2015-2016 Flu Season Key Points
September 10, 2015

Contents

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) Flu vaccination can reduce flu illnesses, doctor visits, and missed work and school due to flu, as well as prevent flu-related hospitalizations.
   c) While there are many different flu viruses, the flu vaccine protects against the viruses that research suggests will circulate the most this season.
   d) Everyone 6 months of age and older should get a 2015-2016 flu vaccine, if possible by October. However, as long as flu viruses are circulating, vaccination should continue throughout the flu season, even in January or later.
   e) Vaccination of people at high risk of developing serious influenza-related complications is especially important to decrease their risk of severe illness as a result of flu.
      - People at high risk of serious flu complications include young children, pregnant women, people with certain chronic health conditions like asthma, diabetes, or heart and lung disease, and people aged 65 years and older.
      - The full list of high-risk conditions is available on the CDC website at http://www.cdc.gov/flu/about/disease/high_risk.htm.
   f) 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.
   g) 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.
   h) (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.
   b) If you are sick with flu-like illness, CDC recommends that you stay home for at least 24 hours after your fever is gone, except to get medical care or for other necessities. (Your fever should be gone without the use of a fever-reducing medicine.)
   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 bacterial infections.

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) Not everyone who has flu symptoms needs antiviral drugs. Your doctor will decide whether antiviral drugs are right for you.

f) 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 have a high risk medical condition, 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 if 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 with a high risk medical condition who is very sick.

i) Three FDA-approved influenza antiviral medications are recommended for use in the United States during the 2015-2016 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.

Statements for General Audiences

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Disease

1. Influenza (the flu) can be a serious disease that can lead to hospitalization and sometimes even death. Anyone can get sick from the flu.
2. While the flu can make anyone sick, certain people are at greater risk of serious flu complications. These people include:

a) Children younger than 5 years, but especially children younger than 2 years old

b) Adults 65 years of age and older
c) Pregnant women
d) Residents of nursing homes and other long-term care facilities
e) American Indians and Alaskan Natives seem to be at higher risk of flu complications
f) People who have medical conditions including:

- Asthma
- Neurological and neurodevelopmental conditions [including disorders of the brain, spinal cord, peripheral nerve, and muscle such as cerebral palsy, epilepsy (seizure disorders), stroke, intellectual disability (mental retardation), moderate to severe developmental delay, muscular dystrophy, or spinal cord injury].
- Chronic lung disease (such as chronic obstructive pulmonary disease [COPD] and cystic fibrosis)
- 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 who are obese with a 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 increased 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 increased risk of serious complications from flu.
5. Symptoms of the flu can include fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills and fatigue. Some people may also have vomiting and diarrhea.
6. People may also be infected with the flu and have no symptoms at all, or have only respiratory symptoms without a fever.
7. Flu viruses are constantly changing. Each flu season, different flu viruses can spread, and they can affect people differently based on differences in their immune systems. Even healthy children and adults can get very sick from the flu.
8. Flu seasons are unpredictable.
9. It is not possible to predict how mild or severe the 2015-2016 flu season will be, or which influenza viruses will predominate.
10. The severity of flu seasons can differ substantially from year to year.
11. While the numbers vary, in the United States, millions of people are sickened, hundreds of thousands are hospitalized and thousands or tens of thousands of people die from flu every year.

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 greater risk of getting seriously ill from flu, like older adults, people with chronic medical conditions and young children (especially infants younger than 6 months old who are too young to get vaccinated).
    c) Flu vaccination also may make your illness milder if you do get sick.
    d) Flu vaccination can reduce the risk of more serious flu outcomes, like hospitalizations.
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.
    b) The second reason that annual vaccination is recommended is that a person's immune protection from the vaccine declines over time. Annual vaccination is needed for best protection.
5. 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 2013-2014, flu vaccination prevented an estimated 7.2 million flu-associated illnesses and 90,000 flu hospitalizations.
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. Even when the vaccine composition does not change, new flu vaccine is manufactured every season. (Most seasonal flu vaccine expires by the end of June, with the exception of LAIV (nasal spray vaccines) which expires throughout the season.)
7. Protect your family from the flu by getting yourself and your family members vaccinated.
8. While the flu can make anyone sick, certain people are at greater risk of serious complications from the flu. These people include:
    a) Children younger than 5 years, but especially children younger than 2 years old
    b) Adults 65 years of age and older

c) Pregnant women

d) American Indians and Alaskan Natives seem to be at higher risk of flu complications

e) People who have medical conditions including:

- Asthma
- Neurological and neurodevelopmental conditions [including disorders of the brain, spinal cord, peripheral nerve, and muscle such as cerebral palsy, epilepsy (seizure disorders), stroke, intellectual disability (mental retardation), moderate to severe developmental delay, muscular dystrophy, or spinal cord injury].
- Chronic lung disease (such as chronic obstructive pulmonary disease [COPD] and cystic fibrosis)
- 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 who are obese with a Body Mass Index, (BMI) of 40 or greater.

9. For more information about people at high risk of serious flu-related complications visit: http://www.cdc.gov/flu/about/disease/high_risk.htm.
10. 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 fever or achiness. The nasal spray flu vaccine might cause congestion, runny nose, sore throat, or cough as side effects. If you do experience them at all, these side effects are mild and short-lived.

11. 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.)
12. A flu vaccine protects against influenza viruses. It will not protect against other respiratory viruses that may cause symptoms that are similar to those seen with flu infection.
13. In addition to the flu vaccine, other vaccines that prevent serious diseases such as shingles, pneumonia caused by pneumococcal bacteria, hepatitis, meningitis and whooping cough are recommended for adults. See Vaccine Information for Adults for more information.
14. Unfortunately, few adults are aware that they need other vaccines, leaving themselves and their loved ones unnecessarily vulnerable to serious diseases.
15. Adults should talk with their doctors or other health care professionals to learn which other vaccines are recommended for them and take steps to stay up-to-date to ensure that they have the best protection.
16. Medicare Part B covers flu, pneumococcal, and hepatitis B vaccines for high-risk persons and tetanus vaccine as part of wound management.

17. Most health insurance plans cover the cost of recommended vaccines. Check with your insurance provider for details of coverage. If you do not currently have health insurance, visit www.HealthCare.gov to learn more about affordable health coverage options.
18. As part of the Affordable Care Act, many insurance plans, including all plans in the Health Insurance Marketplace, will provide many free preventive services when given by an in-network provider, including flu vaccinations. For information about the Health Insurance Marketplace, visit www.HealthCare.gov.
19. For more information about the seriousness of the flu and the benefits of flu vaccination, talk to your doctor or other health care professional, visit www.cdc.gov/flu, or call CDC at 1-800-CDC-INFO.
20. Visit CDC's website on adult vaccination for more information: http://www.cdc.gov/vaccines/adults.
21. Flu and other adult vaccines are offered in many locations, including: doctor's offices, clinics, health departments, retail stores, pharmacies, health centers, as well as by many employers and schools.
22. Even if you don't have a regular doctor or other health care professional, you can get a flu vaccine and other adult vaccines in other locations, like health departments or pharmacies. Vaccines may also be offered at your school, college health center or workplace.
23. Find a place near you to get flu and other recommended vaccines at http://vaccine.healthmap.org/.
24. Take the CDC quiz to find out which vaccines might be right for you: http://www2.cdc.gov/nip/adultimmsched

Vaccination Timing

1. You should get a flu vaccine soon after it becomes available, if possible by October, to ensure that you are protected before flu season begins. However, as long as flu viruses are circulating, vaccination should continue throughout the flu season, even in January or later.
2. It is not possible to know exactly when the flu season will start each year. It is best to get vaccinated before influenza viruses start to spread in your community since it takes 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, most of the time 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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The Flu Shot	The Nasal Spray Vaccine
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 up. 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:**	**People who can get the nasal spray vaccine:** The nasal spray vaccine is approved for use in people 2 years through 49 years of age. **People who cannot get the nasal spray vaccine:** Children younger than 2 years Adults 50 years and older People with a history of severe allergic reaction to any component of the vaccine or to a previous dose of any influenza vaccine People who are allergic to eggs Children or adolescents (2 years through 17 years of age) on long-term aspirin treatment. Pregnant women People with weakened immune systems (immunosuppression) Children 2 years through 4 years who have asthma or who have had a history of wheezing in the past 12 months. People who have taken influenza antiviral drugs within the previous 48 hours. People who care for severely immunocompromised persons who require a protective environment (or otherwise avoid contact with those persons for 7 days after getting the nasal spray vaccine).

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.	**People who should talk to their doctor before getting nasal spray vaccine:** There are also other "warnings and precautions" for the nasal spray flu vaccine. You should talk to your doctor if you have any of these: Asthma: People of any age with asthma might be at increased risk for wheezing after getting the nasal spray vaccine. A chronic condition like lung disease, heart disease, kidney or liver disorders, neurologic/neuromuscular, or metabolic disorders. The safety of the nasal spray vaccine has not been established in people with underlying medical conditions that place them at high risk of serious flu complications. See People at High Risk of Developing Flu–Related Complications. If you ever had Guillain-Barré Syndrome (a severe paralyzing illness, also called GBS). Some people with a history of GBS should not get this vaccine. Talk to your doctor about your GBS history. If you have gotten any other vaccines in the past 4 weeks, or if you are not feeling well.

2015-2016 Influenza Vaccine Options, Indications and Availability

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1. There are several flu vaccine options available for the 2015-2016 flu season.

2. Flu vaccines made to protect against three different flu viruses (called "trivalent" vaccines) will be available this season. In addition, flu vaccines made to protect against four different flu viruses (called "quadrivalent" vaccines) also are available.

   a) **Trivalent** flu vaccines protect against two influenza A viruses (an H1N1 and an H3N2) and an influenza B virus. The following trivalent flu vaccines are available:

      - A 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 up. 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 aged 65 years and older.
      - A trivalent shot containing virus grown in cell culture, which is approved for people 18 and older.
      - A recombinant trivalent shot that is egg-free (RIV3), approved for people 18 years and older.

   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, but there is a quadrivalent flu shot that can be given to children as young as 6 months of age.
      - An intradermal quadrivalent 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.
      - A quadrivalent nasal spray vaccine, approved for people 2 years through 49 years of age. All nasal spray vaccines will be quadrivalent this season.

3. CDC does not recommend one flu vaccine over the other. The important thing is to get vaccinated every year.

4. Flu vaccines can be given in two ways, as a shot or as a nasal spray.

   a) The flu shot is an inactivated vaccine that is made with killed flu virus.
      - The age indications for the different flu shots vary, but all may be given to people with chronic medical conditions.

   b) The nasal spray flu vaccine is made with live, weakened flu viruses.
      - The nasal spray vaccine is approved for use in people 2 years through 49 years of age.
        - See http://www.cdc.gov/flu/about/qa/nasalspray.htm for a complete list of people who can and cannot receive the nasal spray flu vaccine.
      - All nasal spray flu vaccine for the 2015-2016 flu season will be quadrivalent (made to protect against four flu viruses).

5. Flu vaccine is available in doctor's offices, pharmacies, public health clinics and other locations.

6. Flu vaccine is produced by private manufacturers, so supply depends on manufacturers. For this season, manufacturers have projected they will provide between 171 to 179 million doses of vaccine for the U.S. market. (Projections may change as the season progresses.)

7. 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 also is available at that link.
8. 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.
9. 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.)
10. Don't delay getting a flu vaccine if you want a quadrivalent vaccine and it isn't available. The important thing is to get vaccinated against the flu.
11. More quadrivalent flu vaccine is expected to be available during future seasons.
12. Every flu vaccine is formulated to offer important protection from influenza viruses.

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1. Some people should NOT receive the nasal spray vaccine and may be able to get a flu shot instead. There are also precautions for the nasal spray vaccine. (See the section above on nasal spray vaccine or refer to Vaccination: Who Should Do It, Who Should Not and Who Should Take Precautions on the CDC website.)
2. 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 (See the section Vaccine Doses for Children Aged 6 Months through 8 Years.)
3. For the complete list of flu vaccines approved for use during the 2015-2016 season, visit http://www.cdc.gov/flu/protect/vaccine/vaccines.htm.

2015-2016 Influenza Vaccine Formulation

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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. These vaccines are available as both a nasal spray and a shot during the 2015-2016 flu season.
4. Trivalent and quadrivalent flu vaccines are available during the 2015-2016 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 Yamagata 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 Yamagata and Victoria lineages).

5. Quadrivalent vaccines are intended to provide broader protection by adding another B virus to the vaccine.
6. The specific viruses for the 2015-2016 flu season vaccines were recommended by the U.S. Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee (VRBPAC) on February 26, 2015.
   a) All of the 2015-2016 influenza vaccine is made to protect against the following three viruses: an A/California/7/2009 (H1N1)pdm09-like virus, an A/Switzerland/9715293/2013 (H3N2)-like virus, and a B/Phuket/3073/2013-like virus (This is a B/Yamagata lineage virus).
   b) The quadrivalent vaccine also protects against an additional B virus (B/Brisbane/60/2008-like virus). This is a B/Victoria lineage virus.
   c) This represents a change in the influenza A (H3) and influenza B (Yamagata lineage) components compared with the composition of the 2014–15 influenza vaccine.
   d) 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 indicated that these viruses would be the ones most likely to cause illness in the United States during the 2015-2016 season.
8. For more information about the composition of this year's flu vaccine and how viruses for the seasonal flu vaccine are selected, go to http://www.cdc.gov/flu/about/season/vaccine-selection.htm.

Statements for Parents

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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:
      - Are close contacts of, or live with, children younger than 5 years old.
      - Are out-of-home caregivers (nannies, daycare providers, etc.) of children younger than 5 years old.

- Live with or have other close contact with children of any age with a chronic health condition, i.e., asthma, diabetes, etc.
- Are health care workers.

3. Every year in the United States, otherwise healthy children are hospitalized or die from flu complications.
4. In the United States, each year an average of 20,000 children younger than 5 years old are hospitalized due to flu complications.
5. Children younger than 5 years old and especially those younger than 2 years old, are at higher risk of serious flu complications, including hospitalization and death, compared to older children.
6. The risk of serious flu complications requiring hospitalization is highest among children younger than 6 months of age, but they are too young to be vaccinated. The best way to protect them is to ensure people around them get vaccinated.
7. 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.
8. 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.
9. Information about pediatric deaths since the 2004-2005 flu season is available in the interactive pediatric death web application at http://gis.cdc.gov/GRASP/Fluview/PedFluDeath.html.
10. Vaccination is the first and most important step in protecting your family against the flu.
11. Children 6 months and older are recommended to get a yearly flu vaccine.
12. 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.
13. 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.

14. 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.
15. Be sure to let the doctor know if your child has ever experienced a reaction to the flu vaccine. (See Egg Allergy messages.)
16. Children also should be current on other vaccines, including those that can help prevent pneumonia, like pneumococcal and Hib vaccines.
17. Talk to your child's doctor or other health care professional about getting a flu vaccine.
18. CDC also recommends that parents and children take everyday preventive actions to stop the spread of germs. (See Everyday Preventive Actions messages.)
19. 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.
20. It is also important for pregnant women to get vaccinated to protect their unborn babies.
21. Some studies have shown that vaccinating a pregnant woman can give her baby antibodies to protect against flu for six 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 2015-2016 seasonal influenza vaccine if the child has previously received two or more total doses of trivalent or quadrivalent influenza vaccine before July 1, 2015. 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 2015-2016 season. If the vaccination status is unknown any child in this age group, that child should be given two doses of seasonal flu vaccine.

2. Children 2 through 8 years of age who require two doses of flu vaccine do not need to receive matching flu vaccines; the flu shot or the nasal spray vaccine can be used for either dose. (Children 6 months to 2 years should only receive the flu shot.)
3. Everyone 9 years of age and older needs only one dose of 2015-2016 flu vaccine to be protected.
4. To view a chart (algorithm) that shows influenza vaccine dosing recommendations for children aged 6 months through 8 years, visit http://www.cdc.gov/mmwr/preview/mmwrhtml/figures/m6430a3f1.gif.

Statements for Pregnant Women

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1. Getting a flu shot can protect pregnant women and their unborn babies from the flu. Some studies have shown that vaccinating a pregnant woman can give her baby antibodies to protect against flu for six months after they are born.
   a) Flu shots are a safe way to protect the mother and her unborn child from serious illness and complications of flu. The flu shot has been given to millions of pregnant women over many years. The CDC continues to gather data showing that the flu shot is safe during pregnancy.
   b) Pregnant women can receive the flu shot at any time, during any trimester, while pregnant.
   c) Pregnant women are more likely to become severely ill with the flu than women who are not pregnant.
   d) Pregnant women with the flu are more likely to have pregnancy complications affecting their baby, such as premature labor and delivery.
   e) Getting a flu shot is the best way to protect you from the flu and prevent possible flu-associated pregnancy complications.
2. If you have additional questions, talk to your doctor about flu vaccination during pregnancy.
3. Pregnant women are at high risk of serious flu complications. If you get sick with the flu, call your doctor right away. Your doctor may recommend treatment with influenza antiviral drugs (see Antiviral Drugs messages).
4. Babies younger than 6 months of age are too young to get a flu vaccine. To protect infants younger than 6 months from getting the flu, their mothers should get a flu shot during pregnancy.
5. 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.
6. An additional way to protect the baby is for all of the baby's caregivers and close contacts (including parents, brothers and sisters, grandparents and babysitters) to get vaccinated against the flu.

Statements for Adults (18 through 64 years of age)

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1. Persons of all ages are at risk of influenza-related 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. During the 2009 H1N1 pandemic, for example, hospitalizations were high among adults between the ages of 18 and 49 years old.
7. 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.
8. 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).
9. 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.
10. CDC recommends all adults and children also follow everyday preventive actions to help stop the spread of germs. (See Everyday Preventive Actions messages.)
11. 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.
12. If you are at increased risk of serious flu complications and get sick with the flu, your doctor may recommend treatment with antiviral drugs. (See Antiviral Drugs messages.)

Statements for Adults 65 Years and Older

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1. Human immune defenses become weaker with age, which places some people 65 and older at greater risk of flu-related complications.
2. While annual flu vaccination is recommended for all people 6 months and older, vaccination is especially important for those 65 and older because people in this age group are at high risk of getting seriously ill from the flu.
3. 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 seasons, for example, it's estimated that between 80 percent and 90 percent of seasonal flu-related deaths and between 50 and 70 percent of seasonal flu-related hospitalizations in the United States have occurred among people 65 years 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 those aged 65 years and older); other studies have indicated that antibody levels (which are an indicator of immune protection) last through one flu season.

b) Consistent with CDC and Advisory Committee on Immunization Practices' (ACIP) general recommendation, people with weakened immune systems and people 65 years of age and older should be vaccinated, if possible by October. Given the variability of existing study results and the uncertainty and unpredictability of when flu activity will begin in a given community, CDC and ACIP do not recommend delaying vaccination for people in these groups.

c) As long as flu viruses are circulating, vaccination should continue throughout the flu season, even in January or later.

8. People 65 years and older have a vaccine option available to them designed specifically for people in this age group. This "high dose" flu vaccine (Fluzone® High-Dose) contains more antigen (the part of the vaccine that helps your body build up protection against flu viruses) than standard flu shots, and is intended to promote a better immune response in this age group.

   a) Data from studies comparing trivalent Fluzone® vaccines, high dose and standard dose, among people aged 65 years or older indicate that a stronger immune response (i.e. higher antibody levels) occurs after vaccination with Fluzone® High-Dose.

      - Results from a clinical trial of more than 30,000 participants showed that adults older than 65 years of age who received the high dose vaccine had 24.2% fewer influenza infections as compared to those who received the standard dose flu vaccine.

   Note: At this time, CDC and the Advisory Committee on Immunization Practices (ACIP) have not expressed a preference for the high dose vaccine over the standard-dose flu shot for people 65 years of age and older. However, there are ongoing studies looking into this issue and new findings will be considered in ACIP's future policy deliberations.

9. The higher dose flu vaccine may result in more of the mild side effects that can occur with standard-dose seasonal shots. Mild side effects can include pain, redness or swelling at the injection site, headache, muscle ache and fever.

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 jet injector flu vaccine.

12. If you get sick with the flu, your doctor may recommend treatment with antiviral drugs. (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.
    b) 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. And having the flu increases your chances of getting pneumococcal disease.

17. For more information about flu and people 65 years and 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. Your doctor may prescribe antiviral drugs as treatment for flu infection. (See Antiviral Drug messages.)
4. For the full list of medical conditions that put you at a higher risk for serious flu complications, see http://www.cdc.gov/flu/about/disease/high_risk.htm.

Diabetes

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1. While CDC recommends everyone 6 months and older to get vaccinated against the flu, it is especially important to get a flu shot if you have diabetes (type 1 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. If you have diabetes, getting the flu can make you very sick – even if your diabetes is well managed.

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

Asthma

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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. The nasal spray vaccine is approved for use in people 2 through 49 years of age.
    a) Children 2 years through 4 years old who have asthma or who have had a history of wheezing in the past 12 months should not get the nasal spray vaccine.
    b) People of any age with asthma might be at increased risk for wheezing after getting the nasal spray flu vaccine.

7. Family and friends of someone with asthma should get vaccinated to protect themselves and to reduce the chance of getting and spreading the flu to their loved one with asthma.
8. For more information about flu and asthma, visit: http://www.cdc.gov/flu/asthma/index.htm.

Chronic Heart Disease

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

Morbid Obesity

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1. People who have severe obesity,that is individuals 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. Individuals with obesity were disproportionally affected during the 2009 H1N1 pandemic. This was demonstrated in studies worldwide (U.S., Canada, Australia and New Zealand, China, France, and Spain).
4. Various studies showed that 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 2013-2014 flu season, obesity was the most common chronic condition; 42.3% of adults hospitalized with flu during the 2013-14 flu season had obesity. That number was 32.7% during 2014-2015.
6. People who have severe obesity with a 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. 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.)

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.
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 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. Check with your Community Health Representative (CHR) or Community Health Aide (CHA) for more information.
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 loves 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.
   a) As a trusted health care professional, research shows that your recommendation for yearly flu vaccination and taking action to get yourself vaccinated is vital.
   b) Ideally, all health care professionals, including specialists and primary care professionals, should recommend *and* offer flu vaccines to their patients.
   c) Even if you do not stock flu vaccines in your office, assessing your patients' vaccination needs and making a strong recommendation for them to get vaccinated is critical. Health care professionals who don't administer flu vaccines can refer patients to their primary care professional or to a pharmacist or local health department to receive the needed vaccines. You and your patient can visit the HealthMap Vaccine Finder (http://vaccine.healthmap.org/) to find locations in your area that offer the recommended vaccines.

d) Order free prescription-style tear-pads that will allow you to give a customized flu shot reminder to patients at high risk of complications from the flu. Order this product at http://wwwn.cdc.gov/pubs/CDCInfoOnDemand.aspx?ProgramID=1.

e) Take every opportunity to help educate your patients about the importance of flu vaccination this and every year.

3. Flu can spread rapidly in health care settings. Vaccination is the first and most important step physicians and health care workers can take to protect themselves and their patients against the against the flu.
4. Even if you are healthy, you can get sick and spread the flu. Get vaccinated to help protect yourself from the flu and to keep from spreading it to your family, co-workers, and patients. Studies conducted in health care settings show that when a large number of health care workers get vaccinated, vulnerable patients are protected.
5. Health care workers should routinely offer seasonal flu vaccination to everyone aged 6 months and older, if possible by October, and continuing throughout the flu season, which can last as late as May.
6. CDC encourages medical practices, health departments, pharmacists, and other health care professionals to use flu vaccination as an opportunity to remind adult patients about other recommended vaccines.
   http://www.cdc.gov/vaccines/schedules/hcp/adult.html
7. See the Vaccine messages above for CDC-approved messages to communicate to patients related to flu vaccination.
8. For the latest information on flu vaccine supply, including projections and doses distributed, visit http://www.cdc.gov/flu/professionals/vaccination/vaccinesupply.htm.
9. Key information for public health and health care professionals regarding vaccination, infection control, prevention, treatment, and diagnosis of seasonal flu is available at http://www.cdc.gov/flu/professionals.
10. Order free print resources from http://wwwn.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.
11. Visit: http://www.cdc.gov/flu/professionals/acip/ to view the 2015-16 Advisory Committee of Immunization Practices (ACIP) Influenza Vaccine Recommendations.
12. Health care workers should take everyday preventive actions to prevent the spread of germs and suggest the same to their patients. (See Everyday Preventive Actions messages).
13. As part of the Affordable Care Act, many insurance plans, including all plans in the Health Insurance Marketplace, will provide many free preventive services, including flu vaccinations. For information about the Health Insurance Marketplace, visit www.HealthCare.gov.

Flu Vaccine Safety

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General

1. Flu vaccines 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. The vaccines either contain inactivated virus, meaning the viruses are no longer infectious, or a particle designed to look like a flu virus to your immune system. While the nasal spray flu vaccine does contain a live virus, the viruses are weakened so that they cannot give you the flu.

4. Flu vaccine side effects are generally mild and go away on their own within a few days.

5. Common side effects from the flu shot include: soreness, redness, and/or swelling from the shot, headache, fever, fainting (mainly adolescents), muscle aches, and nausea.

6. Common side effects from the flu nasal spray vaccine are runny nose, sore throat, and cough.

7. 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.

8. 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 monitor problems following vaccination. 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

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. Only the flu vaccines in multi-dose vials contain thimerosal, to safeguard against 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.

Guillain-Barré Syndrome

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 respiratory illness.

4. People also can develop GBS after having the flu or other infections (such as cytomegalovirus and Epstein Barr virus).

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.

7. 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.

8. Scientists have multiple theories on why this increased risk may have occurred, but the exact reason for this association remains unknown.

9. 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.

10. 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

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 seizures has been highest in children 12-23 months of age and highest when the flu shot is given together with Pneumococcal conjugate vaccine (PCV13) and/or 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

1. People who have had a severe (life-threatening) allergy or reaction to a previous flu vaccine should not be vaccinated.

2. People who have an egg allergy should discuss flu vaccination with their doctor. However, most people who have an allergy to eggs can safely receive the flu vaccine.

3. FluBlok is a flu vaccine that does not contain any egg protein and is approved for use in individuals 18 years of age and older.

4. Recommendations for flu vaccination of persons with egg allergy can be found at: http://www.cdc.gov/flu/professionals/acip/2013-summary-recommendations.htm.

Flu Vaccine and Pregnancy

1. CDC recommends that pregnant women get a flu shot during any trimester of their pregnancy to protect themselves, their unborn babies, 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. Getting the flu during pregnancy also raises the risks of pregnancy complications, including premature labor and delivery.

5. Studies have shown that vaccinating a pregnant woman can pass antibodies on to the baby that will protect against flu for six months after birth.

6. 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.

7. While the nasal spray is not recommended for pregnant women, researchers were reassured to find that the accidental administration of the nasal spray vaccine to pregnant women did not result in any complications.

8. 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.

9. 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 woman who were not vaccinated.

10. 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.

11. 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.

12. Breastfeeding women should get the flu vaccine to protect themselves from flu.

13. Getting vaccinated reduces a mothers' risk of getting sick and of passing the flu on their babies, thus protecting them from flu also.

14. This is especially important for children younger than 6 months old since they are too young to be vaccinated themselves.

15. Breastfeeding women can get either a flu shot or nasal spray vaccine.

Flu Vaccine Effectiveness

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

3. Researchers try to tell how well a vaccine works in order to continually assess and confirm the value of flu vaccines as a public health measure.
4. CDC typically conducts studies throughout the influenza season to help determine how well flu vaccines are working. These studies are called "vaccine effectiveness" studies or "VE" studies, for short.
5. VE studies and their findings can vary due to study design, outcome(s) measured, population studied and the season in which the vaccine was studied. These differences can make it difficult to compare one study's results with another's.
6. While determining how well a flu vaccine works is challenging, in general, recent studies have supported the conclusion that flu vaccination benefits public health, especially when the viruses in the vaccine and circulating viruses are well matched.
7. Recent studies by CDC researchers and other experts indicate that flu vaccine reduces the risk of doctor visits due to flu by approximately 50-60% among the overall population when the vaccine viruses are like the ones spreading in the community.
8. Some studies* have shown that flu vaccination can reduce the risk of more serious flu outcomes, including hospitalizations.
9. Studies also have shown that flu vaccination is an important preventive tool for people with chronic health conditions.
10. Vaccination helps protect women against influenza during pregnancy and their babies for up to 6 months after they are born. One study showed that giving flu vaccine to pregnant women was 92% effective in preventing hospitalizations of infants for flu.
11. Other studies have shown that flu vaccination can reduce the risk of flu-related hospitalizations in older adults.
12. How well the flu vaccine works can vary by season, virus type/subtype, the vaccine, and age and other host factors of the people being vaccinated.
13. Two factors play an important role in determining the likelihood that flu vaccines will protect a person from flu illness: 1) characteristics of the person being vaccinated (such as their age and health), and 2) the similarity or "match" between the flu viruses in the vaccine and those spreading in the community.
14. In general, the flu vaccine works best among young healthy adults and older children. Lesser effects of flu vaccine are often found in studies of young children (e.g., those younger than 2 years of age) and older adults.
15. Older people, who may have weaker immune systems, often have a lower protective immune response following flu vaccination compared to the immune response of younger, healthier persons following flu vaccination. This can result in lower levels of vaccine effectiveness in these people.
16. The other factor affecting how well the flu vaccine works is the "match" between the flu viruses contained in the vaccine and those spreading in the community. The closer the match, the better the flu vaccine is likely to be in preventing flu illness. If the viruses in the vaccine are very different from circulating flu viruses, vaccine effectiveness can be lower.
17. During years when the viruses in the flu vaccine and circulating flu viruses are not well matched, it's possible that no or minimal benefit from flu vaccination may be observed.
    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.

18. During years when the viruses in the flu vaccine and circulating flu viruses are very well matched, it's possible to measure substantial benefits from flu vaccination in terms of preventing flu illness.
19. However, even during years when the vaccine match is very good, the benefits of flu vaccination will vary across the population, depending on host factors like the health and age of the person being vaccinated and even potentially which flu vaccine was used. The substantial burden of flu-associated illness and death in the United States combined with the overall evidence from a variety of studies showing that flu vaccines do offer protection against flu illness support the current U.S. flu vaccination recommendations.
20. It's important to note, however, that how well flu vaccines work to protect against flu illness will continue to vary each year, depending especially on the match between flu viruses used to make vaccine and the flu viruses that are spreading and causing illness in the community, and the characteristics of the person being vaccinated.
21. A flu vaccination does not guarantee protection against the flu. Some people who get vaccinated might still get sick. However, people who get a flu vaccine are less likely to get sick with flu than someone who does not get vaccinated.

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

Vaccine Effectiveness Last Season

1. The H3N2 virus that was most common last season was very different from the H3N2 virus in the vaccine.
2. This resulted in lower than usual vaccine effectiveness of an estimated 23% overall (13% against H3N2 viruses, 55% against less common influenza B viruses.)
3. Vaccine effectiveness is usually 50% to 60% when the viruses are well-matched to the vaccine virus.
4. That means that a vaccinated person is usually 50% to 60% less likely to get sick with the flu and need a doctor's visit than an unvaccinated person.

Vaccine Effectiveness This Season

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.)
3. Laboratory data to date suggests that most circulating viruses are like the vaccine viruses included in the vaccines for the upcoming season.
4. 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.
5. CDC will continue to carefully look at the results of laboratory studies of currently circulating viruses to look for any evidence of drift that may be occurring in these viruses.

6. 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 illness this season.
7. 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 and particularly undesirable in high-risk groups, where withholding vaccine from people recommended for vaccination would place them at risk for infection, illness and possibly serious complications.
5. For that reason, most recent studies to measure how well flu vaccine works have been observational studies.
6. Many observational studies use a case-control design, in which people with lab-confirmed influenza ("cases") are compared with a group of people who do not have influenza (control group).
7. One aspect of the design of observational studies that can influence results is the choice of the "control" group. The control group can include people who did not have the flu, or who have no record of seeking care for flu symptoms. In some studies, the control group may consist of people who had respiratory symptoms for which they sought medical care, but who tested negative for flu.
8. Members of the control group who don't have the flu should ideally be similar to study subjects with the flu. If they are not similar, the study may show a falsely high or low result for how well the flu vaccine worked. Generally speaking, cases should come from the same population as controls.
9. In addition, it can be difficult to directly compare results between studies that used different comparison groups. Even if both studies were well-conducted, one might expect the results to be different because the choice of the comparison group in non-randomized studies can influence the estimate of the vaccine's effect.
10. Other factors that can affect results are the numbers of cases (people who developed flu illness) in the study and the number of people eligible for, or enrolled in a study (again, smaller numbers can make results less reliable).

11. Therefore, when assessing how well a vaccine works, it is important to consider the study design, population and year.
12. Studies also can assess how well a vaccine works at preventing different outcomes.
    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 the flu vaccine's effectiveness at preventing outpatient medical visits due to laboratory-confirmed influenza.
    d) To assess how well the flu vaccine works across different age groups, CDC's studies of vaccine effectiveness include all people aged 6 months and older recommended for an annual flu vaccination.

    Similar studies are being conducted in Australia, Canada and Europe.
16. During the 2015-2016 season, CDC is planning to conduct multiple studies on the effectiveness of both the flu shot and the nasal-spray flu vaccine (http://www.cdc.gov/flu/professionals/vaccination/effectivenessqa.htm). These studies measure vaccine effectiveness in preventing laboratory-confirmed influenza among persons 6 months of age and older.

Improvements in Vaccine Technology

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

4. An intradermal flu shot that requires less antigen to produce the same immune response is now being produced. This is useful because the same amount of available antigen can be used to make more doses of the vaccine.
5. Recombinant vaccines which can be manufactured more quickly than either egg-based or cell-based vaccines and do not require an egg-grown virus or eggs to produce.
6. Other studies are looking at the use of adjuvants that might improve how well vaccines work.
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.

Background on Waning Immunity

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

2014-2015 Influenza Season: A Summary

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1. The 2014–15 influenza season was characterized as moderately severe overall, but was severe for people 65 and older.
2. During most of the season influenza A (H3N2) viruses predominated, however the country experienced a second wave of influenza B flu activity starting in early March 2015.
3. Flu activity last season increased through late November and December, and peaked in late December. This was somewhat early, comparatively; flu activity in the United States typically begins to increase in late December or early January and peaks most commonly in February.
4. Overall, there were high levels of outpatient illness and flu-associated hospitalizations, especially for people 65 years and older.
5. People 65 years and older accounted for approximately 60% of reported flu-associated hospitalizations last season.
6. While hospitalization rates are almost always highest among people 65 and older, last season CDC recorded the highest hospitalization rates among this age group since this type of record-keeping began in 2005.
7. The cumulative hospitalization rate (per 100,000 population) for people 65 years and older this season was 322.8, which is more than one-and-a-half times greater than the highest rate previously reported for this age group.

2015-2016 Flu Season Key Points continued

8. Nearly half of the children hospitalized with laboratory-confirmed flu had no known underlying health condition.
9. A notable characteristic of the 2014–15 influenza season is that antigenic and genetic characterization of influenza-positive respiratory specimens submitted to CDC indicated that most of the circulating influenza A (H3N2) viruses were different or "drifted" from the H3N2 vaccine virus.
10. The predominance of drifted influenza A (H3N2) viruses likely resulted in reduced vaccine effectiveness (VE) observed against H3N2 viruses this season.
11. End of season estimates showed the 2014-15 flu vaccine reduced the risk of flu-associated medical visits from influenza A (H3N2) viruses by 13%. However, VE against influenza B viruses—which were mostly well-matched to the vaccine viruses was 55-63% overall.
12. When VE against all influenza viruses was combined, the overall VE estimate was 23%. This means the flu vaccine reduced a person's risk of having to seek medical care at a doctor's office for flu illness by 23%.
13. Last season, approximately 147.8 million doses of 2014-2015 influenza vaccine were distributed in the United States.