



2016-2017 INFLUENZA KEY POINTS

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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.
 - a) CDC recommends a yearly flu vaccine as the first and most important step in protecting against flu.
 - b) For the 2016-2017 season, CDC recommends use of the flu shot (inactivated influenza vaccine or IIV) or the recombinant influenza vaccine (RIV).
 - c) The nasal spray flu vaccine (live attenuated influenza vaccine or LAIV) should not be used during 2016-2017. (See section "Recommendation against LAIV" for more information.)
 - d) Flu vaccination can reduce flu illnesses, doctor visits, and missed work and school due to flu, as well as prevent flu-related hospitalizations.
 - e) While there are many different flu viruses, the flu vaccine protects against the viruses that research suggests will circulate the most this season.
 - f) Everyone 6 months of age and older should get a 2016-2017 flu vaccine, by the end of October, if possible. However, as long as flu viruses are circulating, vaccination should continue throughout the flu season, even in January or later.
 - g) Vaccination of people at high risk of developing serious influenza-related complications is especially important to decrease their risk of severe illness from flu.
 - o People at high risk of serious flu complications include young children, pregnant women, people with certain chronic health conditions like asthma, diabetes, or heart or lung disease, and people 65 years and older.
 - o The full list of high-risk conditions is available on the CDC website at http://www.cdc.gov/flu/about/disease/high_risk.htm.
 - h) Vaccination also is especially important for health care workers, and others who live with or care for people at high risk of serious flu-related complications.
 - i) 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 to protect the infant, yourself, and others.
 - j) Find a place near you to get flu and other recommended vaccines at <http://vaccine.healthmap.org/>.
 - k) Take the CDC quiz to find out which vaccines might be right for you: <http://www2.cdc.gov/nip/adultimmsched>.
 - l) (See the [Flu Vaccine section](#) for more key messages related to flu vaccination.)
2. Take everyday preventive actions to stop the spread of germs that can cause respiratory illnesses like the flu. While these actions are helpful, remember that vaccination is the most important step in preventing flu.
 - a) Try to avoid close contact with sick people.

2016-2017 Influenza Key Points continued

- b) If you are sick with flu symptoms, 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 go away without the use of a fever-reducing medicine.)
 - c) While sick, limit contact with others as much as possible to keep from infecting them.
 - d) 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.
 - e) 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.
 - f) Avoid touching your eyes, nose, or mouth because germs spread this way.
 - g) For more information, see <http://www.cdc.gov/flu/protect/habits/>.
3. Take flu antiviral drugs if your doctor prescribes them.
- a) If you get the flu, antiviral drugs can be used to treat your illness.
 - b) Antiviral drugs are prescription medicines (pills, liquid or an inhaled powder) and are not available over the counter.
 - c) Antiviral drugs are different from antibiotics. Antiviral drugs fight viruses (like flu viruses) in your body; antibiotics fight infections in your body that are caused by bacteria.
 - d) Antiviral drugs are not a substitute for getting a flu vaccine. The flu vaccine is the best way modern medicine currently has to protect against this potentially serious disease.
 - e) It's very important that antiviral drugs are used early to treat hospitalized patients, people with severe flu illness, and people who are at high risk of serious flu complications based on their age or health.
 - f) Most people who are otherwise healthy and get the flu do not need to be treated with antiviral drugs, but some people may be treated with antiviral drugs by their doctor. Antiviral drugs can make flu illness milder and shorten the time you are sick.
 - g) There also are data showing that antiviral drugs may prevent serious flu complications. For those with flu who also are at high risk of serious flu complications, treatment with an antiviral drug can mean the difference between having a milder illness instead of a very serious illness that could result in a hospital stay.
 - h) If you get the flu, the earlier you begin taking antivirals, the better. Antiviral drugs work best when started within two days of symptoms first appearing, but there are data to suggest they can still be beneficial in very ill patients even up to five days after getting sick. This would be especially important for a person who is at high risk of serious flu complications and who is very sick.
 - i) Three FDA-approved influenza antiviral drugs are recommended for use in the United States during the 2016-2017 influenza season: oseltamivir (Tamiflu®), zanamivir (Relenza®), and peramivir (Rapivab®). More information about antiviral drugs and antiviral drug resistance can be found at <http://www.cdc.gov/flu/antivirals/index.htm> and <http://www.cdc.gov/flu/about/qa/antiviralresistance.htm>.
 - j) For more information about antiviral drugs, visit <http://www.cdc.gov/flu/antivirals/index.htm>.
 - k) For more information about the flu or the flu vaccine, call 1-800-CDC-INFO or visit www.cdc.gov/flu.

What's New this Flu Season

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1. CDC recommends use of the flu shot (inactivated influenza vaccine or IIV) or the recombinant influenza vaccine (RIV). The nasal spray flu vaccine (live attenuated influenza vaccine or LAIV) should not be used during 2016-2017.
2. Two new flu vaccine options will be available during the 2016-2017 flu season.
 - a) One new vaccine is FLUAD™ which contains MF59, a type of adjuvant, and is licensed for use in people 65 years and older.
 - b) Adjuvant is an ingredient that helps create a stronger immune response in the patient's body.
 - c) A quadrivalent flu shot made with virus grown in cell culture will also be available for the first time this season and is licensed for use in people 4 years and older.
3. The 2016-2017 trivalent vaccines are recommended to contain:
 - a) an A/California/7/2009 (H1N1)pdm09-like virus
 - b) an A/Hong Kong/4801/2014 (H3N2)-like virus
 - c) a B/Brisbane/60/2008-like virus (B/Victoria lineage)
4. The 2016-2017 quadrivalent vaccines will contain the above three viruses as well as a B/Phuket/3073/2013-like virus (B/Yamagata lineage).
5. All cell culture and intradermal vaccines will be quadrivalent this season.
6. The egg allergy recommendations have been updated.
 - a) Anyone with an egg allergy can receive any licensed and recommended flu vaccine, however the vaccine should be administered in an inpatient or outpatient medical setting and they should be supervised by a health care provider who is able to recognize and manage severe allergic conditions.
 - b) People with egg allergies no longer have to wait 30 minutes after receiving their vaccine.
7. The vaccine timing language has been changed to say "You should receive a flu vaccine by the end of October, if possible."
8. Some children 6 months through 8 years old will require two doses of the flu vaccine this season.
 - a) The current recommendation is that children 6 months through 8 years of age need only one dose of 2016-2017 seasonal influenza vaccine if the child has previously received two or more total doses of any trivalent or quadrivalent influenza vaccine (including LAIV) before July 1, 2016. The two doses don't need to have been given during the same season or consecutive seasons.
9. Note: Instead of "morbid obesity" the term "extreme obesity" or "people with extreme obesity" should be used.
10. The 2016-2017 influenza vaccine recommendations were published in a CDC Morbidity and Mortality Weekly Report (MMWR) dated August 26, 2016 that is available at http://www.cdc.gov/mmwr/volumes/65/rr/rr6505a1.htm?s_cid=rr6505a1_w.

Statements for General Audiences

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2016-2017 Influenza Key Points continued

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 high risk of serious flu complications. These people include:
 - a) Children younger than 5 years, but especially children younger than 2 years old
 - b) People 65 years and older
 - c) Pregnant women and women up to 2 weeks after end of pregnancy
 - d) Residents of nursing homes and other long-term care facilities
 - e) American Indians and Alaskan Natives
 - f) People who have medical conditions, including:
 - Asthma
 - Neurological and neurodevelopmental conditions (including disorders of the brain, spinal cord, peripheral nerves, 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)
 - Chronic 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)
 - People younger than 19 years of age who are receiving long-term aspirin therapy
 - People with extreme obesity (Body Mass Index, [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 high risk of 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.
 - a) 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 high 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. Most people who get influenza will recover in several days to less than two weeks, but some people will develop complications as a result of the flu.
8. A wide range of complications can be caused by flu.

2016-2017 Influenza Key Points continued

9. Sinus and ear infections are examples of moderate complications from flu, while pneumonia is a serious flu complication that can result from either influenza virus infection alone or from co-infection of flu virus and bacteria.
10. Other possible serious complications triggered by flu can include inflammation of the heart (myocarditis), brain (encephalitis) or muscle (myositis, rhabdomyolysis) tissues, and multi-organ failure (for example, respiratory and kidney failure).
11. Flu virus infection of the respiratory tract can trigger an extreme inflammatory response in the body and can lead to [sepsis](#), the body's life-threatening response to infection.
12. Flu also can make chronic medical problems worse. For example, people with [asthma](#) may experience asthma attacks while they have the flu, and people with [chronic heart disease](#) may experience a worsening of this condition triggered by flu. 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.
13. Flu seasons are unpredictable.
14. It is not possible to predict how mild or severe the 2016-2017 flu season will be, or which influenza viruses will predominate.
15. The severity of flu seasons can differ substantially from year to year.
16. While the numbers vary, in the United States, millions of people are sickened, hundreds of thousands are hospitalized, and thousands to tens of thousands of people die from flu every year.
 - a) CDC estimates that since 2010, flu-related hospitalizations in the United States have ranged from 140,000 to 710,000 and flu related deaths have ranged from 12,000 to 56,000. <https://www.cdc.gov/flu/about/disease/2015-16.htm>

Vaccination

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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 an annual 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.
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 high 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.

2016-2017 Influenza Key Points continued

4. CDC recommends an annual flu vaccine as the first and best way to protect against the flu. There are two 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. U.S. flu vaccines made for 2016-2017 have been updated from last season's vaccines.
 - 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 the best protection.
5. CDC estimates the number of flu cases, medical visits, and hospitalizations prevented by vaccination each season. (Visit <http://www.cdc.gov/flu/about/disease/burden.htm> for more information.)
 - a) For example, during 2014-2015, flu vaccination prevented an estimated 1.9 million flu illnesses, 966,000 flu-associated medical visits, and almost 67,000 flu-associated hospitalizations even though vaccine effectiveness was only 23% during that season.
6. The composition of the flu vaccine is reviewed each year, and updated to better protect against the influenza viruses that research indicates will be the most common during the upcoming season.
7. The 2016-2017 U.S. flu vaccines have been updated for this season. Also, there are two new flu vaccine formulations available this flu season. (See "2016-2017 Flu Vaccine Options.")
8. Protect your family from the flu by getting yourself and your family members vaccinated.
9. Flu vaccines cannot cause flu infection or flu illness.
 - a) The most common side effects from a flu shot are a sore arm and maybe a low-grade fever or achiness. If you do experience these side effects, they are mild and short-lived.
10. The flu vaccine is used to **prevent** flu illness, not to treat it. Influenza antiviral drugs may be prescribed to **treat** flu. See [Antiviral Drug messages](#) for more information.
11. A flu vaccine protects against influenza viruses. It will not protect against other respiratory illnesses.
12. Most seasonal flu vaccines expire by the end of June, but some expire sooner. Health care providers should check expiration dates before administering the vaccine.
13. 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.

Vaccination Timing

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1. You should get a flu vaccine by the end of October, if possible. 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 since it takes

2016-2017 Influenza Key Points continued

about two weeks after vaccination for antibodies to develop in the body and provide protection against the flu.

3. The timing of flu outbreaks is unpredictable. While seasonal flu outbreaks can happen as early as October, in most seasons flu activity is highest 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.

Vaccination: Who Should Do It, Who Should Not and Who Should Take Precautions

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CDC recommends use of the flu shot (inactivated influenza vaccine or IIV) and the recombinant influenza vaccine (RIV). The nasal spray flu vaccine (live attenuated influenza vaccine or LAIV) should not be used during 2016-2017.

2016-2017 Influenza Key Points continued

The Flu Shot

People who can get the flu shot:

- Different flu shots are approved for people of different ages (see Note), but there are flu shots that are approved for use in people as young as 6 months of age and older. Flu shots are approved for use in pregnant women and people with chronic health conditions.

People who can't get the flu shot:

- Children younger than 6 months are too young to get a flu shot
- People with severe, life-threatening allergies to flu vaccine or any ingredient in the vaccine. See [Special Considerations Regarding Egg Allergy](#) 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.

2016-2017 Influenza Vaccine Options, Indications and Availability

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There are several flu vaccine options available for the 2016-2017 flu season.

1. 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 will be available. The flu vaccines recommended for use during the 2016-2017 season are all injectable vaccines (flu shots).
 - 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 [standard-dose trivalent shot](#) 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 older.

2016-2017 Influenza Key Points continued

Most flu shots are given with a needle. One flu vaccine also can be given with a needle-free [jet injector](#), for persons aged 18 through 64 years.

- A [high-dose trivalent shot](#), approved for people 65 years and older.
 - A [recombinant trivalent shot that is egg-free](#) (RIV3), approved for people 18 years and older.
 - New this season, a [trivalent](#) flu shot made using adjuvant (an ingredient of a vaccine that helps create a stronger immune response in the patient's body), approved for people 65 years and older. (See section "Adjuvanted Flu Vaccine.")
- b) The **quadrivalent** flu vaccine protects against two influenza A viruses and two influenza B viruses. The following quadrivalent flu vaccines are available:
- A [quadrivalent flu shot](#) approved for different ages, including one that can be given to children as young as 6 months of age.
 - An [intradermal quadrivalent flu shot](#), 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. All intradermal vaccines will be quadrivalent this season.
 - New this season, a quadrivalent flu shot ([FLUCELVAX®](#)) containing virus grown in cell culture is approved for people 4 years and older. Cell-based flu vaccine was first approved in 2012 as a trivalent vaccine. This season it will be quadrivalent.

Note: While there is a quadrivalent nasal spray vaccine that is FDA approved for the U.S. market, ACIP and CDC recommend that nasal spray vaccine should not be used during the 2016-2017 season because of concerns about how well it works.

2. CDC recommends use of flu shots during 2016-2017. ACIP and CDC recommend against nasal spray vaccine during 2016-2017.
3. Among injectable vaccines (flu shots), CDC does not have a preference for one vaccine over another. The important thing is to get vaccinated every year.
 - a) Flu shots include inactivated vaccines that are made with killed flu virus, and a recombinant vaccine which is made without flu viruses.
 - The age indications for the different flu shots vary, but all may be given to people with chronic medical conditions who are older than 6 months of age.
4. Flu vaccine is available in doctor's offices, pharmacies, public health clinics, and other locations.
5. Flu vaccine is produced by private manufacturers, so supply depends on manufacturers.
6. For the 2016-2017 season, manufacturers have projected they will provide as many as 157-168 million doses of injectable influenza vaccine.
7. Projections may change as the season progresses.
 - a) Of the total number of injectable influenza vaccine doses projected to be available for the 2016-2017 season, approximately 96 million doses are estimated to be quadrivalent influenza vaccines.
 - b) Of the total number of injectable influenza vaccine doses projected to be available for the 2016-2017 season, approximately 120 million doses are estimated to be thimerosal-free.

2016-2017 Influenza Key Points continued

8. Based on manufacturer projections, health officials expect that supply of IIV for the 2016-2017 season should be sufficient to meet any increase in demand resulting from the change in influenza vaccination policy which recommends against use of LAIV during 2016-2017.
9. Providers may need to check more than one supplier or purchase a flu vaccine brand other than the one they normally select, but overall supply should be adequate.
10. Providers who have purchased or pre-ordered LAIV will need to consult with the manufacturer or vaccine distributor.
11. For the latest information on flu vaccine supply, including projections and doses distributed, visit <http://www.cdc.gov/flu/professionals/vaccination/vaccinesupply.htm>. Information about past numbers of doses distributed is also available at that link.
12. Although flu vaccines are available for purchase from manufacturers and distributors, different health care professionals may receive their vaccine shipments at different times because of production and delivery schedules for different products.
13. While some flu vaccine may become available in 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.)
14. Don't delay getting a flu shot if you want one particular kind and it is not available. The important thing is to get a flu shot.
15. Every flu vaccine is formulated to offer important protection from influenza viruses.
16. For the complete list of flu vaccines approved for use during the 2016-2017 season, visit https://www.cdc.gov/mmwr/volumes/65/rr/rr6505a1.htm?s_cid=rr6505a1_w.

Flu Vaccine and Egg Allergy

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1. CDC and its Advisory Committee on Immunization Practices have updated their guidelines on egg allergy and receipt of influenza (flu) vaccines.
2. Based on new recommendations, people with egg allergies no longer need to be observed for an allergic reaction for 30 minutes after receiving a flu vaccine.
3. People with a history of egg allergy who have experienced only hives after exposure to egg can receive any licensed and recommended flu vaccine (i.e., any form of IIV, or RIV) that is otherwise appropriate for their age and health status.
4. If you are able to eat lightly cooked egg (e.g., scrambled egg) without reaction, you are unlikely to be allergic and can get any licensed and recommended flu vaccine.
5. People who report having had reactions to egg involving symptoms other than hives, such as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention, may similarly receive any licensed and recommended flu vaccine (i.e., any form of IIV, or RIV) that is otherwise appropriate for their age and health status. For these people, the vaccine should be given in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health departments, and physician offices), under the supervision of any health care provider who is able to recognize and manage severe allergic conditions.

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6. A person who has previously experienced a severe allergic reaction to flu vaccine, regardless of the component suspected of being responsible for the reaction, should not get a flu vaccine again.
7. In 2016, the Advisory Committee on Immunization Practices (ACIP) decided to remove the algorithm for ACIP recommendations regarding flu vaccination of persons who report allergy to eggs from the 2016-2017 guidance. CDC has created an updated version of the algorithm to reflect the new recommendations for this season that is available at <https://www.cdc.gov/flu/protect/vaccine/egg-allergies.htm>.

Background:

1. Egg allergy affects about 1.3% of all children and 0.2% of all adults.
2. Egg allergy can be confirmed by a consistent medical history of adverse reactions to eggs and egg-containing foods, plus skin and/or blood testing for immunoglobulin E antibodies to egg proteins.
3. Persons who are able to eat lightly cooked egg (e.g., scrambled egg) without reaction are unlikely to be allergic.
4. Egg-allergic persons might tolerate egg in baked products (e.g., bread or cake).
5. Tolerance to egg-containing foods does not exclude the possibility of egg allergy. Egg allergies can range in severity.
6. Most flu vaccines today are produced using an egg-based manufacturing process and thus contain a small amount of egg protein. There are a number of different egg proteins, but the egg protein content in a vaccine is usually expressed in terms of one of the proteins, ovalbumin.
7. While not all manufacturers disclose the amount of ovalbumin in their vaccines, those that did from 2011–12 through 2014–15 reported maximum amounts of ≤ 1 $\mu\text{g}/0.5$ mL dose for flu shots and 0.24 $\mu\text{g}/0.2$ mL dose for the nasal spray vaccine, a much smaller amount than would be present in an egg.
8. Cell-based flu vaccine (FLUCELVAX®) likely has a much smaller amount of egg protein since the original vaccine virus is grown in eggs, but mass production of that vaccine does not occur in eggs.
9. Recombinant vaccine (Flublok®) is the only vaccine currently available that is completely egg free.
10. Studies that have examined the use of both the nasal spray vaccine and flu shots in egg-allergic and non-egg-allergic patients indicate that severe allergic reactions in people with egg allergies are unlikely.
11. A recent CDC study found the rate of anaphylaxis after all vaccines is 1.31 per one million vaccine doses given.

Adjuvanted Flu Vaccine

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1. In November 2015, the U.S. Food and Drug Administration (FDA) licensed FLUAD™, which is a trivalent adjuvanted inactivated flu vaccine for people 65 years and older.

2016-2017 Influenza Key Points continued

2. An adjuvant is an ingredient added to a vaccine that helps create a stronger immune response to vaccination. The new flu vaccine, FLUAD™, was licensed in November 2015 and will be available for the 2016-2017 flu season.
3. FLUAD™ is a MF59-adjuvanted trivalent inactivated flu vaccine.
4. The adjuvant MF59 is an oil-in-water emulsion of squalene oil.
5. FLUAD™ is the first adjuvanted seasonal flu vaccine marketed in the United States.
6. Studies that have tested FLUAD™'s safety and ability to generate an immune response against an influenza virus (immunogenicity) have found that antibody levels were comparable to levels induced by unadjuvanted trivalent seasonal flu vaccines (e.g., Agriflu), and no safety concerns were identified.
7. FLUAD™ was initially approved in Italy in 1997, and at the time of its U.S. approval in November 2015, it had been licensed in 38 countries, including Canada and 15 European countries. More information about FLUAD™ is located in the package : <http://www.fda.gov/downloads/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM474387.pdf>

2016-2017 Influenza Vaccine Composition

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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.
4. Trivalent and quadrivalent flu vaccines are available during the 2016-2017 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 (from Victoria lineage).
 - 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 Victoria and Yamagata lineages).
5. Quadrivalent vaccines are intended to provide broader protection by adding another B virus to the vaccine.
6. The specific viruses for the 2016-2017 flu season vaccines were recommended by the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) on March 4, 2016.
 - a) All of the 2016-2017 influenza vaccine is made to protect against the following three viruses:
 - an A/California/7/2009 (H1N1)pdm09-like virus, an
 - an A/Hong Kong/4801/2014 (H3N2)-like virus; and
 - a B/Brisbane/60/2008-like virus (this is a B/Victoria lineage virus).
 - b) The quadrivalent vaccine also protects against an additional B virus B/Phuket/3073/2013-like virus. This is a B/Yamagata lineage virus.

2016-2017 Influenza Key Points continued

- c) There are two differences between what was recommended for the 2015-2016 Northern Hemisphere vaccines and the 2016-2017 Northern Hemisphere vaccines.
 - o The H3N2 vaccine virus component was updated. (A/Hong Kong/4801/2014 (H3N2)-like (“A/Hong Kong-like”) virus replaced A/Switzerland/9715293/2013 (H3N2)-like (“A/Switzerland-like”) virus.)
 - d) The B/lineage component in trivalent vaccines was switched with the extra B/ lineage component in quadrivalent vaccines. In trivalent vaccines, this means that a B/Yamagata virus was replaced with the B/Victoria vaccine component. (The quadrivalent vaccine composition remains the same.) The vaccine viruses recommended for inclusion in the 2016-2017 Northern Hemisphere influenza vaccines are the same vaccine viruses that were chosen for inclusion in 2016 Southern Hemisphere seasonal flu vaccines.
 - e) These vaccine recommendations were based on several factors, including global influenza virologic and epidemiologic surveillance, genetic characterization, antigenic characterization, antiviral resistance, and the candidate vaccine viruses that are available for production.
7. International surveillance suggested that these viruses would be the ones most likely to cause illness in the United States during the 2016-2017 season.
8. For more information about the composition of this year’s flu vaccine and how viruses for the seasonal flu vaccine are selected, visit <http://www.cdc.gov/flu/about/season/vaccine-selection.htm>.

Statements for Parents

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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 of 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:
 - o Are close contacts of, or live with, children younger than 5 years old.
 - o Are out-of-home caregivers (e.g. nannies, daycare providers, etc.) of children younger than 5 years old.
 - o Live with or have other close contact with children of any age with a chronic health condition (e.g. asthma, diabetes, etc.).
 - o Are health care workers.

2016-2017 Influenza Key Points continued

3. Every year in the United States, otherwise healthy children are hospitalized for or die from flu complications.
4. During 2015-2016, more than 15,000 children younger than 5 years were hospitalized from flu complications.
5. Flu-related hospitalizations of children younger than 5 years in the United States are estimated to have ranged from 7,000 to 26,000 since 2010.
6. 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.
7. 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.
8. Since 2004-2005, flu-related deaths in children reported to CDC during regular flu seasons have ranged from 37 deaths (during 2011-2012) to 171 deaths (during 2012-2013). During the 2009 H1N1 flu pandemic (April 15, 2009 to October 2, 2010), 358 pediatric deaths were reported to CDC.
9. Past data indicate that among children 6 months and older, 80 to 85 percent of flu-related pediatric deaths occurred in children who have not received a flu vaccine.
10. Information about pediatric deaths since the 2004-2005 flu season is available in the [interactive pediatric death web application](http://gis.cdc.gov/GRASP/Fluview/PedFluDeath.html) at <http://gis.cdc.gov/GRASP/Fluview/PedFluDeath.html>.
11. Vaccination is the first and most important step in protecting your family against the flu.
12. Children 6 months and older are recommended to get a yearly flu vaccine.
13. 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.
14. 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 [Antiviral Drugs messages](#).)
 - 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.
15. Be sure to let the doctor know if your child has any medical conditions like asthma, heart or lung conditions, neurologic conditions, or other medical problems.

2016-2017 Influenza Key Points continued

16. Be sure to let the doctor know if your child has ever experienced a reaction to the flu vaccine. (See [Egg Allergy messages.](#))
17. Children also should be current on other vaccines, including those that can help prevent pneumonia, like pneumococcal and Hib vaccines.
18. Talk to your child's doctor or other health care professional about getting a flu vaccine.
19. CDC also recommends that parents and children take everyday preventive actions to stop the spread of germs. (See [Everyday Preventive Actions messages.](#))
20. 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.
21. It is also important for pregnant women to get vaccinated to protect their developing babies.
22. Some studies have shown that vaccinating a pregnant woman can give her baby antibodies to protect against flu for several months after they are born.

Vaccine Doses for Children Aged 6 Months through 8 Years

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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.
 - a) The current recommendation is that children 6 months through 8 years of age need only one dose of 2016-2017 seasonal influenza vaccine if the child has previously received two or more total doses of any trivalent or quadrivalent influenza vaccine (including LAIV) before July 1, 2016. The two previous doses do not need to have been given during the same season or consecutive seasons.
 - b) [Children](#) 6 months through 8 years who have previously received only 1 dose or no doses of influenza vaccine need two doses of vaccine to be fully protected for the 2016-2017 season. If the vaccination status is unknown any child in this age group, that child should be given two doses of seasonal flu vaccine.
 - c) Some children 6 months through 8 years old will need two doses of vaccine to be protected against flu. Your child's health care professional can tell you whether two doses are recommended for your child.
2. Everyone 9 years of age and older needs only one dose of 2016-2017 flu vaccine to be protected.
3. To view a chart (algorithm) that shows influenza vaccine dosing recommendations for children aged 6 months through 8 years, visit https://www.cdc.gov/mmwr/volumes/65/rr/rr6505a1.htm?s_cid=rr6505a1_w.

Statements for Pregnant Women

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1. Getting a flu shot can protect pregnant women and their babies from the flu.
2. Vaccinating a pregnant woman can protect them from flu.

2016-2017 Influenza Key Points continued

3. Vaccinating a pregnant woman can also protect a baby after birth from flu. (Mom passes antibodies onto the developing baby during her pregnancy.)
 - a) Flu shots are a safe way to protect a mother and her baby from serious illness and complications of flu.
 - b) The flu shot has been given to millions of pregnant women over many years. The CDC continues to gather data showing that the flu shot is safe during pregnancy.
 - c) Pregnant women can receive the flu shot at any time, during any trimester, while pregnant.
 - d) Pregnant women are more likely to become severely ill with the flu than women who are not pregnant.
 - e) There is some evidence to suggest that a pregnant woman sick with the flu has a greater chance of certain pregnancy complications and that a flu vaccine can lessen that risk.
 - f) Getting a flu shot is the best way to protect you and your baby from the flu.
4. If you have additional questions, talk to your doctor about flu vaccination during pregnancy.
5. 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](#)).
6. 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 mothers should get a flu shot during pregnancy.
7. Breastfeeding is fully compatible with flu vaccination, and preventing the flu in mothers can reduce the chances that their babies will get the flu. If you have your baby before getting the flu shot, you should still be vaccinated.
8. 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. Persons of all ages are at risk from influenza illness.
2. Influenza seasons vary from year to year in terms of their timing, severity, and impact on different age groups.
3. All people 6 months of age and older, including all adults 18 years of age and older, are recommended to receive the seasonal flu vaccine annually.
4. Getting sick with the flu can result in missed school, work, and extracurricular activities and can result sometimes in severe illness with complications, hospitalizations, and sometimes even death.
5. Flu doesn't affect just those at high risk of flu complications like young children and seniors; it can affect people in any age group, including younger people who are otherwise healthy.
6. It is not possible to predict which influenza viruses will predominate this season, but it is important for all adults to be vaccinated this season.
7. Vaccination is important for adults with certain long-term medical conditions because they are at increased risk of serious illness if they get the flu. This group includes, for example, people with asthma (even if mild or controlled), heart disease, or diabetes (types 1 and 2).
8. By getting a flu vaccine, adults can help prevent spreading flu to friends and family who are at increased risk for flu complications such as pregnant women, grandparents, young children, and people with certain medical conditions like asthma or diabetes or those with a weakened immune system.
9. CDC recommends all adults and children also follow everyday preventive actions to reduce the spread of germs. (See [Everyday Preventive Actions messages](#).)
10. For the full list of age factors and medical conditions that put someone at increased risk of flu-related complications, see http://www.cdc.gov/flu/about/disease/high_risk.htm.
11. If you are at increased risk of serious flu complications and get sick with the flu, CDC recommends you be treated with antiviral drugs. ([See Antiviral Drugs messages](#).)
12. In addition to the flu vaccine, other vaccines that prevent serious diseases such as shingles, pneumonia caused by pneumococcal bacteria and meningitis, hepatitis, and whooping cough are recommended for adults. See [Vaccine Information for Adults](#) for more information.
13. Unfortunately, many adults are not up-to-date on vaccines recommended for them, leaving themselves and their loved ones unnecessarily vulnerable to serious diseases.
14. Adults should talk with their doctors or other health care professionals to learn which vaccines are recommended for them and take steps to stay up-to-date to ensure that they have the best protection.
15. Flu and other vaccines that adults are offered in many locations, including doctor's offices, health departments, pharmacies, health centers, travel clinics, as well as by many employers and schools.
16. 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

2016-2017 Influenza Key Points continued

pharmacies. Vaccines may also be offered at your school, college health center, or workplace.

Statements for Adults 65 Years and Older

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1. People's immune systems can become weaker with age which can place some people 65 years 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 people 65 years and older because people in this age group are at increased risk of getting seriously ill from the flu.
3. While flu seasons can vary in severity, during most seasons, people 65 years and older bear the greatest burden of severe flu disease.
4. In recent years, for example, CDC estimates that people 65 years and older have accounted for between about 60 to 80 percent of seasonal flu-related deaths and 40-75 percent of seasonal flu-related hospitalizations. So influenza is often quite serious for people 65 and older. This pattern can change depending on which flu viruses are circulating. Vaccination is the best protection against the flu and flu-related complications.
5. Protection provided by flu vaccination can vary depending on a number of factors including the age and health of the person being vaccinated.
6. In general, the flu vaccine works best among healthy adults and older children.
7. Some older people and people with certain chronic illnesses might develop less immunity than healthy children and adults after vaccination. However, even for these people, the flu vaccine still may provide some protection.
(<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 people 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 and older should be vaccinated, if possible, by the end of 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 during January or later.
8. Several flu vaccine options are available for people 65 years and older, including standard dose inactivated influenza vaccine, a high dose influenza vaccine, and a standard dose vaccine with adjuvant.
 - a) One vaccine option is a "high dose" flu vaccine (Fluzone® High-Dose) which contains four-times the antigen (the part of the vaccine that helps your body build up protection against flu viruses) than standard flu shots.
 - o Data from studies comparing trivalent Fluzone® vaccines, high dose and standard dose, among people 65 years and older found a stronger immune response (i.e. higher antibody levels) after vaccination with Fluzone® High-Dose.

2016-2017 Influenza Key Points continued

- 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% fewer influenza infections as compared to those who received the standard dose flu vaccine.
 - b) Another vaccine option is an “adjuvanted” flu vaccine (FLUAD™). FLUAD™ is a trivalent vaccine containing MF59 adjuvant for people 65 years and older. (FLUAD™ is the first adjuvanted flu vaccine marketed in the United States.)
 - In a Canadian observational study of 282 people 65 years and older conducted during the 2011-12 season, FLUAD™ was 63% more effective than regular-dose unadjuvanted flu shots.
 - There are no randomized studies comparing FLUAD™ with Fluzone® High-Dose.
 - Note: At this time, CDC and the ACIP have not expressed a preference for the high dose vaccine or adjuvanted vaccine over the standard-dose flu shot for people 65 years of age and older.
9. The “high dose” and adjuvanted flu vaccines may result in more of the mild side effects that can occur with standard-dose seasonal flu shots. Mild side effects can include pain, redness or swelling at the injection site, headache, muscle ache and malaise. In clinical trials, most people had minimal or no adverse events after receiving the Fluzone® High-Dose vaccine.
 10. Talk to your doctor or other health care professional about the best vaccine option for you.
 11. People 65 years of age and older should not get the nasal spray flu vaccine, the intradermal flu shot, or flu vaccine given using a jet injector.
 12. CDC recommends that people at high risk of serious flu complications be treated with flu antiviral drugs if they get sick with flu.
 - a) Flu antiviral drugs work best if taken within the first 48 hours after your symptoms start. Visit <http://www.cdc.gov/flu/antivirals/index.htm> for more information. (See Antiviral Drugs messages.)
 13. Pneumococcal disease can be a complication of influenza infection and includes pneumonia, meningitis and blood infections.
 14. Learn more about when pneumococcal vaccines are needed for adults: <http://www.cdc.gov/features/adult-pneumococcal>.
 - a) CDC recommends all adults 65 years or older receive 2 types of pneumococcal vaccines.
 - a) One dose of PCV13 first, followed at least 1 year later by one dose of PPSV23.
 15. 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.
 16. 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. Having the flu increases your chances of getting pneumococcal disease.
 17. For more information about flu and people 65 years or older, visit: <http://www.cdc.gov/flu/about/disease/65over.htm>.

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 chronic 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 chronic heart disease, receive a flu vaccine every year.
 - c) Stay in control of your health by getting your flu vaccine.
3. CDC recommends that people at high risk of serious flu complications be treated with flu antiviral drugs if they get sick with flu.
 - a) Flu antiviral drugs work best if taken within the first 48 hours after your symptoms start. Visit <http://www.cdc.gov/flu/antivirals/index.htm> for more information. (See Antiviral Drugs messages.)
4. For the full list of medical conditions that put you at a higher risk for serious flu complications, visit http://www.cdc.gov/flu/about/disease/high_risk.htm.

Diabetes

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1. While CDC recommends everyone 6 months and older get vaccinated against the flu, it is especially important to get a flu shot if you have diabetes (type 1 or 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. For example, flu illness can make it harder to control your blood sugars. Sometimes, when you are sick, your blood sugar goes up.
4. It is also possible for blood sugar levels to decrease, for example, if you can't eat or have nausea from flu illness.
5. People with diabetes sometimes have a harder time fighting infections.
6. 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, either type 1 or type 2 diabetes, should get an annual flu shot to protect themselves from flu.
7. People with diabetes should ask their family and friends to also get a flu vaccine to help reduce their chances of getting sick from flu illness.
8. Flu shots are approved for use in people with diabetes and other health conditions.

2016-2017 Influenza Key Points continued

9. If you have flu 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.
 - a) [Symptoms may include](#): Fever or feeling feverish/chills, cough, sore throat, runny or stuffy nose, muscle or body aches, headaches, fatigue (tiredness), and sometimes vomiting and diarrhea, though this is more common in children than adults.
10. CDC recommends that people at high risk of serious flu complications be treated with flu antiviral drugs if they get sick with flu.
 - a) Flu antiviral drugs work best if taken within the first 48 hours after your symptoms start. Visit <http://www.cdc.gov/flu/antivirals/index.htm> for more information. (See Antiviral Drugs messages.)
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

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1. Although people with asthma are not 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. 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.
7. CDC recommends that people at high risk of serious flu complications be treated with flu antiviral drugs if they get sick with flu.
 - a) Flu antiviral drugs work best if taken within the first 48 hours after your symptoms start. Visit <http://www.cdc.gov/flu/antivirals/index.htm> for more information. (See Antiviral Drugs messages.)
8. For more information about flu and asthma, visit <http://www.cdc.gov/flu/asthma/index.htm>.

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. People with heart disease may experience a worsening of this condition triggered by flu.

2016-2017 Influenza Key Points continued

3. 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.
4. Having the flu can worsen conditions, such as heart failure.
5. Flu shots are approved and highly recommended for use in people with heart disease or who have had a stroke.
6. 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.
7. Complications from the flu, like pneumonia, can put more stress on a person's heart.
8. CDC recommends that people at high risk of serious flu complications be treated with flu antiviral drugs if they get sick with flu.
 - a) Flu antiviral drugs work best if taken within the first 48 hours after your symptoms start. Visit <http://www.cdc.gov/flu/antivirals/index.htm> for more information. (See Antiviral Drugs messages.)
9. For more information about influenza and heart disease, visit <http://www.cdc.gov/flu/heartdisease/>.

Extreme Obesity

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1. People who have extreme obesity (people with a body mass index (BMI) of 40 or greater), 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, 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. People with obesity were disproportionately 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 patients with a BMI of 40 or greater were more likely to experience hospitalization, longer ICU stays, and death during the 2009 H1N1 pandemic.
5. Among adults hospitalized with flu during the 2015-2016 flu season, obesity was the most common chronic condition; 41.8% of adults hospitalized with flu were obese.
6. People with extreme obesity (a body mass index [BMI] of 40 or greater) 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 obese could have unrecognized chronic medical conditions.
7. Getting a flu vaccine is the most important action a person can take to prevent the flu and its complications. Because people who have a BMI of 40 or greater are at higher risk of flu complications, it is especially important that they get vaccinated every year to protect against the flu.
8. CDC recommends that people at high risk of serious flu complications be treated with flu antiviral drugs if they get sick with flu.

2016-2017 Influenza Key Points continued

- a) Flu antiviral drugs work best if taken within the first 48 hours after your symptoms start. Visit <http://www.cdc.gov/flu/antivirals/index.htm> for more information. (See Antiviral Drugs messages.)
9. For more information about those at high risk of flu-related complications and to learn more about body mass index, visit http://www.cdc.gov/flu/about/disease/high_risk.htm and <http://www.cdc.gov/healthyweight/assessing/bmi/>.

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 [Vaccine messages](#) above.)
2. 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 against the threat of flu, regardless of race/ethnicity, age, and health status.
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.)
5. During the 2009 H1N1 pandemic, approximately 10 percent of people hospitalized with flu-related complications were diabetic. Among adults 20 years of age and older, diabetes is more prevalent among Hispanics, with the highest prevalence rates among Mexican Americans and Puerto Ricans, compared with non-Hispanic whites.
6. A CDC study compared trends of flu vaccination coverage by race and ethnicity among children 6 to 23 months of age, and found that African American and Hispanic children had lower full flu vaccination coverage than non-Hispanic white children for 10 consecutive flu seasons (2002-2003 through 2011-2012).

Statements for American Indians and Alaska Natives

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1. 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>
 - b) The increased influenza mortality in AI/AN individuals was due to factors other than racial status. Prevention of influenza deaths should focus on modifiable factors (smoking, early antiviral use, access to care) and identifying high-risk persons for immunization and prompt medical attention.
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.

2016-2017 Influenza Key Points continued

3. 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. Flu is a leading cause of pneumonia. American Indian and Alaska Native people are more likely to die from pneumonia and influenza than other races.
5. 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.
6. 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.
7. The flu vaccine can help protect American Indians and Alaska Natives, including children, adults, and elders against the flu.
8. 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, 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).
9. CDC has prepared general messages for how all people, including American Indians and Alaska Natives, 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 on the Importance of Health Care Professional/Health Care Worker Recommendation and Vaccination

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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.
3. Visit <http://www.cdc.gov/flu/professionals/acip/> to view the 2016-17 Advisory Committee of Immunization Practices (ACIP) Influenza Vaccine Recommendations.
4. This season ACIP and CDC have recommended against use of the live attenuated influenza vaccine (LAIV) because of concerns about effectiveness.
5. During 2016-2017, vaccination is recommended with inactivated influenza vaccine (IIV) and recombinant influenza vaccine (RIV).
 - 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.

2016-2017 Influenza Key Points continued

- 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) Take every opportunity to help educate your patients about the importance of flu vaccination this and every year.
6. 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 flu.
7. 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.
8. Health care professionals should routinely offer seasonal flu vaccination to everyone aged 6 months and older, by the end of October, if possible, and continuing throughout the flu season, which can last as late as May.
9. 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.
<http://www.cdc.gov/vaccines/schedules/hcp/adult.html>
10. Visit [CDC's free influenza resources](http://www.cdc.gov/flu/freeresources/) (<http://www.cdc.gov/flu/freeresources/>) for references and resources to communicate about flu vaccination with patients, partners, and the community.
11. For the latest information on flu vaccine supply, including projections and doses distributed, visit <http://www.cdc.gov/flu/professionals/vaccination/vaccinesupply.htm>.
12. 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>.
13. Order free print resources from <http://www.cdc.gov/pubs/CDCInfoOnDemand.aspx> (search in drop-down box by "Immunization & Vaccines (Influenza/Flu)") or download from <http://www.cdc.gov/flu/freeresources/print.htm>.
14. 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](#)).
15. 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.

Statements for Health Care Personnel in Long-term Care Facilities

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1. All Health Care Personnel (HCP) in the long-term care (LTC) workforce are recommended to receive annual influenza vaccination.

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- a) Health care personnel includes physicians, physician's assistants, nurses, aides, attendants, therapists, emergency medical service personnel, pharmacists, and other categories of workers who do not interact directly with patients or residents. A list of who is considered health care personnel is available on the CDC website at <http://www.cdc.gov/flu/toolkit/long-term-care/snapshot.htm>.
2. Influenza is a serious health threat, especially to vulnerable populations like people 65 and older and those living with certain chronic medical conditions.
 - a) You can get the flu from patients and coworkers who are sick with the flu.
 - b) If you get the flu, you can spread it to others even if you don't feel sick.
 - c) By getting vaccinated, you help protect yourself, your family at home, and your patients.
 - d) People 65 years of age and older are at high risk for hospitalization and complications from the flu and account for the majority of flu hospitalizations and deaths in the United States each year.
3. It's important for people living with and caring for high risk persons, including those who work in long-term care, to get vaccinated against influenza each year.
4. Health care personnel should get their flu vaccine by the end of October, if possible. Ideally they should be protected before flu activity increases in their community.
5. CDC recommends the flu vaccine to long-term health care personnel in order to prevent influenza among health care personnel and to help reduce the spread of flu in resident populations.
 - a) Long-term health care personnel who are not vaccinated against the flu may become infected through contact with infected residents, other infected health care personnel, or infected people in the community, including friends and family members.
 - b) Unvaccinated health care personnel may spread influenza to residents, other health care personnel, and friends and family.
6. CDC reports specific recommendations for flu vaccination of health care personnel and recommendations for persons who live with or care for persons at high risk for influenza-related complications.
7. During flu season, health care personnel should not report to work if experiencing flu symptoms.
8. Studies have found an association between influenza outbreaks in long-term care facilities and hospitals and low flu vaccination coverage rates among health care personnel.
9. People 65 years and older are at high risk of serious complications from the flu compared with young, healthy adults, in part because human immune defenses become weaker with age.
 - a) While flu seasons can vary in severity, during most seasons, people 65 years and older bear the greatest burden of severe flu disease.
 - b) It's estimated that between 80 percent and 90 percent of seasonal flu-related deaths have occurred in people 65 years and older.
 - c) It's estimated that between 50 percent and 70 percent of seasonal flu-related hospitalizations have occurred among people 65 years and older.

2016-2017 Influenza Key Points continued

10. There are several reasons that health care personnel report that they get vaccinated against influenza. During the 2015-2016 influenza season, health care personnel, in general, reported the most common reason was to protect themselves from getting the flu.
 - a) Other commonly reported reasons included an employer requirement for flu vaccination and protecting their friends or family from flu.
11. The Healthy People 2020 annual target goal for influenza vaccination among health care personnel is 90 percent (see Healthy People 2020 objective IID-12.9).

Background:

1. As reported in the September 30, 2016 [Morbidity and Mortality Weekly Report](#) (MMWR), overall, 79.0% of health care personnel reported having received an influenza vaccination for the 2015-2016 season.
 - a) Vaccination coverage was highest among HCP working in hospitals (91.2%) and lowest among health care personnel working in long-term care settings (69.2%).
2. Studies show that during a confirmed influenza outbreak in a long-term care facility, up to one in three residents and one in four staff develop an influenza-like illness.
 - a) Preventing influenza among health care personnel can help reduce the spread of influenza in resident populations.
3. Studies have documented that health care personnel might report to work on days when they have a fever or a respiratory disease because they feel they are needed at work or they do not receive paid sick leave.
 - a) Sometimes health care personnel have mild flu symptoms but do not realize they have influenza and might report to work. During this time, those persons may still spread the virus to others.
 - b) To avoid this, people should stay away from sick people and stay home if sick.
 - c) During the influenza season, health care personnel should be encouraged to report influenza symptoms to their supervisors and to stay home if they are ill.
4. Health care personnel such as nursing assistants or nursing aides, home health aides, personal care aides provide 70-80% of hands-on LTC and personal assistance to vulnerable populations.

Flu Vaccine Safety

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General

1. Flu vaccines are among the safest medical products in use. Hundreds of millions of Americans have safely received flu vaccines over the past 50 years, and there has been extensive research supporting the safety of seasonal flu vaccines.
2. CDC recommends that everyone 6 months of age and older receive a flu vaccine every year. A flu vaccine is the best way to reduce your chances of getting the flu and spreading it to others.
3. The flu vaccine cannot cause flu.
4. Flu vaccine side effects are generally mild and go away on their own within a few days.

2016-2017 Influenza Key Points continued

5. Common side effects from the flu shot include soreness, redness, and/or swelling from the shot, headache, fever, muscle aches, and nausea.
6. Life threatening allergic reactions are rare. These signs would most likely happen within a few minutes to a few hours after the vaccine is given.
7. CDC and the Food and Drug Administration (FDA) closely monitor the safety of vaccines approved for use in the United States. CDC uses two primary systems to monitor the safety of flu vaccines:
 - a) [Vaccine Adverse Event Reporting System \(VAERS\)](#): an early warning system that helps CDC and FDA detect possible safety issues with U.S. vaccines. Anyone can report possible vaccine side effects to VAERS. Generally, VAERS reports cannot determine if an adverse event was caused by a vaccine, but these reports can help determine if further investigations are needed.
 - b) [Vaccine Safety Datalink \(VSD\)](#): A collaboration between CDC and nine health care organizations which allows ongoing monitoring and proactive searches of vaccine-related data.

Thimerosal

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1. Thimerosal is an ethyl mercury-based preservative used in vials that contain more than one dose of a vaccine (multi-dose vials) to prevent germs, bacteria, and/or fungi from contaminating the vaccine.
2. Thimerosal use in medical products has a record of being very safe. Data from many studies show no evidence of harm caused by the low doses of thimerosal in vaccines.
3. Flu vaccines in multi-dose vials contain thimerosal, to prevent contamination of the vial after the first dose has been removed. Most single-dose vials and pre-filled syringes of flu shot and the nasal spray flu vaccine do not contain a preservative because they are intended to be used once.
4. Of the 157-168 million injectable influenza vaccine doses projected to be available for the 2016-2017 season, approximately 120 million doses are estimated to be thimerosal-free.

Guillain-Barré Syndrome

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1. Guillain-Barré syndrome (GBS) is a rare disorder in which a person's own immune system damages their nerve cells, causing muscle weakness and sometimes paralysis.
2. Many things can cause GBS.
3. About two-thirds of people who develop GBS symptoms do so several days or weeks after they have been sick with diarrhea or a lung or sinus illness.
4. People also can develop GBS after having the flu or other infections (such as cytomegalovirus and Epstein Barr virus).

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5. On very rare occasions, people may develop GBS in the days or weeks after getting a vaccination.
6. In 1976 there was a small increased risk of GBS following vaccination with a flu vaccine made to protect against a swine flu virus. The increased risk was approximately 1 additional case of GBS per 100,000 people who got the swine flu vaccine.
 - a) The Institute of Medicine (IOM) conducted a thorough scientific review of this issue in 2003 and concluded that people who received the 1976 swine influenza vaccine had an increased risk for developing GBS.
 - b) Scientists have multiple theories on why this increased risk may have occurred, but the exact reason for this association remains unknown.
7. 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. Studies suggest that it is more likely that a person will get GBS after getting the flu than after vaccination.
8. It is important to keep in mind that severe illness and death are associated with flu, and vaccination is the best way to prevent flu infection and its complications.

Febrile Seizures

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1. A "febrile seizure" refers to a seizure/convulsion in a child associated with a fever.
2. Febrile seizures usually last around one or two minutes and can occur with any illness that causes fever, such as colds, flu, ear infection, or roseola.
3. They are most common with fevers of 102°F (38.9°C) or higher, but they can also happen at lower body temperatures or when a fever is going down. A person experiencing a febrile seizure may lose consciousness.
4. Most febrile seizures happen in children between the ages of 6 months and 5 years. Up to 5% of young children will have at least one febrile seizure. The most common age range for children to have febrile seizures is 14–18 months.
5. Febrile seizures can be frightening, but nearly all children who have a febrile seizure recover quickly, are healthy afterwards, and do not have any permanent neurological damage. Febrile seizures do not make children more likely to develop epilepsy or any other seizure disorder.
6. Several studies of children in the United States have been conducted to see if there is an increased risk for febrile seizures following seasonal flu vaccination.
7. Flu vaccine was not found to be associated with febrile seizures in one study that looked at 45,000 children aged 6 months through 23 months of age who received a flu vaccine from 1991 through 2003.
8. Seasonal flu vaccine and the 2009 H1N1 flu vaccine was not found to be associated with febrile seizures in children during the 2009-10 flu season.
9. Studies have detected a small increased risk of febrile seizures in young children following inactivated influenza vaccine in some influenza seasons. The risk of febrile

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seizures has been highest in children 12 through 23 months of age and highest when the flu shot is given together with [pneumococcal conjugate vaccine \(PCV13\)](#) and/or the combination [diphtheria, tetanus, and pertussis vaccines \(DTaP\)](#). The CDC carefully reviewed the data on febrile seizures and considered the benefits of vaccinating children against these illnesses, and decided that no changes in the childhood immunization recommendations should be made.

Allergy and Flu Vaccine

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1. People who have had a severe (life-threatening) allergy or reaction to a previous flu vaccine should not be vaccinated.
2. For information on the flu vaccine and egg allergy, please see the Flu Vaccine and Egg Allergy section of this document.

Flu Vaccine and Pregnancy

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1. CDC recommends that pregnant women get a flu shot during any trimester of their pregnancy to protect themselves and their newborn babies from flu.
2. Flu is more likely to cause severe illness in pregnant women than in healthy women who are not pregnant.
3. Changes in the immune system, heart, and lungs during pregnancy make pregnant women (and women who have recently given birth) more prone to severe illness from flu, as well as to hospitalizations and even death.
4. There is some evidence to suggest that getting the flu during pregnancy may also raise the risk of certain pregnancy complications, including premature labor and delivery.
5. Vaccination helps protect women during and after pregnancy. Getting vaccinated can also protect a baby after birth from flu. (Mom passes antibodies onto the developing baby during her pregnancy.)
 - a) A study that looked at flu vaccine effectiveness in pregnant women found that vaccination reduced the risk of flu-associated acute respiratory infection by about one half.
 - b) Another study found that babies of women who got a flu vaccine during their pregnancy were up to one-half as likely to get sick with flu than babies of unvaccinated women. This protective benefit was observed for up to four months after birth.
6. Some studies have shown that a flu vaccine may reduce the risk of certain pregnancy complications.
7. Studies also have shown that vaccinating a pregnant woman can pass antibodies on to the baby that will protect against flu for several months after birth.
8. A review of reports to the Vaccine Adverse Reporting System ([VAERS](#)) ([Moro et al, 2011](#)) found no link between pregnancy complications or adverse fetal outcomes among pregnant women and flu shots or nasal spray flu vaccine.

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9. A study using Vaccine Safety Datalink ([VSD](#)) data ([Irving et al, 2013](#)) found no increased risk of miscarriage among pregnant women who received flu vaccines in the 2005-06 or 2006-07 flu seasons.
10. A large study using [VSD](#) data ([Kharbanda et al, 2013](#)) found no increased risk for adverse obstetric events (like chorioamnionitis, pre-eclampsia, or gestational hypertension) for pregnant women who received the flu vaccine from 2002 to 2009 when compared to pregnant women who were not vaccinated.
11. A [VSD](#) study ([Nordin et al, 2014](#)) compared pregnant women who received the flu shot with an equal number of pregnant women who did not receive the flu shot during the 2004-05 and 2008-09 flu seasons, and found no differences between the two groups in the rates of premature delivery or small for gestational age infants. There is a large body of scientific studies that supports the safety of flu vaccine in pregnant women and their babies. The CDC continues to gather data on this topic.
12. The most common side effects experienced by pregnant women are the same as those experienced by other people. They are generally mild and include soreness, redness, and/or swelling from the shot, fainting, headache, fever, muscles aches, nausea, and fatigue.
13. Breastfeeding women should get vaccinated, too. Getting vaccinated reduces the mothers' risk of getting sick and of passing the flu on to her baby, thus protecting the baby from flu as well.
14. Vaccination for a pregnant or breastfeeding mother is especially important for children younger than 6 months old since they are too young to be vaccinated themselves.

Flu Vaccine Effectiveness

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2. Flu vaccines protect against infection and illness caused by flu viruses.
3. Flu vaccines will NOT protect against infection and illness caused by other viruses that can also cause flu symptoms.
 - a) There are many other viruses besides flu that can result in influenza-like illness (ILI) that spread during the flu season.
4. 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.
5. 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.
6. 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.
7. 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.

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8. Recent studies by CDC researchers and other experts indicate that flu vaccine reduces the risk of doctor visits due to flu by approximately 50-60% among the overall population when the vaccine viruses are like the ones spreading in the community.
9. Some studies* have shown that flu vaccination can reduce the risk of more serious flu outcomes, including hospitalizations.
10. Studies also have shown that flu vaccination is an important preventive tool for people with chronic health conditions.
11. Vaccination helps protect women against influenza during pregnancy and their babies for several 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.
12. Other studies have shown that flu vaccination can reduce the risk of flu-related hospitalizations in older adults.
13. How well the flu vaccine works can vary by season, virus type/subtype, the kind of vaccine, and age and other host factors of the people being vaccinated.
14. 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.
15. 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.
16. People 65 years and older, 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.
17. 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 effectiveness can be lower.
18. 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.
 - a) When flu vaccine and the circulating flu viruses are not well matched, the use of influenza antiviral (or "anti-flu") medications may be more important than usual.
19. 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.
20. 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.
21. 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

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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.

22. 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>.*

Vaccine Effectiveness Last Season

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1. During the 2015-2016 season, most circulating flu viruses were like the recommended vaccine viruses.
2. End-of-season vaccine effectiveness estimates were presented to ACIP on June 22, 2016.
3. Overall flu vaccine effectiveness was about 50% during the 2015-2016 season.
4. This finding is comparable to past estimates for seasons when most circulating flu viruses and vaccine viruses have been similar.
5. Effectiveness for LAIV (the nasal spray), however, was poor.
 - a) During the 2015-2016 season, VE data provided by the U.S. Flu VE Network indicated that LAIV offered no significant protection against the predominant flu virus [i.e., influenza A (H1N1)pdm09] among study participants age 2 through 17 years of age.
 - b) Preliminary estimate of VE against any influenza virus for LAIV was 3% (95% CI -49% to 37%), and for IIV was 63% (95% CI 52% to 72%).
 - c) Preliminary estimate of VE against influenza A (H1N1)pdm09 virus for LAIV was -21% (95% CI -108% to 30%), and for IIV it was 65% (95% CI 49% to 76%).
 - d) Preliminary estimate of VE against influenza B viruses, for LAIV among children aged 2 through 17 years was -4% (95% CI -141% to 55%) for Yamagata-lineage viruses, and 31% (95% CI -62% to 70%) for Victoria-lineage viruses.
 - e) In contrast, VE of IIV was 64% (95% CI 31% to 81%) for Yamagata-lineage viruses, and 56% (95% CI 29% to 72%) for Victoria-lineage viruses.
6. There was evidence that VE for IIV was statistically better than LAIV for influenza A (H1N1)pdm09 virus but not for influenza B viruses (lineages combined); VE for influenza A (H3N2) viruses could not be assessed due to too few infections.
7. This data, combined with data from two previous seasons, led ACIP to recommend against use of the LAIV (i.e. nasal spray) vaccine during 2016-2017.

Vaccine Effectiveness This Season

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1. The vaccine composition for the Northern Hemisphere vaccine is reviewed annually in February so that the vaccine can be updated to include vaccine viruses that protect against currently circulating viruses.
2. Two of the vaccine virus components from last season were updated for this season. (The influenza A (H3N2) virus and the influenza B virus components have been updated.)

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3. Laboratory data can give a general indication of how well the vaccine might work. Vaccine effectiveness studies are needed to tell how well the vaccine is actually protecting against illness.
4. CDC will continue to carefully look at the results of laboratory studies of currently circulating viruses to look for any evidence of these viruses.
5. CDC also will conduct vaccine effectiveness studies in 5 sites across the United States to actually measure how well the vaccine is protecting against medically attended flu illness this season.
6. CDC will provide new information about circulating viruses and vaccine effectiveness as it becomes available this season.

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

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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 in a population, 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.

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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.
 - a) 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. 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 flu vaccines' effectiveness at preventing outpatient medical visits and hospitalizations 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.

Similar studies are being conducted in Australia, Canada, and Europe.

Improvements in Vaccine Technology

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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 years 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. An adjuvanted vaccine designed to improve the immune response for people 65 years and older has been approved for use in the United States.
4. Quadrivalent vaccines that protect against four influenza viruses instead of three are now being produced.

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5. 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.
6. Recombinant vaccines can be manufactured more quickly than either egg-based or cell-based flu vaccines and do not require an egg-grown virus or eggs to produce.
7. 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.

2015-2016 Influenza Season: A Summary

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1. On June 10, 2016, a report titled "Influenza Activity – United States, 2015-16 Season and Composition of the 2016-17 Influenza Vaccine," was published in a [Morbidity and Mortality Weekly Report \(MMWR\)](http://www.cdc.gov/mmwr/index.html). <http://www.cdc.gov/mmwr/index.html>
2. Influenza activity remained low from October 2015 until late December 2015 and peaked in mid-March 2016.
3. Influenza A (H1N1)pdm09 viruses predominated overall, but influenza A (H3N2) viruses were more commonly identified from October through December, and influenza B viruses were more commonly identified from mid-April through mid-May.
4. Compared with recent previous seasons (2012-13, 2013-14, 2014-15), this was a moderate season with lower activity and a later peak.
5. Of the most recent 18 influenza seasons, including the 2015-16 season, only two other seasons have peaked in March (i.e., 2011-12 and 2005-06).
6. The peak month is when, relative to other months in the season, laboratories report the highest portion of influenza-positive specimens. Individual regions often peak at different times.
7. The season was also less severe overall compared with the preceding three seasons, including 2013-14, when influenza A (H1N1)pdm09 viruses predominated.
8. Compared with the three preceding seasons, overall there was a lower percentage of outpatient visits for influenza-like illness (ILI), lower hospitalization rates, and a lower percentage of deaths attributed to pneumonia and influenza (P&I).

Interim Recommendation Against Use of LAIV

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1. The Advisory Committee on Immunization Practices and CDC have recommended annual influenza vaccination for all persons 6 months and older since February 2010. The so-called "universal" recommendation remains in place.
2. On June 22, 2016, however, ACIP voted to recommend a change in U.S. influenza vaccination policy for 2016-2017.
3. The ACIP recommendation has been reviewed and approved by CDC's Director.
4. The 2016-2017 influenza vaccine recommendations were published in a CDC Morbidity and Mortality Weekly Report (MMWR) dated August 26, 2016 that is available at http://www.cdc.gov/mmwr/volumes/65/rr/rr6505a1.htm?s_cid=rr6505a1_w.
5. As advised by the CDC Advisory Committee on Immunization Practices (ACIP), CDC recommends:

2016-2017 Influenza Key Points continued

- a) Injectable flu vaccines — inactivated influenza vaccine (IIV) or recombinant influenza vaccine (RIV) — should be used during 2016-2017.
 - b) The intranasal live attenuated influenza vaccine (LAIV) sold under the Trade Name “FluMist Quadrivalent,” should not be used during the 2016-2017 flu season.
6. This is an interim recommendation that applies to the 2016-2017 season only.
 7. The recommendation against the use of LAIV is based on concerns about effectiveness. (There were no safety concerns associated with LAIV.)
 8. LAIV was initially licensed during 2003 by the Food and Drug Administration (FDA) as a trivalent (three-component) vaccine under the Trade Name “FluMist.” It was approved for use among healthy, non-pregnant persons 5 years through 49 years of age, and was later licensed for persons 2 years through 49 years of age.
 9. During 2012, “FluMist Quadrivalent” (four-component LAIV) was licensed.
 10. Data on LAIV effectiveness has been inconsistent over time.
 11. VE data for LAIV before and soon after the original licensure suggested LAIV was either comparable to, or better than, IIV.
 12. Data from 2013-14 and 2015-16, however, showed poor or relatively lower effectiveness of LAIV against the predominant circulating H1N1 viruses.
 13. FluMist Quadrivalent is still an FDA-licensed product.
 14. As such, there may be some available supply of FluMist Quadrivalent in the United States during the 2016-2017 season.
 15. It is important for clinicians and the public to be aware that because of concerns about this vaccine’s effectiveness, CDC recommends that this vaccine not be used during the 2016-2017 influenza season.
 16. FDA and CDC have important but different roles with regard to the use of vaccines in the U.S.
 17. FDA evaluates drugs and vaccines for safety and efficacy and has the regulatory authority for approval of vaccines in the United States. FDA approves vaccines for use and determines the purpose and populations for which use is approved (also called “indications”). Flu vaccines are generally approved (indicated) for the prevention of influenza in specific age groups.
 18. CDC and its Advisory Committee on Immunization Practices (ACIP) make public health recommendations for the use of approved vaccines. Consideration of effectiveness and safety data may sometimes lead to recommendations that are more specific or more limited than those outlined in the FDA-approved indications.
 19. The change in the recommendation underscores the importance of ongoing efforts to measure and evaluate the effectiveness of public health interventions, including VE studies, which can have significant implications for public health policy.
 20. This is an example of using new data to hone public health practice to be most beneficial.
 21. Based on manufacturer projections, health officials expect that supply of IIV for the 2016-2017 season should be sufficient to meet any increase in demand resulting from the ACIP recommendation, though providers may need to check more than one supplier or purchase a flu vaccine brand other than the one they normally select.