts.

2. Funds are provided to state and local health departments, universities, and other public and private agencies.

nd. No data

SOURCE: Federal Funds - Commonwealth of Pennsylvania, Office of the Budget, *Governor's Executive Budget, 2002-03 through 2004-05* <http://www.budget.state.pa.us/budget/cwp/view.asp?a=3&q=167632> (07/23/2004); CDC funds - HHS, CDC, *State Health Profiles, 2002-2003* <http://www.cdc.gov/epo/shp/index.htm> (07/23/2004).

## **IMMUNIZATION GRANT PROGRAM**

The Federal Immunization Grant Program (also called the "317 Grant Program") provides funding to state, local, and territorial public health agencies for program operations and vaccine purchases. Most of this funding is dedicated to routine childhood programs, with a smaller portion remaining for adult immunization programs.

To qualify for grants, the applicants must meet numerous criteria, such as the implementation of effective immunization practices and proper use of vaccines to achieve high immunization coverage. The grants also support infrastructure for activities such as immunization registries, outreach, disease surveillance, outbreak control, education, and service delivery.

The five-year history of Federal Immunization Grant funding for Pennsylvania shows some variation over the years. The 2001 grant award for infrastructure was \$6.2 million, which grew to \$7.5 million for 2003. PADOH was awarded \$7.7 million for infrastructure support for 2004. The award for vaccine purchases has varied substantially over the years, starting with \$16.9 million in 2001, rising to \$24 million in 2002 and declining to \$15.4 million in 2003. PADOH received \$16.3 million to date for 2004.

Despite the variation in overall Federal Immunization Grants, the grants to PADOH specifically tagged for influenza vaccine purchases has grown steadily from 1999/2000 onward. This increase is particularly evident in the Vaccines For Children program, which was awarded \$56,760 in 1999/2000 and reached \$469,860 for 2003. PADOH received \$739,400 for 2004. See Table 9.

The Commonwealth, in turn, provides influenza immunizations to eligible persons through several programs. Children can receive immunizations through the Children's Health Insurance Program (CHIP), the federal funded Pennsylvania VFC program, and Medicaid. Eligible adults can receive immunization through the Medicaid program. Seniors can also benefit from the PDA.

TABLE 9  
 FEDERAL IMMUNIZATION GRANT PROGRAM  
 FUNDING FOR PENNSYLVANIA DEPARTMENT OF HEALTH  
 1999-2004

Budget period	Infrastructure award	Vaccine award	Influenza Vaccine Purchases		Total
			Immunization Grant Program <sup>1</sup>	Vaccines For Children	
1999/2000 <sup>a</sup>	\$12,100,000 <sup>a</sup>	\$23,000,000 <sup>a</sup>	\$134,805	\$56,760	\$191,565 <sup>b</sup>
2001	6,200,000	16,900,000	221,695	125,320	346,996
2002	7,000,000	24,000,000	327,637	177,744	488,826
2003	7,500,000	15,400,000	515,700	469,860	959,880
2004 <sup>c</sup>	7,700,000	16,300,000	403,000	739,400	1,142,400

1. Also known as the 317 Grant Program.  
 a. Two year budget cycle.  
 b. 2000 calendar year.  
 c. Funding is as of July and \$34 million was requested for vaccine award.

SOURCE: Data provided by the PADOH, July 2004.

## MEDICAID

Medicaid provides payment for healthcare services on behalf of eligible low-income persons and individuals with limited income and high medical expenses. Influenza immunizations are covered services under this program. There is a co-payment of between \$.50 and \$1.00 required of the recipient, and the Commonwealth reimburses the provider for the cost of the vaccine but not for its administration.<sup>166</sup>

## CHILDREN'S HEALTH INSURANCE PROGRAM

CHIP is a health insurance program for uninsured and underinsured children who meet eligibility requirements based on family income. Children who are eligible for Medicaid, or have health insurance are not eligible for CHIP. The program is directed by the Pennsylvania Department of Insurance and is operated by private insurers who are contracted throughout the Commonwealth. CHIP provides for immunizations of enrolled children at either no cost or at

<sup>166</sup> Sara Rosenbaum, et al, *Medicaid Coverage of Immunizations for Non-Institutionalized Adults*, George Washington University Medical Center, Center for Health Services Research and Policy, November 2003 (Washington, D.C.: George Washington University Medical Center), pages 6, 14, 17, AII7 and AIII10  
[http://www.gwhealthpolicy.org/downloads/Medicaid\\_Immunization\\_Study.pdf](http://www.gwhealthpolicy.org/downloads/Medicaid_Immunization_Study.pdf) (07/20/2004).

substantially reduced cost.<sup>167</sup> Most recent figures indicate that approximately 168,000 children were eligible for CHIP and of those eligible approximately 137,000 were enrolled.<sup>168</sup>

The adolescent immunization rate for 2003 for CHIP was 37% while the national and regional rates were 22% and 28%, respectively. The immunization rate for 2-year olds was 64% for that same year while the national and regional rates were 60% and 67%, respectively.<sup>169</sup> While it is not possible to determine the number of influenza vaccinations that were administered through CHIP, the higher vaccination rates among CHIP enrollees might indicate that they are being immunized against influenza at a higher rate than their non-enrolled peers.

## VACCINES FOR CHILDREN

VFC is a Federally funded program that provides free vaccines for children enrolled in Medicaid, or are uninsured, American Indian, or Alaskan Native. The Federal Omnibus Budget Reconciliation Act (OBRA) created the VFC program as Section 1928 of the Social Security Act on August 10, 1993.<sup>170</sup> The VFC program is contained in the Medicaid law and is funded by the Federal government through the Centers for Medicare and Medicaid Services (CMS), Medicaid program. Each state Medicaid program must file a Medicaid State plan amendment covering its Pediatric Immunization Program in order to receive Federal funds to operate its Medicaid program and to receive vaccines from the VFC program.<sup>171</sup> According to a VFC progress report issued by the CDC, the VFC program is widely accepted by private healthcare providers that serve VFC eligible children. Private provider participation has created a “shift” in the provision of vaccination services over the last 10 years from public health clinics to private healthcare offices.<sup>172</sup>

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<sup>167</sup> Act of Jun. 17, 1998, P.L. 464, No. 68, §2311(l)(6).

<sup>168</sup> Commonwealth of Pennsylvania, Department of Insurance, 2003 CHIP Annual Report to the Legislature, <http://www.ins.state.pa.us/ins/cwp/view.asp?a=1279&q=527075&insNav=|>, (07/23/2004).

<sup>169</sup> Ibid.

<sup>170</sup> HHS, CDC, NIP, VFC, *Omnibus Budget Reconciliation Act (Medicaid -- Immunizations 13, B4-1 PART IV-Immunizations*, undated, [http://www.cdc.gov/nip/vfc/st\\_immz\\_proj/prog\\_distrib\\_vacc.htm](http://www.cdc.gov/nip/vfc/st_immz_proj/prog_distrib_vacc.htm) (07/23/2004).

<sup>171</sup> HHS, CDC, NIP, *Aspects of Medicaid and How Medicaid & VFC Work Together*, January 16, 2004, [http://www.cdc.gov/nip/vfc/provider/medicaid\\_faqs.htm#primer](http://www.cdc.gov/nip/vfc/provider/medicaid_faqs.htm#primer) (07/23/2004).

<sup>172</sup> HHS, CDC, *A Progress Report on the VFC-AFIX Initiative: A National Strategy to Improve the Quality of Immunization Practices among VFC Providers*, May 2003, <http://www.cdc.gov/nip/afix/ImmunizProjs/annualrpt2002-webver.pdf> (08/02/2004).



In calendar year 2003, there were \$975 million dollars awarded to state, local, and territorial public health agencies through the VFC program for purposes of purchasing vaccines and program operations.<sup>173</sup>

Vaccine prices as of July 30, 2004 were posted on the VFC website.<sup>174</sup> Prices for providers purchasing through the VFC program ranged from \$6.80 for a ten dose package of Aventis Pasteur's Fluzone to \$13.49 per pack of 10 single-dose sprayers of MedImmune Vaccines, Inc.'s FluMist™. Chiron Corporation was offering Fluvirin for \$7.54 per 10 dose package, while Aventis Pasteur was offering preservative free Fluzone® for \$10.00 for a 10 pack of 1 dose syringes. Private sector purchases were slightly more costly, at \$8.50 and \$12.00 for the two varieties available from Aventis Pasteur, \$8.50 for the vaccine available from Chiron Corporation, and \$22.50 for the vaccine available from MedImmune Vaccines, Inc. See Table 10.

TABLE 10  
CDC INFLUENZA VACCINE PRICES  
AS OF JULY 30, 2004

Brandname/ tradename	Packaging	CDC cost/dose	Private sector cost/doses	Contract end date	Manufacturer
Fluzone® <sup>1</sup>	10 dose vials	\$6.80	\$8.50	4/30/05	Aventis Pasteur
Fluzone® pediatric dose preservative- free	10 pack - 1 dose syringes	\$10.00	\$12.00	4/30/05	Aventis Pasteur
Fluvirin® <sup>1</sup>	10 dose vials	\$7.54	\$8.50	4/30/05	Chiron Corporation
FluMist™ (live intranasal)	pack of 10 ingle-dose sprayers	\$13.49	\$22.50	3/31/05	MedImmune Vaccines, Inc.

1. These are vaccines which contain Thimerosal as a preservative.

SOURCE: Data found at the CDC's website, [http://www.cdc.gov/nip/vfc/cdc\\_vac\\_price\\_list.htm](http://www.cdc.gov/nip/vfc/cdc_vac_price_list.htm) (08/02/2004).

<sup>173</sup> HHS, CDC, "Vaccines For Children Program," *Program in Brief*, January 2004, <http://www.cdc.gov/nip/vfc/> (07/23/2004).

<sup>174</sup> HHS, CDC, NIP, CDC, *Vaccine Price List*, [http://www.cdc.gov/nip/vfc/cdc\\_vac\\_price\\_list.htm](http://www.cdc.gov/nip/vfc/cdc_vac_price_list.htm) (08/02/2004).

## COST-EFFECTIVENESS OF INFLUENZA VACCINE

Not only does the influenza vaccine help to prevent influenza deaths and influenza-related health complications, getting the flu shot can also result in an overall economic cost savings for most individuals. According to a May 2004 report by the ACIP,

[s]tudies of adults aged <65 years have reported that vaccination can reduce both direct medical costs and indirect costs from work absenteeism. Reductions of 34%--44% in physician visits, 32%--45% in lost workdays, and 25% in antibiotic use for influenza-associated illnesses have been reported. One cost-effectiveness analysis estimated a cost of approximately \$60--\$4,000/illness averted among healthy persons age 18--24 years, depending on the cost of vaccination, the influenza attack rate, and vaccine effectiveness against influenza-like illness. Another cost-benefit economic model estimated an average annual savings of \$13.66/person vaccinated. In the second study, 78% of all costs prevented were costs from lost work productivity, whereas the first study did not include productivity losses from influenza illness. Economic studies specifically evaluating the cost-effectiveness of vaccinating persons aged 50--64 years are not available, and the number of studies that examine the economics of routinely vaccinating children with inactivated or live, attenuated vaccine are limited. However, in a study of inactivated vaccine that included all age groups, cost utility improved with increasing age and among those with chronic medical conditions. Among persons aged  $\geq 65$  years, vaccination resulted in a net savings per quality-adjusted life year (QALY) gained and resulted in costs of \$23--\$256/QALY among younger age groups.<sup>175</sup>

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<sup>175</sup> HHS, CDC, *supra* note 5.

## **RECOMMENDATIONS**

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### **PARTNERSHIPS**

Numerous governmental entities around the world are engaged in influenza surveillance, prevention, and treatment. Over the years, strong collaborative relationships have developed among these different entities, with each contributing its own expertise to prevent and combat influenza epidemics.

In the U.S., the CDC is the umbrella organization for the nation's influenza efforts. It is a source of information, expertise and coordination for federal, state, and local governments.

#### ***Recommendation***

PADOH should continue to take full advantage of its partnership with the CDC to prepare for outbreaks, purchase vaccines, and successfully staunch an epidemic should one establish itself.

### **PUBLIC EDUCATION**

Public education about the dangers of influenza and ways to reduce one's vulnerability are vital components of federal, state, and local health programs. Collaborations between state departments, such as the Prime Time Health Program coordinated by PDA and PADOH, are advantageous in the fight against influenza, and have proven their worth over the years. It would be similarly advantageous to develop cooperative efforts between state health agencies and other public and private entities to help educate as many of Pennsylvania's citizens as possible.

#### ***Recommendation***

PADOH should encourage employers and schools to implement influenza education programs that highlight the dangers of flu and encourage immunizations.

## **HEALTHCARE PROVIDERS**

Data show that too few healthcare workers are immunized against influenza. Because healthcare workers are often in close proximity of highly vulnerable individuals, those individuals are at increased risk if the workers themselves are not immunized.

### ***Recommendation***

Healthcare workers should be strongly encouraged to get annual vaccinations. In order to accomplish this goal, it is recommended that they be educated about the dangers posed by not being immunized. Further, it is recommended that their employers reduce or remove barriers, such as cost or inconvenience, that may discourage immunization.

## **INCREASE IMMUNIZATIONS**

The federal government's plan for the nation's health, *Healthy People 2010* calls for influenza immunization rates of at least 90 percent for all institutionalized persons and for adults aged 65 and older. *Healthy People 2010* also calls for influenza immunization rates of at least 60 percent for all noninstitutionalized high risk persons ages 18 to 64. ACIP recommends that healthy children aged 6--23 months, and close contacts of children aged 0--23 months, be vaccinated against influenza. The immunization rates for all age groups have been increasing steadily over the years. With the added emphasis on caring for immuno-compromised individuals and children, it will be necessary to provide an increasing number of vaccines and perhaps broaden the range of venues through which vaccines are available.

### ***Recommendation***

PADOH should continue its partnerships with local and private entities to provide immunizations at shelters, churches, community centers, and low-income housing sites. PADOH should also continue to investigate including daycare centers as potential vaccination venues.

## **VACCINE SUPPLY**

Vaccine shortages in recent years illustrated the importance of having a strong distribution and redistribution system. The diverse distribution streams are vital to efforts to provide as many vaccines to as many venues as possible. Vulnerabilities exist, however, to the diversity of supply streams. Because distribution is decentralized, it can be difficult to target high risk individuals during shortages. Further, because the supply is market driven it can be difficult for healthcare providers and government agencies to plan for all impediments that may arise.

### ***Recommendation***

PADOH should continue its innovative use of PA-HAN, VACMAN, and SIIS to monitor and redistribute vaccines when necessary.



# APPENDIX A: HOUSE RESOLUTION 598

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PRINTER'S NO. 3436

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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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## HOUSE RESOLUTION

No. 598 Session of  
2004

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INTRODUCED BY SAYLOR, KENNEY, ARGALL, HESS, WEBER, DeWEESE, BALDWIN, BEBKO-JONES, BELARDI, BENNINGHOFF, BROWNE, CAPPELLI, CRAHALLA, CRUZ, DALEY, DeLUCA, DiGIROLAMO, DONATUCCI, J. EVANS, GEIST, GEORGE, GILLESPIE, GOOD, GOODMAN, GRUCELA, HERMAN, HERSHEY, KELLER, KIRKLAND, LEACH, LEDERER, MARKOSEK, MARSICO, MUSTIO, PALLONE, PISTELLA, READSHAW, REICHLEY, SATHER, SCAVELLO, SCHRODER, SEMMEL, STERN, E. Z. TAYLOR, THOMAS, TIGUE, WASHINGTON, WOJNAROSKI AND YOUNGBLOOD, MARCH 16, 2004

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INTRODUCED AS NONCONTROVERSIAL RESOLUTION UNDER RULE 35, MARCH 16, 2004

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### A RESOLUTION

- 1 Directing the Joint State Government Commission to examine the  
2 availability and accessibility of influenza vaccine in  
3 Pennsylvania to determine the Commonwealth's readiness to  
4 address an influenza epidemic and to determine outreach needs  
5 to educate and encourage the citizens of this Commonwealth to  
6 take advantage of vaccines made available.
- 7 WHEREAS, Influenza, commonly called "the flu," is caused by  
8 the influenza virus, which infects the respiratory tract; and  
9 WHEREAS, Influenza infection can cause severe illness and  
10 serious, life-threatening complications, including death, in all  
11 age groups; and  
12 WHEREAS, Epidemics of influenza typically occur during the  
13 winter months and were responsible for an average of  
14 approximately 36,000 deaths per year in the United States from  
15 1990 through 1999; and  
16 WHEREAS, Influenza viruses can cause pandemics during which

1 rates of illness and death from influenza-related complications  
2 increase dramatically worldwide; and

3 WHEREAS, Rates of infection are highest among children, but  
4 rates of serious illness and death are highest among persons 65  
5 years of age and older and persons of any age who have medical  
6 conditions which place them at increased risk for complications  
7 from influenza; and

8 WHEREAS, Influenza vaccine is the most important preventive  
9 measure for individuals, especially persons at high risk for  
10 serious complications; and

11 WHEREAS, Vaccination is associated with reductions in  
12 influenza-related respiratory illness and physician visits among  
13 all age groups, reductions in hospitalization and death among  
14 persons at high risk, and reductions in work absenteeism among  
15 adults; and

16 WHEREAS, The influenza season for 2003-2004 began early in  
17 the United States, spreading through 47 states and resulting in  
18 135 deaths of children under 15 years of age; and

19 WHEREAS, In 2003 manufacturers produced about 87.1 million  
20 doses of influenza vaccine, including about 4 million in the  
21 form of nasal-spray flu vaccine; and

22 WHEREAS, Due to increased consumer demand and early onset of  
23 the flu season, shortages of vaccine have been reported across  
24 the country; therefore be it

25 RESOLVED, That the House of Representatives direct the Joint  
26 State Government Commission to examine the accessibility and  
27 availability of influenza vaccine to determine the  
28 Commonwealth's preparedness for a flu epidemic, make  
29 recommendations to prevent future influenza vaccine shortages in  
30 order to assure that Pennsylvania is prepared for potential

20040H0598R3436

- 2 -



1 influenza epidemics and report to the House of Representatives  
2 on its activities, findings and recommendations by August 1,  
3 2004.



## **APPENDIX B: ACRONYMS USED IN REPORT**

<b><u>ACRONYM</u></b>	<b><u>FULL NAME</u></b>
AAA	Area Agencies on Aging
ACIP	Advisory Committee on Immunization Practices
AIDS	Acquired Immune Deficiency Syndrome
BRFSS	Behavioral Risk Factor Surveillance System
CBER	Center for Biologics Evolution and Research
CDC	United States Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CMS	Center for Medicare and Medicaid Services
CPR	Cardiopulmonary Resuscitation
DNA	Deoxyribonucleic Acid
DOD	United States Department of Defense
DPW	Pennsylvania Department of Welfare
FDA	United States Food and Drug Administration
GAO	General Accounting Office
GPO	Government Printing Office
H	Hemagglutinin
HHS	United States Department of Health and Human Services
HIV	Human Immunodeficiency Virus
HRSA	United States Health Resources and Services Administration
IAC	Immunization Action Coalition
ICD	International Classification of Diseases
ILI	Influenza-like Illness
LAIV	Live Attenuated Influenza Vaccine
MA	Medical Assistance
MMWR	Morbidity and Mortality Weekly Report
N	Neuraminidase
NCID	National Center for Infectious Diseases
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NIP	National Immunization Program
NREVSS	National Respiratory and Enteric Virus Surveillance System
NVAC	National Vaccine Advisory Committee
NVPO	National Vaccine Program Office
OBRA	Omnibus Budget Reconciliation Act
PADOH	Pennsylvania Department of Health

PA-HAN	Pennsylvania Health Alert Network
PDA	Pennsylvania Department of Aging
PHLS	Public Health Laboratory Service
PMED	Particle-mediated Epidermal Delivery
QALY	Quality-Adjusted Life Year
SIIS	Statewide Immunization Information System
USAID	United States Agency for International Development
VACMAN	Vaccine Management Information System
VFC	Vaccines For Children
WHO	World Health Organization

## APPENDIX C: EXAMPLE OF INFLUENZA-RELATED HEALTH ALERT

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### PA Department of Health

Pennsylvania Department of Health Web Site

SEARCH

Go

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[Home](#) [Help](#) [Contact Us](#)

### Health Alert Network

[Show Images](#)

{Pennsylvania Department of Health}

### PENNSYLVANIA DEPARTMENT OF HEALTH HEALTH ALERT #67

**To:** Health Alert Network  
**From:** Calvin B. Johnson, M.D., M.P.H.  
Secretary of Health  
**Date:** January 23, 2004  
**Subject:** **Influenza Vaccine Availability in PA**

**This transmission is a "Health Alert," conveys the highest level of importance; warrants immediate action or attention.**

**HOSPITALS:** PLEASE SHARE THIS WITH ALL MEDICAL, INFECTION CONTROL, NURSING, LABORATORY & PHARMACY STAFF IN YOUR HOSPITAL

**FQHCs:** PLEASE DISTRIBUTE AS APPROPRIATE

**LOCAL HEALTH JURISDICTIONS:** PLEASE DISTRIBUTE AS APPROPRIATE

**NURSING HOMES:** PLEASE DISTRIBUTE AS APPROPRIATE

**EMS COUNCILS:** PLEASE SHARE WITH ALL YOUR COUNTY PERSONNEL

**PROFESSIONAL HEALTH ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP AS APPROPRIATE

The Pennsylvania Department of Health (PADOH) is releasing the following information regarding availability of Influenza Vaccine in the Commonwealth of PA.

PADOH has obtained additional doses of influenza vaccine for individuals four years of age and older. This will be made available to health care providers at no cost for administration to their patients. **Providers may not charge for the vaccine, but may charge for its administration.**

Health care providers interested in obtaining influenza vaccine should call **1-877-PA-HEALTH**. The available vaccine will be distributed on a first com-first serve basis.

Although it is late in the influenza season, the Centers for Disease Control and Prevention (CDC) and PADOH continue to recommend that individuals who have not yet received the flu vaccine should contact their health care provider or PADOH and make arrangements to receive it.

Following are [CDC](#) and the [Advisory Committee for Immunization Practices \(ACIP\)](#) recommendation for vaccine administration:

#### **Who Should Be Vaccinated With the Flu Shot This Season**

- Emphasis should be placed on targeting trivalent inactivated vaccine (flu shot) to persons at high risk for complications from influenza including: all children aged 6–23 months, adults aged > 65 years, pregnant women in their second or third trimester during influenza season, and persons aged > 2 years with underlying chronic conditions.
- Persons at high risk should be encouraged to search locally for vaccine if their usual health-care provider no longer has vaccine available.
- All children at high risk of complications from influenza, including those aged 6–23 months, who present for vaccination should be vaccinated with a first or second dose, depending on vaccination status. Doses should not be held in reserve to ensure that two doses will be available.
- Next priority should be given to vaccinating those persons at greatest risk for transmission of disease to persons at high risk, including household contacts and health-care workers.

#### **Who Should Be Vaccinated With LAIV**

- Healthy persons aged 5–49 years should be encouraged to be vaccinated with intranasally administered live, attenuated influenza vaccine.

## Other Vaccination Recommendations

- Decisions about vaccinating healthy persons, including adults aged 50–64 years, with inactivated influenza vaccine should be made on a case-by-case basis, depending on local disease activity, vaccine coverage, feasibility, and supply.
- Health departments should work with their health-care providers to reallocate influenza vaccine to health-care providers in need when possible.

## Who Should Not Get Flu Vaccine

People in the following groups should not get flu vaccine before talking with their doctor:

- People who are have a severe allergy (i.e. anaphylactic allergic reaction) to hens' eggs
- It is prudent to avoid vaccination in people who previously developed [Guillain-Barré syndrome \(GBS\)](#) the 6 weeks after getting a flu shot

All providers in Pennsylvania are reminded to check the [CDC website](#) on a regular basis for updates and [new information on Influenza](#).

If clinicians have any questions or patients of concern they would like to discuss, please call the Department of Health at **1-877-PA-HEALTH**.

### Categories of Health Alert messages:

**Health Alert:** conveys the highest level of importance; warrants immediate action or attention.

**Health Advisory:** provides important information for a specific incident or situation; may not require immediate action.

**Health Update:** provides updated information regarding an incident or situation; no immediate action necessary.

**This information is current as of January 23, 2004, but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.**





## **APPENDIX D: AAAs EDUCATIONAL MATERIAL**

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# **ALL ABOUT THE FLU**



Developed by:  
Ann Barlet  
Berks County PrimeTime Health Coordinator  
Berks County Senior Citizens Council, Inc.  
Reading, PA

Influenza, “the flu”, is a contagious disease caused by a virus. It can be particularly dangerous to individuals over the age of 65. Learn about the flu by reviewing the following questions and answers.

**What is the proper name for the “flu”?**

The answer is influenza.

### **General Flu**

**The flu is a disease caused by?**

A virus.

**Is the flu contagious?**

Yes.

**What areas of the body does the flu affect?**

Lungs, respiratory – nose, throat.

**Symptoms of the flu include?**

Sudden high fever, chills, sneezing, headaches, severe muscle & joint aches, sore throat, dry cough, runny nose.

**How is the flu transmitted?**

Airborne through inhalation. Via hands after coughing, sneezing or improper hand washing, especially before eating.

### **History**

**What disease killed 20 million people worldwide in 1918?**

Influenza.

**Flu season runs from ?**

December through March.

**More than half the casualties of servicemen during WWI were caused by what?**

The flu.

**What strain of the flu caused some health concerns in the '70's?**

Swine flu (vaccine).

**When did they begin administering flu immunizations?**

Started giving immunizations in the '40's in the military, according to CDC.

## **Vaccine**

**How often should I get the flu shot?**

Once a year. Flu shots only work for a single season since the strain of virus changes annually.

**What is the flu vaccine made of?**

Current vaccines use inactivated viruses that cannot cause the flu.

**How do they determine what type of vaccine to make?**

Each spring the National Center for Disease Control determines which viruses are expected the following fall. Those specific viruses are used to produce the flu shot.

**What is the name of the "gun" that is used to inject the vaccine?**

Biojector.

**What is used in the Biojector?**

It uses compressed gas (carbon dioxide).

**Flu Clinic**

**What do you need to bring with you when receiving the flu shot?**

Medicare card or other insurance cards.

**Where you can get the flu shot?**

Grocery store, doctor's office, senior centers, drug stores.

**Does Medicare pay for the vaccine?**

Yes.

**Pneumonia**

**How often should you get the pneumococcal vaccine?**

Usually, only once.

**Where can you get the pneumococcal vaccine?**

Your doctor's office (and some public vaccination sites).

**Can you die from the flu or pneumonia?**

Yes.

**Does Medicare pay for the pneumococcal vaccine?**

Yes.

**Can the pneumococcal vaccine be given at the same time as the influenza vaccine?**

Yes – by using different injection sites without increasing side effects.

## **Cautions**

### **When should you get the flu shot?**

The best time is mid-October to mid-November.

- If you don't want to get the flu.
- If you are a senior citizen.
- If you have a serious medical problem, such as respiratory or heart problems.
- If you want to safeguard other family members and friends.

### **Who should get the flu shot?**

- People 65 yrs of age or older.
- With a chronic illness, especially heart or lung problems.
- Who live or work with chronically ill people.
- Who are around children frequently.
- Who have a type of cancer or immunological disorder (or use certain types of medications) that lowers the body's normal resistance to infection.
- Who provide health care services.
- Who have demanding family or work responsibilities & can't risk being sick or taking sick leave.
- Who are 18 yrs of age or older and wish to reduce their chance of catching the flu.

**What side effects can you expect after receiving the flu shot?**

- Some redness, slight soreness at the injection site.
- Even smaller percentage has a headache or fever.

**Who should not get the vaccine?**

- Women who are in first trimester of pregnancy – consult physician.
- Anyone allergic to eggs, chicken or chicken feathers.
- Those who are sensitive to thimerosal (a mercurial antiseptic).
- Anyone who has had a severe reaction to a previous influenza vaccination.
- Anyone with a history of Guillain Barre Syndrome or other active neurologic disorder.
- Anyone who has had any type of vaccination within the last 14 days.
- Persons who are ill and have a fever.

**Summary**

Serious complications can result from the cold & flu, such as pneumonia, so it is important to get the influenza shot.

- No one gets the flu from the flu shot.
- Inexpensive or no expense to get the flu vaccine.
- The flu vaccine is being given in many convenient locations for older adults.
- Frequent hand washing, especially during flu season, can help to avoid getting the flu.

For more information go to the website of the American Lung Association at:  
<http://www.lungusa.org/>

# INACTIVATED INFLUENZA VACCINE

## WHAT YOU NEED TO KNOW

### 2004-2005

#### 1 Why get vaccinated?

**Influenza ("flu") is a serious disease.**

It is caused by a virus that spreads from infected persons to the nose or throat of others.

Influenza can cause:

- fever
- sore throat
- chills
- cough
- headache
- muscle aches

Anyone can get influenza. Most people are ill with influenza for only a few days, but some get much sicker and may need to be hospitalized. Influenza causes an average of 36,000 deaths each year in the U.S., mostly among the elderly.

**Influenza vaccine can prevent influenza.**

#### 2 Influenza vaccine

Two types of influenza vaccine are now available. Inactivated (killed) influenza vaccine, given as a shot, has been used in the United States for many years. A live, weakened vaccine was licensed in 2003. It is sprayed into the nostrils.

Influenza viruses change often. Therefore, influenza vaccine is updated every year.

Protection develops about 2 weeks after getting the shot and may last up to a year.

Some people who get flu vaccine may still get flu, but they will usually get a milder case than those who did not get the shot.

Flu vaccine may be given at the same time as other vaccines, including pneumococcal vaccine.

Some inactivated flu vaccine contains thimerosal, a form of mercury, as a preservative. Some contains only a trace of thimerosal. There is no scientific evidence that thimerosal in vaccines is harmful, and the known benefits of the vaccine outweigh any potential risk from thimerosal. If you have questions about thimerosal or reduced-thimerosal flu vaccine, ask your doctor.

#### 3 Who should get inactivated influenza vaccine?

People 6 months of age and older at risk for getting a serious case of influenza or influenza complications, and people in close contact with them (including all household members) should get the vaccine.

An annual flu shot is recommended for:

- **All children 6-23 months of age.**
- **Household contacts and out-of-home caretakers of infants from 0-23 months of age.**
- **People 50 years of age or older.**
- Residents of **long-term care facilities** housing persons with chronic medical conditions.
- People who have **long-term health problems** with:
  - heart disease
  - kidney disease
  - lung disease
  - metabolic disease, such as diabetes
  - asthma
  - anemia, and other blood disorders
- People with a **weakened immune system** due to:
  - HIV/AIDS or another disease that affects the immune system
  - long-term treatment with drugs such as steroids
  - cancer treatment with x-rays or drugs
- People 6 months to 18 years of age on **long-term aspirin treatment** (these people could develop Reye Syndrome if they got the flu).
- Women who will be **pregnant** during influenza season.
- Physicians, nurses, family members, or anyone else coming in **close contact with people at risk** of serious influenza.
- Anyone else who wants to **reduce their chance of catching influenza.**

An annual flu shot should be *considered* for:

- People who provide **essential community services.**
- People at high risk for flu complications who **travel** to the Southern hemisphere between April and September, or who travel to the tropics or in organized tourist groups at any time.
- People living in **dormitories** or under other crowded conditions, to prevent outbreaks.

Inactivated Influenza Vaccine

5/24/04

## 4 When should I get influenza vaccine?

The best time to get a flu shot is in October or November.

Some people should get their flu shot in *October* or earlier. This includes:

- people **50 years of age and older**,
- younger people at **high risk** from flu and its complications (including **children 6 through 23 months of age**),
- **household contacts** of persons at high risk,
- **health care workers**, and
- **children under 9 years of age** getting the flu shot for the first time.

The flu season can peak anywhere from December through March, but most often it peaks in February. So getting the vaccine in December, or even later, can be beneficial in most years.

Most people need only one flu shot each year to prevent influenza. **Children under 9 years old getting flu vaccine for the first time** should get 2 doses. With the inactivated vaccine, these doses are given one month apart. Children in this age group who got one dose the previous year, even if it was the first time they got the vaccine, need only one dose this year.

## 5 Some people should talk with a doctor before getting influenza vaccine

Talk with a doctor before getting a flu shot if you:

- 1) ever had a serious allergic reaction to eggs or to a previous dose of influenza vaccine, or
- 2) have a history of Guillain-Barré Syndrome (GBS).

If you have a fever or are severely ill at the time the shot is scheduled, you should probably wait until you recover before getting influenza vaccine. Talk to your doctor or nurse about whether to reschedule the vaccination.

## 6 What are the risks from inactivated influenza vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Serious problems from inactivated flu vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine.

### Mild problems:

- soreness, redness, or swelling where the shot was given
- fever
- aches

If these problems occur, they usually begin soon after the shot and last 1-2 days.

### Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is within a few minutes to a few hours after the shot.
- In 1976, swine flu vaccine was associated with a severe paralytic illness called Guillain-Barré Syndrome (GBS). Influenza vaccines since then have not been clearly linked to GBS. However, if there is a risk of GBS from current influenza vaccines, it is estimated at 1 or 2 cases per million persons vaccinated . . . much less than the risk of severe influenza, which can be prevented by vaccination.

## 7 What if there is a moderate or severe reaction?

### What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

### What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at [www.vaers.org](http://www.vaers.org), or by calling 1-800-822-7967.

*VAERS does not provide medical advice.*

## 8 How can I learn more?

- Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-2522 (English)
  - Call 1-800-232-0233 (Español)
  - Visit CDC websites at [www.cdc.gov/ncidod/diseases/flu/fluvirus.htm](http://www.cdc.gov/ncidod/diseases/flu/fluvirus.htm) or [www.cdc.gov/nip](http://www.cdc.gov/nip)



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR DISEASE CONTROL AND PREVENTION  
NATIONAL IMMUNIZATION PROGRAM

Inactivated Influenza Vaccine (5/24/04) Vaccine Information Statement



# LIVE, INTRANASAL INFLUENZA VACCINE

## WHAT YOU NEED TO KNOW

### 2004-2005

#### 1 Why get vaccinated?

Influenza (“flu”) is a serious disease.

It is caused by a virus that spreads from infected persons to the nose or throat of others.

Influenza can cause:

- fever
- sore throat
- chills
- cough
- headache
- muscle aches

Anyone can get influenza. Most people are ill with influenza for only a few days, but some get much sicker and may need to be hospitalized. Influenza causes an average of 36,000 deaths each year in the U.S., mostly among the elderly.

**Influenza vaccine can prevent influenza.**

#### 2 Live, intranasal influenza vaccine

Two types of influenza vaccine are now available, an inactivated vaccine and a live vaccine.

Live, intranasal influenza vaccine (trade-name FluMist™) was licensed in 2003. FluMist contains live, attenuated (weakened) influenza virus. It is sprayed into the nostrils rather than injected into the muscle.

Inactivated influenza vaccine, sometimes called the “flu shot,” has been used for many years, and is given by injection. It contains killed influenza virus.

#### 3 Who can get live, intranasal influenza vaccine?

Live, intranasal influenza vaccine is approved for healthy children and adults from 5 through 49 years of age, including household contacts of most people at high risk for influenza complications. However, FluMist should not be used by people with some medical conditions, pregnant women, or others at risk of influenza-related complications (see Section 4).

#### 4 Who should *not* get live, intranasal influenza vaccine?

The following people should not get intranasal influenza vaccine. They should check with their health care provider about getting **inactivated influenza vaccine**.

- **Adults 50 years of age or older or children younger than 5.**
- People who have **long-term health problems** with:
  - heart disease
  - kidney disease
  - lung disease
  - metabolic disease, such as diabetes
  - asthma
  - anemia, and other blood disorders
- People with a **weakened immune system** due to:
  - HIV/AIDS or another disease that affects the immune system
  - long-term treatment with drugs that weaken the immune system, such as steroids
  - cancer treatment with x-rays or drugs
- Children or adolescents on **long-term aspirin treatment** (these people could develop Reye syndrome if they get the flu).
- **Pregnant women.**
- Anyone with a history of **Guillain-Barré Syndrome (GBS)**.

The flu shot (inactivated vaccine) is preferred over live, intranasal influenza vaccine for physicians, nurses, family members, or anyone else coming in **close contact with anyone with a severely weakened immune system** (that is, requiring care in a protected environment).

The following people should talk with a doctor before getting *either* flu vaccine:

- Anyone who has ever had a serious allergic reaction to **eggs** or to a **previous dose** of influenza vaccine.
- If you have a fever or are severely ill at the time the vaccination is scheduled, you should probably wait until you recover before getting influenza vaccine. Talk to your doctor or nurse about whether to reschedule the vaccination.

## 5 When should I get influenza vaccine?

The best time to get flu vaccine is in **October** or **November**. The flu season can peak anywhere from December through March, but most often peaks in February. So getting the vaccine in December, or even later, can be beneficial in most years.

Most people need only one flu vaccination each year to prevent influenza. But **children under 9 years of age getting influenza vaccine for the first time** should get 2 doses of vaccine. For the live influenza vaccine, these doses should be 6-10 weeks apart. These children should get their first dose in October or earlier. Children in this age group who got one dose the previous year, even if it was the first time they got the vaccine, need only one dose this year.

Live, intranasal flu vaccine may be given at the same time as other vaccines. This includes other live vaccines, such as MMR or chickenpox. But if two live vaccines are not given on the same day, they should be given at least 4 weeks apart.

Influenza viruses change often. Therefore, influenza vaccines are updated every year, and an annual vaccination is needed.

## 6 What are the risks from live, intranasal influenza vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. However, the risk of a vaccine causing serious harm, or death, is extremely small.

Chances of live influenza vaccine viruses spreading from person to person are very small. Even if such spread should occur, it is unlikely to cause illness.

Live, intranasal influenza vaccine can cause mild symptoms in the recipient (see below).

### Mild problems:

Some children and adolescents 5-17 years of age have reported mild reactions, including:

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

These symptoms did not last long and went away on their own. Even when they occur after vaccination, they may not have been caused by the vaccine.

### Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.
- If rare reactions occur with any new product, they may not be identified until many thousands, or millions, of people have used the product. Like all vaccines, live, intranasal influenza vaccine is being monitored for unusual or severe problems.

## 7 What if there is a moderate or severe reaction?

### What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

### What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at [www.vaers.org](http://www.vaers.org), or by calling 1-800-822-7967.

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## 8 How can I learn more?

- Ask your immunization provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
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  - Visit CDC websites at [www.cdc.gov/ncidod/diseases/flu/fluivirus.htm](http://www.cdc.gov/ncidod/diseases/flu/fluivirus.htm) or [www.cdc.gov/nip](http://www.cdc.gov/nip)



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(5/24/04)