

Centers for Disease Control and Prevention (CDC) Atlanta GA 30329-4027

2018-2019 Influenza Technical Key Points September 28, 2018

Contents

Overarching Framework of CDC Influenza Messaging	3
Take 3 Messages	3
What's New this Flu Season	5
Statements for General Audiences	6
Disease	6
Vaccination	8
Vaccine Benefits	9
Vaccination Timing	11
Vaccination: Who Should Do It, Who Should Not and Who Should Take Pre	ecautions 11
2018-2019 Influenza Vaccine Options, Indications and Availability	15
Flu Vaccine and Egg Allergy	16
2018-2019 Influenza Vaccine Composition	18
Statements for Parents	19
Vaccine Doses for Children Aged 6 Months through 8 Years	21
Statements for Pregnant Women	22
Statements for Adults (18 through 64 years of age)	24
Statements for Adults 65 Years and Older	25
Statements for Adults with Certain Medical Conditions	27
General Messages	27
Diabetes	27
Asthma	29
Heart Disease	29
Severe Obesity	30
People with Disabilities* and Caregivers:	31
Statements for American Indians and Alaska Natives	32
Statements on the Importance of Health Care Personnel Recommendary	
Statements for Health Care Personnel in Long-term Care Facilities	35
Flu Vaccine Safety	37
General	37

Thimerosal	38
Guillain-Barré Syndrome	38
Febrile Seizures	39
Allergy and Flu Vaccine	40
Flu Vaccine and Pregnancy	40
Shoulder Injury and Safe Vaccination	41
Flu Vaccine Effectiveness	41
VE Studies	44
U.S. Flu VE Network	45
Hospitalized Adult Influenza Vaccine Effectiveness Network (HAIVEN)	45
Ways to Measure How Well Flu Vaccines Work (Study Methods)	46
Vaccine Effectiveness Last Season (2017-2018)	48
U.S. Flu VE Network: Outpatient Illness VE Estimates (2017-2018)	48
HAIVEN: Hospitalization VE Estimates (2017-2018)	50
Improvements in Vaccine Technology	51
Flu Vaccine Coverage in the United States	52
2017-18 Flu Vaccine Coverage Among Children	53
2017-18 Flu Vaccine Coverage Among Pregnant Women	53
2017-18 Flu Vaccine Coverage Among Health Care Professionals	55
2017-2018 Influenza Season: A Summary	56
Flu Burden and Burden-Averted Vaccination Estimates	56
Range of Flu-Related Hospitalizations and Deaths	57
Recommendation For Use of LAIV	

Overarching Framework of CDC Influenza Messaging

(Back to table of contents)

Take 3 Messages

CDC recommends a three-step approach to fighting flu: vaccination, everyday preventive actions, and use of flu 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 and its potentially serious complications.
 - b) For the 2018-2019 flu season, CDC and its Advisory Committee on Immunization Practices (ACIP) recommend annual flu vaccination for everyone 6 months and older with any licensed, age-appropriate flu vaccine. (This includes inactivated, recombinant or live attenuated nasal spray flu vaccines).
 - Nasal spray flu vaccine is again a vaccination option.
 - o There is no preferential recommendation for one flu vaccine over another.
 - c) Flu vaccination can reduce flu illnesses, doctors' visits, and missed work and school due to flu, as well as prevent flu-related hospitalizations.
 - d) Flu vaccination has been shown to significantly reduce a child's risk of dying from influenza.
 - o In 2017, a study in the journal Pediatrics was the first of its kind to show that flu vaccination significantly reduced a child's risk of dying from influenza. See "Influenza Vaccine Effectiveness Against Pediatric Deaths: 2010-2014" by Brendan Flannery et al. in Pediatrics at http://pediatrics.aappublications.org/content/early/2017/03/30/peds.2016-4244.
 - While there are many different flu viruses, the flu vaccine protects against the viruses that research suggests will circulate the most this season (3 or 4 viruses, depending on the vaccine).
 - Three-component (trivalent) flu vaccines contain an influenza A(H3N2), an H1N1 and an influenza B virus.
 - o Four-component (quadrivalent) flu vaccines have an additional B virus component. See <u>Vaccine Virus Selection</u> for this season's vaccine composition (https://www.cdc.gov/flu/about/season/vaccine-selection.htm).
 - e) Everyone 6 months of age and older should get a 2018-2019 flu vaccine, by the end of October. However, as long as flu viruses are circulating, vaccination should continue throughout the flu season, even in January or later.
 - f) Vaccination of high risk persons
 high risk.htm) is especially important to decrease their risk of severe flu illness.
 - People at high risk of serious flu complications include children younger than 5 years, pregnant women, and people with certain chronic health conditions like asthma, diabetes, or heart or lung disease, and people 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.

- g) Vaccination also is especially important for health care personnel, and others who live with or care for people at high risk of serious flu complications to keep from spreading flu to them.
 - 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.
 - Find a place near you to get flu and other recommended vaccines at http://vaccine.healthmap.org/.
 - Take the CDC quiz to find out which vaccines might be right for you: http://www2.cdc.gov/nip/adultimmsched.

See the Vaccine section for more key messages related to flu vaccination.

- 2. <u>Take everyday preventive actions to help slow the spread of germs that can cause respiratory illnesses like flu</u>. While these actions may be helpful, remember that vaccination is the most important step in preventing flu.
 - a) Try to avoid close contact with sick people.
 - b) If you get sick, limit contact with others as much as possible to keep from infecting them.
 - c) If you are sick with flu 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.)
 - 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.
 - q) 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 sick with flu, flu antiviral drugs can be used to treat your illness.
 - b) Flu 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. Flu antiviral drugs fight 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. Flu vaccines are the best way modern medicine currently has to protect against flu infection and its potentially serious consequences.
 - e) It is very important that antiviral drugs are used early to treat hospitalized flu patients, people with severe flu illness, and people with flu symptoms who are at high risk of serious flu complications based on their age or health.
 - f) CDC recommends prompt flu antiviral treatment of people who are severely ill and people who are at high risk of serious flu complications who develop flu symptoms.
 - g) Most people who are otherwise healthy and get flu do not need to be treated with flu antiviral drugs, but some people may be treated with antiviral drugs by their doctor.

- h) Antiviral drugs can make flu illness milder and shorten the time you are sick.
- There also are data showing that antiviral drugs may prevent serious flu complications.
 - In 2015, a CDC study found that early treatment of flu-hospitalized people 65
 years and older with flu antiviral medications cut the duration of their hospital
 stay and reduced their risk of needing extended care after discharge.
 - This study entitled "Impact of Prompt Influenza Antiviral Treatment on Extended Care Needs After Influenza Hospitalization Among Community-Dwelling Older Adults" by Sandra Chaves et al. is available from the Clinical Infectious Diseases journal website at http://cid.oxfordjournals.org/content/early/2015/09/01/cid.civ733.
- j) For people with flu who are at high risk of developing 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.
- k) If you get sick with flu, the earlier you begin taking antivirals, the better.
 - Studies show that antiviral drugs work best when started within 48 hours of getting sick, but starting them later can still be helpful, especially if the sick person has a high-risk health condition or is very sick from flu.
 - There are data to suggest antiviral drugs can still be beneficial in very ill patients even up to five days after getting sick with flu.
- I) Three FDA-approved influenza antiviral drugs are recommended for use in the United States during the 2018-2019 influenza season: oseltamivir (Tamiflu® and generic), zanamivir (Relenza®), and peramivir (Rapivab®).
- m) More information about antiviral drugs can be found at http://www.cdc.gov/flu/antivirals/index.htm.
- n) For more information about flu or flu vaccines, call 1-800-CDC-INFO or visit www.cdc.gov/flu.

What's New this Flu Season

- 1. For the 2018-2019 flu season, providers may choose to administer any licensed, ageappropriate flu vaccine, including inactivated influenza vaccine (IIV), recombinant influenza vaccine (RIV), or live attenuated nasal spray influenza vaccine (LAIV4).
- 2. The nasal spray vaccine (live attenuated influenza vaccine or "LAIV") is again a recommended option for influenza vaccination of persons for whom it is otherwise appropriate.
 - a) LAIV is recommended as an option for use in non-pregnant individuals, 2 years through 49 years of age, however there is a precaution against the use of LAIV in people with certain medical conditions, and for persons with some specific medical conditions it is not recommended.
- 3. Flu vaccines have been updated to better match circulating viruses [the B/Victoria component was changed and the influenza A(H3N2) component was updated].
- 4. The 2018-2019 trivalent (three-component) vaccines are recommended to contain:

- a) A/Michigan/45/2015 (H1N1)pdm09-like virus
- b) A/Singapore/INFIMH-16-0019/2016 A(H3N2)-like virus (updated)
- c) B/Colorado/06/2017-like (Victoria lineage) virus (updated)
- 5. The 2018-2019 quadrivalent (four-component) vaccines, which protect against a second lineage of B viruses, are recommended to contain:
 - a) the three recommended trivalent vaccine viruses, plus B/Phuket/3073/2013-like (Yamagata lineage) virus.
- 6. Trivalent and quadrivalent vaccine will be available this season.
- 7. Most regular-dose egg-based flu shots will be quadrivalent for the 2018-2019 flu season.
- 8. All recombinant vaccines will be quadrivalent during the 2018-2019 flu season.
- 9. All LAIV (nasal spray vaccines) will be quadrivalent.
- 10. Cell-grown flu vaccine will be quadrivalent.
- 11. For cell-grown vaccine, the influenza A(H3N2) and both influenza B reference viruses will be cell-derived, and the influenza A(H1N1) will be egg-derived.
- 12. High-dose inactivated influenza vaccine will be trivalent.
- 13. Adjuvanted inactivated influenza vaccine will be trivalent.
- 14. No intradermal flu vaccine will be available during the 2018-2019 flu season.
- 15. The age indications for two vaccines were changed:
 - a) The age recommendation for "Fluarix Quadrivalent" was changed from 3 years and older to 6 months and older in January 2018 to be consistent with Food and Drug Administration (FDA)-approved labeling.
 - b) The age recommendation for Afluria Quadirvalent was changed from 18 years old and older to 5 years old and older August 2017 to be consistent with Food and Drug Administration (FDA)-approved labeling.
- 16. The 2018-2019 influenza vaccine recommendations were published in a CDC Morbidity and Mortality Weekly Report (MMWR) dated August 24th, 2018 that is available at https://www.cdc.gov/mmwr/volumes/67/rr/rr6703a1.htm?scid=rr6703a1 w.
- 17. The report focuses on the recommendations for use of vaccines for the prevention and control of flu during the 2018-19 flu season in the United States. A background document containing further information and a brief summary of these recommendations are available at https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html.
- 18. A Background section to the ACIP recommendations will be available online at https://www.cdc.gov/flu/professionals/acip/2018-2019/2018-19background.htm.

Statements for General Audiences

(Back to table of contents)

Disease

1. Influenza (flu) can be a serious disease that can lead to hospitalization and sometimes even death. Anyone can get sick from flu.

- 2. While flu can make anyone sick, certain people are at high risk of serious flu complications. These people include:
 - a) Children younger than 5 years old, but especially children younger than 2 years old
 - b) People 65 years and older
 - c) Pregnant women and women up to 2 weeks after the 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:
 - i) Asthma
 - ii) 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)]
 - iii) Chronic lung disease (such as chronic obstructive pulmonary disease [COPD] and cystic fibrosis)
 - iv) Chronic heart disease (such as congenital heart disease, congestive heart failure and coronary artery disease)
 - v) Blood disorders (such as sickle cell disease)
 - vi) Endocrine disorders (such as diabetes mellitus)
 - vii) Kidney disorders
 - viii) Liver disorders
 - ix) Metabolic disorders (such as inherited metabolic disorders and mitochondrial disorders)
 - x) Weakened immune system due to disease or medication (such as people with HIV or AIDS, or cancer, or those on chronic steroids)
 - g) People younger than 19 years of age who are taking aspirin or salicylate-containing medications
 - h) People with severe obesity (Body Mass Index, [BMI] of 40 or greater)
 - i) For more information about people at high risk of serious flu-related complications visit: http://www.cdc.gov/flu/about/disease/high-risk.htm.
- 3. 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.
- 4. Symptoms of 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.
- 5. People may also be infected with flu and have no symptoms at all, or have only respiratory symptoms without a fever.

- 6. 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 flu.
- 7. A wide range of complications can be caused by flu.
 - a) 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.
 - b) Other possible serious complications triggered by flu can include inflammation of the heart (myocarditis), brain (encephalitis) or muscle tissues (myositis, rhabdomyolysis), and multi-organ failure.
 - c) Flu virus infection of the respiratory tract can trigger an extreme inflammatory response in the body and can lead to <u>sepsis</u>, the body's life-threatening response to infection.
 - d) Flu also can make chronic medical problems worse. For example, people with <u>asthma</u> may experience asthma attacks while they have flu, and people with <u>chronic heart</u> <u>disease</u> may experience a worsening of this condition triggered by flu.
- 8. Even healthy children and adults can get very sick from flu.
- 9. Flu seasons are unpredictable.
- 10. Flu viruses are constantly changing.
- 11. Each flu season, different flu viruses can spread, and they can affect people differently based on differences in their immune systems.
- 12. It is not possible to predict how mild or severe the 2018-2019 flu season will be, or which influenza viruses will predominate.
 - a) The severity of flu seasons can differ substantially from year to year.
- 13. 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.
- 14. CDC estimates that influenza has resulted in between 9.2 million and 35.6 million illnesses, between 140,000 and 710,000 hospitalizations, and between 12,000 and 56,000 deaths annually since 2010.

See section "Flu Burden and Burden-Averted Vaccination Estimates" for more specific information.

Vaccination

- 1. The first and most important step in protecting against 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. CDC recommends an annual flu vaccine as the first and best way to protect against flu. There are two reasons to get a flu vaccine every year:

- a) The first reason is that since flu viruses are constantly changing, flu vaccines may be updated from one season to the next if necessary 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 vaccination declines over time. Annual vaccination is needed for the best protection.
- 3. While how well flu vaccine works can vary from year to year, there are many reasons to get a flu vaccine each year.

Vaccine Benefits

- a) Flu vaccination can reduce flu illnesses, doctors' visits, and missed work and school due to flu, as well as prevent flu-related hospitalizations.
- b) Flu vaccination can keep you from getting sick with flu.
 - i) Flu vaccine prevents millions of illnesses and flu-related doctor's visits each year. For example, during <u>2016-2017</u>, flu vaccination prevented an estimated 5.3 million influenza illnesses, 2.6 million influenza-associated medical visits, and 85,000 influenza-associated hospitalizations.
 - ii) In seasons when the vaccine viruses matched circulating viruses, flu vaccine has been shown to reduce the risk of having to go to the doctor with flu by 40 percent to 60 percent.
- Flu vaccination can reduce the risk of flu-associated hospitalization for children, working age adults, and older adults.
 - Flu vaccine prevents tens of thousands of hospitalizations each year. For example, during <u>2016-2017</u>, flu vaccination prevented an estimated 85,000 flurelated hospitalizations.
 - ii) A <u>2014 study</u> showed that flu vaccine reduced children's risk of flu-related pediatric intensive care unit (PICU) admission by 74% during flu seasons from 2010-2012.
 - iii) In recent years, <u>flu vaccines have reduced the risk of flu-associated</u>
 <u>hospitalizations among adults</u> on average by about 40%.
 - iv) A <u>2018 study</u> showed that from 2012 to 2015, flu vaccination among adults reduced the risk of being admitted to an intensive care unit (ICU) with flu by 82 percent.
- d) Flu vaccination is an important preventive tool for people with chronic health conditions.

- Vaccination has been associated with <u>lower rates of some cardiac events</u> among people with heart disease, especially among those who had had a cardiac event in the past year.
- ii) Flu vaccination also has been shown in <u>separate studies</u> to be associated with reduced hospitalizations among people with <u>diabetes</u> and <u>chronic lung disease</u>.
- e) Vaccination helps <u>protect women during and after pregnancy</u>.
 - Vaccination reduces the risk of flu-associated acute respiratory infection in pregnant women by up to <u>one-half</u>.
 - ii) Getting vaccinated can also protect a baby after birth from flu. (Mom passes antibodies onto the developing baby during her pregnancy.)
 - (1) A number of studies have shown that in addition to helping to protect pregnant women, a flu vaccine given during pregnancy helps protect the baby from flu infection for several months after birth, when he or she is not old enough to be vaccinated.
- f) Flu vaccine can be life-saving in children.
 - i) A 2017 <u>study</u> was the first of its kind to show that flu vaccination can significantly reduce a child's risk of dying from influenza.
- g) Flu vaccination has been shown in several studies to reduce severity of illness in people who get vaccinated but still get sick.
 - A 2017 <u>study</u> showed that flu vaccination reduced deaths, intensive care unit (ICU) admissions, ICU length of stay, and overall duration of hospitalization among hospitalized flu patients.
 - ii) A <u>2018 study</u> showed that among adults hospitalized with flu, vaccinated patients were 59 percent less likely to be admitted to the ICU than those who had not been vaccinated. Among adults in the ICU with flu, vaccinated patients on average spent 4 fewer days in the hospital than those who were not vaccinated.
- h) **Getting vaccinated yourself may also protect people around you**, including those who are more vulnerable to serious flu illness, like babies and young children, older people, and people with certain chronic health conditions.
- i) *References for the studies listed above can be found at <u>Publications on Influenza</u>

 <u>Vaccine Benefits</u>. Also, see the Why Get a Flu Vaccine[237 KB, 2 pages] fact sheet.
- 4. Protect your family from flu by getting yourself and your family members vaccinated.
- 5. 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 lowgrade fever or achiness. For most people who experience these side effects, they are mild and short-lived.
- b) The most common side effects from the nasal spray vaccine are a runny nose and maybe a low-grade fever or achiness. The viruses in nasal spray vaccine are weakened and do not cause severe symptoms often associated with influenza illness.
- 6. The flu vaccine is used to prevent flu illness, not to treat it. Influenza antiviral drugs may be prescribed to treat or prevent flu.

See Antiviral Drug messages for more information.

- 7. A flu vaccine protects against influenza viruses. It will not protect against other respiratory illnesses.
- 8. 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.
- 9. For more information about the seriousness of flu and the benefits of flu vaccination, talk to your doctor or other health care personnel, visit www.cdc.gov/flu, or call CDC at 1-800-CDC-INFO.

Vaccination Timing

(Back to table of contents)

- 1. You should get a flu vaccine by the end of October. 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 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 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.
- 5. Children who need two doses of flu vaccine to be protected should start the vaccination process sooner, because the two doses must be given at least four weeks apart.
 - See <u>Vaccine Doses for Children Aged 6 Months through 8 Years</u> messages for more information

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

- 1. Everyone 6 months and older is recommended for annual flu vaccination with rare exception.
- 2. For the 2018-2019 flu season, providers may choose to administer any licensed, age-appropriate flu vaccine (IIV, RIV4, or LAIV4) with no preference expressed for one vaccine over another.
- 3. Different flu vaccines are recommended for use in different groups of people. Factors that can determine a person's suitability for vaccination, or vaccination with a particular vaccine, include a person's age, health (current and past) and any allergies to flu vaccine or its components.

The Flu Shot

People who can get a flu shot:

 Different flu shots are 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 recommended for use in pregnant women and people with chronic health conditions.

People who can't get a 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 <u>Special</u> <u>Considerations Regarding Egg Allergy</u> for more information about egg allergies and flu vaccine.

Note: There are certain flu shots that have different age indications. For example, people younger than 65 years of age should not get the <u>high-dose flu shot</u> and people who are younger than 18 years should not get the recombinant flu shot.

People who should talk to their doctor before getting a 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

The Nasal Spray Vaccine

People who can get the nasal spray vaccine:

 The nasal spray vaccine is approved for use in non-pregnant individuals,
 2 years through 49 years of age.

People who can't get the nasal spray vaccine:

- Children younger than 2 years;
- Adults 50 years and older;
- People with severe, life-threatening allergies to flu vaccine or any ingredient in the vaccine. See <u>Special Considerations Regarding</u> <u>Egg Allergy</u> for more information about egg allergies and flu vaccine;
- Children 2 years through 17 years of age who are receiving aspirintherapy or salicylate-containing medications;
- Children 2 years through 4 years who have asthma or who have had a history of wheezing in the past 12 months;
- Pregnant women;
- People with weakened immune systems (immunosuppression);
- People who care for severely immunocompromised persons who require a protective environment (or otherwise avoid contact with

- 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.
- those persons for 7 days after getting the nasal spray vaccine);
- People who have taken influenza antiviral drugs within the previous 48 hours.

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

There is a <u>precaution against the use of</u>
<u>nasal spray flu vaccine (LAIV)</u> in people
with certain underlying medical conditions.
You should talk to your doctor if you have:

- Moderate to severe acute illness with or without fever;
- History of Guillain-Barré syndrome;
- Asthma: People 5 years of age and older 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 FluRelated Complications.

2018-2019 Influenza Vaccine Options, Indications and Availability

(Back to table of contents)

There are several flu vaccine options available for the 2018-2019 flu season.

- 1. For the 2018-2019 flu season, providers may choose to administer any licensed, ageappropriate flu vaccine, including injectable and nasal spray vaccine (This includes inactivated influenza vaccine or IIV, recombinant influenza vaccine or RIV4, or live attenuated influenza vaccine or LAIV4, which is the vaccine given via nasal spray.)
- 2. Flu vaccines made to protect against three different flu viruses (called "trivalent" vaccines) will be available this season.
- 3. In addition, flu vaccines made to protect against four different flu viruses (called "quadrivalent" vaccines) also will be available. (Most vaccine this season will be quadrivalent.)
 - a) **Trivalent** flu vaccines protect against two influenza A viruses (an H1N1 and an H3N2 virus) and an influenza B virus. The following trivalent flu vaccines are available:
 - i) One <u>standard-dose trivalent shot</u> that is manufactured using virus grown in eggs can be given with a needle for people aged 5 years and older or with a needle-free <u>jet injector</u> for persons aged 18 through 64 years.
 - ii) A high-dose trivalent shot, approved for people 65 years and older.
 - iii) A trivalent flu shot (<u>FLUAD™</u>) 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.
 - b) The **quadrivalent** flu vaccine protects against two influenza A viruses and two influenza B viruses. The following quadrivalent flu vaccines are available:
 - i) Standard-dose <u>quadrivalent flu shots</u> that are manufactured using virus grown in eggs. Different flu shots are approved for different age groups. Some are approved for children as young as 6 months of age. Most flu shots are given in the arm (muscle) with a needle. One quadrivalent flu shot can be given either with a needle (for people aged 5 years and older) or with a jet injector (for people aged 18 through 64 years only).
 - ii) A <u>recombinant quadrivalent (RIV4) flu shot that is egg-free</u>, approved for people 18 years and older.
 - iii) A <u>quadrivalent cell-based flu shot (FLUCELVAX®)</u> containing virus grown in cell culture, which is approved for people 4 years and older.
 - iv) A <u>quadrivalent live attenuated influenza nasal spray vaccine (LAIV4)</u> made with attenuated (weakened) live flu viruses, approved for use in people 2 years through 49 years of age. This vaccine is not recommended for use in pregnancy. There also is a <u>precaution against the use of nasal spray flu vaccine (LAIV)</u> in people with certain underlying medical conditions, and for people with some specific medical conditions it is not recommended.
- 4. There is no preference expressed for any one vaccine over another. The most important thing is to get vaccinated every year.
- 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.
- 7. For the 2018-2019 season, manufacturers have projected they will provide as many as 163 million to 168 million doses of influenza vaccine, which is similar to projected supply for last season.
- 8. Projections may change as the season progresses.
 - a) Of the total number of influenza vaccine doses projected to be available for the 2018-2019 season, approximately 136 million (range: 114 million to 124 million) are estimated to be quadrivalent influenza vaccines (up from projected 119 million doses last season).
 - i) More than 80 percent of the projected vaccine supply produced for the 2018-2019 flu season will be quadrivalent (4-component) vaccines.
 - b) Of the total number of influenza vaccine doses projected to be available for the 2018-2019 season, approximately 135 million doses (range: 126 million to 133 million) are estimated to be thimerosal-free (up from 130 million projected for last season).
 - i) More than 80 percent of projected vaccine supply produced for the 2018-2019 flu season will be thimerosal-free (i.e., preservative-free).
- 9. Based on manufacturer projections, health officials expect that supply of influenza vaccine for the 2018-2019 season should be sufficient to meet demand.
- 10. For the latest information on flu vaccine supply, including projections and doses distributed, visit https://www.cdc.gov/flu/about/qa/index.htm. For information about past numbers of doses distributed, visit https://www.cdc.gov/flu/about/qa/index.htm.
- 11. Although flu vaccines are available for purchase from manufacturers and distributors, different health care personnel may receive their vaccine shipments at different times because of production and delivery schedules for different products.
- 12. 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.*)
- 13. 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.
- 14. Every flu vaccine is formulated to offer important protection from influenza viruses.
- 15. For the complete list of flu vaccines approved for use during the 2018-2019 season, visit https://www.cdc.gov/flu/about/qa/vaxsupply.htm.

Flu Vaccine and Egg Allergy

- 1. CDC and its Advisory Committee on Immunization Practices during the 2016-2017 season updated their guidelines on egg allergy and receipt of influenza (flu) vaccines.
 - a. The 2018-2019 season guidelines on egg allergy remains the same as the 2016-2017 guidelines.
- 2. People with egg allergies do not 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, or LAIV4) 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, or LAIV4) 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.
 - a. [Alternative: People who have severe egg allergies should be vaccinated in a medical setting and be supervised by a health care provider who is able to recognize and manage severe allergic reactions.]
- 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.
- 8. CDC created a summary of the current recommendations 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 $\leq 1 \mu g/0.5 \text{ mL}$ dose for flu shots and 0.24 $\mu g/0.2 \text{ mL}$ dose for the nasal spray vaccine, a much smaller amount than would be present in a whole egg.
- 8. Cell-based flu vaccine (FLUCELVAX®) likely has a much smaller amount of egg protein since one of the four original vaccine viruses it contains is initially raised 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.

2018-2019 Influenza Vaccine Composition

- 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 2018-2019 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 2018-2019 flu season vaccines were <u>recommended</u> by the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) on March 1, 2018.
 - a) All of the 2018-2019 influenza vaccine is made to protect against the following three viruses:
 - i) an A/Michigan/45/2015 (H1N1)pdm09-like virus.
 - ii) an A/Singapore/INFIMH-16-0019/2016 A(H3N2)-like virus (updated from last season); and

- iii) a B/Colorado/06/2017-like virus (Victoria lineage virus) (updated from last season).
- b) The quadrivalent vaccine also protects against an additional B virus B/Phuket/3073/2013-like virus. This is a B/Yamagata lineage virus.
- c) There are two differences between what was recommended for the 2017-2018 Northern Hemisphere vaccines and the 2018-2019 Northern Hemisphere vaccines.
 - i) Flu vaccines have been updated to better match circulating viruses [the B/Victoria component was changed and the influenza A(H3N2) component was updated].
- d) Vaccine virus recommendations are 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 2018-2019 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

- 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.
- 3. 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.
- 4. Adults who meet any of the following criteria:
 - a) Are close contacts of, or live with, children younger than 5 years old.
 - b) Are out-of-home caregivers (e.g., nannies, daycare providers, etc.) of children younger than 5 years old.
 - c) Live with or have other close contact with children of any age with a chronic health condition (e.g., asthma, diabetes, etc.).
 - d) Are health care personnel.
- 5. Each year, millions of children get sick with seasonal flu; thousands of children are hospitalized and some children die from flu.

- 6. During the 2017-2018 flu season, the number of flu-related deaths in children reported during a single flu season (excluding pandemics) set a record high. Approximately 80% of these deaths occurred in children who had not received a flu vaccination.
 - a) Most children who die from flu have not been fully vaccinated.
- 7. Since 2011-2012, between 70% and 85% of reported pediatric deaths have occurred in children who were not fully vaccinated.
- 8. CDC estimates that since 2010, flu-related hospitalizations among children younger than 5 years ranged from 7,000 to 26,000 in the United States. For more information, see https://www.cdc.gov/flu/protect/children.htm.
- 9. 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.
- 10. 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 these children is for their mother to get a flu shot during pregnancy and for people around them to get vaccinated, as well. A flu vaccine given during pregnancy has been shown to help protect the baby from flu infection for several months after birth, before he or she is old enough to be vaccinated.
- 11. Since 2004-2005, flu-related deaths in children reported to CDC during regular flu seasons have ranged from 37 deaths (during 2011-2012) to 179 deaths (during 2017-2018). During the 2009 H1N1 flu pandemic (April 15, 2009 to October 2, 2010), 358 pediatric deaths were reported to CDC.
- 12. The majority of flu-related deaths occur in children who are not fully vaccinated.
- 13. Information about pediatric deaths since the 2004-2005 flu season is available in the interactive pediatric death web application.
- 14. Vaccination is the first and most important step in protecting your family against flu.
- 15. Flu vaccination can prevent illness, hospitalization, and deaths in children.
- 16. Children 6 months and older are recommended to get a yearly flu vaccine.
- 17. A seasonal influenza vaccination every year is especially important for children with asthma, diabetes (type 1 and 2), neurologic conditions (conditions affecting the brain and nerves), or certain other long-term medical conditions, because they are at high risk for complications from flu if they get sick. A full list of people at high risk for flu-related complications is at https://www.cdc.gov/flu/about/disease/high_risk.htm
 - a) The flu can make some medical conditions worse. For example, children with asthma (even if it's mild or controlled by medication) who catch flu are more likely to have worsening of their condition, for example, more asthma attacks.
 - b) Children with asthma (even if the asthma is mild or controlled by medication) are more likely than children who don't have asthma to develop serious complications from flu (like pneumonia) and to need to be hospitalized for flu-related complications.
 - c) Children with neurologic disorders and neurodevelopmental conditions, such as cerebral palsy, intellectual disability (decreased ability to think, learn, and reason), muscular dystrophy or spinal cord injury, are at high risk of developing flu-related complications, hospitalization, and even death. Children with these conditions sometimes:

- d) Have trouble with muscle function, lung function, or difficulty coughing, swallowing or clearing fluids from their airways.
- e) Have limited mobility and cannot avoid coming into contact with others who may be infected, like caretakers and family members.
- f) Have trouble understanding or practicing measures to prevent infections like the flu, such as hand washing or avoiding contact with people who are sick.
- g) Cannot communicate if they are sick.
- 18. 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 flu, your doctor may recommend treatment with flu antiviral drugs. (See <u>Antiviral Drugs</u> <u>messages</u>.)
 - b) For the full list of age factors and medical conditions that put someone at high risk of flu, see http://www.cdc.gov/flu/about/disease/high-risk.htm.
- 19. 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.
- 20. Be sure to let the doctor know if your child has ever experienced a reaction to flu vaccine. (See Egg Allergy messages.)
- 21. Children also should be current on other vaccines, including those that can help prevent pneumonia, like pneumococcal and Hib vaccines.
- 22. Talk to your child's doctor or other health care personnel about getting a flu vaccine.
- 23. CDC also recommends that parents and children take everyday preventive actions to stop the spread of germs. (See Everyday Preventive Actions messages.)
- 24. 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.
- 25. It is also important for <u>pregnant women to get vaccinated</u> to protect themselves and their babies.
- 26. More information about influenza and influenza vaccination in pregnant women is available at https://www.cdc.gov/flu/protect/vaccine/pregnant.htm.

Vaccine Doses for Children Aged 6 Months through 8 Years

- 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 personnel 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 2018-2019 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, 2018. The two previous doses do not need to have been given during the same season or consecutive seasons.

- b) <u>Children</u> 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 2018-2019 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. Everyone 9 years of age and older needs only one dose of 2018-2019 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/66/rr/rr6602a1.htm?scid=rr6602a1 w.

Statements for Pregnant Women

- 1. Influenza can be dangerous for pregnant women and may be harmful for their developing baby.
 - a) Flu is more likely to cause severe illness in pregnant women than in women of reproductive age who are not pregnant, particularly during the second and third trimesters.
 - b) Changes in the immune system, heart, and lungs during pregnancy make pregnant women (and women up to two weeks postpartum) more prone to severe illness from flu, including illness resulting in hospitalization.
 - c) Flu also may be harmful for a pregnant woman's developing baby.
 - i) A common flu symptom is fever, which may be associated with neural tube defects and other adverse outcomes for a developing baby.
- 2. Flu shots have been given to millions of pregnant women over many years with a good safety record.
 - a) There is a lot of evidence that flu vaccines can be given safely during pregnancy, though these data are limited for the first trimester.
 - b) CDC and ACIP recommend that pregnant women get vaccinated during any trimester of their pregnancy.
- 3. Getting a flu shot can help protect pregnant women and their babies (after birth) from flu.
 - a) There are a number of studies that show flu vaccines protect pregnant women from flu the same way that they protect people who are not pregnant (i.e., pregnant women develop antibodies against flu after vaccination).
 - b) Many vaccine effectiveness studies show that getting a flu shot reduces risk of illness by 40% to 60% during seasons when the vaccine is well-matched to circulating viruses.
 - c) Vaccination has been shown to reduce the risk of flu-associated acute respiratory infection in pregnant women by up to one-half.
 - d) Other studies have shown that similar protection is provided against flu-associated hospitalization.

- e) Though not specifically examined among pregnant women, there are some studies that suggest that flu vaccination may make illness milder among people who do still get sick.
- f) Pregnant women who get a flu vaccine are helping to protect their babies from flu illness for the first several months after their birth, when they are too young to get vaccinated. (i.e., a mother passes antibodies to the developing baby during her pregnancy).
 - [Alternative] In addition to helping to protect the pregnant woman, a flu vaccine given during pregnancy has been shown to help protect the baby from flu infection for several months after birth, before he or she is old enough to be vaccinated.
- g) Babies younger than 6 months of age are too young to get a flu vaccine. The best way to protect them is for their mother to get a flu shot during pregnancy and for people around them to get vaccinated, as well.
- h) An additional way to protect babies is for all caregivers and close contacts (including parents, brothers and sisters, grandparents, and babysitters) to get a flu vaccine.
- 4. If you have additional questions, talk to your doctor about flu vaccination during pregnancy.
- 5. In addition to getting a flu shot, pregnant women should take the same <u>everyday</u> <u>preventive actions CDC recommends of everyone, including covering coughs, washing</u> hands often, and avoiding people who are sick.
- 6. Pregnant women are at high risk of serious flu complications and should be treated with flu antiviral medications if they become ill with flu.
 - a) Oral oseltamivir is the preferred treatment for pregnant women because it has the most studies available to suggest that it is safe and beneficial.
 - b) Having a fever caused by flu infection or other infections early in pregnancy may be linked to birth defects in a baby. In addition to taking antiviral drugs, pregnant women who get a fever should treat their fever with Tylenol® (or store brand equivalent) and contact their doctor immediately.
- 7. If you are pregnant and get sick with flu symptoms, call your doctor right away. Your doctor may recommend treatment with influenza antiviral drugs (see <u>Antiviral Drugs messages</u>).
- 8. Influenza vaccination is recommended for breastfeeding women.
 - a) If you have your baby before getting a flu shot, you should still be vaccinated. Preventing flu in mothers can reduce the chances that their babies will get flu.
- 9. In 2017, a study in the journal Pediatrics was the first of its kind to show that flu vaccination also significantly reduced a child's risk of dying from influenza.
 - a) See "Influenza Vaccine Effectiveness Against Pediatric Deaths: 2010-2014: by Brendan Flannery et al. in Pediatrics at http://pediatrics.aappublications.org/content/early/2017/03/30/peds.2016-4244.
- 10. <u>Learn</u> about the vaccines you will need before and during your pregnancy to help protect yourself and your newest family member from serious diseases.

- a) Vaccines are an important part of planning and having a healthy pregnancy. If you are planning to get pregnant, check with your doctor to make sure you are up-to-date on your vaccines.
- b) If you are pregnant now, CDC, the American Academy of Pediatrics, the American College of Nurse midwives, and many other professional medical groups recommend you get two vaccines during your pregnancy:
 - ii) Tdap to help protect against whooping cough (pertussis)
 - iii) A flu shot to help protect against influenza (flu). (Note, flu vaccination is recommended during any trimester of pregnancy.)

Statements for Adults (18 through 64 years of age)

- 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 flu can result in missed school, work, and extracurricular activities and may result in severe illness with complications, hospitalization, and sometimes even death.
- 5. Flu does not affect just those at high risk of flu complications like young children and seniors; it can affect people in any age group, including people who are otherwise healthy.
- 6. It is not possible to predict which influenza viruses will be most common this season, and it is important for all adults to be vaccinated this season.
- 7. Vaccination is especially important for adults with certain long-term medical conditions because they are at increased risk of serious illness if they get sick with flu. This 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 also can help prevent spreading flu to friends and family who are at increased risk for flu complications including pregnant women, grandparents, young children, and people with certain long-term medical conditions like asthma or diabetes or people with a weakened immune system.
- 9. CDC recommends all adults and children also take everyday preventive actions to reduce the spread of germs. (See <u>Everyday Preventive Actions messages</u>.)
- 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 flu, CDC recommends you be treated with antiviral drugs. (See Antiviral Drugs messages.)
- 12. In addition to a flu vaccine, other vaccines that prevent serious diseases such as shingles, pneumococcal disease, meningococcal disease, hepatitis, and whooping cough are recommended for some adults. See <u>Vaccine Information for Adults</u> for more information.

- 13. Unfortunately, many adults are not up-to-date on all 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 personnel to learn which vaccines are recommended for them and take steps to stay up-to-date to ensure that they have the best protection against disease.
- 15. Flu and other vaccines for adults are offered in many locations, including doctor's offices, pharmacies, health centers, travel clinics, as well as by many employers and schools.

Statements for Adults 65 Years and Older

- 1. Older people with weaker immune systems often have a lower protective immune response after flu vaccination compared to younger, healthier people. This can make them more susceptible to the flu.
- 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 flu.
- 3. During most flu seasons, people 65 years and older bear the greatest burden of severe flu disease.
- 4. During recent seasons, for example, it's estimated that between 70 percent and 85 percent of seasonal flu-related deaths in the United States have occurred among people 65 years and older.
 - a) It's estimated that between 54 percent and 70 percent of seasonal flu-related hospitalizations in the United States have occurred among people 65 and older.
 - b) This pattern can change depending on which flu viruses are circulating. Vaccination is the best protection against 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, flu vaccine works best among healthy younger adults and older children.
- 7. Vaccine effectiveness in preventing flu hospitalizations among older adults has been similar compared to younger adults against H1N1 and influenza B viruses.
- 8. Vaccine effectiveness in preventing flu hospitalizations among older adults has sometimes been lower compared to younger adults against influenza A(H3N2) viruses.
- 9. Some older people and people with certain long-term medical conditions might develop less immunity than healthy children and adults after vaccination. However, even for these people, a flu vaccine is still the best protection against flu. (http://www.cdc.gov/flu/about/ga/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's and the Advisory Committee on Immunization Practices' (ACIP) general recommendation, people with weakened immune systems and people 65 years and older should be vaccinated each flu season 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.
- c) As long as flu viruses are circulating, it is not too late to get a flu shot, even in January or later.
- 10. 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 immune protection against flu viruses) of standard dose flu shots.
 - i) Data from studies comparing trivalent Fluzone® High-Dose and trivalent standard dose vaccines among people 65 years and older found a stronger immune response (i.e., higher antibody levels) after vaccination with Fluzone® High-Dose.
 - ii) Results from a clinical trial of more than 30,000 participants showed that adults 65 years of age and older 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.
 - i) 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.
 - ii) There are no randomized studies comparing FLUAD™ with Fluzone® High-Dose.
 - c) Note: At this time, CDC and 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.
- 11. 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.
- 12. Talk to your doctor or other health care provider about the best vaccine option for you.
- 13. 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.
- 14. 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 symptoms start. Visit http://www.cdc.gov/flu/antivirals/index.htm for more information. (See Antiviral Drugs messages)
- 15. Pneumococcal disease can be a complication of influenza infection and includes pneumonia, meningitis and blood infections.
 - a) Having the flu increases your risk of getting pneumococcal disease(https://www.cdc.gov/pneumococcal/about/infection-types.html).

- b) Pneumococcal pneumonia is an example of a serious <u>flu-related</u> <u>complication(https://www.cdc.gov/flu/about/disease/complications.htm)</u> that can cause death.
- 16. Two vaccines help prevent pneumococcal disease: PCV13 (pneumococcal conjugate vaccine) and PPSV23 (pneumococcal polysaccharide vaccine). You can get either pneumococcal vaccine (but not both) when you get a flu vaccine.
 - a) 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.
- 17. 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. One dose of PCV13 first, followed at least 1 year later by one dose of PPSV23.
- 18. 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. Getting sick with flu increases your chances of getting pneumococcal disease.
- 19. 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

(Back to table of contents)

General Messages

- Most people who get sick with 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 lung disease, 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) 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, 2 and gestational), 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

- 1. While CDC recommends everyone 6 months and older get vaccinated against flu, it is especially important to get a flu shot if you have diabetes (type 1, type 2, gestational diabetes).
- 2. People with diabetes (type 1, type 2 or gestational), even when well-managed, are at high risk of serious <u>flu complications</u>, which can result in hospitalization and sometimes even death. 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. Flu can make chronic health problems, like diabetes, worse. This is because diabetes can make the immune system less able to fight infections.
- 4. In addition, illness can make it harder to control your blood sugar. The illness might raise your sugar but sometimes people don't feel like eating when they are sick, and this can cause blood sugar levels to fall.
 - a) It is important to follow the <u>sick day guidelines</u> for people with diabetes.
- 5. A study showed that people with diabetes were more than two times more likely to be hospitalized with a flu-related illness than people without diabetes.
- 6. Everyone with diabetes, either type 1, type 2 or gestational diabetes, should get a flu vaccine each year to protect themselves from flu.
 - a) Flu vaccination has been shown to reduce the risk of getting sick with flu as well as reduce the risk of having a serious flu outcome like a stay in the hospital or even being admitted to the intensive care unit.
 - b) Flu vaccination also has been <u>associated with reduced hospitalizations</u> among people with diabetes (79%), including hospitalization for diabetes without mention of complications, diabetic coma, and ketoacidosis.
- 7. People with diabetes should ask their family and friends to get a flu vaccine as well to help reduce their chances of getting sick from flu illness.
- 8. Flu shots are recommended for use in people with diabetes (type 1, type 2 or gestational).
- 9. There is a <u>precaution against the use of nasal spray flu vaccine (LAIV)</u> in people with certain underlying medical conditions, including diabetes.
- 10. 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 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.
- 11. CDC recommends that people at high risk of serious flu complications such as people with diabetes be treated with flu antiviral drugs if they get sick with flu.
- 12. 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 Antivirals/index.htm for more information.
- 13. Take everyday steps to protect your health, like staying home when you are sick and washing your hands often. Visit: http://www.cdc.gov/flu/protect/habits/index.htm.
- 14. For more information about flu and diabetes, visit http://www.cdc.gov/flu/diabetes/.

Asthma

(Back to table of contents)

- 1. Asthma is not known to be a risk factor for flu, but flu infection can be more serious for people with asthma, even if their asthma is mild or their symptoms are well-controlled by medication.
- 2. People with asthma have swollen and sensitive airways, and influenza can cause further inflammation of the airways and lungs.
- 3. Flu infection in the lungs can also trigger asthma attacks and a worsening of asthma symptoms. It can also lead to pneumonia and other acute respiratory diseases.
- 4. Adults and children with asthma are more likely to develop pneumonia after getting sick with flu.
- 5. Asthma is the most common chronic medical condition among children hospitalized with flu and one of the more common medical conditions among hospitalized adults.
- 6. Flu shots are recommended for use in people 6 months of age or older with asthma.
- 7. There is a <u>precaution against the use of nasal spray flu vaccine (LAIV)</u> for children aged 5 years and older who have asthma. LAIV is not recommended for children aged 2 through 4 years who have asthma.
- 8. Family and friends of someone with asthma should get vaccinated to protect themselves and to reduce the chance of getting and spreading flu to their loved one with asthma.
- 9. 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.)
- 10. For more information about flu and asthma, visit http://www.cdc.gov/flu/asthma/index.htm.

Heart Disease

- 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 their condition when triggered by flu.
- 3) Studies have shown that influenza is associated with an increase in heart attacks and stroke.
- 4) Flu vaccination has been associated with lower rates of some <u>cardiac events</u>, <u>such as a heart attack</u>, <u>among people with heart disease</u>, especially among those who had had a cardiac event in the 12 months prior to flu vaccination.
 - a) Not only can a flu vaccine reduce your risk of getting sick with flu and reduce your risk of serious flu complications including being hospitalized or admitted to the intensive care unit, flu vaccination has been associated with lower rates of some cardiac events among people with heart disease. See "What are the benefits of flu vaccination?" for more information.

- 5) Flu shots are recommended for use in people with heart disease or who have had a stroke. LAIV is recommended as an option for use in non-pregnant individuals, 2 years through 49 years of age, however there is a precaution against the use of LAIV in people with certain medical conditions, including chronic heart disease.
 - a) Flu vaccination is especially important for people with heart disease because they are at high risk for complications from flu.
- 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 flu, like pneumonia, can put more stress on a person's heart.
- 8) In addition to getting the flu shot, people with heart disease or who have had a stroke should take additional <u>everyday preventive actions</u>, including covering coughs, washing hands often, and avoiding people who are sick.
 - a) Specific Health Actions for People with Heart Disease or who have had a stroke:
- 9) Maintain a two week supply of your regular medications during flu season.
- 10)Do not stop taking your regular medications without first consulting your doctor, especially in the event that you get the flu or another respiratory infection.
- 11)People with heart failure should be alert to changes in their breathing and should promptly report changes to their doctor.
- 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) For more information about influenza and heart disease, visit http://www.cdc.gov/flu/heartdisease/.

Severe Obesity

- 1. 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 had obesity.
- 2. Adults who have severe obesity (adults 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.
- 3. People 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. 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.
- 5. Various studies showed that adults with a BMI of 40 or greater were more likely to experience hospitalization, longer ICU stays, and death during the 2009 H1N1 pandemic.

- 6. People with severe 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 adults with severe obesity could have unrecognized chronic medical conditions.
- 7. Getting a flu vaccine is the most important action a person can take to prevent 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 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.
 - 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/healthyweight/assessing/bmi/.

People with Disabilities* and Caregivers:

- * The term "disability" refers to a reduced capacity to move parts of the body (mobility limitation) or to think, understand, remember, or reason (cognitive limitation). Disability includes people with conditions that affect how their brains and nerves function (neurological and neuro-developmental conditions). This includes disorders of the brain, spinal cord, nerves, and muscles, such as cerebral palsy, spinal cord injury, muscular dystrophy, and intellectual disability (the decreased ability to think, learn, and reason). These long-term conditions can make it difficult for a person to do certain activities or to interact in the world around them. Disability also includes people with other long-term health conditions, such as heart disease, asthma, and diabetes, which can interfere with and limit participation in daily activities.
- 1. People with certain types of disability are at high risk for developing flu-related complications that could require hospitalization. A full list of people at high risk for flu-related complications is at https://www.cdc.gov/flu/about/disease/high-risk.htm.
- 2. Flu is particularly dangerous for people who may have trouble with muscle function, lung function or difficulty coughing, swallowing or clearing fluids from their airways. Serious flu complications can include pneumonia, secondary bacterial infections that can lead to blood infections (sepsis), and sudden difficulties breathing (acute respiratory distress syndrome).
- 3. People with disabilities may be at risk of getting flu and/or having unrecognized flu symptoms because they
 - a) Have limited mobility and cannot avoid coming into contact with others who may be infected, like caretakers and family members;
 - b) Have trouble understanding or practicing measures to prevent infections like the flu, such as hand washing, or avoiding contact with people who are sick;
 - c) May not be able to communicate if they are sick;
 - d) May not be monitored closely for symptoms of illness.

- 4. Getting a flu vaccine (flu shot) is the most important action a person with disabilities can take to prevent flu and its complications. Caregivers and family members of people with disabilities can also help to protect them by getting a flu vaccine themselves.
- 5. CDC recommends that people at high risk of serious flu complications be treated with flu antiviral drugs if they get sick with flu. Antiviral drugs can make the flu illness milder and shorten the time being sick. They may also prevent serious flu complications.
 - a) Flu antiviral drugs work best if taken within the first 48 hours after symptoms start. Visit http://www.cdc.gov/flu/antivirals/index.htm for more information.
 - b) Ask your healthcare provider or pharmacist about possible drug interactions and side effects of your regular prescriptions with flu-related medications. (See <u>Antiviral Drugs messages</u>.)
- 6. Take everyday steps to protect your health. Visit http://www.cdc.gov/flu/protect/habits/index.htm.

Statements for American Indians and Alaska Natives

- During the 2009 H1N1 pandemic, indigenous populations from Australia, Canada, New Zealand, and the United States, including American Indians and Alaska Natives, experienced a rate of hospitalization and death associated with infection with the 2009 H1N1 flu virus that was three to eight times higher than what was seen in other populations.
 - a) A study of 12 states, including Alaska, showed that the death rate from 2009 H1N1 flu in American Indian and Alaska Natives was four times higher compared to the death rate from 2009 H1N1 flu in all other racial/ethnic populations combined. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5848a1.htm
 - b) The increased influenza mortality in American Indian and Alaska Native 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. https://www.ncbi.nlm.nih.gov/pubmed/26118767
 - c) A study of racial-ethnic disparities in 2009 H1N1 pandemic illness severity found that self-reported influenza-like-illness (ILI) was higher among American Indians and Alaska Natives (16.2%) compared to non-Hispanic whites (8.5%). Also, rates of hospitalization were higher among American Indians and Alaska Natives than for non-Hispanic whites.
 - i) See "Racial and Ethnic Disparities in Hospitalization and Deaths Associated with 2009 Pandemic Influenza A (H1N1) Virus Infections in the United States" by Deborah Lee et al. Annals of Epidemiology, 21:8 (2011) pp 623-630 at https://doi.org/10.1016/j.annepidem.2011.03.002.
- 2. Studies by doctors in Alaska suggest that several factors may increase infection risk and serious complications associated with bacterial and viral pathogens (including 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.
- 3. 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.

- 4. American Indians and Alaska Natives are included in the list of people at high risk for complications from flu and for whom vaccination is especially important.
- 5. American Indians and Alaska Natives can protect themselves by getting flu and pneumococcal vaccines. These vaccines are available at your local health care facility (even if you don't have a regular doctor or other health care personnel); mobile and community-based immunization clinics that are held in many locations; and at pharmacies and grocery stores where available.
 - a) American Indian and Alaska Native children younger than 19 years of age are eligible for the Vaccines for Children (VFC) Program. Learn more at https://www.cdc.gov/vaccines/programs/vfc/providers/eligibility.html
- 6. A flu vaccine can help protect American Indians and Alaska Natives, including children, adults, and elders against flu.
- 7. 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).
- 8. CDC has prepared general messages for how all people, including American Indians and Alaska Natives, can protect themselves and their loves ones from flu. (*Please see the sections titled Take 3, Vaccination and Everyday Preventive Actions for these messages*).

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

- 1. As a health care provider, you are a trusted and valuable source of health information. Patients may view you as their primary or preferred source of information. This provides you the opportunity to assess your patients' vaccination status and possibly to administer the appropriate vaccines.
- 2. As a health care provider, your strong recommendation is a critical factor that affects whether your patients get a flu vaccine.
- 3. Research indicates that most adults are likely to get their flu vaccine if their doctor or health care provider recommends it to them.
- 4. Most adults believe vaccines are important, but they need a reminder from their health care provider to get vaccinated.
- 5. Recommend flu vaccination for all of your patients 6 months of age and older. Make plans to vaccinate your patients, your staff, and yourself.
- 6. CDC suggests using the SHARE method to make a strong vaccine recommendation and provide important information to help patients make informed decisions about vaccinations.
 - a) SHARE the reasons why the flu vaccine is right for the patient given his or her age, health status, lifestyle, occupation, or other risk factors
 - b) HIGHLIGHT positive experiences with flu vaccines (personal or in your practice), as appropriate, to reinforce the benefits and strengthen confidence in flu vaccination
 - c) ADDRESS patients questions and any concerns about the flu vaccine, including side effects, safety, and vaccine effectiveness in plain and understandable language

- d) REMIND patients that flu vaccines protect them and their loved ones from serious flu illness and flu-related complications
- e) EXPLAIN the potential costs of getting flu, including serious health effects, time lost (such as missing work or family obligations), and financial costs
- 7. Visit http://www.cdc.gov/flu/professionals/acip/ to view the 2018-19 Advisory Committee on Immunization Practices (ACIP) Influenza Vaccine Recommendations.
- 8. For the 2018-2019 season, the nasal spray flu vaccine (live attenuated influenza vaccine or LAIV) is an option for influenza vaccination for persons for whom it is otherwise appropriate.
- 9. During 2018-2019 season, providers may choose to administer any licensed, ageappropriate flu vaccine (inactivated influenza vaccine (IIV), recombinant influenza vaccine (RIV), or live attenuated influenza vaccine (LAIV4)).
 - a) As a trusted health care provider, research shows that your recommendation to patients for yearly flu vaccination and taking action to get yourself vaccinated is vital.
 - b) Ideally, all health care personnel, 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 <u>strong recommendation</u> for them to get vaccinated is critical. Health care personnel 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 flu shot. You and your patient can visit the HealthMap Vaccine Finder (http://vaccine.healthmap.org/) to find locations in your area that offer recommended vaccines.
 - d) Take every opportunity to help educate your patients about the importance of flu vaccination this and every year.
 - e) For more information on how to make a strong flu vaccine recommendation, visit https://www.cdc.gov/flu/professionals/vaccination/flu-vaccine-recommendation.htm.
- 10. Flu can spread rapidly in health care settings. Vaccination is the first and most important step physicians and health care personnel can take to protect themselves and their patients against flu.
- 11. Even if you are otherwise healthy, you can get sick and spread flu. Get vaccinated to help protect yourself from 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 personnel get vaccinated, vulnerable patients are better protected against flu.
- 12. Health care personnel should routinely offer seasonal flu vaccination to all patients aged 6 months and older. Its recommended patients get a flu vaccine by the end of October, but vaccination should continue throughout the flu season, which can last as late as May.
- 13. Optimally, vaccination should occur before onset of influenza activity in the community. In any given season, however, the optimal time to vaccinate cannot be predicted precisely because influenza seasons vary in timing and duration. Moreover, more than one flu outbreak might occur in a given community in a single influenza season.
- 14. While seasonal influenza (flu) viruses are detected year-round in the United States, flu viruses are most common during the fall and winter.

- 15. The exact timing and duration of flu seasons in the U.S. can vary, but influenza activity often begins to increase in October.
- 16. Most of the time flu activity peaks between December and February, although flu activity can last as late as May.
- 17. ACIP and CDC recommend flu vaccination by the end of October; however, providers should try to avoid missed opportunities for vaccination of patients who they might see before October and continue to vaccinate patients throughout the influenza season.
- 18. CDC encourages providers in medical practices, health departments, pharmacies, and other health care settings to use flu vaccination as an opportunity to remind adult patients about other recommended vaccines. http://www.cdc.gov/vaccines/schedules/hcp/adult.html
- 19. Visit <u>CDC's free influenza resources</u> for references and resources to communicate about flu vaccination with patients, partners, and the community.
- 20. For the latest information on flu vaccine supply, including projections and doses distributed, visit https://www.cdc.gov/flu/about/qa/index.htm.
- 21. Key information for public health and health care personnel regarding vaccination, infection control, prevention, treatment, and diagnosis of seasonal flu is available at http://www.cdc.gov/flu/professionals.
- 22. Order free flu 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.
- 23. Health care personnel should take everyday preventive actions to prevent the spread of germs and suggest the same to their patients. (See <u>Everyday Preventive Actions</u> <u>messages</u>).
- 24. As part of the Affordable Care Act, many insurance plans, including all plans in the Health Insurance Marketplace, provide many free preventive services, including flu vaccinations, without charging a <u>copayment</u> or <u>coinsurance</u>. For information about the Health Insurance Marketplace, visit www.HealthCare.gov.

Statements for Health Care Personnel in Long-term Care Facilities

- 1. All health care personnel (HCP) in the long-term care (LTC) workforce are recommended to receive annual influenza vaccination.
 - a) Health care personnel include 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 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 sick with flu from patients and coworkers who are sick with flu.
 - b) If you get sick with 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 flu and account for the majority of flu-related 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 LTC settings, to get vaccinated against influenza each year.
- 4. Health care personnel should get their flu vaccine by the end of October. Ideally they should be protected before flu activity begins in their community.
- 5. CDC recommends flu vaccine to health care personnel working in LTC settings in order to prevent influenza among health care personnel and to help reduce the spread of flu in resident populations.
 - a) Health care personnel in long-term care facilities who are not vaccinated against 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 makes 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 high flu vaccination coverage rates among health care personnel and increased protection against flu among people in long-term care facilities and hospitals.
 - a) For example, see "Effect of Influenza Vaccination of Healthcare Personnel on Morbidity and Mortality Among Patients: Systematic Review and Grading of Evidence" by Ahmed et al. in *Clinical Infectious Diseases* at https://academic.oup.com/cid/article/58/1/50/372080/Effect-of-Influenza-Vaccination-of-Healthcare.
- 9. People 65 years and older are at high risk of serious complications from flu compared with young, healthy adults, in part because human immune defenses become weaker with age.
 - a) During most flu seasons, people 65 years and older bear the greatest burden of severe flu disease.
 - b) It's <u>estimated</u> that between 71 percent and 85 percent of seasonal flu-related deaths have occurred in people 65 years and older.
 - c) It's estimated that between 54 percent and 70 percent of seasonal flu-related hospitalizations have occurred among people 65 years and older.
- 10. There are several reasons that health care personnel report that they get vaccinated against influenza. During the 2017-2018 influenza season, health care personnel, in general, reported the most common reason was to protect themselves from getting sick with 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 target for seasonal influenza vaccination among health care personnel is 90 percent (see Healthy People 2020 objective IID-12.9).

Background:

- 1. As reported in the October 29, 2017 Morbidity and Mortality Weekly Report (MMWR), overall, 78.6% of health care personnel reported having received an influenza vaccination for the 2016-2017 season.
 - a) Vaccination coverage was highest among HCP working in hospitals (92.3%) and lower among health care personnel working in ambulatory (76.1%) and long-term care settings (68.0%).
- 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 personnel may spread the virus to others.
 - b) To avoid this, HCP 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, and personal care aides provide hands-on and personal assistance to vulnerable populations, including LTC residents. Among health care personnel, vaccination rates are lower among people in these occupations.
- 5. A <u>recent large, randomized clinical trial</u> tested whether a high-dose flu vaccine with four times the antigen of a standard flu vaccine could reduce the risk of hospitalization among vulnerable adults aged 65 years or older.
 - a) <u>The study shows</u>, when compared with standard-dose vaccine, high-dose influenza vaccine can reduce risk of respiratory-related hospital admissions from nursing home residents aged 65 years and older.
 - b) More immunogenic, high-dose vaccines can reduce the number of hospital admissions for people aged 65 years or older, among those living in nursing homes.
 - c) <u>The same study shows</u> that high-dose influenza vaccine has greater effectiveness than the standard-dose influenza vaccine against respiratory and all-cause hospital admissions in a long-term care population.

Flu Vaccine Safety

(Back to table of contents)

General

1. Flu vaccines are among the safest medical products in use. Hundreds of millions of Americans have safely received flu vaccines during 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 sick with 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.
- 5. Common side effects from the flu shot include soreness, redness, and/or swelling from the shot, headache, fever, muscle aches, and nausea.
- 6. Severe allergic reactions are rare. They 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) <u>Vaccine Safety Datalink (VSD):</u> A collaboration between CDC and eight integrated health care organizations conducts near real-time vaccine safety monitoring and epidemiologic studies.

Thimerosal

(Back to table of contents)

- 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 when doses are withdrawn from the vial.
- 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. 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 total number of influenza vaccine doses projected to be available for the 2018-2019 season (163 million to 168 million), approximately 135 million doses are estimated to be thimerosal-free (up from 130 million projected for last season)

Guillain-Barré Syndrome

(Back to table of contents)

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. 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.
- 3. People also can develop GBS after getting sick with flu or other infections (such as cytomegalovirus and Epstein Barr virus).
- 4. On very rare occasions, people may develop GBS in the days or weeks after getting a vaccination.
- 5. 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.
- 6. 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 1-2 in a million.
- 7. Studies suggest that it is more likely that a person will get GBS after getting flu than after a flu 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

- 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.
- 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 <u>study</u> 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. Other 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 is increased when a flu shot is given at the same time as pneumococcal conjugate vaccine (PCV13) and/or the combination diphtheria, tetanus, and pertussis vaccine (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

(Back to table of contents)

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

For information on the flu vaccine and egg allergy, please see the <u>Flu Vaccine and Egg</u> Allergy section of this document.

Flu Vaccine and Pregnancy

(Back to table of contents)

Influenza vaccines have a good safety record.

- 1. There is a lot of evidence that flu vaccines are safe during pregnancy, although fewer data are available for vaccination in the first trimester of pregnancy.
- 2. The most common side effects of flu vaccination 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 fatique.
- 3. Several examples of recent flu vaccine safety studies conducted in pregnant women are provided below:
 - a) A review of reports to the Vaccine Adverse Reporting System (<u>VAERS</u>) (<u>Moro et al</u>, <u>2011</u>) found no link between pregnancy complications or adverse fetal outcomes among pregnant women and flu shots or nasal spray flu vaccine.
 - b) A large study using <u>VSD</u> data (<u>Kharbanda et al, 2013</u>) 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.
 - c) A <u>VSD</u> study (<u>Nordin et al, 2014</u>) compared pregnant women who received a flu shot with an equal number of pregnant women who did not receive a 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.
 - d) A study using Vaccine Safety Datalink (<u>VSD</u>) data (<u>Irving et al, 2013</u>) found no increased risk of miscarriage among pregnant women who received flu vaccines in the 2005-06 or 2006-07 flu seasons. A similar study 2010-2012, however, found that women in early pregnancy who received two consecutive annual flu vaccines

had an increased risk of miscarriage in the 28 days after receiving the second vaccine. Other studies have not found increased risks of miscarriage following flu immunization. A larger follow up investigation to study this issue further is ongoing. More information on this topic is available at

https://www.cdc.gov/flu/professionals/vaccination/vaccination-possible-safety-signal.html

4. 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.

Shoulder Injury and Safe Vaccination

(Back to table of contents)

- 1. Shoulder injury related to vaccine administration (SIRVA) is a rare condition that can occur with any injectable vaccine, including influenza vaccine.
- 2. SIRVA happens when a vaccine is injected into or too close to the structures of the shoulder joint, such as the bursa or tendons. These injections likely occur too high on the shoulder near the joint rather than into the thickest part of the deltoid muscle on the side of the shoulder.
- 3. Using proper technique when administering any vaccine (including injectable influenza vaccine) by intramuscular injection is important for preventing SIRVA.
- 4. To promote safe vaccination, CDC has a campaign to educate and remind providers about proper influenza (flu) vaccine administration technique to help avoid injuries.
 - a) The materials include links to comprehensive <u>vaccine administration information</u> and a <u>short video</u> on the correct technique for intramuscular injection, as well as a link to a new vaccine administration e-Learn.
 - b) <u>LAIV should be administered</u> by an intranasal squirt using appropriate technique described in the package insert.

Flu Vaccine Effectiveness

- 1. Flu vaccines protect against infection and illness caused by flu viruses.
- 2. Flu vaccines will **NOT** protect against infection and illness caused by **other viruses** that can also cause flu 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 conduct studies each year to measure how well flu vaccines work in order to continually assess and confirm their value as a public health measure. Part of the need for this continued assessment is that flu viruses that circulate each year tend to change and evolve, and so the components of the flu vaccine are changed relatively frequently to protect against these new circulating viruses.
- 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.
- 6. Two general types of VE studies are used to determine how well influenza vaccines work: randomized controlled trials and observational studies. For more information, (see "VE Study Methods" Messages)
- 7. 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.
- 8. 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.
- 9. During years when the viruses in the flu vaccine and circulating flu viruses are well matched, it's possible to measure substantial benefits from flu vaccination in terms of preventing flu illness.
- 10. However, even during years when the vaccine match is 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.
- 11. A flu vaccination does not guarantee protection against 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.
- 12. Recent studies by CDC researchers and other experts indicate that flu vaccination reduces the risk of influenza illness by 40% to 60% among the overall population when the vaccine viruses are like the ones spreading in the community.
- 13. Effectiveness against influenza A(H3N2) viruses tends to be lower than against other types of influenza viruses.
 - a) Even when recommended vaccine viruses and circulating influenza viruses are alike (i.e., well-matched), the amount of protection provided by flu vaccines may vary by influenza virus type or subtype.
 - b) Since 2009, VE studies looking at how well flu vaccines protect against medically attended illness have suggested that when vaccine viruses and circulating flu viruses are well-matched, flu vaccines provide better protection against influenza B or influenza A(H1N1) viruses than against influenza A(H3N2) viruses.
 - c) There are a number of reasons why flu vaccine effectiveness against influenza A(H3N2) viruses may be lower.
 - i) While all influenza viruses undergo frequent genetic changes, the changes that have occurred in A(H3N2) viruses have more frequently resulted in differences (i.e., antigenic changes) between the H3N2 component of the flu vaccine and circulating H3N2 viruses compared with H1N1 and influenza B viruses.
 - ii) That means that between the time when the composition of the flu vaccine is recommended and when the vaccine is delivered, H3N2 viruses are more likely

- than H1N1 or influenza B viruses to have changed in ways that could impact how well the vaccine works. Explained a different way, flu experts have a difficult time finding and choosing a H3N2 virus component for the seasonal flu vaccine that will be well-matched to all of the circulating H3N2 viruses.
- iii) Growth in eggs is part of the production process for most seasonal flu vaccines. While all influenza viruses undergo changes when they are grown in eggs, the egg-adapted changes that occur in influenza A(H3N2) viruses tend to be more likely to result in antigenic changes compared to other influenza viruses.
- iv) These so-called "egg-adapted changes" are present in the vaccine viruses that are used for vaccines produced in eggs and may reduce its effectiveness against circulating influenza viruses.
- v) Egg-adapted changes can result in significant antigenic differences between vaccine viruses and circulating viruses. When this occurs, the resulting vaccine may not provide immune protection against the corresponding viruses in circulation. For more information on egg-adapted changes, see https://www.cdc.gov/flu/protect/vaccine/how-fluvaccine-made.htm#egg-based.
- 14. Some studies have shown that flu vaccination can reduce the risk of more serious flu outcomes, including hospitalizations.
 - a) Those studies have often shown that flu vaccines provide similar protection against flu-associated hospitalization and outpatient flu-associated illness during the same season.
- 15. In 2017, a study in the journal *Pediatrics* was the first of its kind to show that flu vaccination also significantly reduced a child's risk of dying from influenza.
 - a) This study, which looked at data from four flu seasons between 2010 and 2014, found that flu vaccination reduced the risk of flu-associated death by half (51 percent) among children with underlying high-risk medical conditions, and it reduced the risk of flu-associated death by nearly two-thirds (65 percent) among healthy children.
 - b) Researchers estimated how effective the vaccine was at preventing flu-related deaths by comparing the vaccination status of the children who died from flu to comparison groups of children. The comparison groups were obtained from two national surveys and a database of commercial insurance claims.
 - c) During the study period, 358 laboratory-confirmed, flu-associated child deaths were reported to CDC. Of the reported pediatric deaths with known vaccination status (291), only one in four children (26 percent) had been vaccinated.
 - d) The study findings underscore the importance of the recommendation by CDC and the American Academy of Pediatrics (AAP) that all children 6 months and older get an annual flu vaccine.
 - e) The study is available at http://pediatrics.aappublications.org/content/early/2017/03/30/peds.2016-4244.
- 16. Studies also have shown that flu vaccination is an important preventive tool for people with chronic health conditions.
- 17. In addition to helping to protect the pregnant woman, a flu vaccine given during pregnancy has been shown to help protect the baby from flu infection for several months after birth, before he or she is old enough to be vaccinated.

- a) For example, a review of four randomized controlled trials conducted in South Africa, Mali, Nepal and Bangladesh assessed the efficacy of flu vaccination during pregnancy against laboratory confirmed flu infection in mothers and their infants. In these trials, vaccination of pregnant women resulted in vaccine efficacy in infants that ranged from 30% in Nepal to 63% in Bangladesh.
 - i) "Maternal Immunization" by Saad Omer et al. N Engl J Med; 376:1256-1267.
- 18. 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.
 - a) Note: additional factors, such as egg-adapted changes that can occur as part of the process to create flu vaccines (see bullet 10.c for more information), can affect the match between the vaccine and circulating flu viruses.
- 19. In groups at increased risk of influenza complications and severe influenza (i.e. young children, older adults and persons with chronic medical conditions), studies have shown that flu vaccine reduces risk of influenza.
- 20. Although <u>immune responses may be lower in the elderly</u>, vaccine effectiveness has been similar in most flu seasons among older adults and those with chronic health conditions compared to younger, healthy adults.
- 21. During years when the viruses in the flu vaccine and circulating flu viruses are not well matched, it is possible that no or minimal benefit from flu vaccination may be observed.
 - a) When flu vaccines and circulating flu viruses are not well matched, the use of influenza antiviral medications may be more important than usual.
- 22. The substantial burden of flu-associated illness and death in the United States combined with the overall evidence from a variety of studies that show flu vaccines offer protection against flu illness support the current U.S. flu vaccination recommendations.
- 23. It is important to note; however, that how well flu vaccines work to protect against flu illness will continue to vary each year.
- 24. Flu vaccination does not guarantee protection against flu. Some people who get vaccinated might still get sick. However, people who get vaccinated are less likely to get sick with flu than someone who does not get vaccinated.

VE Studies

- 1. CDC has been working with researchers at universities and hospitals since the 2003-2004 flu season to estimate how well flu vaccines work each season.
 - a) Each influenza season since 2004-2005, CDC has estimated the effectiveness of seasonal influenza vaccine to prevent influenza-associated, medically attended, acute respiratory illness (ARI).
- 2. CDC has established two VE networks that collect data each year against two different outcomes:
 - a) the "U.S. Flu Vaccine Effectiveness Network" collects VE data on outpatient illness (i.e., doctor's visits) with laboratory-confirmed flu; and

- b) the recently established "Hospitalized Adult Influenza Vaccine Effectiveness Network" (HAIVEN), which collects VE data on hospitalizations associated with laboratory-confirmed flu among adults 18 years of age and older.
- 3. CDC partners with universities and hospitals to conduct observational studies each year using data collected through these two VE networks.
- 4. These studies currently use a very accurate and sensitive laboratory test known as RT-PCR (reverse transcription polymerase chain reaction) to confirm medically-attended flu virus infections as a specific outcome.
- 5. In the future, a 3rd network, the New Vaccine Surveillance Network, may contribute VE data on hospitalizations associated with laboratory-confirmed flu among children.

For more information on each of these VE networks, see the sections entitled "<u>U.S. Flu VE</u> <u>Network"</u> and "<u>Hospitalized Adult Influenza Vaccine Effectiveness Network (HAIVEN)"</u> below.

U.S. Flu VE Network

(Back to table of contents)

- The U.S. Flu Vaccine Effectiveness (VE) network is designed to provide estimates of clinical effectiveness of licensed vaccines by age group and by influenza type and subtype.
- 2. Enrollees are patients evaluated in outpatient settings for acute respiratory symptoms with cough.
- 3. The network consists of five study sites spread across the United States, including sites in the following states:
 - a) Wisconsin;
 - b) Michigan;
 - c) Washington;
 - d) Pennsylvania; and
 - e) Texas.
- 4. Enrollment begins after laboratory-confirmed influenza cases are reported in local surveillance for two consecutive weeks and continues for the rest of flu season.
- 5. Patients are eligible if they are older than 6 months of age (thus being eligible to receive influenza vaccination), they have reported acute respiratory illness with cough within seven days, and they have not been treated with influenza antiviral medications.
- 6. Eligible patients complete an enrollment interview and answer basic questions regarding their influenza vaccination status, age, underlying health conditions, and other characteristics. Influenza vaccination status is later confirmed by reviewing records. Following enrollment, a respiratory specimen is collected and tested for influenza by the CDC real-time reverse transcription polymerase chain reaction (RT-PCR) assay. Influenza-positive samples are then typed and subtyped.

Hospitalized Adult Influenza Vaccine Effectiveness Network (HAIVEN)

- 1. At the ACIP meeting on June 20, 2018, CDC presented VE estimates of flu vaccine effectiveness against flu-associated hospitalizations in adults using data from the U.S. Hospitalized Adult Influenza Vaccine Effectiveness Network (HAIVEN).
- 2. HAIVEN was created to estimate how well the flu vaccine works at preventing labconfirmed flu-related hospitalizations, especially among older adults.

- a) VE in older adults is important because this age group has the highest hospitalization rates compared to other age groups. Also, adults who are hospitalized may have more underlying conditions and be more frail than older adults enrolled in the outpatient network.
- 3. HAIVEN is funded by the Centers for Disease Control and Prevention (CDC). Participating sites are located in four states:
 - a) Michigan,
 - b) Texas,
 - c) Pennsylvania, and
 - d) Tennessee.
- 4. In 2017-2018, 10 enrolling hospitals participated.
- 5. HAIVEN was piloted during the 2015-2016 season, during which seven hospitals participated. During the past two flu seasons (2016-2017 and 2017-2018), 10 enrolling hospitals participated.
- 6. HAIVEN uses an observational study design and collects data at the participating hospitals.
- 7. The study uses a test-negative case-control study design to calculate the odds of having lab-confirmed influenza among unvaccinated hospitalized patients with odds of having lab-confirmed influenza among vaccinated hospitalized patients.
- 8. HAIVEN calculates VE by comparing the frequency of influenza among hospitalized adults who were either vaccinated or not vaccinated against influenza.
 - a) Adults who were admitted to participating hospitals were invited to enroll in the study if their symptoms could be caused by influenza infection.
 - b) If they chose to enroll, patients were asked if they got their flu vaccine for that season.
 - c) Patients also were tested for influenza using highly accurate lab tests (RT-PCR) to verify the outcome.
 - d) Patient medical charts were reviewed.
 - e) In addition, information was provided by patients' self-reports, and data also was collected from vaccination providers and immunization registries to confirm receipt of vaccination.
- 9. In addition to information about VE, the HAIVEN data provided insight into severe influenza outcomes, such as length of hospital stay and need for intensive care.

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

(Back to table of contents)

1. Two general types of studies are used to determine how well flu vaccines work: randomized controlled trials (RCTs) and observational studies. These study designs are described below.

- a) In a RCT, volunteers are assigned randomly to receive a flu vaccine or a placebo (e.g., a shot of saline).
- b) Vaccine efficacy is measured by comparing the frequency of influenza illness in the vaccinated and the unvaccinated (placebo) groups.
- c) The RCT study design minimizes bias that could lead to invalid study results. Bias is an unintended systematic error in the way researchers select study participants, measure outcomes, or analyze data that can lead to inaccurate results
- d) In a RCT, vaccine allocation is usually double-blinded, which means neither the study volunteers nor the researchers know if a given person has received vaccine or placebo.
- e) RCTs are the "gold standard" (best method) for determining how well a vaccine works.
- f) The measurement of vaccine effect from an RCT is referred to as "efficacy." Vaccine efficacy refers to vaccine protection measured in RCTs usually under optimal conditions where vaccine storage and delivery are monitored and participants are usually healthy.
- g) 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.
- 2. The second type of study design is an "observational study."
 - a) Observational studies assess how flu vaccines work by comparing the frequency of flu between people who have and have not been vaccinated.
 - b) This means that vaccination of study subjects is not randomized and factors linked with vaccination have to be carefully accounted for.
 - c) The measurement of vaccine effect from an observational study is referred to as "effectiveness." Vaccine effectiveness refers to vaccine protection measured under real-world conditions.
 - d) Most recent studies to measure how well flu vaccine works have been observational studies.
 - e) There are several types of observational studies, including cohort and case-control studies.
 - f) Many observational studies use a case-control design, in which people with lab-confirmed flu ("cases") are compared with a group of people who do not have flu (i.e., the "control" group).
 - g) The choice of the "control group" is an important aspect of the design of observational studies that can influence their results.
 - i) Members of the control group who do not have flu should come from the same population as the cases, and should be sampled in a way that is not related to exposure (i.e., vaccination). If this is not done, the results may show a falsely high or low result (i.e., bias).
 - h) 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 VE estimate.

- i) Other factors that can affect results are the numbers of cases (i.e., 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). Therefore, when assessing how well a vaccine works, it is important to consider the study design, population and year.
- 3. Studies also can assess how well a vaccine works at preventing different outcomes.
 - a) For example, the outcomes can be broad syndromes associated with flu, like measuring influenza-like illness* (which includes illness caused by other viruses in addition to flu viruses),
 - b) 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.
 - c) *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.
- 4. 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).
- 5. Flu vaccine can only prevent the portion of illnesses that is caused by flu. Studies that report flu vaccination prevents a large proportion of deaths due to "all causes" or "all respiratory illnesses" or "all respiratory-related hospitalizations" when only a small proportion are caused by flu may have unidentified errors or bias.

Vaccine Effectiveness Last Season (2017-2018)

(Back to table of contents)

- 1. CDC vaccine effectiveness (VE) studies for the influenza A(H3N2)-predominant 2017-2018 flu season showed that flu vaccination reduced the risk of getting sick and having to go the doctor because of flu by 40% overall. These studies also showed that flu vaccination provided better protection against influenza B viruses (49%) than against the most common influenza A(H3N2) viruses (24%).
- 2. The preliminary VE estimate against flu-associated hospitalization was 22%.
- 3. These results are consistent with what has been observed during previous seasons when vaccine viruses and circulating viruses have been well-matched. In recent years, VE against H3N2 viruses has been lower than against other viruses. The 2017-18 season's effectiveness estimates compare best with the 2016-17 season when VE was 42% and CDC estimated that vaccine prevented 5.3 million illnesses, 2.6 million doctor visits, and 85,000 hospitalizations.
- 4. While these VE results underscore the importance of developing better, more effective flu vaccines, they also show that current flu vaccines do offer substantial public health benefit and that increased coverage could provide additional benefit.

U.S. Flu VE Network: Outpatient Illness VE Estimates (2017-2018)

(Back to table of contents)

1. On <u>June 20, 2018</u>, CDC presented end-of-season estimates for the 2017-2018 flu vaccine's effectiveness (VE) at preventing laboratory confirmed, flu-associated medical visits for acute respiratory illness (ARI) collected through the U.S. Flu VE Network.

- 2. The overall vaccine effectiveness of the 2017-2018 flu vaccine against both influenza A and B viruses was estimated to be 40% (95% confidence interval (CI): 34%-46%).
 - a) In practical terms, this means flu vaccine reduced a person's risk of having to seek medical care at a doctor's office for flu illness by 40%.
- 3. VE against outpatient illness caused specifically by influenza A (H3N2) viruses was estimated to be 24% (95% CI: 15%-33%).
- 4. VE against influenza B/Yamagata viruses was estimated to be 49% (95% CI: 40%-56%).
- 5. VE against influenza A (H1N1) viruses was estimated to be 65% (95% CI: 55%-73%).
- 6. Young children had the highest VE point estimates of all age groups. VE against influenza A and B viruses for children 6 months to 8 years of age was 53% (95% CI: 42%-62%). Against H3N2 viruses, it was 37% (95% CI: 17% to 52%).
- 7. These updated VE estimates incorporate additional data collected since CDC published its interim VE estimates in the February 16, 2018 edition of the MMWR.
- 8. This VE report used data from 8,635 children and adults enrolled in the five participating sites in the U.S. Influenza Vaccine Effectiveness Network (U.S. Flu VE Network) during November 2, 2017 April 20, 2018.
- 9. These preliminary end-of-season estimates may change slightly as additional data are collected through the summer. The final end-of-season VE estimates for 2017-2018 will be made available in fall 2018.

Methods

- 10. At the five U.S. Flu VE Network study sites, patients aged 6 months of age and older seeking outpatient medical care for ARI with cough within seven days of illness onset were enrolled.
- 11. Study enrollment began after one or more laboratory-confirmed cases of influenza were identified through local surveillance for two or more consecutive weeks.
- 12. Patients were eligible for enrollment if they:
 - a) Were 6 months of age or older on September 1, 2017 (and therefore, eligible for vaccination);
 - b) Reported ARI with cough and fewer than seven days of symptoms; and
 - c) Had not been treated with influenza antiviral medication during this illness.
- 13. Patients were interviewed to collect demographic data, general and current health status, symptoms, and 2017-2018 influenza vaccination status.
- 14. Respiratory specimens were collected from each patient using nasal and throat swabs.
- 15. Specimens were tested at U.S. Flu VE Network laboratories using CDC's real-time reverse transcription polymerase-chain reaction (rRT-PCR) protocol.

Data

- 16. Among the 8,635 children and adults with ARI enrolled at the five study sites from November 2, 2017 through April 20, 2018 and included in analyses, 3,097 (36%) tested positive for influenza virus by rRT-PCR.
 - a) 2,152 (69%) of these viruses were influenza A,
 - b) and 970 (31%) were influenza B viruses
 - c) Note that 25 were positive for more than one influenza virus and are included in more than one category.
- 17. Among 2,152 subtyped influenza A viruses, 1,790 (83%) were A (H3N2) viruses.
- 18. These estimates will be posted here when the presentation becomes available on the ACIP web site: https://www.cdc.gov/flu/professionals/vaccination/effectiveness-studies.htm

HAIVEN: Hospitalization VE Estimates (2017-2018)

- 1. At the ACIP meeting on June 20, 2018, CDC presented preliminary VE estimates against flu-associated hospitalizations in adults using data collected through the U.S. Hospitalized Adult Influenza Vaccine Effectiveness Network (HAIVEN).
- 2. HAIVEN VE estimates for the 2017-2018 season are as follows:
 - a) Vaccine offered significant protection against flu hospitalizations.
 - b) Adjusted total VE against hospitalization was 22% (95% CI: 8%-35%) This means that the flu vaccine reduced a person's risk of hospitalization due to flu by 22%.
 - i) Adjusted VE against A(H3N2) for all adult age groups: 16% (95% CI: -5%-32%)
 - ii) Adjusted VE against A(H3N2) in people 50-64 years of age: 33% (95% CI: 2%-54%)
 - iii) With regard to A (H3N2) viruses, no other age groups had statistically significant VE estimates.
 - (1) Note, when a VE estimate is "not statistically significant," it means the confidence interval crosses zero, and therefore, the true value could be zero and if the point estimate is above zero this could be due to chance.
 - iv) Adjusted VE against A(H1N1) for all adult age groups: 58% (95% CI: 36%-73%)
 - v) Adjusted VE against B/Yamagata for all adult age groups: 35% (95% CI: 11%-52%)

Methods

- 3. HAIVEN was piloted during the 2015-2016 season, during which seven hospitals participated. This season and in 2016-2017, a total of 10 hospitals participated.
- 4. A test-negative case-control study design was used to estimate VE from HAIVEN data for the 2017-2018 flu season.
- 5. The study calculated the odds of having lab-confirmed influenza among unvaccinated hospitalized patients with odds of having lab-confirmed influenza among vaccinated hospitalized patients.

- 6. Adults who were admitted to participating hospitals were invited to enroll in the study if their symptoms could be caused by influenza infection.
- 7. If they chose to enroll, patients were asked if they got their flu vaccine for that season.
- 8. Patients also were tested for influenza using a highly accurate lab test called 'PCR' to verify the outcome.
- 9. Patient medical charts were reviewed. In addition, information was provided by patients' self-reports, and data was also collected from vaccination providers and immunization registries to confirm receipt of vaccination.
- 10. These data provided insight into patients' length of stay, need for intensive care or mechanical ventilation, discharge disposition, repeat hospitalizations, medical care utilization, history of medically attended visits for acute respiratory visits, and antiviral and other medication use.
- 11. Estimates were adjusted for study site, age, sex, race/ethnicity, days from onset to enrollment, calendar time of onset, number of hospitalizations in past year, frailty, and home oxygen use.

Data

- 12. Among the 3,597 adults enrolled at four participating sites (10 hospitals) from October 6, 2017 through April 28, 2018 and included in analyses, 856 (24%) tested positive for influenza virus by rRT-PCR.
 - a) 633 (74%) of these viruses were influenza A,
 - b) and 223 (26%) were influenza B viruses
- 13. Among 633 subtyped influenza A viruses, 506 (80%) were A (H3N2) viruses.
- 14. The 2017-2018 flu season was an H3N2-predominant season. Adults 65 years and older typically fare worse than other age groups during H3N2-predominant seasons and are hospitalized at comparatively higher rates.
- 15. These estimates will be posted here when the presentation becomes available on the ACIP web site: https://www.cdc.gov/flu/professionals/vaccination/effectiveness-studies.htm

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 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 was 24.2% more effective than 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 now make up the majority of flu vaccines produced for use in the United States.

- 5. While not being produced for 2018-2019, an intradermal flu shot that requires less antigen to produce the same immune response was approved in 2011. This is useful because the same amount of available antigen can be used to make more doses of the vaccine.
- 6. A cell-based flu vaccine (Flucelvax) was developed and approved for use in 2016. Cell-based flu vaccines are an alternative to the egg-based flu vaccine manufacturing process.
- 7. 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.
- 8. A longer term goal for flu vaccines is the development of a single vaccine that would provide safe, effective and long-lasting immunity against a broad spectrum of influenza viruses, both seasonal and novel. A flu vaccine with these qualities is often referred to as a "universal flu vaccine."
- 9. 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.

Flu Vaccine Coverage in the United States

- 1. Last flu season was horrible.
- 2. CDC estimates that there were more than 900,000 hospitalizations and more than 80,000 flu deaths last season.
- 3. Our collective flu experience underscores how important it is to get a flu vaccine each year. Flu vaccination can:
 - a) Save children's lives.
 - b) Reduce the risk of flu illness and serious flu outcomes like hospitalization or ICU admission.
 - c) Helps prevent serious medical events associated with some chronic conditions (heart and lung disease, diabetes).
 - d) Protect pregnant women during and after pregnancy and that baby for several months after birth.
 - e) Help you get back on your feet sooner if do get sick.
- 4. CDC flu vaccine coverage estimates from the 2017-18 flu season suggest that, despite a bad season:
 - a) Flu vaccination decreased slightly among young children.
 - b) About half of pregnant women didn't get a flu shot last season, leaving themselves and their babies more vulnerable to serious flu complications.
 - c) 1 out of 3 assistants, aids and workers in long term care facilities did not get a flu vaccine last season.
- 5. Release of the flu vaccination adult coverage data is being delayed about 1 month as CDC performs additional analysis to address differences in last season's survey methodology.

- 6. CDC recommends everyone 6 months and older get a flu vaccine every year as the best way to protect against flu.
- 7. For more information on the 2017-18 flu vaccination coverage estimates, visit https://www.cdc.gov/flu/fluvaxview/1718season.htm.

2017-18 Flu Vaccine Coverage Among Children

- 1. CDC estimates from the 2017-18 flu season suggest that flu vaccination decreased slightly among children.
- 2. Flu vaccine coverage among children varied by age, is highest among the youngest children and decreases with increasing age:
 - a) 67.8% for children 6-4 years
 - b) 59.5% for children 5-12 years
 - c) 47.4% for children 13-17 years
 - d) This is consistent with past seasons.
- 3. Among children age 6 months through 17 years, flu vaccination coverage during the 2017-18 flu season was an estimated 57.9%, which was 1.1 percentage points lower than the estimate for the 2016-17 season (59.0%).
- 4. The decrease in flu vaccine coverage for the 2017-18 season compared with the 2016-17 season was driven by a drop in coverage among young children 6 months to 4 years of age, where coverage declined from an estimated 70% to 67.8% (2.2% decline in that age group).
- 5. The observed decrease may reflect true lower coverage or may be due to limitations of the telephone survey method.
- 6. There was large variability in flu coverage among children aged 6m through 17 years from state to state, ranging from a low of 43.2% to a high of 76.2%.
- 7. Common reasons parents give for not having their child receive a flu vaccination include: the child is unlikely to get the flu or get very sick from the flu, the child is not in a high risk group, and concern about side effects from the vaccine.
- 8. Children younger than 5 years are at high risk of serious flu complications even if they are otherwise healthy just because of their age.
- 9. Of the pediatric deaths reported to CDC last season, more than one-third of these occurred among children between the ages of 6 months and 4 years (there were 180 reported pediatric-associated deaths last season).
- 10. Seeing a decline in coverage in this age group is very concerning.
- 11. Children 6 months through 8 years getting vaccinated for the first time, and those who have only previously gotten one dose of vaccine, should get two doses of vaccine this season.
- 12. Other children need only one dose of flu vaccine this season.
- 13. It's worth noting that nasal spray flu vaccine is again an option for children 2 and older this season.

2017-18 Flu Vaccine Coverage Among Pregnant Women

- 1. CDC estimates that about half of pregnant women didn't get a flu shot last season, leaving themselves and their babies more vulnerable to serious flu complications.
- 2. During the 2017–18 influenza season, 49.1% of pregnant women received influenza vaccination before or during pregnancy.
- 3. While a change in the survey methology makes head to head comparisons difficult, estimated flu vaccine coverage among pregnant women is thought to be similar to what has been seen during recent seasons.
- 4. A provider recommendation combined with an offer to administer a flu vaccine at the time of visit remains one of the best ways to increase flu vaccination among pregnant women.
 - a) Pregnant women who reported receiving a provider recommendation for and an offer of flu vaccination had higher vaccination coverage (63.8%) than pregnant women who reported receiving a recommendation but no offer (37.6%) or who reported receiving no recommendation (9.0%).
 - b) 66.6% of pregnant women reported receiving both a recommendation and offer and 19.0% received no provider recommendation or offer.
- 5. Previous studies haves shown a provider offer of vaccination was associated with higher vaccination coverage even among pregnant women with negative perceptions regarding the safety and efficacy of vaccination and pregnant women who were not concerned about flu infection.
- 6. The most commonly reported reason for not receiving influenza vaccination before or during pregnancy was belief that the vaccine is not effective (20.2%). The second most commonly reported reason for nonreceipt of was concern about safety risks to the baby.
- 7. Health care providers play a key role in increasing flu vaccination coverage among pregnant women.
- 8. CDC encourages doctors, nurses, midwifes, and other providers to give a clear direct flu vaccination recommendation at every visit.
- 9. Health care providers can take action to protect pregnant women from flu.
- 10. Systems supporting provider recommendations and offers, such as standing orders and provider reminder systems, can reduce missed opportunities for vaccination and improve vaccination coverage.
- 11. Health care providers who are not able to administer a flu vaccine at the time of the visit should still recommend flu vaccination and refer the pregnant patient to a place where vaccinations are provided.
- 12. Each provider's recommendation can be an important opportunity to improve vaccination coverage, especially where differences in coverage are seen among certain sub-groups based on education level and race/ethnicity.
- 13. Pregnant women are at high risk of serious complications from the flu.
- 14. Vaccinating pregnant woman helps protect them from flu illness and hospitalization, and also has been shown to help protect the baby from flu infection for several months after birth, before the baby can be vaccinated.
- 15. Vaccination reduces the risk of flu-associated acute respiratory infection in pregnant women by up to one-half.
- 16. Getting vaccinated can also help protect a baby after birth from flu. (Mom passes antibodies onto the developing baby during her pregnancy.)

- 17. Because pregnant women are at high risk of serious flu complications, they are recommended for influenza vaccination during any trimester of their pregnancy.
- 18. Millions of flu vaccines have been given for decades, including to pregnant women, with a good safety record.

2017-18 Flu Vaccine Coverage Among Health Care Professionals

- 1. While overall coverage among health care workers remains stable, many health care professionals (HCP) still are not getting vaccinated. 1 out of 3 assistants and aides and long term care workers did not get a flu shot last season.
 - a) The coverage rate for HCP was 78.4% for the 2017-18 season, which is similar to last year's rate of 78.6%, as well as similar to coverage from the previous four seasons.
 - b) Coverage remained highest among physicians (96.1%), pharmacists (92.2%), nurses (90.5%), and nurse practitioners and physician assistants (87.8%) during the 2017-18 flu season.
 - c) Coverage by occupation was lowest for assistants and aides (71.1%) and nonclinical personnel (72.8%).
 - i) Non-clinical personnel include administrative support staff or managers, and nonclinical support staff (food service workers, housekeeping staff, maintenance staff, janitors, laundry workers, etc.).
 - d) Flu vaccination among healthcare personnel remained high overall for the last 4 seasons. However, 71% of assistants and aides were vaccinated, while coverage was over 90% for physicians, nurses, nurse practitioners, and pharmacists.
- 2. Employers can take action to protect their staff from flu and reduce absences. Flu vaccination coverage was highest in settings with employer flu vaccination requirements or promotion of flu vaccination.
 - a) Coverage was highest among HCPs working in settings with flu vaccination requirements (94.8%).
 - i) 44.1% of surveyed HCP were required to be vaccinated, similar to recent seasons, but an increase from 35.5% in the 2013–14 season.
 - b) Comprehensive, work-site intervention strategies that include education, promotion, and easy access to vaccination at no cost for multiple days can increase HCP vaccination coverage.
 - c) In the absence of an employer requirement for vaccination, coverage was higher among HCP who had access to free, on-site vaccinations over multiple days (76.0%) than HCPs whose employers had no policies related to vaccination promotion (47.6%)
- 3. Coverage by occupational setting was highest for HCP working in hospitals (91.9%), and remained lowest among HCP in long-term care (LTC) settings (67.4%).
 - a) Vaccination of HCP in LTC settings is extremely important because:
 - i) Many LTC residents are people 65 years and older who are at greater risk of serious complications from the flu.
 - ii) Flu vaccine effectiveness may be lower in some older people, making vaccination of close contacts even more critical.

iii) Some studies have demonstrated health benefits to patients, including reduced flu-related complications and reduced risk of death, with vaccination of HCP in LTC settings.

2017-2018 Influenza Season: A Summary

(Back to table of contents)

- 1. On June 7, 2018, a report titled "<u>Update: Influenza Activity in the United States During the 2017-18 Season and Composition of the 2018-19 Influenza Vaccine</u>," was published in a Morbidity and Mortality Weekly Report (MMWR).
- 2. The 2017-2018 influenza season was a high severity, A(H3N2) predominant season. This season was the first to be classified as a high severity season for all age groups.
- 3. For more information, see https://www.cdc.gov/flu/about/season/flu-season-2017-2018.htm.

Flu Burden and Burden-Averted Vaccination Estimates

- 1. Influenza places a substantial burden on the health of people in the United States each year.
- 2. CDC estimates that from 2010-2011 to 2014-2015, influenza resulted in 9.2 million to 35.6 million illnesses, 4.3 million to 16.6 million medical visits, and 140,000 to 710,000 hospitalizations each year.
- 3. During 2016-2017, CDC estimates that there were 31 million flu illnesses, 15 million flu medical visits and 600,000 flu-associated hospitalizations, figures which are on the high end of the 5-year range.
- 4. During the 2016-2017 season, flu vaccination prevented an estimated 5.3 million influenza illnesses, 2.6 million influenza-associated medical visits, and 85,000 influenza-associated hospitalizations.
- 5. These findings underscore the important benefits provided by influenza vaccination, which has been recommended annually in the United States for all persons 6 months and older since 2010.
- 6. The 2016-2017 estimates reflect a 12 percent reduction in the burden of flu-related hospitalizations as a result of vaccination.
- 7. The number and proportion of flu hospitalizations prevented by vaccination during 2016–2017 varied by age group, due to age-specific differences in influenza burden, vaccine coverage, and vaccine effectiveness.
 - a) Vaccination prevented the lowest proportion of hospitalizations among adults aged 18 to 49 years, who had the lowest vaccine coverage, and adults 65 years and older, who had higher vaccine coverage but the lowest VE during this past season.
 - b) Vaccination prevented the greatest proportion of these outcomes among children aged 6 months to 4 years and 5 to 17 years, where the burden of influenza illness and medical visits was high and VE was greatest.
- 8. CDC is working to finalize <u>preliminary estimates</u> of the burden of influenza in the United States during the 2017-2018 flu season. The <u>2017-2018 flu season</u> was classified as a <u>high severity</u> season with a significant burden of influenza in the U.S. The information on disease burden of influenza will be updated in the coming weeks based on finalized estimates.

Range of Flu-Related Hospitalizations and Deaths

(Back to table of contents)

- 9. CDC estimates that influenza has resulted in between 9.2 million and 35.6 million illnesses, between 140,000 and 710,000 hospitalizations and between 12,000 and 56,000 deaths annually since 2010
- 10. CDC believes that providing a range of flu-related hospitalizations from more recent seasons is a more complete representation of the variability and severity of influenza than an average.
- 11. CDC also has estimated how many children younger than 5 years are hospitalized from flu complications every year. Since 2010, CDC estimates that flu-related hospitalizations among children younger than 5 years ranged from 7,000 to 26,000 in the United States.
- 12. CDC estimates that from 2010-2011 to 2013-2014, influenza-associated deaths in the United States ranged from a low of 12,000 (during 2011-2012) to a high of 56,000 (during 2012-2013).

Recommendation For Use of LAIV

- 1. CDC and the Advisory Committee on Immunization Practices (ACIP) recommend that everyone 6 months of age and older get an annual influenza vaccine. CDC and ACIP do not make a preferential recommendation for the type of vaccination individuals receive.
- 2. For the 2018-2019 U.S. influenza season, CDC and its vaccines advisory committee (ACIP) recommend that providers use any licensed, age-appropriate influenza vaccine (Inactivated influenza vaccines (IIV), Recombinant influenza vaccine (RIV), or live attenuated influenza vaccine (LAIV4) with no preference expressed for one vaccine over another.
 - a) For the 2018-2019 flu season, providers may choose to administer any licensed, age-appropriate flu vaccine (IIV, RIV4, or LAIV4).
- 3. For the 2018-19 season, the nasal spray flu vaccine (live attenuated influenza vaccine or LAIV) is an option for influenza vaccination for persons for whom it is otherwise appropriate.
- 4. The nasal spray vaccine (or LAIV) is approved for use in people 2 through 49 years of age. LAIV is contraindicated (i.e., should not be given to or is not recommended) for people with some specific medical conditions or for pregnant women. Certain other medical conditions are <u>precautions to the use of LAIV</u>. These are conditions in which the vaccine should generally not be used, but where it might be appropriate in some specific circumstances. Your health care provider can help you decide which vaccine is right for you.
- 5. According to previous data, LAIV was generally effective against influenza B viruses, and has similar effectiveness to inactivated influenza viruses (IIV) against H3N2 viruses.
- 6. LAIV is a licensed product. Additional options for vaccination of children may provide a means to improve coverage, particularly in school-based settings.
- 7. 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.
- 8. During 2012, "FluMist Quadrivalent" (four-component LAIV) was licensed.
- 9. Data on LAIV effectiveness has been inconsistent over time.
- 10. Vaccine effectiveness data for LAIV before and soon after the original licensure suggested LAIV was either comparable to, or better than, IIV (particularly for younger children).
- 11. Data from 2013-2014 and 2015-2016, however, showed poor or relatively lower effectiveness of LAIV against the predominant circulating H1N1 viruses among 2 through 17-year-olds.
- 12. While data from 2010-11 through 2015-16 flu seasons indicate that LAIV was not effective among 2 through 17-year-olds against H1N1pdm09 influenza viruses in the U.S., LAIV was effective against influenza B viruses, and was similarly effective to inactivated influenza vaccines against H3N2 viruses, according to observational data.
- 13. While data suggest that the new H1N1 virus strain included in the current LAIV vaccine will have improved effectiveness against circulating H1N1 viruses, no published effectiveness estimates are available yet.
- 14. 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.
- 15. 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.
- 16. The change in the recommendation underscores the importance of ongoing efforts to measure and evaluate the effectiveness of public health interventions, including vaccine effectiveness studies, which can have significant implications for public health policy.