2014-2015 Flu Season Key Points (10-31-14)

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Overarching Framework of CDC Influenza Messaging

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Take 3 Messages

- CDC recommends a three-step approach to fighting the flu: vaccination, everyday preventive actions, and use of antiviral drugs if your doctor prescribes them.
- 1. Take time to get a flu vaccine.
 - CDC recommends a yearly flu vaccine as the first and most important step in protecting against flu.
 - Flu vaccination can reduce flu illnesses, doctor visits, and missed work and school due to flu, as well as prevent flu-related hospitalizations and deaths.
 - While there are many different flu viruses, the flu vaccine protects against the viruses that research suggests will circulate the most this season.
 - Everyone 6 months of age and older should get a 2014-2015 flu vaccine, ideally by October. However, as long as flu viruses are circulating, vaccination should continue throughout the flu season, even in January or later.
 - Vaccination of people at high risk of developing serious influenza-related complications is especially important to decrease their risk of severe illness as a result of flu.
 - People at high risk of serious flu complications include young children, pregnant women, people with certain chronic health conditions like asthma, diabetes, or heart and lung disease, and people age 65 years and older.
 - The full list of high risk conditions is available on the CDC website at http://www.cdc.gov/flu/about/disease/high_risk.htm.
 - Vaccination also is especially important for health care workers, and others who live with or care for people at high risk for serious flu-related complications.
 - Children younger than 6 months are at high risk of serious flu illness, but are too young to get a flu vaccine. If you live with or care for an infant younger than 6 months of age, you should get a flu vaccine.
 - o (See the Flu Vaccine section for more key messages related to flu vaccination.)
- 2. <u>Take everyday preventive actions to stop the spread of germs that can cause respiratory illnesses like the flu</u>. While these actions are helpful, remember that vaccination is the most important step in preventing flu.
 - Try to avoid close contact with sick people.
 - If you are sick with flu-like illness, CDC recommends that you stay home for at least 24 hours after your fever is gone, except to get medical care or for other necessities. (Your fever should be gone without the use of a fever-reducing medicine.)
 - While sick, limit contact with others as much as possible to keep from infecting them.
 - Cover your nose and mouth with a tissue when you cough or sneeze. After using a tissue, throw it in the trash and wash your hands.

- Wash your hands often with soap and water for at least 20 seconds. If soap and water are not available, use an alcohol-based hand rub. Avoid touching your eyes, nose or mouth because germs spread this way.
- For more information, see http://www.cdc.gov/flu/protect/habits/.
- 3. Take flu antiviral drugs if your doctor prescribes them.
 - o If you get the flu, antiviral drugs can be used to treat your illness.
 - o Antiviral drugs are prescription medicines (pills, liquid or an inhaled powder) and are not available over-the-counter.
 - o Antiviral drugs are different from antibiotics. Antiviral drugs fight viruses (like flu viruses) in your body; antibiotics fight bacterial infections.
 - Antiviral drugs are not a substitute for getting a flu vaccine. The flu vaccine is t best way modern medicine currently has to protect against this serious disease.
 - Not everyone who has flu symptoms needs antiviral drugs. Your doctor will decide whether antiviral drugs are right for you.
 - o Antiviral drugs can make flu illness milder and shorten the time you are sick.
 - There also are data showing that antiviral drugs may prevent serious flu complications. For those with flu who also have a high risk medical condition, treatment with an antiviral drug can mean the difference between having a milder illness versus a very serious illness that could result in a hospital stay.
 - If you get the flu, the earlier you begin taking antivirals, the better. Antiviral drugs
 work best if started within two days of symptoms first appearing, but there is data
 to suggest they can still be beneficial even up to five days after getting sick. This
 would be especially important for a person with a high risk medical condition that is
 very sick.
 - Two FDA-approved influenza antiviral medications are recommended for use in the United States during the 2014-2015 influenza season: oseltamivir (Tamiflu®) and zanamivir (Relenza®). More information about antiviral drugs and antiviral drug resistance can be found at http://www.cdc.gov/flu/about/qa/antiviralresistance.htm.
 - For more information about antiviral drugs, visit http://www.cdc.gov/flu/antivirals/index.htm.
 - For more information about the flu or the flu vaccine, call 1-800-CDC-INFO, visit www.cdc.gov/flu.

Statements for General Audiences

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Disease

- 1. Influenza (the flu) can be a serious disease that can lead to hospitalization and sometimes even death. Anyone can get sick from the flu.
- 2. While the flu can make anyone sick, certain people are at greater risk for serious complications from the flu. These people include:
 - a) Children younger than 5, but especially children younger than 2 years old

- b) Adults 65 years of age and older
- c) Pregnant women
- d) American Indians and Alaskan Natives seem to be at higher risk of flu complications
- e) People who have medical conditions including:
 - o Asthma
 - Neurological and neurodevelopmental conditions [including disorders of the brain, spinal cord, peripheral nerve, and muscle such as cerebral palsy, epilepsy (seizure disorders), stroke, intellectual disability (mental retardation), moderate to severe developmental delay, muscular dystrophy, or spinal cord injury].
 - Chronic lung disease (such as chronic obstructive pulmonary disease [COPD] and cystic fibrosis)
 - Heart disease such as congenital heart disease, congestive heart failure and coronary artery disease)
 - Blood disorders (such as sickle cell disease)
 - Endocrine disorders (such as diabetes mellitus)
 - o Kidney disorders
 - Liver disorders
 - Metabolic disorders (such as inherited metabolic disorders and mitochondrial disorders)
 - Weakened immune system due to disease or medication (such as people with HIV or AIDS, or cancer, or those on chronic steroids)
 - o People younger than 19 years of age who are receiving long-term aspirin therapy
 - o People who are morbidly obese (Body Mass Index, or BMI, of 40 or greater)
- 3. For more information about people at high risk of serious flu-related complications visit: http://www.cdc.gov/flu/about/disease/high_risk.htm.
- 4. Much of the U.S. population is at increased risk from serious flu complications, either because of their age or because they have a medical condition like asthma, diabetes (type 1 and 2), or heart conditions; or because they are pregnant.
 - For example, more than 30 percent of people 50 through 64 years of age have one or more chronic medical conditions that put them at increased risk of serious complications from flu.
- 5. Symptoms of the flu can include fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills and fatigue. Some people may also have vomiting and diarrhea.
- 6. People may also be infected with the flu and have no symptoms at all, or have only respiratory symptoms without a fever.
- 7. Flu viruses are constantly changing. Each flu season, different flu viruses can spread, and they can affect people differently based on differences in their immune systems. Even healthy children and adults can get very sick from the flu.
- 8. In the United States, thousands of healthy adults and children see a doctor or are hospitalized from flu complications each year. Flu vaccination can help protect you and your family from the flu and its complications.
- 9. Flu seasons are unpredictable. The severity of flu seasons can differ substantially from year to year.
- 10. Over a period of 30 years, between 1976 and 2006, estimates of yearly flu-associated deaths in the United States ranged from a low of about 3,000 to a high of about 49,000 people during the most severe season.

- a) Each year in the United States on average, an estimated 5 to 20 percent of the population can be infected with the flu, and more than 200,000 people may be hospitalized during a flu season.
- b) The 2009 H1N1 pandemic is an example from recent years of how unpredictable the flu can be. For more information about the 2009 H1N1 pandemic, see http://www.cdc.gov/h1n1flu/.
- 11. Since 2004-2005, flu-related deaths in children reported to CDC during regular flu seasons have ranged from 37 deaths (during 2011-2012) to more than 170 deaths (during 2012-2013). During the 2009 H1N1 flu pandemic, (April 15, 2009 to October 2, 2010), 348 pediatric deaths were reported to CDC.
 - a) More information about pediatric deaths since the 2004-2005 flu season is available in the interactive pediatric death web application at http://gis.cdc.gov/GRASP/Fluview/PedFluDeath.html.
- 12. Most flu-related pediatric deaths occurred in children who were not vaccinated against flu.
- 13. During most flu seasons, it is estimated that 90 percent of seasonal flu-related deaths and between 50 and 60 percent of seasonal flu-related hospitalizations in the United States occur in people age 65 years and older (Kostova/Reed models). However, this pattern can change depending on which influenza viruses are circulating.
- 14. Influenza seasons where H3N2 influenza viruses are predominant can be particularly hard on older adults. During the 2012-2013 flu season, when H3N2 viruses were most common, hospitalization rates were three to twelve times higher among adults aged 65 years and older than hospitalization rates among younger age groups.
- 15. It is not possible to predict how mild or severe the 2014-2015 flu season will be, or which influenza viruses will predominate.

Vaccination

- 1. The first and most important step in protecting against the flu is to get a flu vaccine each season.
 - a) Everyone 6 months of age and older is recommended to get the 2014-2015 flu vaccine, with rare exceptions.
- 2. Flu vaccination can reduce flu illnesses, doctors' visits, and missed work and school due to flu, as well as prevent flu-related hospitalizations and deaths.
- 3. While how well the flu vaccine works can vary from year to year, there are many reasons to get a flu vaccine each year.
 - a) Flu vaccination can keep you from getting sick from flu. Protecting yourself from flu also protects the people around you who are more vulnerable to serious flu illness.
 - b) Flu vaccination can help protect people who are at greater risk of getting seriously ill from flu, like older adults, people with chronic medical conditions and young children (especially infants younger than 6 months old who are too young to get vaccinated).
 - c) Flu vaccination also may make your illness milder if you do get sick.

- d) Flu vaccination can reduce the risk of more serious flu outcomes, like hospitalizations and deaths.
- 4. CDC recommends an annual flu vaccine as the first and best way to protect against the flu. There are two important reasons to get a flu vaccine every year:
 - a) The first reason is that because flu viruses are constantly changing, flu vaccines may be updated from one season to the next to protect against the viruses that research indicates will be most common during the upcoming flu season.
 - b) The second reason that annual vaccination is recommended is that a person's immune protection from the vaccine declines over time. Annual vaccination is needed for best protection.
- 5. Flu vaccination prevented an estimated 13.6 million flu cases, 5.8 million medical visits and nearly 113,000 flu-related hospitalizations in the United States over a six-year period (from 2005 to 2011) according to a study by CDC experts.
- 6. The composition of the flu vaccine is reviewed each year. If needed, the vaccine is updated to protect against the influenza viruses that research indicates will be the most common during the upcoming season. Even in years when the vaccine composition does not change, new flu vaccine is manufactured every season. (All seasonal flu vaccine expires by the end of June.)
- 7. Protect your family from the flu by getting yourself and your family members vaccinated.
- 8. Getting a yearly flu vaccine is especially important for people at high risk of serious flurelated health complications and their close contacts. People at high risk of serious flu complications include:
- 9. While the flu can make anyone sick, certain people are at greater risk for serious complications from the flu. These people include:
 - a) Children younger than 5, but especially children younger than 2 years old
 - b) Adults 65 years of age and older
 - c) Pregnant women
 - d) American Indians and Alaskan Natives seem to be at higher risk of flu complications
 - e) People who have medical conditions including:
 - Asthma
 - Neurological and neurodevelopmental conditions [including disorders of the brain, spinal cord, peripheral nerve, and muscle such as cerebral palsy, epilepsy (seizure disorders), stroke, intellectual disability (mental retardation), moderate to severe developmental delay, muscular dystrophy, or spinal cord injury].
 - Chronic lung disease (such as chronic obstructive pulmonary disease [COPD] and cystic fibrosis)
 - Heart disease such as congenital heart disease, congestive heart failure and coronary artery disease)
 - Blood disorders (such as sickle cell disease)
 - Endocrine disorders (such as diabetes mellitus)
 - Kidney disorders
 - Liver disorders
 - Metabolic disorders (such as inherited metabolic disorders and mitochondrial disorders)

- Weakened immune system due to disease or medication (such as people with HIV or AIDS, or cancer, or those on chronic steroids)
- o People younger than 19 years of age who are receiving long-term aspirin therapy
- People who are morbidly obese (Body Mass Index, or BMI, of 40 or greater)
- 10. For more information about people at high risk of serious flu-related complications visit: http://www.cdc.gov/flu/about/disease/high_risk.htm.
- 11. Flu vaccines cannot cause flu infection or illness.
 - a) The most common side effects from a flu shot are a sore arm and maybe a low fever or achiness. The nasal spray flu vaccine might cause congestion, runny nose, sore throat, or cough as side effects. If you do experience them at all, these side effects are mild and short-lived.
- 12. The flu vaccine is used to **prevent** flu illness, not to treat it. (Influenza antiviral drugs may be prescribed to **treat** flu. See <u>Antiviral Drug messages</u> for more information.)
- 13. A flu vaccine protects against influenza viruses. It will not protect against other respiratory viruses that may cause symptoms that are similar to those seen with flu infection.
- 14. In addition to flu vaccine, other vaccines are recommended for adults that prevent serious diseases such as shingles, pneumonia caused by pneumococcal bacteria, hepatitis, meningitis and whooping cough.
- 15. Unfortunately, few adults are aware that they need other vaccines, leaving themselves and their loved ones unnecessarily vulnerable to serious diseases.
- 16. Adults should talk with their doctors or other health care professionals to learn which other vaccines are recommended for them and take steps to stay up-to-date to ensure that they have the best protection.
- 17. "Medicare Part B covers flu, pneumococcal, and hepatitis B vaccines for high risk persons and tetanus vaccine as part of wound management."
- 18. Most health insurance plans cover the cost of recommended vaccines. Check with your insurance provider for details of coverage. If you do not currently have health insurance, visit www.HealthCare.gov to learn more about affordable health coverage options.
- 19. For more information about the seriousness of the flu and the benefits of flu vaccination, talk to your doctor or other health care professional, visit www.cdc.gov/flu, or call CDC at 1-800-CDC-INFO.
- 20. Visit CDC's website on adult vaccination for more information: http://www.cdc.gov/vaccines/adults.
- 21. Flu and other adult vaccines are offered in many locations, including: doctor's offices, clinics, health departments, retail stores, pharmacies, health centers, as well as by many employers and schools.
- 22. Even if you don't have a regular doctor or other health care professional you can get a flu vaccine and other adult vaccines in other locations, like health departments or pharmacies. Vaccines may also be offered at your school, college health center or workplace.
- 23. Find a place near you to get flu and other vaccines at http://vaccine.healthmap.org/.
- 24. Take the CDC quiz to find out which vaccines might be right for you: http://www2.cdc.gov/nip/adultimmsched

Vaccination Timing

- 1. You should get a flu vaccine soon after it becomes available, ideally by October, to ensure that you are protected before flu season begins. However, as long as flu viruses are circulating, vaccination should continue throughout the flu season, even in January or later.
- 2. It is not possible to know exactly when the flu season will start each year. It is best to get vaccinated before influenza viruses start to spread in your community.
- 3. The timing of flu outbreaks is unpredictable. While seasonal flu outbreaks can happen as early as October, most of the time flu activity peaks between December and February, although activity can last as late as May. Sometimes more than one flu virus type or subtype will cause outbreaks in a community in a single season. As long as flu activity is ongoing, it's not too late to get vaccinated, even in January or later.
- 4. When you get your flu vaccine, your body starts to make antibodies that help protect you from influenza virus infection. It takes about two weeks after vaccination for the immune system to fully respond and for these antibodies to provide protection.
- 5. Since it takes about two weeks after flu vaccination for antibodies to develop in the body that protect against flu virus infection, it is best that people get vaccinated so they are protected before flu begins spreading in their community.

<u>Vaccination: Who Should Do It, Who Should Not and Who Should Take</u> Precautions

The Flu Shot	The Nasal Spray Vaccine
People who can get the flu shot:	People who can get the nasal spray
Different flu shots are approved for people	vaccine:
of different ages, (see Note), but there are	The nasal spray vaccine is approved for use
flu shots that are approved for use in people	in people 2 years through 49 years of age.
as young as 6 months of age and up. Flu	
shots are approved for use in pregnant	People who cannot get the nasal spray
women and people with chronic health	vaccine:
conditions.	Children younger than 2 years
	Adults 50 years and older
People who can't get the flu shot:	People with a history of severe allergic
Children younger than 6 months are too	reaction to any component of the vaccine or
young to get a flu shot	to a previous dose of any influenza vaccine
People with severe, life-threatening allergies	People who are allergic to eggs
to flu vaccine or any ingredient in the	Children or adolescents (2 years through 17

vaccine. This might include gelatin, antibiotics, or other ingredients. See <u>Special Considerations Regarding Egg Allergy</u> for more information about egg allergies and flu vaccine.

Note: There are certain flu shots that have different age indications. For example people younger than 65 years of age should not get the high-dose flu shot and people who are younger than 18 years old or older than 64 years old should not get the intradermal flu shot.

People who should talk to their doctor before getting the flu shot:

If you have an allergy to eggs or any of the ingredients in the vaccine. Talk to your doctor about your allergy.

If you ever had Guillain-Barré Syndrome (a severe paralyzing illness, also called GBS). Some people with a history of GBS should not get this vaccine. Talk to your doctor about your GBS history.

If you are not feeling well. Talk to your doctor about your symptoms.

years of age) on long-term aspirin treatment.

Pregnant women

People with weakened immune systems (immunosuppression)

Children 2 years through 4 years who have asthma or who have had a history of wheezing in the past 12 months.

People who have taken <u>influenza antiviral</u> <u>drugs</u> within the previous 48 hours.

People who care for severely immunocompromised persons who require a protective environment (or otherwise avoid contact with those persons for 7 days after getting the nasal spray vaccine).

People who should talk to their doctor before getting nasal spray vaccine:

There are also other "warnings and precautions" for the nasal spray flu vaccine. You should talk to your doctor if you have any of these:

Asthma: People of any age with asthma might be at increased risk for wheezing after getting the nasal spray vaccine.

A chronic condition like lung disease, heart disease, kidney or liver disorders, neurologic/neuromuscular, or metabolic disorders. The safety of the nasal spray vaccine has not been established in people with underlying medical conditions that place them at high risk of serious flu complications. See People at High Risk of

Developing Flu-Related Complications.
If you ever had Guillain-Barré Syndrome (a
severe paralyzing illness, also called GBS).
Some people with a history of GBS should
not get this vaccine. Talk to your doctor
about your GBS history.
If you have gotten any other vaccines in the
past 4 weeks, or if you are not feeling well.

2014-2015 Influenza Vaccine Options, Indications and Availability

- 1. There are several flu vaccine options available for the 2014-2015 flu season.
- 2. Flu vaccines made to protect against three different flu viruses (called "trivalent" vaccines) will be available this season. In addition, flu vaccines made to protect against four different flu viruses (called "quadrivalent" vaccines) also are available.
 - a) Trivalent flu vaccines protect against two influenza A viruses (an H1N1 and an H3N2) and an influenza B virus. The following trivalent flu vaccines are available:
 - A <u>standard-dose trivalent shot</u> (IIV3) that is manufactured using virus grown in eggs. Different flu shots are approved for people of different ages, but there are flu shots that are approved for use in people as young as 6 months of age and up. Most flu shots are given with a needle. One flu vaccine also can be given with a jet injector.)
 - An <u>intradermal trivalent shot</u>, which is injected into the skin instead of the muscle and uses a much smaller needle than the regular flu shot. It is approved for people 18 through 64 years of age.
 - A high-dose trivalent shot, approved for people aged 65 years and older.
 - A <u>trivalent shot containing virus grown in cell culture</u>, which is approved for people 18 and older.
 - A <u>recombinant trivalent shot that is egg-free</u> (RIV3), approved for people 18 through 49 years of age.
 - b) The quadrivalent flu vaccine protects against two influenza A viruses and two influenza B viruses. The following quadrivalent flu vaccines are available:
 - A <u>quadrivalent flu shot (IIV4)</u> approved for different ages, but there is a quadrivalent flu shot that can be given to children as young as 6 months of age.
 - A <u>quadrivalent nasal spray vaccine</u>, approved for people 2 years through 49 years of age (recommended preferentially for <u>healthy* children age 2 years through 8 years old</u> when immediately available and there are no contraindications or precautions).

- 3. For anyone 9 years and older, CDC does not recommend one flu vaccine over the other. The important thing is to get vaccinated every year.
- 4. Flu vaccines can be given in two ways, as a shot or as a nasal spray.
 - a) The flu shot is an inactivated vaccine that is made with killed flu virus.
 - The age indications for the different flu shots vary, but all may be given to people with chronic medical conditions.
 - b) The nasal spray flu vaccine is made with live, weakened flu viruses.
 - The nasal spray vaccine is approved for use in people 2 years through 49 years of age
 - See http://www.cdc.gov/flu/about/qa/nasalspray.htm for a complete list of people who can and cannot receive the nasal spray flu vaccine.
 - All nasal spray flu vaccine for the 2014-2015 flu season will be quadrivalent (made to protect against four flu viruses).
- 5. For healthy* children 2 through 8 years of age, CDC recommends the nasal spray flu vaccine when it is available. While the flu shot and the nasal spray vaccine both can protect your child from getting the flu, there is evidence to suggest that the nasal spray vaccine may work better in younger children than a regular flu shot. (See section on Nasal Spray Vaccine).
- 6. Those who care for or are in contact with persons who have severely impaired immune function (i.e., immune function is impaired to a level that requires a protective environment) should receive the flu shot rather than the nasal spray vaccine.
- 7. Flu vaccine is available in doctor's offices, pharmacies, public health clinics and other locations.
- 8. Of the overall flu vaccine supply projected for the 2014-2015 season, manufacturers estimate that 77 million doses will be available as quadrivalent flu vaccines.
 - Of the total quadrivalent flu vaccine supply, as many as 18 million doses of the nasal spray influenza vaccine (LAIV) have been projected by the manufacturer to be available.
- 9. For the latest information on flu vaccine supply, including projections and doses distributed, visit http://www.cdc.gov/flu/professionals/vaccination/vaccinesupply.htm. Although flu vaccines are available for purchase from manufacturers and distributors, individual health care professionals may receive their vaccine shipments at different times because of production and delivery schedules for different products.
- 10. While some flu vaccine became available late July and August, the vaccine supply is usually most abundant in September and October and thereafter. (For information about the recommended timing of flu vaccination, see Timing of Vaccination section.)
- 11. Some points to keep in mind:
 - a) All nasal spray flu vaccine offered during the 2014-2015 season will be quadrivalent vaccine.
 - b) Both quadrivalent and trivalent flu shots will be available.
 - c) Don't delay getting a flu vaccine if you want a quadrivalent vaccine and it isn't available. Most of the flu vaccine offered this year will be trivalent. The important thing is to get vaccinated against the flu.

- d) More quadrivalent flu vaccine is expected to be available during future seasons.
- 12. Every flu vaccine is formulated to offer important protection from influenza viruses.

(*"Healthy" in this instance refers to children 2 years through 8 years old who do not have an underlying medical condition that predisposes them to influenza complications.)

New LAIV Recommendation for 2014-2015 - Nasal Spray Vaccine

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- 1. Recent studies suggest that the nasal spray flu vaccine may work better than the flu shot in younger children. Specifically in these studies, the nasal spray flu vaccine prevented about thirty to fifty percent more cases of flu than the flu shot in young children.
- 2. Starting in 2014-2015, CDC and its Advisory Committee on Immunization Practices (ACIP) recommend use of the nasal spray vaccine for healthy* children 2 years through 8 years of age when it is immediately available and if the child has no contraindications or precautions to that vaccine.
- 3. If the nasal spray vaccine is not immediately available, these children should get the flu shot (IIV). Vaccination should not be delayed in order to obtain the nasal spray flu vaccine when the flu shot is available. (Typically, nasal spray vaccine makes up a smaller portion of total available vaccine each year.)
- 4. There is no preferential recommendation between the trivalent or quadrivalent flu shot.
- 5. Some people should NOT receive the nasal spray vaccine and may be able to get a flu shot instead. There are also precautions for the nasal spray vaccine. (See the <u>section above</u> on nasal spray vaccine or refer to <u>Vaccination: Who Should Do It, Who Should Not and Who Should Take Precautions on the CDC website.)</u>
- Some children 8 years old and younger will need two doses of vaccine to be protected against flu. (See the section <u>Vaccine Doses for Children Aged 6 Months through 8 Years</u>.)
- 7. For the complete list of flu vaccines approved for use during the 2014-2015 season, visit http://www.cdc.gov/flu/protect/vaccine/vaccines.htm.

(*Healthy" in this instance refers to children 2 years through 8 years old who do not have an underlying medical condition that predisposes them to influenza complications.)

2014-2015 Influenza Vaccine Formulation

- 1. Each year, experts must select which flu viruses the flu vaccine should protect against many months in advance of the flu season in order for vaccine to be produced and delivered on time.
- 2. Because influenza (flu) viruses are constantly changing and the composition of the flu vaccine must be determined so far in advance, selecting the right influenza viruses for the flu vaccine to protect against is a challenging task.
- 3. In 2012, the Food and Drug Administration (FDA) approved flu vaccines that protect against four viruses (called "quadrivalent" flu vaccines) for use in the United States. These vaccines are available as both a nasal spray and a shot during the 2014-2015 flu season.

- 4. Trivalent and quadrivalent flu vaccines are available during the 2014-2015 season.
 - a) Trivalent flu vaccines protect against three flu viruses: an influenza A (H1N1) virus, an influenza A (H3N2) virus and an influenza B virus.
 - b) Quadrivalent flu vaccines protect against four flu viruses: an influenza A (H1N1) virus, an influenza A (H3N2) virus and two influenza B viruses (from Yamagata and Victoria lineages).
- 5. Quadrivalent vaccines are intended to provide broader protection against influenza B viruses by adding another B virus to the vaccine.
- 6. The specific viruses for the 2014-2015 flu season vaccines were recommended by the U.S. Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee (VRBPAC) on February 28, 2014.
- 7. International surveillance indicated that these viruses would be the ones most likely to cause illness in the United States during the 2014-2015 season.
- 8. For more information about the composition of this year's flu vaccine and how viruses for the seasonal flu vaccine are selected, go to http://www.cdc.gov/flu/about/season/vaccine-selection.htm.

Statements for Parents

- 1. Flu can be a serious disease for children of all ages and can lead to hospitalization or, in rare cases, even death.
 - a) [Alternative] Flu can be a serious disease for children of all ages, causing them to miss school, activities, or even be hospitalized.
- 2. Vaccination is especially important for certain people who are at high risk for serious complications from flu or who are in close contact with people at high risk, including the following groups:
 - a) Children younger than 5 years of age, and especially those younger than 2 years of age.
 - b) Children of any age with a long-term health condition like asthma, diabetes or disorders of the brain or nervous system. These children are at higher risk of serious flu complications (like pneumonia). For the complete list of those at high risk, visit http://www.cdc.gov/flu/about/disease/high_risk.htm.
 - c) Adults who meet any of the following criteria:
 - Are close contacts of, or live with, children younger than 5 years old.
 - Are out-of-home caregivers (nannies, daycare providers, etc.) of children younger than 5 years old.
 - Live with or have other close contact with children of any age with a chronic health condition, i.e., asthma, diabetes, etc.
 - Are health care workers.
- 3. Every year in the United States, otherwise healthy children are hospitalized or die from flu complications.

- 4. In the United States, each year an average of 20,000 children younger than 5 years old are hospitalized due to flu complications.
- 5. Children younger than 5 years old and especially those younger than 2 years old, are at higher risk of serious flu complications, including hospitalization and death, compared to older children.
- 6. The risk of serious flu complications requiring hospitalization is highest among children younger than 6 months of age, but they are too young to be vaccinated. The best way to protect them is to ensure people around them get vaccinated.
- 7. It is also important for pregnant women to get vaccinated to protect their unborn babies. Studies have shown that getting a flu shot during pregnancy can decrease your baby's chance of getting the flu for up to 6 months after birth.
- 8. Getting vaccinated during pregnancy is safe and can protect the mother and the baby for up to 6 months after birth.
- 9. Children have been significantly impacted by the 2009 H1N1 virus. This virus is expected to continue circulating during the 2014-2015 flu season, along with other influenza viruses.
- 10. During the 2013-2014 flu season—a flu season when 2009 H1N1 influenza viruses predominated—more than 100 flu-related pediatric deaths were reported.
 - a) During the 2009-2010 flu season (April 15, 2009-September 30, 2010), 348 flu-associated pediatric deaths were reported to CDC as a result of the 2009 H1N1 pandemic.
 - b) During the 2011-2012 season, 35 flu-associated pediatric deaths were reported to CDC, representing the lowest number of pediatric deaths recorded since this kind of record-keeping began.
- 11. Among children 6 months and older, 80 to 85 percent of flu-related pediatric deaths occurred in children who had not received a flu vaccine.
- 12. Information about pediatric deaths since the 2004-2005 flu season is available in the interactive pediatric death web application at http://gis.cdc.gov/GRASP/Fluview/PedFluDeath.html.
- 13. Vaccination is the first and most important step in protecting your family against the flu.
- 14. Children 6 months and older are recommended to get a yearly flu vaccine.
- 15. Vaccination is especially important for children with asthma, diabetes (type 1 and 2), or certain other long-term medical conditions because they are at increased risk for serious complications from flu if they get sick.
 - a) The flu can make some medical conditions worse. For example, children with asthma (even if it's mild or controlled by medication) are more likely to develop serious complications from the flu (like pneumonia) and/or a worsening of their chronic condition (for example, asthma attacks) compared to children without asthma.
 - b) Children with asthma (even if the asthma is mild or controlled by medication) are more likely to be hospitalized for flu-related complications than children who don't have asthma.

- 16. If you live with or care for a child who is at high risk of serious complications from flu, it is particularly important for you and your children 6 months of age and older to get vaccinated.
 - a) If your child is at high risk of serious flu complications and gets sick with the flu, your doctor may recommend treatment with flu antiviral drugs. (See <u>Antiviral Drugs messages</u>.)
 - b) For the full list of age factors and medical conditions that put someone at high risk, see http://www.cdc.gov/flu/about/disease/high-risk.htm.
- 17. Be sure to let the doctor know if your child has a severe allergy to eggs or has any medical conditions like asthma, other heart or lung conditions, neurologic conditions, or other medical problems. (See Egg Allergy messages.)
- 18. Be sure to let the doctor know if your child has ever experienced a reaction to the flu vaccine.
- 19. Children also should be current on other vaccines, including those that can help prevent pneumonia, like pneumococcal and Hib vaccines.
- 20. Talk to your child's doctor or other health care professional about getting a flu vaccine.
- 21. CDC also recommends that parents and children take everyday preventive actions to stop the spread of germs. (See <u>Everyday Preventive Actions messages</u>.)
- 22. The Flu Guide for Parents (http://www.cdc.gov/flu/freeresources/print-family.htm) provides detailed information for parents on the seriousness of flu illness in children, how to protect them, and how to care for children with flu illness.

Vaccine Doses for Children Aged 6 Months through 8 Years

- 1. Some children 6 months through 8 years of age will require two doses of flu vaccine for adequate protection from flu. Children in this age group who are getting vaccinated for the first time will need two doses of flu vaccine, spaced at least 28 days apart. Some children who have received flu vaccine previously also may need two doses. Your child's doctor or other health care professional can tell you if your child needs two doses.
- 2. The current recommendation is that children 6 months through 8 years of age need only one dose of 2014-2015 seasonal influenza vaccine: (1) if the child has received at least one dose of the 2013-2014 seasonal vaccine, or (2) if the child is known to have received at least two seasonal flu vaccines since the 2010-2011 season. If the vaccination status is unknown any child in this age group, that child should be given two doses of seasonal flu vaccine.
 - The 2009 H1N1 virus continues to circulate and cause illness. Seasonal flu vaccine was not formulated to protect against the 2009 H1N1 virus until the 2010-2011 flu season. This means that children who did not get either the monovalent 2009 H1N1 flu vaccine during the 2009-2010 season—or who have not had a seasonal flu vaccine since the 2010-2011 season—will not be fully protected from the 2009 H1N1 flu virus until they have received two doses of the 2014-2015 flu vaccine.
- 3. Children 6 months through 8 years of age who require two doses of flu vaccine do not need to receive matching flu vaccines; the flu shot or the nasal spray vaccine can be used for either dose.

- 4. Everyone 9 years of age and older needs only one dose of 2014-2015 flu vaccine to be protected.
- 5. To view a chart (algorithm) that shows influenza vaccine dosing recommendations for children aged 6 months through 8 years, visit http://www.cdc.gov/mmwr/preview/mmwrhtml/figures/m6332a3f1.gif

Statements for Pregnant Women

- 1. Getting a flu shot protects pregnant women from the flu. Studies also have shown that getting a flu shot while you are pregnant can decrease your baby's risk of getting the flu for up to 6 months after birth.
 - a) Flu shots are a safe way to protect the mother and her unborn child from serious illness and complications of flu. The flu shot has been given to millions of pregnant women over many years. Flu shots have not been shown to cause harm to pregnant women or their babies.
 - b) Pregnant women can receive the flu shot at any time, during any trimester, while pregnant.
 - c) Pregnant women are more likely to become severely ill with the flu than women who are not pregnant.
 - d) Pregnant women with the flu have a greater chance for serious problems for their unborn baby, including premature labor and delivery.
 - e) Getting a flu shot is the best way to protect you from the flu and prevent possible flu-associated pregnancy complications.
 - f) When pregnant women get flu shots, they and their babies (after birth) get the flu less often.
- 2. If you have additional questions, talk to your doctor about flu vaccination during pregnancy.
- 3. Pregnant women are at high risk of serious flu complications. If you get sick with the flu, call your doctor right away. Your doctor may recommend treatment with influenza antiviral drugs (see Antiviral Drugs messages).
- 4. Babies younger than 6 months of age are too young to get a flu vaccine. To protect infants younger than 6 months from getting the flu, their mother should get a flu shot during her pregnancy.
- 5. If you have your baby before getting the flu shot, you still need to get vaccinated. If you breastfeed your infant, antibodies that help protect the baby from flu may be passed in breast milk.
- 6. An additional way to protect the baby is for all of the baby's caregivers and close contacts (including parents, brothers and sisters, grandparents and babysitters) to get vaccinated against the flu.

Statements for Adults (18 through 64 years of age)

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- 1. All people 6 months of age and older, including adults 18 through 64 years of age, are recommended to receive the seasonal flu vaccine annually.
- 2. Getting sick with the flu can result in missed school, work, and extracurricular activities.
- 3. Nearly 60 percent of influenza-related hospitalizations reported to CDC's influenza surveillance system were among adults 18-64 years old during the 2013-2014 season.
- 4. A similar increase in hospitalizations among non-elderly adults was also seen during the 2009 H1N1 pandemic, especially among adults between the ages of 18 and 49 years old.
- 5. Studies have shown that adults younger than 65 years old experience more severe flurelated illness during flu seasons when H1N1 influenza viruses predominate.
- 6. While the percentage of influenza-related hospitalizations among adults 65 years and older remained the highest among all age groups, hospitalizations among young and middle-age adults were higher during the 2013-2014 season than in the past three influenza seasons. More deaths than usual also occurred in this younger age group last season.
- 7. H1N1 influenza virus is expected to continue circulating during the 2014-2015 flu season, along with other influenza viruses. The H1N1 virus is covered by the 2014-2015 flu vaccine.
- 8. It is not possible to predict which influenza viruses will predominate this season, but it is important for all adults age 18-64 to be vaccinated this season.
- 9. Vaccination is particularly important for adults with certain long-term medical conditions because they are at high risk of serious illness if they get the flu. This group includes, for example, people with asthma (even if mild or controlled) and diabetes (types 1 and 2).
- 10. By getting a flu vaccine, adults can help prevent spreading flu to friends and family who are at high risk for flu complications such as grandparents, younger siblings, and people with certain medical conditions like asthma or diabetes.
- 11. CDC recommends adults 18-64 years of age also follow everyday preventive actions to help stop the spread of germs. (See Everyday Preventive Actions messages.)
- 12. For the full list of age factors and medical conditions that put someone at high risk of flu complications, see http://www.cdc.gov/flu/about/disease/high_risk.htm.
- 13. If you are at high risk of serious flu complications and get sick with the flu, your doctor may recommend treatment with antiviral drugs. (See Antiviral Drugs messages.)

Statements for Adults 65 Years and Older

- 1. Human immune defenses become weaker with age, which places some people 65 and older at greater risk of flu-related complications.
- 2. While annual flu vaccination is recommended for all people 6 months and older, vaccination is especially important for those 65 and older because people in this age group are at high risk of getting seriously ill from the flu.

- 3. On average, nearly 90 percent of flu-related deaths and between 50 and 60 percent of seasonal flu-related hospitalizations in the United States occur among people 65 years and older; however, this pattern can change depending on which flu viruses are circulating. Vaccination is the best protection against the flu and flu-related complications.
- 4. Protection provided by flu vaccination can vary depending on a number of factors. (http://www.cdc.gov/flu/about/qa/vaccineeffect.htm.)
 - a) Some studies have indicated that immunity may last for shorter periods of time in some people (for example, in people with weaker immune systems, which may include those aged 65 years and older); other studies have indicated that antibody levels (which are an indicator of immune protection) last through one flu season.
 - b) Consistent with CDC and Advisory Committee on Immunization Practices' (ACIP) general recommendation, people with weakened immune systems and people 65 years of age and older should ideally be vaccinated by October. Given the variability of existing study results and the uncertainty and unpredictability of when flu activity will begin in a given community, CDC and ACIP do not recommend delaying vaccination for people in these groups.
 - c) As long as flu viruses are circulating, vaccination should continue throughout the flu season, even in January or later.
- 5. Adults 65 years and older are often most impacted by serious flu disease each year that can result in hospitalization or death. A recent study conducted by CDC experts shows that flu vaccines prevent flu-associated hospitalizations in people 65 years and older, even during seasons when overall flu vaccine effectiveness is low.
- 6. People 65 years and older have a vaccine option available to them designed specifically for people in this age group. This "high dose" flu vaccine (Fluzone® High-Dose) contains more antigen (the part of the vaccine that helps your body build up protection against flu viruses) than standard flu shots, and is intended to promote a better immune response in this age group.
 - a) Data from studies comparing trivalent Fluzone® vaccines, high dose and standard dose, among people aged 65 years or older indicate that a stronger immune response (i.e. higher antibody levels) occurs after vaccination with Fluzone® High-Dose.
 - Results from a clinical trial of more than 30,000 participants showed that adults older than 65 years of age who received the high dose vaccine had 24.2% fewer influenza infections as compared to those who received the standard dose flu vaccine.

Note: CDC and the Advisory Committee on Immunization Practices (ACIP) have not expressed a preference for the high dose vaccine over the standard-dose flu shot for people 65 years of age and older.

- 7. The higher dose flu vaccine may result in more of the mild side effects that can occur with standard-dose seasonal shots. Mild side effects can include pain, redness or swelling at the injection site, headache, muscle ache and fever.
- 8. Talk to your doctor or other healthcare professional about the best vaccine option for you.
- 9. People 65 years of age and older should not get the nasal spray flu vaccine or the intradermal flu shot.

- 10. If you get sick with the flu, your doctor may recommend treatment with antiviral drugs. (See Antiviral Drugs messages.)
- 11. Pneumococcal disease can be a complication of influenza infection and includes pneumonia, meningitis and blood infections.
- 12. Learn more about when pneumococcal vaccines are needed for adults: http://www.cdc.gov/features/adult-pneumococcal.
 - CDC recommends all adults 65 years or older receive 2 types of pneumococcal vaccines.
 - One dose of PCV13 first, followed 6 to 12 months later by one dose of PPSV23.
- 13. It is safe to get either of the pneumococcal vaccines at the same time as the influenza (flu) vaccine, but you need to get the two pneumococcal vaccines at different times.
- 14. While you don't need a pneumococcal vaccine every year, it is important to get a flu vaccine each flu season. Flu can be serious, even for otherwise healthy people. And having the flu increases your chances of getting pneumococcal disease.

Statements for Adults with Certain Medical Conditions

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General Messages

- 1. Most people who get the flu will have mild illness, will not need medical care or antiviral drugs, and will recover in less than two weeks. Some people, however, are more likely to have serious flu-related complications that may result in being hospitalized and occasionally result in death.
- 2. Diabetes, asthma, and heart disease (even if well managed) are among the most common long-term medical conditions that place people at higher risk for serious flu complications.
 - a) The flu also can make long-term health problems worse, even if they are well managed.
 - b) It is particularly important that all adults with chronic medical conditions like asthma, diabetes (types 1 and 2), and heart disease, receive a flu vaccine every year.
 - c) Stay in control of your health by getting your flu vaccine.
- 3. Your doctor may prescribe antiviral drugs as treatment for flu infection. (See <u>Antiviral Drug messages</u>.)
- 4. For the full list of medical conditions that put you at a higher risk for serious flu complications, see http://www.cdc.gov/flu/about/disease/high_risk.htm.

Diabetes

- 1. While CDC recommends everyone 6 months and older to get vaccinated against the flu, it is especially important to get a flu shot if you have diabetes (type 1 and 2).
- 2. Even if your diabetes is well managed, you can get the flu and have serious complications. It's important that you know the signs and symptoms of flu and make a plan with your doctor about what to do in case you get sick.
- 3. If you have diabetes, getting the flu can make you very sick even if your diabetes is well managed.
- 4. For example, flu illness can cause blood glucose (sugar) levels to rise and fall (or go up and down), making it harder to manage diabetes.
- 5. It is also possible for blood glucose (sugar) levels to decrease, for example, when people experience a decreased appetite or nausea from flu illness.
- 6. People with diabetes sometimes have a harder time fighting infections.
- 7. A study showed that people with diabetes were more than two times more likely to be hospitalized with a flu-related illness. (Everyone with diabetes, including both type 1 and type 2 diabetes, should be protected from flu with an annual flu shot.)
- 8. People with diabetes should ask their family and friends to also get a flu vaccine; this can also help reduce their chances of getting sick from flu illness.
- 9. Flu shots are approved for use in people with diabetes and other health conditions. There is a precaution against giving nasal spray flu vaccine to people with diabetes because the safety of the nasal spray vaccine in people with diabetes and some other high risk conditions has not been established.
- 10. If you have flu-like symptoms, call a doctor, nurse, or clinic right away even if you have had a flu shot. A doctor or clinic can prescribe medicine to treat the flu and reduce your chance of serious illness. It's important to start taking this medicine as soon as possible. The medicine works best if taken within the first 48 hours after your symptoms start. Visit: http://www.cdc.gov/flu/about/disease/symptoms.htm.
- 11. Take everyday steps to protect your health. Visit: http://www.cdc.gov/flu/protect/habits/index.htm.
- 12. For more information about flu and diabetes, visit: http://www.cdc.gov/flu/diabetes/.

Asthma

- 1. Although people with asthma are <u>not</u> more likely to get flu, flu is more serious for people with asthma, even when asthma is mild or the symptoms are well managed.
- 2. People with asthma are more likely to have breathing problems if they get the flu.
- 3. The flu can also trigger asthma attacks or cause pneumonia and other acute respiratory diseases. Adults and children with asthma are more likely to develop pneumonia after getting sick with the flu.
- 4. Asthma is the most common chronic medical condition among children hospitalized with the flu.
- 5. Flu shots are approved for use in people with asthma.
- 6. The nasal spray vaccine is approved for use in people 2 through 49 years of age.

- a) Children 2 years through 4 years who have asthma or who have had a history of wheezing in the past 12 months should not get the nasal spray vaccine.
- b) People of any age with asthma might be at increased risk for wheezing after getting the nasal spray flu vaccine.
- 7. Family and friends of someone with asthma should get vaccinated to protect themselves and to reduce the chance of getting and spreading the flu to their loved one with asthma.

Heart Disease

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- 1. People with heart disease or who have had a stroke are at increased risk for developing serious complications from the flu and should get a flu shot every year.
- 2. Flu vaccination has been associated with lower rates of some cardiac events among people with heart disease, especially among those who had had a cardiac event in the 12 months prior to flu vaccination.
- 3. Flu vaccination can prevent worsening of heart disease, including heart attacks.
- 4. Flu shots are approved and highly recommended for use in people with heart disease or who have had a stroke. There is a precaution about giving nasal spray flu vaccine to these people because the safety of the nasal spray vaccine has not been established in this group.
- 5. Despite the known increased risk of severe flu-related complications in patients with heart disease and recommendations for vaccination, many patients are still not getting vaccinated.
- 6. For more information about influenza and heart disease, visit http://www.cdc.gov/flu/heartdisease/.

Morbid Obesity

- 1. People who are morbidly obese are included in the Advisory Committee on Immunization Practices (ACIP) list of people for whom flu vaccination is especially important due to their high-risk status.
- 2. During the 2009 H1N1 pandemic, morbid obesity (having a body mass index of 40 or greater) was shown to be an independent risk factor for serious complications related to influenza infection.
- 3. Obese individuals were disproportionally affected during the 2009 H1N1 pandemic. This was demonstrated in studies worldwide (U.S., Canada, Australia and New Zealand, China, France, and Spain).
- 4. Various studies showed that morbidly obese patients were more likely to experience hospitalization, longer ICU stays and death during the 2009 H1N1 pandemic.
- 5. Among Americans 20 years and older in 2011-2012, approximately 6% were morbidly obese (with a body mass index, or BMI, of 40 or greater).

- 6. Among adults hospitalized with flu during the 2013-2014 flu season, obesity was the most common chronic condition; 43% of adults hospitalized with flu during the 2013-14 flu season had obesity.
- 7. People who are morbidly obese often suffer from other medical conditions that put them at high risk of flu complications, such as pneumonia and death.
 - a. It is possible that some people who are morbidly obese could have unrecognized chronic medical conditions.
- 8. Getting a flu vaccine is the most important action a person can take to prevent the flu and its complications. Because people who are morbidly obese are at higher risk of flu complications, it is especially important that they get vaccinated every year to protect against the flu.
- 9. For more information about those at high risk for flu-related complications and to learn more about body mass index, visit http://www.cdc.gov/flu/about/disease/high_risk.htm.

Statements for African Americans and Hispanics

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- 1. CDC recommends that African Americans and Hispanics get vaccinated every year against the flu. (See the <u>Vaccine messages</u> above.)
- 2. This year, HHS, CDC, and state and local public health officials are continuing to work with leaders in African American and Hispanic communities to promote flu prevention messages and activities.
- 3. Flu vaccines are the best protection for everyone, regardless of race/ethnicity, age and health status, against the threat of flu.
- 4. CDC has prepared general messages for how all people, including African Americans and Hispanics, can protect themselves and their loved ones from the flu. (Please see the sections titled Take 3, Vaccine and Everyday Preventive Actions for these messages.)

Statements for American Indians and Alaska Natives

- During the 2009 H1N1 pandemic, indigenous populations from Australia, Canada, New Zealand, and the United States, including American Indians and Alaska Natives, experienced a rate of hospitalization and death associated with infection with the 2009 H1N1 flu virus that was three to eight times higher than what was seen in other populations.
 - a) A study of 12 states, including Alaska, showed that the death rate from 2009 H1N1 flu in American Indian and Alaska Natives was four times higher compared to the death rate from 2009 H1N1 flu in all other racial/ethnic populations combined. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5848a1.htm
- 2. According to Alaska health officials, American Indians and Alaska Natives make up 16 percent of the state's population, but they represented almost 30 percent of all of the state's hospitalized flu cases that occurred early in the 2009-2010 flu season.
- 3. Health officials were unable to find a specific reason why American Indians and Alaska Natives were disproportionately affected by the 2009 H1N1 virus during the 2009 flu pandemic. However, studies by doctors in Alaska suggest that several factors may increase infection risk and serious complications associated with bacterial and viral

- pathogens (including the flu) in these groups. These factors include household crowding; a lack of sanitation services, such as running water in remote villages; and limited access to timely medical care for persons living in remote areas.
- 4. American Indians and Alaska Natives are included in the list of people at high risk for complications from the flu and for whom vaccination is especially important.
- 5. American Indians and Alaska Natives can protect themselves by getting flu and pneumococcal vaccines. These vaccines are available at your local health care facility (even if you don't have a regular doctor or other health care professional); mobile and community-based immunization clinics that are held in many locations; and at pharmacies and grocery stores where available. Check with your Community Health Representative (CHR) or Community Health Aide (CHA) for more information.
- 6. The flu vaccine can help protect American Indians and Alaska Natives, including children, adults, and elders against the flu.
- 7. The flu can cause severe illness that may require hospital care, even in healthy adults and children. A flu vaccine reduces your risk of illness, hospitalization or even death, and can prevent you from spreading the virus to your loved ones. By reducing the risk of severe illness, a flu vaccine can offer life-saving protection, especially in communities that do not have a hospital with an emergency department or Intensive Care Unit (ICU).
- 8. CDC has prepared general messages for how all people, including American Indians and Alaska Natives, can protect themselves and their loves ones from the flu. (Please see the sections titled Take 3, Vaccine and Everyday Preventive Actions for these messages).

<u>Statements on the Importance of Health Care Professional/Health</u> Care Worker Recommendation and Vaccination

- 1. As a health care professional, you are a trusted and valuable source of health information. Patients may view you as their primary or preferred source of care. This provides you the opportunity to assess your patients' vaccination status and possibly even to administer the appropriate vaccines.
- 2. Recommend flu vaccination for all of your patients 6 months of age and older. Make plans to vaccinate your patients, staff, and yourself.
 - a) As a trusted health care professional, research shows that your recommendation for yearly flu vaccination and taking action to get yourself vaccinated is vital.
 - b) Ideally, all health care professionals, including specialists and primary care professionals, should recommend *and* offer flu vaccines to their patients.
 - c) Even if you do not stock flu vaccines in your office, assessing your patients' vaccination needs and making a strong recommendation for them to get vaccinated is critical. Health care professionals who don't administer flu vaccines can refer patients to their primary care professional or to a pharmacist or local health department to receive the needed vaccines. You and your patient can visit the HealthMap Vaccine Finder (http://vaccine.healthmap.org/) to find locations in your area that offer the recommended vaccines.

- d) Order free prescription-style tear-pads that will allow you to give a customized flu shot reminder to patients at high risk for complications from the flu. Order this product at http://wwwn.cdc.gov/pubs/CDCInfoOnDemand.aspx?ProgramID=1.
- e) Take every opportunity to help educate your patients about the importance of flu vaccination this and every year.
- 3. Flu can spread rapidly in health care settings. Vaccination is the first and most important step physicians and health care workers can take to protect themselves and their patients against the against the flu.
- 4. Even if you are healthy, you can get sick and spread the flu. Get vaccinated to help protect yourself from the flu and to keep from spreading it to your family, co-workers, and patients. Studies conducted in health care settings show that when a large number of health care workers get vaccinated, vulnerable patients are protected.
- 5. Health care workers should routinely offer seasonal flu vaccination to everyone aged 6 months and older, ideally by October, and continuing throughout the flu season, which can last as late as May.
- 6. CDC encourages medical practices, health departments, pharmacists, and other health care professionals to use flu vaccination as an opportunity to remind adult patients about other recommended vaccines.
- 7. See the <u>Vaccine messages</u> above for CDC-approved messages to communicate to patients related to flu vaccination.
- 8. For the latest information on flu vaccine supply, including projections and doses distributed, visit http://www.cdc.gov/flu/professionals/vaccination/vaccinesupply.htm.
- 9. Key information for public health and health care professionals regarding vaccination, infection control, prevention, treatment, and diagnosis of seasonal flu is available at http://www.cdc.gov/flu/professionals.
- 10. Free print resources can be ordered from http://www.cdc.gov/pubs/CDCInfoOnDemand.aspx?ProgramID=1 or downloaded from http://www.cdc.gov/flu/freeresources/print.htm.
- 11. Visit: http://www.cdc.gov/flu/professionals/acip/ to view the 2014-15 Advisory Committee of Immunization Practices (ACIP) Influenza Vaccine Recommendations.
- 12. Health care workers should take everyday preventive actions to prevent the spread of germs and suggest the same to their patients. (See Everyday Preventive Actions messages).
- 13. As part of the Affordable Care Act, many insurance plans, including all plans in the Health Insurance Marketplace, will provide many free preventive services, including flu vaccinations. For information about the Health Insurance Marketplace, visit www.HealthCare.gov.

Flu Vaccine Safety

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General

- 1. Flu vaccines have been used in the United States for more than 50 years.
- 2. Millions of people have safely received seasonal flu vaccines.

- 3. Each year, CDC works closely with the U.S. Food and Drug Administration (FDA), and other partners to ensure the highest safety standards for flu vaccines. CDC also works closely with the FDA to ensure systems are in place to promptly detect unexpected or unusual patterns of adverse events following vaccination.
- 4. The safety of flu vaccines is closely monitored with long-established systems that have demonstrated their usefulness in detecting vaccine safety problems. See www.cdc.gov/vaccinesafety. Data from clinical trials indicate that seasonal flu vaccines made to protect against four flu viruses have a similar safety profile as seasonal flu vaccines made to protect against three flu viruses—mostly mild—side effects.
- 5. The flu shot cannot give you the flu. Flu vaccines that are administered with a needle are currently made in two ways: the vaccine is made either with a) flu vaccine viruses that have been 'inactivated' and are therefore not infectious, or b) with no flu vaccine viruses at all (which is the case for recombinant influenza vaccine, or RIV3). The most common side effects from the flu shot are soreness, redness, tenderness or swelling where the shot was given. Low-grade fever, headache and muscle aches also may occur.
- 6. The nasal spray vaccine cannot give you the flu. The viruses contained in the nasal spray flu vaccine are attenuated (i.e., weakened). These weakened viruses are also cold-adapted, meaning they are designed to cause only mild infection at the cooler temperatures found within the nose. These viruses cannot infect the lungs or other areas of the body where warmer temperatures exist. The nasal spray is well tolerated and the most commonly reported side effects are mild and include runny nose, nasal congestion and cough.
- 7. Life-threatening allergic reactions from vaccines are very rare, and effective medical treatment is available. If they do occur, it is usually within a few minutes to a few hours after the vaccination.

Thimerosal

- 1. Thimerosal is a preservative that protects multi-dose vial vaccines against contamination. Flu vaccines are available with and without thimerosal. Both options are safe for protecting you and your family from the flu. If you have questions, discuss them with your doctor or other health care professional.
- 2. There is a large body of scientific evidence on the safety of thimerosal. Data from many studies show that the low doses of thimerosal contained in vaccines are safe for adults and children.
- 3. Most people don't have any side effects from thimerosal, but some people will have mild reactions like redness and swelling at the place where the shot was given, which only last one to two days. It's very unlikely you will have an allergic reaction to thimerosal.
- 4. For a complete list of vaccines and their thimerosal content level, visit the http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM09622
 8. Or ask your doctor or other health care provider or pharmacist for a copy of the vaccine "package insert." The package insert lists ingredients in the vaccine and discusses any known adverse reactions from vaccination.

Guillain-Barré Syndrome (GBS)

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- 1. Guillain-Barré Syndrome (GBS) is a rare disorder in which a person's own immune system damages the nerves, causing muscle weakness and sometimes paralysis.
- 2. Anyone can develop GBS; however, it is more common among older adults. The occurrence of GBS increases with age, and people older than 50 years are at greatest risk for developing GBS.
- 3. Each year, between 3,000 and 6,000 people in the United States get GBS, regardless of vaccination.
- 4. While it is not fully known what causes GBS, it is known that about two-thirds of the people who get GBS do so several days or weeks after they have been sick with diarrhea or a lung or upper respiratory illness. An infection with the bacteria Campylobacter jejuni, which can cause diarrhea, is one of the most common risk factors for GBS.
- 5. In 1976 there was a small increased risk of GBS after vaccination with the 1976 swine influenza vaccine.
 - Influenza viruses that commonly circulate in swine are called "swine influenza viruses" or "swine flu viruses." Swine flu viruses do not normally infect humans. However, sporadic human infections with swine influenza viruses have occurred.
- 6. The Institute of Medicine (IOM) conducted a scientific review of this issue in 2003 and found that people who received the 1976 swine influenza vaccine had an increased risk for developing GBS.
- 7. The increased risk was approximately one additional case of GBS for every 100,000 people who got the swine flu vaccine. Scientists have several theories about the cause, but the exact reason for this link remains unknown.
 - a) The link between GBS and flu vaccination in other years is unclear, and if there is any risk for GBS after seasonal flu vaccines, it is very small, about one in a million.
 - b) Studies suggest that it is more likely that a person will get GBS after getting the flu than after vaccination. It is important to keep in mind that severe illness and death are associated with flu, and getting vaccinated is the best way to prevent flu infection and its complications.
- 8. Flu infection and illness also can, in rare cases, lead to GBS.
- 9. The benefits of flu vaccination continue to outweigh the possible risk of GBS.
- 10. People who have experienced GBS should consult with their doctor about getting a flu vaccine.
- 11. Vaccine safety monitoring systems are used to investigate cases of GBS that start after vaccination.

Febrile Seizures

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1. In the <u>2010-2011</u> and 2011-2012 seasons, CDC monitoring detected an increased risk for febrile seizures in young children in the U.S. following receipt of inactivated

influenza vaccine (IIV, also known as the flu shot). During the <u>2012-2013 flu season</u>, no increased risk was detected. The reason for the difference between these flu seasons is not known. However, the composition of flu vaccines changed between the 2011-2012 and the 2012-2013 seasons. Flu vaccine <u>composition often changes year-to-year</u>, and CDC and FDA will continue to closely monitor the safety of flu vaccines each season.

2. Due to past findings of febrile seizures, no changes in the use of inactivated influenza vaccine (IIV) or PCV13 are recommended for the 2014-15 flu season. As stated previously, Advisory Committee for Immunization Practices (ACIP) does not recommend the U.S.-licensed CSL Biotherapies' IIV, Afluria, for children younger than 9 years old.

Egg Allergy and Flu Vaccination

- 1. Serious allergic reactions can be caused by various components of flu vaccine. Fortunately, the risk of such reactions is low.
- 2. A severe allergic reaction to flu vaccine no matter what vaccine component may have caused the reaction is a contraindication to future receipt of the flu vaccine. Examples of severe allergic reactions to flu vaccine include: anaphylaxis or a reaction involving angioedema (i.e., similar to hives but swelling is under the skin instead of on the skin surface); respiratory distress; lightheadedness; or recurrent vomiting; or a reaction that required emergency medical care or epinephrine.
- 3. Because most flu vaccines are produced by inoculating flu virus into eggs, most finished flu vaccines contain a trace amount of egg protein. This trace amount of egg protein could cause a reaction in susceptible people. However, several recent studies have documented safe receipt of the flu shot in people with egg allergy, particularly those with a history of less severe reactions to egg. Persons with mild reactions to egg specifically, those who have only experienced hives may either receive the recombinant, egg-free vaccine (Flublok®) or the inactivated flu vaccine (the flu shot) with some additional safety measures.
- 4. Flublok® is a seasonal flu vaccine that does not use eggs in its production. Flublok® also does not use flu virus in its production and contains no egg proteins, antibiotics or preservatives.
- 5. Persons who have severe reactions to egg (i.e., those listed above) should either receive Flublok® or should receive inactivated influenza vaccine from a health care professional with expertise in the management of allergic conditions.
- 6. Recommendations for flu vaccination of persons with egg allergy can be found at: http://www.cdc.gov/flu/professionals/acip/2013-summary-recommendations.htm.
- 7. All personnel and facilities providing flu vaccinations should have procedures in place for anaphylaxis management. Providers should be familiar with the office emergency plan.
- 8. Some people who report allergy to eggs may not be egg-allergic. Those who are able to eat lightly cooked eggs (e.g., scrambled eggs) without reaction are unlikely to be allergic.
- 9. Egg allergic persons may tolerate eggs in baked products (e.g., bread and cake). Tolerance to such egg-containing foods does not exclude the possibility of egg allergy.

Egg allergy may be confirmed by a consistent medical history of adverse reactions to eggs and egg-containing foods, in addition to a skin or blood test.

Flu Vaccine Safety and Pregnancy

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- CDC and FDA monitor the safety of seasonal flu vaccines and other vaccines licensed for use in the United States, in cooperation with state and local health departments, health care providers, and other partners. Monitoring the safety of seasonal flu vaccine in pregnant women is part of this effort.
- 2. Millions of pregnant women have safely received flu shots for many years.
- 3. The flu shot has not been shown to cause harm to pregnant women, their unborn child, or to newborns of vaccinated women. The evidence that the flu shot is safe in pregnant women continues grow.
 - a) Studies have shown that vaccinating a pregnant woman can give her baby antibodies that protect against flu for up to six months after they are born.
 - b) In a review of reports submitted to the <u>Vaccine Adverse Events Reporting System</u> (<u>VAERS</u>) of pregnant women who received the seasonal flu vaccine and/or monovalent 2009 H1N1 influenza vaccine, no unusual patterns of pregnancy complications or fetal outcomes following receipt of flu vaccines were observed.
 - c) Studies of flu vaccine safety and pregnancy conducted through the <u>Vaccine Safety Datalink (VSD)</u> show that flu vaccine given to pregnant women does not increase the risk of adverse obstetric events, was not associated with an increased risk of premature delivery or small for gestational age infants, and does not increase the risk of spontaneous abortion when given during the first trimester of pregnancy (See <u>What studies has CDC conducted on adverse events in pregnant women who received seasonal flu vaccine?</u> on the CDC website.)
- 4. Pregnant women should receive the flu shot to protect both the mother and baby.
- 5. The flu shot can be given at any time during pregnancy.
- 6. Women who have just delivered (postpartum) are also at risk for the flu and should be vaccinated, if they have not yet received a flu vaccine.
- 7. The nasal spray vaccine is not licensed for use in pregnant women, but postpartum women can receive the flu shot or the nasal spray vaccine. Pregnant and postpartum women do not need to avoid contact with persons recently vaccinated with the nasal spray vaccine. (See <u>Statements for Pregnant Women</u> section for more information.)
- 8. The flu shot is safe for women who plan to breastfeed, and the vaccine (either the shot or the nasal spray) can be given to mothers who are breastfeeding.
- 9. More information on flu vaccine safety in pregnant women is available at http://www.cdc.gov/flu/protect/vaccine/qa_vacpregnant.htm.

Vaccine Coverage

Overall Coverage Estimates

- To estimate monthly cumulative flu vaccination coverage for the 2013-2014 season, CDC analyzed the <u>National Immunization Survey (NIS)</u> data for children 6 months-17 years and the <u>Behavioral Risk Factor Surveillance System (BRFSS)</u> data for adults ≥18 years.
- For further information, visit: http://www.cdc.gov/flu/fluvaxview/coverage-1314estimates.htm
- Among all people ≥6 months, flu vaccination coverage during the 2013–14 flu season was 46.2%, which was 1.2 percentage points higher than the 2012–13 season (45.0%).
- State-specific flu vaccination coverage among all people ≥6 months ranged from 36.4% (Nevada) to 57.4% (South Dakota).
- For adults overall, flu vaccination coverage increased less than 1 percentage point for the 2013-14 season (42.2%) compared to the 2012-13 season;
- Among children 6 months through 17 years, there was an increase of 2.3 percentage points to 58.9%.

Coverage by Age

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- Last season, more children were vaccinated than ever before.
 - Flu vaccination coverage among children 6 months-17 years increased to 58.9% for the 2013-14 season, a 2.3 percentage point increase compared to the 2012-13 season (56.6%).
 - It's critical to continue this progress. There were more than 100 deaths among U.S. children last flu season.
- Flu vaccination coverage among all adults was 42.2% for the 2013-14 season.
- Coverage for children decreased with age:
 - o 74.3% for children 6-23 months
 - o 68.1% for children 2-4 years
 - o 61.0% for children 5-12 years
 - o 46.4% for children 13-17 years
- Coverage for adults increased with increasing age:
 - \circ 32.3% for adults 18-49 years
 - 45.3% for adults 50-64 years
 - o 65.0% for adults 65 years and older

Coverage by Race/Ethnicity

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Flu vaccine coverage increased for children in some race/ethnic groups in the 2013-14 season.

Coverage for non-Hispanic Asian children (70.6%), Hispanic children (66.0%), non-Hispanic American Indian/Alaska Native children (65.5%), and non-Hispanic children of other or multiple races (59.2%) was significantly higher than for non-Hispanic white children (55.2%). Coverage of non-Hispanic black children was similar at 57.2%.

Coverage among adults aged 18 years and older only increased slightly compared to the 2012–13 season among non-Hispanic whites; there were no statistically significant increases in the other racial/ethnic groups.

 Among adults, coverage for non-Hispanic whites (45.4%) was higher than coverage for non-Hispanic blacks (35.6%), Hispanics (33.1%), and adults of other or multiple races (34.9%); non-Hispanic whites had similar coverage to Asian (43.6%) and AI/AN (44.1%) adults.

Methods and Background

- CDC analyzed NIS-Flu and BRFSS data collected September (BRFSS) or October (NIS-Flu) 2013 through June 2014 from all 50 states and the District of Columbia to estimate national and state level flu vaccination coverage from July 2013 through May 2014 for the 2013–14 flu season. These findings were compared to 2012–13 flu season estimates.
- NIS-Flu data were used to estimate coverage for children 6 months through 17 years and BRFSS data were used to estimate coverage for adults ≥18 years.

Coverage among Pregnant Women

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Pregnant women are at high risk for flu-related severe illness, hospitalization, and death.

- Flu vaccination can protect pregnant women and their unborn babies, and even protect their newborn babies younger than 6 months old who are too young to be vaccinated themselves.
- Flu shots are a safe way to protect the mother and her unborn child from serious illness and complications of flu, regardless of trimester.
- A health care provider recommendation and offer for flu vaccination was associated with increased vaccination coverage in all demographic groups, including women with a negative perception about flu vaccination.

Flu vaccination coverage for pregnant women remains similar to last season.

- Coverage among women who were pregnant during the 2013-14 flu season was 52.2%, similar to coverage in 2012-13 (50.5%) but higher than the estimate for the 2011-12 season (46.4%).
- While stable, it means that near half of all pregnant women and their babies were not protected from the flu.

There were differences in coverage among pregnant women based on age.

- Younger women (18-24 years of age) had lower vaccination coverage (45.6%) compared to older women (35-49 years of age), who had vaccination coverage of 53.0%.
- Coverage was highest among women age 25-34 years of age at 56.5%, a 6.0 percentage point increase from the 2012-13 flu season.

Non-Hispanic black women were less likely to get vaccinated than other races/ethnicities.

- Non-Hispanic black women had vaccination coverage of 42.7%.
- Hispanic women had vaccination coverage of 56.7%, a 6.0 percentage point increase from the 2012-13 flu season.
- Non-Hispanic white women had vaccination coverage of 52.0%.
- Other non-Hispanic women had vaccination coverage of 61.9%, an 8.8 percentage point increase from the 2012-13 flu season.

Women with higher education levels reported vaccination more frequently than other women.

• Women with education level beyond a college degree had higher coverage (65.9%) compared to women with less than a college education (44.6%).

Health care providers play a key role in increasing flu vaccination coverage among pregnant women.

- A provider recommendation combined with an offer to administer the flu vaccine at the time of visit remains one of the best ways to increase flu vaccination among pregnant women.
- Pregnant women who reported receiving a clinician recommendation and an offer of flu vaccination had higher vaccination coverage (70.5%) compared with women who reported receiving a recommendation but no offer (32.0%) or reported receiving no recommendation (9.7%).
- 81.2% of pregnant women reported that they received a provider recommendation for vaccination. However, only 65.1% received both a recommendation and offer.
 - A clinician offer of vaccination was associated with higher vaccination coverage even among women with negative perceptions regarding the safety and efficacy of vaccination and women who were not concerned about flu infection.
- Systems supporting provider recommendation and offer, such as standing orders and provider reminder systems, can reduce missed opportunities for vaccination and improve vaccination coverage.
- Healthcare professionals not able to administer the flu vaccine at the time of the visit, should still recommend flu vaccination and refer the pregnant patient to a place where vaccinations are provided.
- Each provider recommendation can be an important opportunity to improve vaccination coverage, especially where differences in coverage are seen among certain sub-groups such as education and race/ethnicity.

Education messages from health care professionals to their pregnant patients should emphasize that vaccination can protect not only the pregnant woman, but also her unborn baby and her baby up to 6 months after birth.

- Providers should offer information to pregnant patients on the safety and effectiveness of flu vaccination for both mother and baby.
- The top three reasons given for receiving an flu vaccination were 1) to protect their baby from flu (31.1%), 2) to protect themselves from flu (23.3%), and because their health care provider recommended it (14.8%).

• Tailored education of pregnant women designed to increase their knowledge about flu risks, vaccine safety, and vaccine effectiveness in support of a strong recommendation may increase demand and vaccination coverage.

Methods and Background

• The results of this report were based on an Internet panel survey conducted in March and April 2014 among a total of 1,619 women who were pregnant at any time during October 2013 through January 2014.

Coverage among All Health Care Providers (Internet Panel Survey)

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Health care personnel (HCP) should be vaccinated for flu every flu season to protect themselves, their patients, and their families from seasonal flu.

- The coverage rate for HCP was estimated at 75.2% for the 2013-14 season, similar to coverage of 72.0% in the 2012-13 season.
- Coverage was highest among HCP working in settings with flu vaccination requirements (97.8%).
- Among health care professionals, last season more nurses led by example and protected themselves, their families, and their patients by getting an annual flu vaccine.
 - Coverage increased 5.7 percentage points last season compared to 2012-13 among nurses (from 84.8% to 90.5%) and increased 5.5 percentage points for other clinical personnel (from 81.9% to 87.4%).

There were differences in coverage by occupation and occupational setting.

- Coverage was highest among physicians (92.2%) and nurses (90.5%), followed by nurse practitioners/physicians assistants (89.6%), other clinical personnel (87.4), and pharmacists (85.7%).
- Coverage by occupation was lowest for assistants/aides (57.7%) and non-clinical personnel (68.6%).
 - Non-clinical personnel include administrative support staff or managers, and non-clinical support staff (food service workers, housekeeping staff, maintenance staff, janitors, laundry workers, etc.).
- Coverage by occupational setting was highest for HCP working in hospitals (89.6%), a 6.5 percentage point increase from the 2012-13 season (81.9%).
- Coverage by setting was lowest for those working in LTC settings (63.0%).
 - Vaccination of HCP in LTC settings is extremely important because:
 - People 65 years and older are at greater risk of serious complications from the flu.
 - Flu vaccine effectiveness is generally lowest in the elderly, making vaccination of close contacts even more critical.
 - Multiple studies have demonstrated health benefits to patients, including reduced flu-related complications and reduced risk of death, with vaccination of HCP in LTC settings.

Flu vaccination coverage was highest in settings with employer flu vaccination requirements and promotion of flu vaccination.

- Overall coverage among HCP reporting that their employer required them to receive flu vaccination was 97.8%, with coverage above 96% in all occupational health care settings requiring vaccination, including LTC settings.
- Coverage was 72.4% among HCP whose employers promoted but did not require flu vaccination.
- Coverage was lowest (47.9%) among HCP working in facilities where employers did not require or promote flu vaccination.
- Comprehensive, work-site intervention strategies that include education, promotion, and easy access to vaccination at no cost for multiple days can increase HCP vaccination coverage.
- Cost and convenience of flu vaccine in the workplace affected vaccination coverage.
 - In the absence of an employer requirement for vaccination, coverage was higher (80.4%) among HCP who had access to free, on-site vaccinations over multiple days compared to HCP whose employers did not offer flu vaccination at no cost to employees (49.0%).

Methods and Background

• The results of this report were based on an Internet panel survey of a total of 1,944 HCP from April 2014.

<u>Influenza Vaccination Performance Measurement Among Acute Care</u> Hospital-Based Health Care Personnel

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Background

For the first time, we are reporting performance measurement data for acute care hospital-based healthcare professionals (HCPs).

Public reporting of HCP vaccination data is an important strategy to increase vaccination.

In addition to sampling surveys that provide estimates of vaccine coverage based on self-report of vaccinations, NHSN now allows CDC to receive direct reporting of healthcare personnel flu vaccination from participating healthcare facilities.

Thanks to a partnership between CDC and the Centers for Medicare and Medicaid Services, in December, facility-level data from CDC on the proportion of hospital-based healthcare workers who are vaccinated for flu will be publicly available on the CMS Hospital Compare website.

Main Points and Summary

The data indicate 82% of hospital-based HCP were reported by their hospitals as vaccinated against flu in 2013-14.

- This is exciting news. It provides a starting point for monitoring flu vaccination among hospital-based healthcare professionals. New measures are important because, what gets measured gets done.
- The Centers for Medicare and Medicaid Services now requires acute care hospitals participating in its Hospital Inpatient Quality Reporting Program to report HCP flu vaccination data through CDC's National Healthcare Safety Network (NHSN).
 - In addition to sampling surveys that provide estimates of vaccine coverage based on self-report of vaccinations, NHSN now allows CDC to receive direct

reporting of healthcare personnel flu vaccination from participating healthcare facilities.

It is important that all healthcare personnel, regardless of specialty, job duties, or practice setting, receive annual seasonal flu vaccination to protect themselves and patients.

- Overall, US hospitals reported that 81.8% of their hospital-based healthcare professionals had were reported by their facilities as vaccinated against flu during the 2013-14 flu season.
- Among healthcare professionals working in hospitals, higher proportions of employees were reported vaccinated compared with licensed independent practitioners (LIPs) and adult students/trainees and volunteers.
- LIPs and adult students/trainees and volunteers may also have substantial contact with patients.
 - Reported vaccination among hospital employees was 86.1%
 - Reported vaccination among adult students/trainees and volunteers was 79.9%
 - Reported vaccination among LIPs was 61.9%
- Reported flu vaccination among hospital based healthcare professionals varied by state.
 - Reported vaccination for all hospital based healthcare professionals varied from 62.4% in New Jersey to 96.4% in Maryland
 - Reported vaccination among hospital employees varied from 69.0% in Hawaii to 97.6% in Utah
 - Reported vaccination among adult students/trainees and volunteers varied from 50.3% in New Jersey to 96.3% in Rhode Island
 - Reported vaccination among LIPs varied from 33.8% in Florida to 93.6% in Maryland

Background, Methods, and Limitations

- Public reporting of HCP vaccination data is an important strategy to increase vaccination. A voluntary public reporting program among Iowa hospitals resulted in a 20 percentage-point increase in median employee flu vaccination coverage over four years.
- Thanks to a partnership between CDC and the Centers for Medicare and Medicaid Services, in December, facility-level data from CDC on the proportion of hospital-based healthcare workers who are vaccinated for flu will be publicly available on the CMS Hospital Compare website.
 - This will be the first time that healthcare consumers can see how their hospital is doing at vaccinating its workers against flu.
- The National Healthcare Safety Network (NHSN) is the nation's most widely used healthcare-associated infection tracking system. It is a secure, voluntary, web-based surveillance system managed by the Division of Healthcare Quality Promotion at CDC.

- Data were reported from 4,254 acute care hospitals, which represent 85% of community hospitals in the United States. This is the most complete accounting available of hospital-based HCP flu vaccination measurement.
- This performance measurement provides a baseline for measuring changes in hospital-based reporting of HCP flu vaccination in the future.
 - States and hospitals can use these data to evaluate the effectiveness of efforts to increase HCP flu vaccination.
- Tracking vaccination of LIPs was challenging. LIPs had the lowest reported proportion vaccinated and the highest proportion of unknown vaccination status nationally.
 - Improvements in hospitals' ability to track LIPs will likely result in higher reported proportions vaccinated for future flu seasons.
 - LIPs are highly mobile, can work in multiple facilities, and may enter hospitals infrequently.
 - Many LIPs are likely to receive flu vaccination outside of reporting facilities, so the true proportion of LIPs vaccinated is likely higher than reported.

Flu Vaccine Effectiveness

- 1. Flu vaccines protect against infection and illness caused by flu viruses.
- 2. Flu vaccines will NOT protect against infection and illness caused by other viruses that can also cause flu-like symptoms.
 - a) There are many other viruses besides flu that can result in influenza-like illness (ILI) that spread during the flu season.
- 3. Researchers try to tell how well a vaccine works in order to continually assess and confirm the value of flu vaccines as a public health measure.
- 4. CDC typically conducts studies throughout the influenza season to help determine how well flu vaccines are working. These studies are called "vaccine effectiveness" studies or "VE" studies, for short.
- 5. VE studies and their findings can vary due to study design, outcome(s) measured, population studied and the season in which the vaccine was studied. These differences can make it difficult to compare one study's results with another's.
- 6. While determining how well a flu vaccine works is challenging, in general, recent studies have supported the conclusion that flu vaccination benefits public health, especially when the viruses in the vaccine and circulating viruses are well matched.
- 7. Recent studies by CDC researchers and other experts indicate that flu vaccine reduces the risk of doctor visits due to flu by approximately 60% among the overall population when the vaccine viruses are like the ones spreading in the community.
- 8. Some studies* have shown that flu vaccination can reduce the risk of more serious flu outcomes, including hospitalizations.
 - a) A study conducted during flu seasons from 2010 to 2012 showed that flu vaccine reduced children's risk of flu-related pediatric intensive care unit (PICU) admission by 74%.

- b) A study conducted during the 2011-2012 flu season showed that flu vaccination was associated with a 71% reduction in flu-related hospitalizations among adults of all ages and a 77% reduction among adults 50 years of age and older.
- 9. Studies also have shown that flu vaccination is an important preventive tool for people with chronic health conditions.
 - a) Flu vaccination was associated with lower rates of some cardiac events among people with heart disease, especially among those who had had a cardiac event in the past year.
 - b) Flu vaccination also has been shown to be associated with reduced hospitalizations among people with diabetes and chronic lung disease.
- 10. Vaccination helps protect women against influenza during pregnancy and their babies for up to 6 months after they are born. One study showed that giving flu vaccine to pregnant women was 92% effective in preventing hospitalizations of infants for flu.
- 11. Other studies have shown that flu vaccination can reduce the risk of flu-related hospitalizations in older adults. A study that looked at flu vaccine effectiveness over the course of three flu seasons estimated that flu vaccination lowered the risk of hospitalizations by 61% in people age 50 years and older.
- 12. How well the flu vaccine works can vary by season, virus type/subtype, the vaccine, and age and other host factors of the people being vaccinated.
- 13. Two factors play an important role in determining the likelihood that flu vaccines will protect a person from flu illness: 1) characteristics of the person being vaccinated (such as their age and health), and 2) the similarity or "match" between the flu viruses in the vaccine and those spreading in the community.
- 14. In general, the flu vaccine works best among young healthy adults and older children. Lesser effects of flu vaccine are often found in studies of young children (e.g., those younger than 2 years of age) and older adults.
- 15. Older people, who may have weaker immune systems, often have a lower protective immune response following flu vaccination compared to the immune response of younger, healthier persons following flu vaccination. This can result in lower levels of vaccine effectiveness in these people.
- 16. The other factor affecting how well the flu vaccine works is the "match" between the flu viruses contained in the vaccine and those spreading in the community. The closer the match, the better the flu vaccine is likely to be in preventing flu illness. If the viruses in the vaccine are very different from circulating flu viruses, vaccine effects can be lower.
- 17. During years when the viruses in the flu vaccine and circulating flu viruses are not well matched, it's possible that no or minimal benefit from flu vaccination may be observed.
- 18. During years when the viruses in the flu vaccine and circulating flu viruses are very well matched, it's possible to measure substantial benefits from flu vaccination in terms of preventing flu illness.
- 19. However, even during years when the vaccine match is very good, the benefits of flu vaccination will vary across the population, depending on host factors like the health and age of the person being vaccinated and even potentially which flu vaccine was used. The substantial burden of flu-associated illness and death in the United States combined with the overall evidence from a variety of studies showing that flu vaccines do offer protection against flu illness support the current U.S. flu vaccination recommendations.

- 20. It's important to note, however, that how well flu vaccines work to protect against flu illness will continue to vary each year, depending especially on the match between flu viruses used to make vaccine and the flu viruses that are spreading and causing illness in the community, and the characteristics of the person being vaccinated.
- 21. A flu vaccination does not guarantee protection against the flu. Some people who get vaccinated might still get sick. However, people who get a flu vaccine are less likely to get sick with flu than someone who does not get vaccinated.

*A list of references for the research studies mentioned above is available on the CDC website http://www.cdc.gov/flu/about/qa/benefit-publications.htm.

Ways to Measure How Well Flu Vaccines Work (Study Methods)

- 1. How well a flu vaccine works can be measured through different kinds of studies.
- 2. "Randomized studies," in which people are randomly assigned to receive either vaccine or placebo (e.g., saline solution) and then followed to see how many in each group get the flu, confirmed by lab tests, are the "gold standard" (best method) for determining how well a vaccine works. The measurement of vaccine effect from a randomized (placebo-controlled) study is referred to as "efficacy."
- 3. "Observational studies" are studies in which each person with their doctor or other health care provider decides about vaccination. This means that vaccination of study subjects is not randomized and factors linked with vaccination have to be carefully accounted for. The measurement of vaccine effect from an observational study is referred to as "effectiveness."
- 4. Randomized studies are difficult to conduct after vaccines are recommended and particularly undesirable in high-risk groups, where withholding vaccine from people recommended for vaccination would place them at risk for infection, illness and possibly serious complications.
- 5. For that reason, most recent studies to measure how well flu vaccine works have been observational studies.
- 6. Many observational studies use a case-control design, in which people with lab-confirmed influenza ("cases") are compared with a group of people who do not have influenza (control group).
- 7. One aspect of the design of observational studies that can influence results is the choice of the "control" group. The control group can include people who did not have the flu, or who have no record of seeking care for flu symptoms. In some studies, the control group may consist of people who had respiratory symptoms for which they sought medical care, but who tested negative for flu.
- 8. Members of the control group who don't have the flu should ideally be similar to study subjects with the flu. If they are not similar, the study may show a falsely high or low result for how well the flu vaccine worked. Generally speaking, cases should come from the same population as controls.
- 9. In addition, it can be difficult to directly compare results between studies that used different comparison groups. Even if both studies were well-conducted, one might expect the results to be different because the choice of the comparison group in non-randomized studies can influence the estimate of the vaccine's effect.

- 10. Other factors that can affect results are the numbers of cases (people who developed flu illness) in the study and the number of people eligible for, or enrolled in a study (again, smaller numbers can make results less reliable).
- 11. Therefore, when assessing how well a vaccine works, it is important to consider the study design, population and year.
- 12. Studies also can assess how well a vaccine works at preventing different outcomes.
 - For example, the outcomes can be more broad, like measuring influenza-like illness* (which includes illness caused by other viruses in addition to flu viruses), or they can be more specific to flu, like measuring laboratory-confirmed influenza virus infection. Also, laboratory-confirmed influenza can be associated with mild illness that doesn't require medical care or more severe illness that requires hospitalization.
 - *Influenza-like illness (ILI) is defined as fever (temperature of 100°F [37.8°C] or greater) and a cough and/or a sore throat.
- 13. The use of laboratory-confirmed flu cases is likely to yield more accurate estimates than studies that use non-specific case definitions (such as influenza-like illness).
- 14. Generally, the lowest estimates of flu vaccine effectiveness are found in studies using non-influenza specific, non-laboratory-confirmed outcomes, such as studies using all deaths or all respiratory illnesses or all respiratory-related hospitalizations.
- 15. A study by Bridges et al (JAMA 2000) conducted among healthy adults illustrates how the outcome measured can impact estimates of how well a vaccine works. The results from this study showed that the inactivated influenza vaccine (IIV, also known as the flu shot) was 86% efficacious against laboratory-confirmed flu, but only 10% efficacious against all respiratory illnesses in the same population and year.
- 16. Scientists continue to work on better ways to design, conduct and evaluate non-randomized (i.e., observational) studies to assess how well flu vaccines work.
 - a) CDC has been working with researchers at universities and hospitals since the 2003-2004 flu season to estimate how well flu vaccine works through non-randomized, observational studies using laboratory-confirmed flu as the outcome.
 - b) These studies currently use RT-PCR (reverse transcription polymerase chain reaction) confirmed medically attended flu virus infections as a specific outcome.
 - c) CDC's studies are conducted in five sites across the United States that measure the flu vaccine's effectiveness at preventing outpatient medical visits due to laboratory-confirmed influenza.
 - d) To assess how well the flu vaccine works across different age groups, CDC's studies of vaccine effectiveness include all people aged 6 months and older recommended for an annual flu vaccination.
 - e) Similar studies are being conducted in Australia, Canada and Europe.

Background on Flu Vaccine Effectiveness

How well the flu vaccine works can vary from year to year and from one person to another.

- 1. Vaccine effectiveness (VE) can vary depending on vaccine match and the health and age of the person getting vaccinated.
- 2. If the influenza viruses spreading are very different from the vaccine viruses, the vaccine won't work as well.
- 3. Another factor that influences VE is the age and health of the person being vaccinated.
- 4. In general, the flu vaccine works best among young healthy adults and older children.
- 5. Some older people and people with certain chronic illnesses might develop less immunity than healthy young adults after vaccination.
- 6. This means that VE can vary by season; it can vary by virus type and strain and it can vary from person to person, depending on how well they respond to vaccination.
- 7. While the vaccine match can vary, when match is good, vaccination offers substantial benefit, reducing illnesses, antibiotic use, doctors' visits and lost work and preventing hospitalizations and deaths.

VE is difficult to measure and study results can vary widely based on a) the study design, b) the outcome being measured and c) the population being studied.

- 1. "Randomized studies," in which people either get vaccine or placebo and then are followed to see who gets flu and who doesn't, are the "gold standard" for determining the effectiveness of a vaccine, but withholding a potentially life-saving vaccine, especially among high-risk people, has ethical implications, so CDC does not conduct randomized influenza vaccine effectiveness studies in the United States.
- 2. Studies to determine how effective a vaccine is often use a study method where "case" patients with influenza are compared to "control" patients who do not have influenza infections. Investigators have shown that study results can vary considerably on the basis of how control patients are selected and not because of the vaccines.
- 3. Vaccine effectiveness can be measured by looking at different outcomes, for example, measuring influenza-like illness (which can include non-influenza illness), or measuring laboratory-confirmed influenza infection which means that a laboratory test has been done to determine if a patient with respiratory illness has influenza or an infection caused by another respiratory pathogen. A broader outcome such as protection against influenza-like illness will be less precise than a more specific outcome such as laboratory-confirmed influenza infection; a more specific outcome is likely to give a better measure of VE.

In recent years, CDC has developed new and improved methodology to measure VE.

- 1. CDC has been working with researchers at universities and hospitals since 2003-04 to estimate VE in non-randomized studies using culture- or RT-PCR- confirmed influenza infection as the outcome.
- 2. CDC's study methodology currently uses RT-PCR-confirmed medically attended influenza infections as an outcome and is therefore likely to be more accurate and more specific.
- 3. The CDC study methodology looks at outcomes in several different sites across the United States to gather more representative data.

- 4. The methodology also looks at people of all age groups, so it should give a more accurate assessment of VE across the different age groups.
- 5. This study methodology should capture VE by season.

Recent studies show vaccine can protect about 6 out of 10 people from getting the flu during a well-matched season.

- 1. CDC-supported recent studies looked at outcomes in four different sites across the United States.
- 2. Overall estimates of vaccine effectiveness during the U.S. 2010-2011 through 2013-2014 influenza seasons ranged between about 50% and 60%.
- 3. Similar outcomes have been reported in other publications. Examples:
 - a) A randomized study (Monto et al.) looking at the 2007-2008 influenza season found trivalent inactivated vaccine (flu shot) protected 7 out of 10 people from influenza illness.
 - b) The main study that led to the licensure of LAIV was one conducted in children that showed that LAIV protected up to 9 out of 10 children vaccinated against the flu.
 - c) A meta-analysis of randomized clinical trials of LAIV in children found that 2 doses of LAIV in vaccine-naïve children prevented infection with 77% of antigenically similar viruses and 72% of all viruses regardless of antigenic similarity.
 - d) A meta-analysis of efficacy and effectiveness studies published in the Lancet Infectious Diseases in October 2011 found:
 - Overall, the flu shot (i.e., trivalent influenza vaccine or TIV, for short) had 59% efficacy against flu in healthy adults, according to the journal article.
 - The nasal spray flu vaccine (i.e., live attenuated influenza vaccine or LAIV, for short) prevented flu in 83% of children 7 years of age or younger.
 - The 2009 H1N1 monovalent vaccine used during the 2009 H1N1 pandemic had a median effectiveness of 69% against medically attended 2009 H1N1 illness in people younger than 65 years of age.
- 4. This is considered a moderate rate of vaccine effectiveness compared with effectiveness of many childhood vaccines and it is relatively stable across many age groups.
- 5. Improvements in vaccine technology to increase vaccine effectiveness are needed.
- 6. However, while not perfect, the flu vaccine offers the best protection we have against influenza right now.

There have been improvements in vaccine technology.

- 1. Vaccine manufacturers and researchers are working on improved influenza vaccines.
- 2. High-dose vaccine that creates a stronger immune response is being produced for people 65 and older. (Results from a clinical trial of more than 30,000 participants showed that adults older than 65 years of age who received the high dose vaccine had 24.2% fewer influenza infections as compared to those who received the standard dose flu vaccine.)
- 3. Quadrivalent vaccines that protect against four influenza viruses instead of three are now being produced.

- 4. An intradermal flu shot that requires less antigen to produce the same immune response is now being produced. This is useful because the same amount of available antigen can be used to make more doses of the vaccine.
- 5. Other studies are looking at the use of adjuvants that might improve how well vaccines work.

While continued improvements in vaccine technology are needed, influenza vaccination with currently available vaccines offers the best protection we have against seasonal flu at this time.

- 1. Vaccine manufacturers and researchers are working on improved influenza vaccines.
- 2. But recent studies have shown that when vaccine match is good, the vaccine can protect 6 out of every 10 people vaccinated from getting the flu.
- 3. Also, when more people are vaccinated, then more people are protected.
- 4. Some people don't respond well to vaccines. For these people, getting others around them vaccinated helps protect them.

Background on Waning Immunity

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- 1. Multiple studies conducted over different seasons and across vaccine types and flu virus subtypes have shown that the body's immunity to flu viruses (acquired either through natural infection or vaccination) declines over time. This decline in protective antibody has the potential to leave some people more vulnerable to infection, illness and possibly serious complications from the same flu viruses a year after being vaccinated.
- 2. Getting vaccinated each year provides the best protection against the flu throughout flu season.

2013-2014 Influenza Season: A Summary

- 1. The 2013-2014 flu season was a reminder of the unpredictability of flu.
- 2. After several recent flu seasons when H3N2 viruses predominated, H1N1 viruses were most common during the 2013-2014 season. The 2013-2014 flu season was the first season that 2009 H1N1 viruses have predominated since the 2009 H1N1 pandemic.
- 3. Flu activity in the United States peaked during the week ending December 28, 2013 (week 52) for the 2013-2014 season and began a downward trend in early January.
- 4. Since 2009, H1N1 viruses have been associated with relatively more frequent reports of severe flu illness among young and middle-aged adults.
- 5. During 2013-2014, CDC received reports of severe flu illness among young and middle-aged adults, many of whom were infected with the 2009 H1N1 virus. More than 60% of influenza-related hospitalizations were in people 18 to 64 years of age.

- 6. Among adults hospitalized with flu during the 2013-2014 flu season for whom hospital records were available, 89% had at least one underlying medical condition that increased their risk for influenza complications.
 - a) Obesity was the most common chronic health condition; 43% of adults hospitalized with flu during the 2013-2014 flu season were obese.
 - b) Other common chronic health conditions in adults hospitalized with flu were metabolic disorders and heart disease.
- 7. Among children hospitalized with flu during the 2013-2014 flu season for whom medical records were available, nearly 60% had at least one underlying medical condition. Asthma and neurologic disorders were the most common medical conditions among hospitalized children.
- 8. Among hospitalized women of childbearing age (15-44 years old) who were hospitalized with flu, more than 20% were pregnant. Flu vaccination is especially important for pregnant women to protect them from flu infection and to protect their unborn babies for up to six months after birth. (See <u>Statements for Pregnant Women</u>)
- 9. Last season, 105 laboratory-confirmed influenza-related pediatric deaths were reported to CDC. Neurologic disorders and pulmonary disease were among the most commonly reported medical conditions reported about children who died from flu.
- 10. One case of human infection with a novel influenza A virus (H3N2v) occurred during the 2013-2014 season in a child with known swine exposure.
- 11. Nearly all influenza virus specimens sent to CDC for antigenic characterization were like the components of the 2013-2014 Northern Hemisphere influenza vaccine.
- 12. By late February, 134 million doses of 2013-2014 influenza vaccine had been distributed in the United States.
- 13. CDC's estimate of the effectiveness of flu vaccines to prevent visiting a doctor due to flu illness was 61% for all age groups. This VE estimate means that getting a flu vaccine during the 2013-2014 flu season reduced the vaccinated population's risk of having to go to the doctor because of the flu by approximately 60% for both children and adults.
- 14. A report outlining influenza activity in the United States for the 2013-2014 flu season is available as an MMWR report: "Influenza Activity United States, 2013-14 Season and Composition of the 2014-15 Influenza Vaccines", http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6322a2.htm?s_cid=mm6322a2_w.