



Seasonal Influenza Vaccines

Current as of 3/2/2022



I will provide a discussion of the epidemiology of Influenza virus as well as the vaccine recommendations for preventing Influenza in the United States.

About This Publication

This publication was designed to help prelicensure nursing faculty incorporate appropriate elements of the [IRUN Curriculum Framework](#) into their existing curricula. This resource was designed in a PowerPoint file located on the [IRUN web page](#).

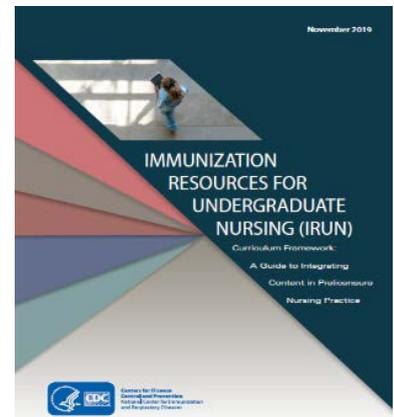
Please submit questions or comments about this publication via the [IRUN web page](#).

This publication was funded by the Centers for Disease Control and Prevention (CDC) through Cooperative Agreement Number 5NU36OE000008-03-00 with the Association for Prevention Teaching and Research (APTR). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of APTR, CDC, or the Department of Health and Human Services.

N/A – disclosures

Immunization Resources for Undergraduate Nursing (IRUN) Curriculum Framework Topics

- Public Health Perspective
- Immunization Strategies
- Immune System/Immunology
- Vaccine-Preventable Diseases
- Types of Vaccines
- Immunization Schedules
- Communications
- Legal/Ethical Issues
- Vaccine Storage and Handling
- Vaccine Administration
- Documentation
- Vaccine Safety



- The Immunization Resources for Undergraduate Nursing (IRUN) Curriculum Framework consists of 12 topic areas with corresponding learning objectives and suggested resources. In this slide deck, we will use these topical areas and framework to learn about Influenza vaccines.
- For more information about the IRUN Curriculum Framework Topics or resources, please visit the IRUN web page, which can be accessed by clicking on the graphic on this slide.

Learning Objectives

- Describe the etiologic agent, pathogenesis, epidemiology and clinical manifestations of Influenza.
- Describe barriers to vaccination and strategies to increase influenza vaccine coverage.
- Describe the influenza vaccine, including immunogenicity, indications, contraindications, and precautions for vaccination.
- Discuss the importance of appropriate spacing and timing of influenza vaccine doses.
- Describe correct influenza vaccine storage and handling.
- Describe the steps for proper influenza vaccine administration.
- Describe proper influenza vaccine documentation and adverse event reporting practices.
- Explain the nurse's role in preventing influenza through immunization.
- Locate resources relevant to current influenza vaccine recommendations.

Following today's lecture, you will be able to meet these nine learning objectives.

[READ SLIDE]

PUBLIC HEALTH PERSPECTIVE

Global Impact of Seasonal Influenza

- Influenza is a serious global threat that impacts all countries
- Every year, worldwide, there are an estimated:
 - 1 billion cases of influenza
 - 3-5 million severe cases of influenza
 - 290,000-650,000 influenza-related respiratory deaths
- Most deaths associated with influenza in industrialized countries are among individuals age 65 years and older.
- An estimated 99% of deaths in children 5 years of age and younger with influenza-related lower respiratory tract infections are found in developing countries.

Information from World Health Organization, *Global influenza strategy 2019-2030*,

https://www.who.int/influenza/Global_Influenza_Strategy_2019_2030_Summary_English.pdf?ua=1; [https://www.who.int/news-room/fact-sheets/detail/influenza-\(seasonal\)](https://www.who.int/news-room/fact-sheets/detail/influenza-(seasonal))

- Influenza is a serious global threat that impacts all countries
- Every year, worldwide, there are an estimated 1 billion cases, with 3-5 million of those cases considered severe cases, and 290,000-650,000 resulting in influenza-related respiratory deaths.
- Most deaths associated with influenza in industrialized countries are among individuals age 65 years and older.
- The effects of seasonal influenza epidemics in developing countries are not fully known, but research estimates that 99% of deaths in children under 5 years of age with influenza-related lower respiratory tract infections are found in developing countries.

Global Influenza Strategy

- The Global Influenza Strategy for 2019–2030 provides a framework to enhance and build influenza surveillance, prevention, and control programs.
- Vision: Attainment of the highest possible influenza prevention, control and preparedness to safeguard the health of all people.
- Goals:
 - Reduce the burden of seasonal influenza.
 - Mitigate the impact of pandemic influenza.

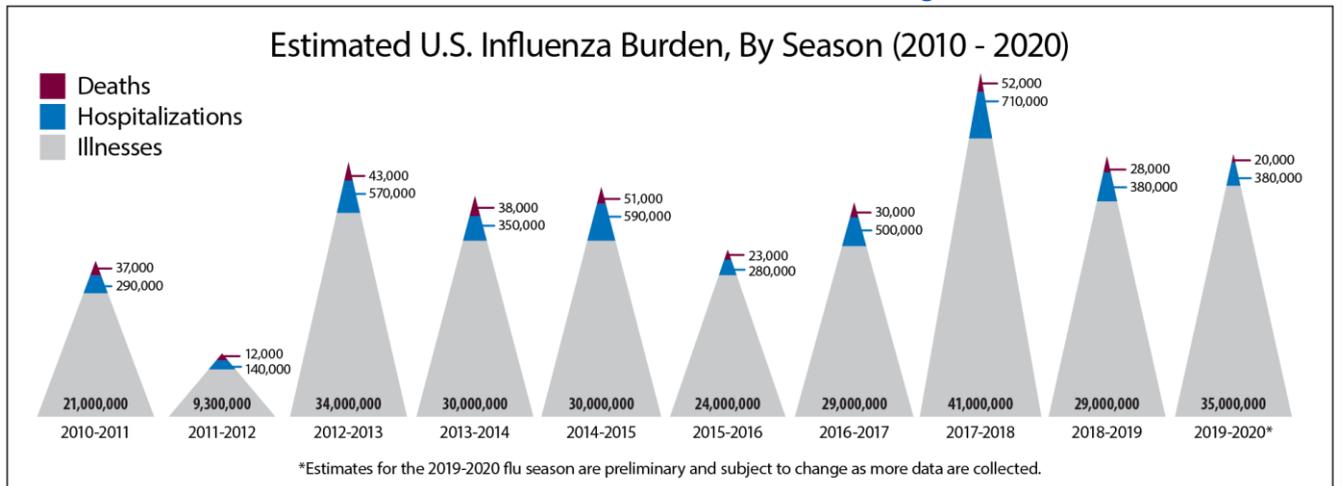


Information from World Health Organization, *Global influenza strategy 2019-2030*,
https://www.who.int/influenza/Global_Influenza_Strategy_2019_2030_Summary_English.pdf?ua=1

- The Global Influenza Strategy for 2019-2030 provides a framework to enhance and build influenza surveillance, prevention, and control programs.
- The vision of this framework is to attain the highest possible influenza prevention, control and preparedness to safeguard the health of all people.
- The two main goals of this framework are 1) Reduce the burden of seasonal influenza; 2) Mitigate the impact of pandemic influenza.

Impact of Seasonal Influenza in the United States

Estimated Influenza Disease Burden, by Season United States, 2010-11 through 2019-20 Influenza Seasons



Information from <https://www.cdc.gov/flu/about/burden/index.html>; <https://www.cdc.gov/flu/about/burden/faq.htm>

- The exact number of people who have been sick and affected by influenza is unknown because influenza is not a reportable disease in most areas of the U.S. However, CDC has estimated the burden of influenza since 2010 using a mathematical model that is based on data collected through the U.S. Influenza Surveillance System, a network that covers approximately 8.5% of the U.S. population (~27 million people).
 - modeling is used to estimate the number of influenza illnesses, medical visits, hospitalizations, and deaths related to flu that occurred in a given season.
- Seasonal influenza is associated with large numbers of illnesses, which can impact school attendance, worker absenteeism, and daily productivity. The results of CDC's influenza burden estimates demonstrate the substantial health impact of influenza and underscore the importance of yearly influenza vaccination for everyone 6 months and older.

Impact of Seasonal Influenza in the United States

Estimated Range of Annual Burden of Influenza United States, 2010-11 through 2019-20 Influenza Seasons

- The burden of influenza disease in the United States can vary widely and is determined by a number of factors, including the characteristics of circulating viruses, the timing of the season, how well the vaccine is working to protect against illness, and how many people got vaccinated. While the impact of influenza varies, it places a substantial burden on the health of people in the United States each year.
- CDC estimates that from 2010-2020, influenza has resulted in between 9 million – 41 million illnesses, between 140,000 – 710,000 hospitalizations and between 12,000 – 52,000 deaths annually.



Information and Image from <https://www.cdc.gov/flu/about/burden/index.html>

[Read slide]

Changes in Influenza and Other Respiratory Virus Activity During the COVID-19 Pandemic — United States, 2020–2021

- For the 2021–22 season it is anticipated that influenza and COVID-19 will continue to circulate at the same time as well as other common respiratory viruses.
- Nonpharmaceutical interventions (e.g., cessation of global travel, mask use, physical distancing, and staying home) introduced to mitigate the impact of COVID-19 reduced transmission of common respiratory viruses in the United States.
 - Influenza viruses circulated at historic lows during the 2020–2021 season.
- Influenza vaccination campaigns are important as schools and workplaces resume in-person activities with relaxed COVID-19 mitigation practices.

Information from Changes in Influenza and Other Respiratory Virus Activity During the COVID-19 Pandemic — United States, 2020–2021 | MMWR (cdc.gov)

- For the 2021–22 season it is anticipated that influenza and COVID-19 will continue to circulate at the same time as well as other common respiratory viruses.
- Nonpharmaceutical interventions (e.g., cessation of global travel, mask use, physical distancing, and staying home) introduced to mitigate the impact of COVID-19 reduced transmission of common respiratory viruses in the United States.
- Influenza viruses circulated at historic lows during the 2020–2021 season.
- Reduced circulation of influenza viruses during the 2020–21 season might affect the severity of the upcoming influenza season given the prolonged absence of ongoing natural exposure to influenza viruses. Lower levels of population immunity, especially among younger children, could portend more widespread disease and a potentially more severe epidemic when influenza virus circulation resumes. With schools and workplaces reopening, in addition to the use of recommended everyday preventive actions, clinicians should encourage influenza vaccination for all persons aged ≥ 6 months.
- Influenza vaccination campaigns are important as schools and workplaces resume in-person activities with relaxed COVID-19 mitigation practices.

IMMUNIZATION STRATEGIES

Barriers to Routine Vaccination in the United States: Health Care Access

- **Barriers to health care access:**
 - Language barriers
 - Lack of trust in providers
 - Transportation problems
 - Inconvenient office hours
 - Patient/parent misinformation
 - Vaccine hesitancy
 - Competing provider priorities
 - Low awareness of vaccination benefits
 - Receipt of care from multiple providers
 - Complex vaccination schedule
 - Vaccine cost
 - Breaks in insurance coverage
- Vaccination coverage among children enrolled in Medicaid or with no health insurance was lower than that among children who were privately insured.
 - Influenza vaccine coverage (≥ 2 doses) by age 24 months among children by insurance status was higher in children with private health insurance (69.6%) compared with children with Medicaid (49.3%) and children who were uninsured (35.7%).

Information from Hill HA, Yankey D, Elam-Evans LD, Singleton JA, Pingali SC, Santibanez TA. Vaccination Coverage by Age 24 Months Among Children Born in 2016 and 2017 — National Immunization Survey-Child, United States, 2017–2019. *MMWR Morb Mortal Wkly Rep* 2020;69:1505–1511. DOI: <http://dx.doi.org/10.15585/mmwr.mm6942a1>; Walker TY, Elam-Evans LD, Yankey D, et al. National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years—United States, 2018. *MMWR Morb Mortal Wkly Rep*. 2019;68:718–723 DOI: <http://dx.doi.org/10.15585/mmwr.mm6833a2>

- To effectively develop and employ strategies to increase vaccination coverage in our communities, we must have a thorough understanding of what barriers exist, that prevent individuals from vaccination.

Barriers

- Barriers to health care access and use among the publicly insured include language barriers, lack of trust in providers, transportation problems, inconvenient office hours, patient/parent misinformation, vaccine hesitancy, competing provider priorities, low awareness of vaccination benefits, receipt of care from multiple providers, complex vaccination schedules, vaccine cost, breaks in coverage and other individual and systems level barriers.
- Health insurance and poverty status are interrelated factors associated with lower vaccination coverage in young children. Vaccination coverage among children enrolled in Medicaid or with no health insurance was lower than that among children who were privately insured.
- Influenza vaccine coverage (≥ 2 doses) by age 24 months among children by insurance status was higher in children with private health insurance (69.6%) compared with children with Medicaid (49.3%) and children who were uninsured (35.7%).

Strategies for High Vaccination Coverage: Vaccines for Children (VFC) Program

- Vaccines for Children program created in 1993
- Children through age 18 years of age who meet at least one of the following criteria are eligible to receive VFC vaccine:
 - Medicaid eligible
 - Uninsured
 - American Indian or Alaska Native
 - Underinsured



Information from Hill HA, Elam-Evans LD, Yankey D, Singleton JA, Kang Y. Vaccination Coverage Among Children Aged 19–35 Months — United States, 2016. MMWR Morb Mortal Wkly Rep 2017;66:1171–1177. DOI: <https://www.cdc.gov/mmwr/volumes/67/wr/mm6740a4.htm>; <https://www.cdc.gov/vaccines/programs/vfc/about/index.html>; <https://www.cdc.gov/vaccines/programs/vfc/providers/eligibility.html>.
Image from <https://www.cdc.gov/vaccines/programs/vfc/index.html>

- Partially, in response to a U.S. based measles outbreak between 1989-1991, Congress passed the Omnibus Budget Reconciliation Act (OBRA) on August 10, 1993, creating the Vaccines for Children (VFC) Program. VFC became operational October 1, 1994. Known as section 1928 of the Social Security Act, the Vaccines for Children program is an entitlement program (a right granted by law) for eligible children, age 18 and younger.
- Children living below and up to a certain percentage above the poverty level are eligible for Medicaid and are entitled to vaccines through the Vaccines for Children, or VFC.
- Uninsured children, American Indians or Alaska natives are eligible for VFC benefits.
- And finally, a child who is insured, but doesn't have insurance that covers VFC program vaccines, is eligible to receive VFC vaccine through federally qualified health center or rural health clinic.
- Although many children are eligible for VFC vaccine coverage, some families might not be aware of the VFC program, might be unable to afford fees for visits to a vaccine provider, or might need assistance locating a physician who participates in the VFC program. Thus, CDC has undertaken several activities designed to elucidate potential barriers to early childhood vaccination from the perspective of state immunization programs and health care providers enrolled in the VFC program. There are also plans to assess parental experience with and barriers to accessing vaccination services.

Strategies for High Vaccination Coverage

- Reduce barriers to immunization.
- Provide recommendation for vaccination and reinforcement.
- Reduce missed opportunities.
- Schedule next immunization visit before patient leaves the office.
- Utilize reminder and recall for patients.

Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. <https://www.cdc.gov/vaccines/pubs/pinkbook/strat.html>; Vaccination Coverage by Age 24 Months Among Children Born in 2015 and 2016—National Immunization Survey-Child, United States, *MMWR*/ October 18, 2019 / 68(41):913–918.; <https://www.cdc.gov/vaccines/programs/iqip/index.html>; ; <https://www.cdc.gov/vaccines/hcp/admin/reminder-sys.html>

- As described in a previous slide, recognizing the barriers to immunization and implementing strategies minimize barriers is necessary to increase vaccination coverage.
- Recommending the vaccine is one of the most effective strategies for increasing vaccination coverage for patients of all. As the most trusted profession in the U.S, nurses play a critical role in recommending vaccines to those in their communities. We will discuss more strategies for recommending vaccines in subsequent slides.
- “Reducing missed opportunities” means establishing a policy to vaccinate at every visit if vaccinations are indicated. To decrease missed opportunities, providers need to use every patient encounter to screen for, strongly recommend, and offer needed vaccinations to patients, taking advantage of tools, such as the ones shown later in this presentation, to support effective communication with patients and parents.
- Another strategy to increase vaccination coverage is scheduling the next immunization visit before the patient leaves the office.
- Reminder/recall systems are cost-effective methods to identify and notify families when children are due for vaccinations or are already behind. Reminders (for vaccines due soon) and recalls (for overdue vaccines) can be delivered by telephone, text message, letter, postcard, or other methods. Most reminder and recall notices are tailored for individuals, and many include educational messages about the importance of vaccination.

Strategies for High Vaccination Coverage

- Employ Immunization Quality Improvement For Providers (IQIP) Process and Strategies:
 - <https://www.cdc.gov/vaccines/programs/iqip/at-a-glance.html>
- Maintain thorough documentation in patient records.
- Utilize Immunization Information Systems (IISs).

Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. www.cdc.gov/vaccines/pubs/pinkbook/index.html; <https://www.cdc.gov/vaccines/programs/iis/index.html>

- The Immunization Quality Improvement for Providers process and strategies promotes and supports implementation of provider-level strategies designed to help increase on-time vaccination of children and adolescents. More information about the IQIP program can be found using the link on this slide.
- Other important strategies consist of good record-keeping through documentation in patient records and the use of immunization information systems to assess vaccination status and record vaccines administered.

Immunization Information Systems (IISs)

- IISs are confidential, computerized databases that record all vaccine doses administered by providers to persons residing within a given geopolitical area.
- IISs provide consolidated immunization histories that help in determining appropriate vaccinations.
- All immunization providers are encouraged to document all administered vaccines in an IIS.

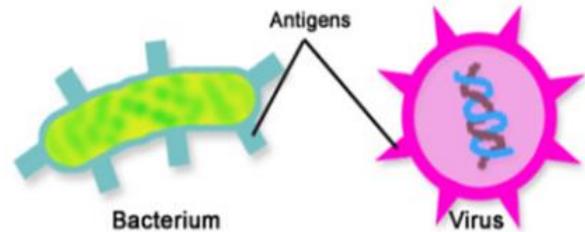
Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021., <https://www.cdc.gov/vaccines/pubs/pinkbook/strat.html>; About Immunization Information Systems <https://www.cdc.gov/vaccines/programs/iis/about.html>;

- By 2 years of age, over 20% of children in the U.S. typically have seen more than one health care provider, resulting in scattered paper medical records. Immunization information systems (IISs) help providers and families by consolidating immunization information into one reliable source. IISs are confidential, population-based, computerized information systems that collect and consolidate vaccination data from multiple health care providers within a geographic area.
- Immunization providers are strongly encouraged to participate in an IIS. Laws governing use of IISs vary by state or region. Some states mandate use of an IIS to document vaccinations for certain patients. Providers should be aware of state and/or regional requirements for IIS reporting in their jurisdiction.

IMMUNE SYSTEM/IMMUNOLOGY

Human Immune System

- Complex network of interacting cells and proteins whose purpose is to identify and eliminate foreign substances called antigens on the surface of organisms like bacteria or viruses.
- Antigens chosen for vaccination can either be live or inactivated.

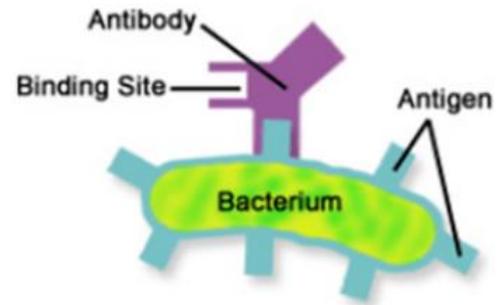


Information and graphic from Centers for Disease Control and Prevention. *You Call the Shots*. Dale Babcock, BS, Jennifer Hamborsky, MPH, MCHES, M. Suzanne Johnson-DeLeon MPH, Tina S. Objio, MSN, MHA, RN, ,Raymond Strikas, MD, MPH, <https://www2.cdc.gov/nip/isd/ycts/mod1/courses/gbp/index.html>; <https://www2.cdc.gov/vaccines/ed/pinkbook/2020/downloads/pb1/PB1.pdf> ; <https://www.cdc.gov/vaccines/pubs/pinkbook/prinvac.html#immunology>

- To understand how vaccines work and the foundation of recommendations for their use, it is helpful to understand the basic function of the human immune system. The following description is simplified; many excellent immunology textbooks provide additional detail.
- Immunity is the ability of the human body to tolerate the presence of material indigenous to the body and to eliminate foreign substances. This discriminatory ability to eliminate foreign substances is performed by a complex system of interacting cells called the immune system.
- The most effective immune responses are generally produced in response to antigens, (which are substances that can stimulate the immune system), present in a live organism. However, an antigen does not necessarily have to be present in a live organism to produce an immune response. Some antigens, such as hepatitis B surface antigen, are easily recognized by the immune system and produce adequate protection even if they are not carried on the live hepatitis B virus. Other materials are less effective antigens, and the immune response they produce may not provide good protection.

Human Immune System

- When the immune system identifies organisms invading the body, it goes to work to defend the body against those organisms. This is called the immune response.
- Antibodies are protein molecules directed against antigens that help infection-fighting cells recognize and kill the microorganism.
 - Specific to a single antigen or group of closely related antigens



Information and graphic <https://www2.cdc.gov/nip/isd/ycts/mod1/courses/gbp/index.html>;
<https://www2.cdc.gov/vaccines/ed/pinkbook/2020/downloads/pb1/PB1.pdf>; <https://www.cdc.gov/vaccines/pubs/pinkbook/prinvac.html#immunology>

- Since most organisms (e.g., bacteria, viruses, and fungi) are identified as foreign, the ability to identify and eliminate these substances provides protection from infectious diseases. Immunity is generally specific to a single organism or group of closely related organisms.
- The immune system develops a defense against antigens. This defense is known as the immune response and usually involves the production of:
 - Protein molecules (immunoglobulins or antibodies, the major component of humoral immunity) by B-lymphocytes (B-cells)
 - Specific cells, including T-lymphocytes (also known as cell-mediated immunity)

Active and Passive Immunity

- Mechanism for acquired immunity
 - Active immunity is protection that is produced by the person’s own immune system. (e.g., natural infection, vaccine).
 - Passive immunity is protection produced by animal or human and transferred to another human, usually by injection. (e.g., immune globulin, newborn baby acquires passive immunity from mother through placenta).

Active Immunity [video]



Passive Immunity [video]



Information from Centers for Disease Control and Prevention. *You Call the Shots*. Dale Babcock, BS, Jennifer Hamborsky, MPH, MCHES, M. Suzanne Johnson-DeLeon MPH, Tina S. Objio, MSN, MHA, RN, Raymond Strikas, MD, MPH, <https://www2.cdc.gov/nip/isd/ycts/mod1/courses/gbp/index.html>; Media files from <https://www2.cdc.gov/vaccines/ed/pinkbook/2020/downloads/pb1/PB1.pdf>

[play videos]

- There are two basic mechanisms for acquired immunity—active and passive.
- Active immunity is protection that is produced by the person’s own immune system. This type of immunity usually lasts for many years, often throughout a lifetime.
- Active immunity results when exposure to a disease organism triggers the immune system to produce antibodies to that disease. Exposure to the disease organism can occur through infection with the actual disease (resulting in natural immunity), or introduction of a killed or weakened form of the disease organism through vaccination (vaccine-induced immunity).
- Passive immunity is protection produced by animal or human and transferred to another human, usually by injection. Passive immunity often provides effective protection, but this protection wanes with time, usually within a few weeks or months.
- The most common form of passive immunity is that which an infant receives from its mother. Antibodies are transported across the placenta during the last one to two months of pregnancy. As a result, a full-term infant will have the same antibodies as its mother. These antibodies will protect the infant from certain diseases for up to a year. Protection is better against some diseases (e.g., measles, rubella, tetanus) than others (e.g., polio, pertussis).
- The video clips on the right describe active and passive immunity in more detail.

Factors Affecting Immune Response to Vaccines

- Host factors
 - Examples: age, nutritional factors, genetics, and coexisting disease
- Maternal antibody
- Nature and dose of antigen
- Route of administration
- Presence of an adjuvant
- Storage and handling of vaccine

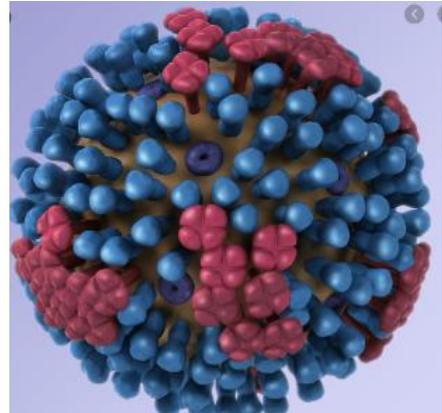
Information from <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html>; <https://www.cdc.gov/vaccines/vac-gen/immunity-types.htm>; <https://www.cdc.gov/vaccines/Pubs/pinkbook/downloads/prinvac.pdf>

- Many factors may influence the immune response to vaccination. These include host factors such as age, nutritional factors, genetics, and coexisting disease.
- In addition, the presence of maternal antibody and vaccine-specific factors such as nature and dose of antigen, route of administration, and the presence of an adjuvant (e.g., aluminum-containing material added to improve the immunogenicity of the vaccine) can affect the immune response. Failure to adhere to recommended specifications for storage and handling of vaccines can reduce or destroy their potency, resulting in inadequate or no immune response in the recipient.

VACCINE-PREVENTABLE DISEASES

Influenza Virus

- Single-stranded, RNA virus of the orthomyxovirus family
- Influenza A and B cause most human illness responsible for flu season each year



Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. <https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html>;
<https://www.cdc.gov/flu/about/viruses/types.htm>
Image source <https://www.cdc.gov/flu/resource-center/freeresources/graphics/images.htm>

[READ SLIDE]

Influenza Virus Continued

- Three types affect humans:
 - Type A influenza: Associated with seasonal influenza and causing rare influenza pandemics. Eight H subtypes (H1, H2, H3, H5, H6, H7, H9, H10) and six N subtypes (N1, N2, N6, N7, N8, and N9) have been detected in humans.
 - Type B influenza: classified into two lineages: B/Yamagata and B/Victoria.
 - Type C influenza: rarely reported; most subclinical and not associated with epidemics.

Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. <https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html>;
<https://www.cdc.gov/flu/about/viruses/types.htm>

[READ SLIDE]

Influenza Virus Continued

- Antigenic drift
 - Small changes (or mutations) in the genes of influenza viruses that can lead to changes in the surface proteins of the virus, HA (hemagglutinin) and NA (neuraminidase).
 - Changes can accumulate over time resulting in the emergence of new strains
 - Primary reason people can get influenza more than once
 - Results in annual influenza epidemics
- Antigenic shift
 - Abrupt, major change in one or both surface antigens (H or H-N combination)
 - May lead to pandemic

Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. <https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html>; Centers for Disease Control and Prevention. *How the Flu Virus Can Change: "Drift" and "Shift"*. Retrieved from: <https://www.cdc.gov/flu/about/viruses/change.htm>

Antigenic Changes

- Virus surface antigens hemagglutinin and neuraminidase continually change. Changes in influenza viruses can take the form of antigenic drift or antigenic shift.
- Antigenic drift
 - Antigenic drift involves small mutations in the genes of influenza viruses that lead to changes in HA and NA that accumulate over time, resulting in the emergence of a strain that the human immune system may not recognize. These strains are the influenza virus's evolutionary adaptations to a strong population-wide immune response.
 - Antigenic drift is the primary reason people can get influenza more than once and why it is necessary to annually review and update the composition of influenza vaccines.
 - Antigenic drift, along with waning immunity, results in annual influenza epidemics, since the protection that remains from past exposures to similar viruses is incomplete. Drift occurs in all three types of influenza virus (A, B, C).
- Antigenic shift
 - Antigenic shift involves an abrupt, major change in one or both surface antigens (H or H-N combination).
 - An antigenic shift may result in a worldwide pandemic if the virus is efficiently transmitted from person to person. Since the late 19th century, five antigenic shifts have led to pandemics in 1889-1891, 1918-1920, 1957-1958, 1968-1969, and 2009-2010.

Influenza Pathogenesis

- Respiratory transmission
- The virus attaches to and penetrates respiratory epithelial cells in the trachea and bronchi.
- Replication in respiratory epithelium with subsequent destruction of host cell.
- Viremia rarely documented
- Virus shed in respiratory secretions for 5–10 days

Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. <https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html#Pathogenesis>

- Following respiratory transmission, the virus attaches to and penetrates respiratory epithelial cells in the trachea and bronchi. Viral replication occurs, which results in the destruction of the host cell. Regeneration of epithelium takes about 3 to 4 weeks. Viremia, or presence of virus in the blood, has rarely been documented. Virus is shed in respiratory secretions for 5 to 10 days, with a peak of 1 to 3 days following illness onset.

Seasonal Influenza Epidemiology

Reservoir	Type A infects humans and some animals Type B generally infects humans Type C infects only humans
Transmission	Person-to-person via large virus-laden droplets Aerosol transmission of small droplets Exposure to fomites
Temporal pattern	October–April or May in Northern hemisphere April–September in Southern hemisphere Year round in tropical climates
Communicability	1 day before to 5 to 7 days after (adults) or 10 days after onset (children)

Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. <https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html#Epidemiology>

Occurrence

- Influenza occurs throughout the world.

Reservoir

- Influenza A viruses may infect both humans and some animals. Examples of animals include, but are not limited to, wild birds, poultry, pigs, horses, mink, and ferrets. There is no chronic carrier state. Influenza B generally infects humans, but at least two reports have documented influenza B in seals. Humans are the only known reservoir of influenza type C.

Transmission

- Influenza is primarily transmitted from person-to-person via large, virus-laden droplets (more than 5 microns in diameter) that are generated when infected persons cough or sneeze. These large droplets can then settle on the mucosal surfaces of the upper respiratory tracts of susceptible persons who are within six feet of infected persons. Aerosol transmission of small droplets may also transmit influenza. Transmission may occur through direct or indirect contact with respiratory secretions, such as when touching surfaces contaminated with influenza virus and then touching the eyes, nose, or mouth.

Temporal Pattern

- In the Northern Hemisphere, influenza season can begin as early as October and last as late as April or May, while in the Southern Hemisphere, the season typically occurs during April–September. Influenza occurs throughout the year in tropical areas. In the United States, for 75% of influenza seasons from the 1982–1983 through the 2017–2018 season, peak influenza activity has not occurred until January or later. In 58% of seasons, the peak was in February or later.

Communicability

- Adults can transmit influenza from the day before symptom onset to approximately 5 to 7 days after symptoms begin. Children can transmit influenza to others for 10 or more days after symptoms begin.

Seasonal Influenza Clinical Features

- Incubation period 2 days (range 1–4 days)
- About 8% of the U.S. population gets sick each influenza season.
- Sudden onset of symptoms
 - Respiratory: cough, sore throat, runny or stuffy nose
 - Systemic: fever, chills, headache, malaise, myalgia
 - Gastrointestinal: vomiting, diarrhea
- Rapid recovery: fever usually resolves within 3 to 4 days and other symptoms within approximately 7 days. Some patients may have lingering asthenia (lack of strength or energy) for several weeks.

Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. <https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html#Clinical>;
<https://www.cdc.gov/flu/about/keyfacts.htm>

- The incubation period for influenza is usually 2 days but can vary from 1 to 4 days. Influenza illness can range from asymptomatic to severe infection. On average, about 8% of the U.S. population gets sick from influenza each season (range between 3% and 11%).
- Onset of influenza symptoms is sudden. Respiratory symptoms include cough, sore throat, and runny or stuffy nose. Systemic symptoms generally include fever, chills, headache, malaise, and myalgia. Vomiting and diarrhea may also occur, especially in children. Recovery is rapid; fever usually resolves within 3 to 4 days and other symptoms within approximately 7 days. Some patients may have lingering asthenia (lack of strength or energy) for several weeks.
- Influenza symptoms (e.g., pain and fever) can be controlled with over-the-counter medications. Aspirin and salicylate-containing products should not be used for children or adolescents because it may increase the risk for developing Reye syndrome.

Influenza Complications

- Common complications
 - Secondary bacterial pneumonia
 - Exacerbations of underlying respiratory conditions
 - Otitis media
 - Laryngotracheobronchitis
 - Bronchitis
- Additional complications
 - Encephalitis
 - Meningitis
 - Transverse myelitis
 - Myocarditis
 - Pericarditis
 - Guillain-Barre syndrome
 - Reye Syndrome*
- Most deaths due to influenza typically occur among persons age 65 years and older.

* Reye syndrome is a complication that occurs almost exclusively in children taking aspirin.

Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. <https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html#Clinical>

- People most at risk of developing serious influenza-related complications include people age 65 years and older, people with chronic medical conditions (e.g., heart disease or diabetes), pregnant people, and young children, especially those younger than age 2 years. More common complications of influenza include secondary bacterial pneumonia (e.g., *Streptococcus pneumoniae*, *Haemophilus influenzae*, or *Staphylococcus aureus*), exacerbations of underlying respiratory conditions, otitis media, laryngotracheobronchitis, and bronchitis.
- Other complications may include primary pneumonia, encephalitis, aseptic meningitis, transverse myelitis, myocarditis, pericarditis, Guillain-Barré syndrome, and Reye Syndrome. Reye syndrome is a complication that occurs almost exclusively in children taking aspirin, primarily in association with influenza B virus (or varicella zoster virus), and presents with severe vomiting and confusion, which may progress to coma due to swelling of the brain.
- Most deaths due to influenza typically occur among persons age 65 years and older.

People at Higher Risk of Influenza Complications

When vaccine supply is limited, vaccination efforts should focus on administering vaccination to persons at higher risk for medical complications attributable to severe influenza who do not have contraindications, which includes:

- All children aged 6 through 59 months;
- All persons aged ≥ 50 years;
- Adults and children who have chronic pulmonary (including asthma), cardiovascular (excluding isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus);
- Persons who live with or care for those who are at increased risk (e.g., health care personnel, household contacts, and caregivers);
- Persons who are immunocompromised due to any cause (including but not limited to immunosuppression caused by medications or HIV infection);

Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. <https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html>; <https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm>; <https://www.cdc.gov/flu/highrisk/index.htm>

[READ SLIDE]

People at Higher Risk of Influenza Complications Continued

- Women who are or will be pregnant during the influenza season;
- Children and adolescents (aged 6 months through 18 years) who are receiving aspirin- or salicylate-containing medications and who might be at risk for experiencing Reye syndrome after influenza virus infection;
- Residents of nursing homes and other long-term care facilities;
- American Indians/Alaska Natives; and
- Persons who are extremely obese (body mass index ≥ 40 for adults).

Antiviral medications - adjunct to vaccination

Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. <https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html>; <https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm>; <https://www.cdc.gov/flu/highrisk/index.htm>

[READ SLIDE]

- When used for treatment, antiviral drugs can lessen symptoms and shorten the time you are sick by 1 or 2 days. They also can prevent serious influenza complications, like pneumonia. For people at higher risk of serious influenza complications, treatment with antiviral drugs can mean the difference between milder or more serious illness possibly resulting in a hospital stay.

TYPES OF VACCINES

Classification of Vaccines

- Inactivated Vaccines
 - Not live and do not replicate in body
 - Require multiple doses to produce immunity
- Live, attenuated vaccines
 - Derived from “wild” viruses or bacteria that are weakened
 - Replicate in the body to produce an immune response that is virtually identical to that produced by a natural infection

Inactivated Vaccine [video]



Live Attenuated Vaccine [video]

Information from <https://www.cdc.gov/vaccines/pubs/pinkbook/prinvac.html>; Media files from <https://www2.cdc.gov/vaccines/ed/pinkbook/2020/pb1.asp>

- There are two basic types of vaccines: inactivated and live attenuated. The characteristics of inactivated and live attenuated vaccines are different, and these characteristics determine how the vaccine is used.
- Inactivated vaccines are produced by growing the bacterium or virus in culture media, then inactivating it with heat and/ or chemicals (usually formalin). In the case of fractional vaccines, the organism is further treated to purify only those components to be included in the vaccine (e.g., the polysaccharide capsule of pneumococcus).
- Inactivated vaccines are not alive and cannot replicate. The entire dose of antigen is administered in the injection. These vaccines cannot cause disease from infection, even in an immunodeficient person. Inactivated antigens are less affected by circulating antibody than are live agents, so they may be given when antibody is present in the blood (e.g., in infancy or following receipt of antibody-containing blood products).
- Inactivated vaccines always require multiple doses. In general, the first dose does not produce protective immunity, but “primes” the immune system. A protective immune response develops after the second or third dose. In contrast to live vaccines, in which the immune response closely resembles natural infection, the immune response to an inactivated vaccine is mostly humoral. Little or no cellular immunity results. Antibody titers against inactivated antigens diminish with time. As a result, some inactivated vaccines may require periodic supplemental doses to increase, or “boost,” antibody titers.
- To produce an immune response, live attenuated vaccines must replicate (grow) in the vaccinated person. A relatively small dose of virus or bacteria is administered, which replicates in the body and creates enough of the organism to stimulate an immune response. The immune response is virtually identical to natural infection.
- With live viruses in the vaccine are weakened so that they will not cause disease in a person with a competent immune system, but they will induce a protective immune response in most vaccinated persons.
- The videos on the right provide more detail about inactivated and live attenuated vaccines.

Seasonal Influenza Vaccine Abbreviations

- IIV = Inactivated influenza vaccine
- LAIV = Live, attenuated influenza vaccine
- RIV= Recombinant influenza vaccine
- Prefixes: SD = standard dose
HD = high dose
a = adjuvanted
cc = cell culture-based
- Numeric suffixes (e.g., RIV3, IIV4) indicate trivalent or quadrivalent, respectively.

[READ SLIDE]

Vaccine Composition Influenza Vaccine – 2021–2022 Season

- All seasonal influenza vaccines available in the United States for the 2021–22 season are quadrivalent.
- U.S.-licensed seasonal influenza vaccines are formulated to protect against influenza viruses known to cause epidemics, including: one influenza A(H1N1) virus, one influenza A(H3N2) virus, one influenza B/Victoria lineage virus, and one influenza B/Yamagata lineage virus.
- The 2021–2022 seasonal influenza vaccines in the U.S. for the Influenza A (H1N1) component:
 - An A/Victoria/2570/2019 (H1N1)-like virus for egg-based vaccines
 - An A/Wisconsin/588/2019 (H1N1)-like virus for cell culture-based and recombinant-based vaccine

Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. <https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html>; Grohskopf LA, Alyanak E, Ferdinands JM, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2021–22 Influenza Season. MMWR Recomm Rep 2021;70(No. RR-5):1–28. DOI: <http://dx.doi.org/10.15585/mmwr.rr7005a1>

[READ SLIDE]

Influenza Vaccines for the 2021-22 Season

- Quadrivalent Live Attenuated Influenza Vaccine (LAIV4)
 - Administered intranasally
 - Contains residual egg protein
- Quadrivalent Inactivated Influenza Vaccines (IIV4, cIIV4, HD-IIV4, aIIV4)
 - Administered by intramuscular injection
 - Available in multiple presentations (manufacturer-filled syringe, single-dose vials, and multidose vials) and in preservative-free formulations.
 - Multidose vials contain thimerosal
 - Some products contain residual egg protein

Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. <https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html>; Grohskopf LA, Alyanak E, Ferdinands JM, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2021–22 Influenza Season. MMWR Recomm Rep 2021;70(No. RR-5):1–28. DOI: <http://dx.doi.org/10.15585/mmwr.rr7005a1>

[READ SLIDE]

Seasonal Influenza Vaccines Continued

- Quadrivalent Recombinant Influenza Vaccine (RIV4 recombinant HA vaccine)
 - Administered by intramuscular injection
 - Does not contain egg protein
 - Uses genetic engineering technology to insert a segment of the viral gene into the gene of a yeast cell or virus.

Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. <https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html>;

[READ SLIDE]

Influenza Vaccine Products for 2021–22 Season

Classification of Vaccine	Type of Vaccine	Trade Name (Manufacturer)	Egg-based
Live, attenuated influenza vaccine	LAIV4	FluMist Quadrivalent (AstraZeneca)	YES
Inactivated influenza vaccine	IIV4 (standard-dose, egg-based vaccines)	Afluria Quadrivalent (Seqirus)	YES
		Fluarix Quadrivalent (GlaxoSmithKline)	
		FluLaval Quadrivalent (GlaxoSmithKline)	
		Fluzone Quadrivalent (Sanofi Pasteur)	
	HD-IIV4 (high-dose, egg-based vaccine [†])	Fluzone High-Dose Quadrivalent (Sanofi Pasteur)	YES
	aIIV4 (standard-dose, egg-based [†] vaccine with MF59 adjuvant)	Fluad Quadrivalent (Seqirus)	YES
	cIIV4 (standard-dose, cell culture–based vaccine)	Flucelvax Quadrivalent (Seqirus)	NO
Recombinant influenza vaccine	RIV4 (recombinant HA vaccine)	Flublok Quadrivalent (Sanofi Pasteur)	NO

[†] Although a history of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of egg-based IIV4s and LAIV4, ACIP recommends that persons with a history of egg allergy may receive any licensed, recommended influenza vaccine that is otherwise appropriate for their age and health status. Those who report having had reactions to egg involving symptoms other than urticaria (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent emesis) or who required epinephrine or another emergency medical intervention should be vaccinated in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health departments, and physician offices) supervised by a health care provider who is able to recognize and manage severe allergic reactions, if a vaccine other than cIIV4 or RIV4 is used.

Brand names do not constitute endorsement

Information from https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm?s_cid=rr7005a1_w

- Here is a chart of the many different influenza vaccine products available, including live, attenuated influenza vaccine (LAIV), inactivated influenza vaccine (IIV), and Recombinant influenza vaccine (RIV).

Immunogenicity, Efficacy, and Effectiveness of Seasonal Influenza Vaccines

- Duration of immunity less than one year due to waning and antigenic drift
- Estimates of vaccine efficacy (i.e., prevention of illness among vaccinated persons enrolled in controlled clinical trials) and vaccine effectiveness (i.e., prevention of illness in vaccinated populations) of influenza vaccines depend on many factors.
 - Study design, diagnostic testing measures, and the outcome being measured
 - Age and immunocompetence of the vaccine recipient
 - Degree of similarity of the vaccine strain(s) to the circulating strain(s)
 - Type of vaccine administered

Information from <https://www.cdc.gov/flu/vaccines-work/effectivenessqa.htm>; Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021.
<https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html#Vaccines>

- For practical purposes, the duration of immunity following influenza vaccination is less than one year because of vaccine-induced antibody waning and antigenic drift of circulating influenza viruses.
- Influenza vaccine effectiveness depends on many factors including the similarity of the vaccine strain(s) to the circulating strain(s), the age and health status of the recipient, and the type of vaccine administered.

Immunogenicity, Efficacy, and Effectiveness of Seasonal Influenza Vaccines (Continued)

- Vaccination is effective in reducing the risk of influenza illness by 40% to 60% in the overall population when vaccine strains and circulating viruses are similar.
- During the 2010–2011 to 2018–2019 influenza seasons, adjusted overall vaccine efficacy has ranged from 19% to 60% in patients age 6 months and older.
 - Circulating A/H3N2 influenza viruses drifted significantly after strain selection for the 2014–2015 vaccines, contributing to a lower vaccine efficacy of 19% during that season.
- In general, current flu vaccines tend to work better against influenza B and influenza A(H1N1) viruses and offer lower protection against influenza A(H3N2) viruses.

Information from <https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html>; <https://www.cdc.gov/flu/vaccines-work/vaccineeffect.htm>

- Vaccination is effective in reducing the risk of influenza illness by 40% to 60% in the overall population when vaccine strains and circulating viruses are similar. However, the vaccine can be less effective in preventing illness among persons age 65 years and older.
- During the 2010–2011 to 2018–2019 influenza seasons, adjusted overall vaccine efficacy has ranged from 19% to 60% in patients age 6 months and older. Circulating A/H3N2 influenza viruses drifted significantly after strain selection for the 2014–2015 vaccines, contributing to a lower vaccine efficacy of 19% during that season.
- In general, current flu vaccines tend to work better against influenza B and influenza A(H1N1) viruses and offer lower protection against influenza A(H3N2) viruses.
- A number of influenza vaccines from different manufacturers are available each season. Where there is more than one influenza vaccine available that is appropriate for a given recipient, ACIP does not express a preference for any one vaccine over another.

IMMUNIZATION SCHEDULES

Advisory Committee on Immunization Practices (ACIP)

- A group of medical and public health experts who develop recommendations on the use of vaccines in the civilian population of the United States
- Provides guidance on use of vaccines and other biologic products to U.S. Department of Health and Human Services, CDC, and the U.S. Public Health Service
- ACIP recommendations are standard of health care in the United States.

Information from Advisory Committee on Immunization Practices <https://www.cdc.gov/vaccines/acip/committee/index.html>

- The Advisory Committee on Immunization Practices (ACIP) is a group of medical and public health experts that develops recommendations on the use of vaccines in the civilian population of the United States. ACIP recommendations are considered standard of care in the U.S.

ACIP 2021–22 Influenza Season Vaccine Recommendations

- Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications.
 - Recommendations regarding timing of vaccination, considerations for specific populations, the use of specific vaccines, and contraindications and precautions are summarized in the sections that follow.
- During the 2021–22 influenza season, it is expected that SARS-CoV-2 will continue to circulate in the United States, and COVID-19 vaccinations are expected to continue.
 - COVID-19 vaccines can be administered with other vaccines, including influenza vaccines.

Information from <https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm>

- ACIP recommends routine annual influenza vaccination for all persons aged ≥6 months who do not have contraindications.
 - Recommendations regarding timing of vaccination, considerations for specific populations, the use of specific vaccines, and contraindications and precautions are summarized in the sections that follow.
- During the 2021–22 influenza season, it is expected that SARS-CoV-2 will continue to circulate in the United States, and COVID-19 vaccinations are expected to continue.
 - Current guidance for the administration of COVID-19 vaccines see [Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC](#)
 - Guidance for vaccine planning during the pandemic is available at [Routine and Influenza Immunization Services During the COVID-19 Pandemic: Interim Guidance | CDC](#)
 - Additional discussion of coadministration of influenza and COVID-19 vaccines can be found in the section on Administration of Influenza Vaccines with Other Vaccines.

Primary Changes and Updates – 2021–22 Influenza Vaccination

- The approved age indication for the cell culture–based inactivated influenza vaccine (cclIV), Flucelvax Quadrivalent (cclIV4), has been expanded from ages ≥ 4 years to ages ≥ 6 months.
- A history of a severe allergic reaction (e.g., anaphylaxis) to a previous dose of any egg-based IIV, LAIV, or RIV is a precaution to use of cclIV4. A history of a severe allergic reaction (e.g., anaphylaxis) to a previous dose of any egg-based IIV, cclIV, or LAIV is a precaution to use of RIV4.
 - Use of cclIV4 and RIV4 in such instances should occur in an inpatient or outpatient medical setting under supervision of a provider who can recognize and manage a severe allergic reaction.
- For cclIV4, history of a severe allergic reaction (e.g., anaphylaxis) to any cclIV of any valency or any of component of cclIV4 is a contraindication to future use of cclIV4. For RIV4, history of a severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency or any component of RIV4 is a contraindication to future use of RIV4.

Information from <https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm>; <https://www.fda.gov/vaccines-blood-biologics/vaccines/flucelvax-quadrivalent>

[READ SLIDE]

ACIP Seasonal Influenza Vaccine Recommendations: Pediatric

Routine pediatric recommendations are found in the [Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger](#).

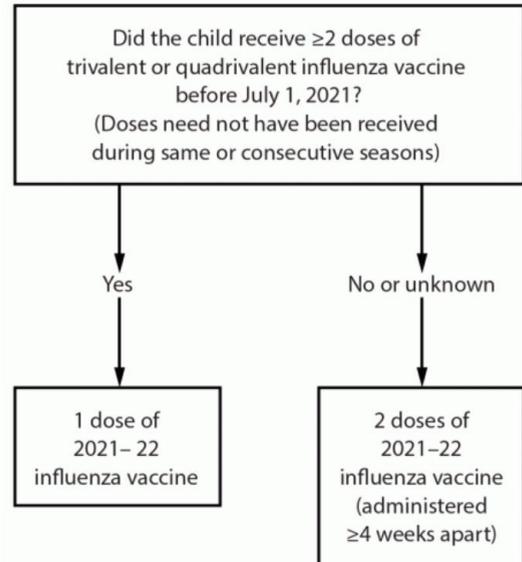
Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19-23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13-15 yrs	16 yrs	17-18 yrs	
Influenza (IIV) or Influenza (LAIV)					Annual vaccination 1 or 2 doses										Annual vaccination 1 dose only			
												Annual vaccination 1 or 2 doses		Annual vaccination 1 dose only				

Information from www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html.

- ACIP recommends influenza vaccine be given annually beginning at 6 months of age. Routine pediatric recommendations are found in the [Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger](#). Influenza vaccine recommendation from Immunization Schedule can be found here.
- Influenza vaccination (minimum age: 6 months [IIV], 2 years [LAIV4], 18 years [recombinant influenza vaccine, RIV4])
- For the 2021–22 season, see the 2021–22 ACIP influenza vaccine recommendations.

Pediatric Seasonal Influenza Vaccine Dosing Algorithm

- Influenza vaccine dosing algorithm for children aged 6 months through 8 years
- For children aged 8 years who require 2 doses of vaccine, both doses should be administered even if the child turns age 9 years between receipt of dose 1 and dose 2.



Information from <https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm#F1> down

Influenza vaccination dosing algorithm

- Use any influenza vaccine appropriate for age and health status annually:
 - 2 doses, separated by at least 4 weeks, for children age 6 months–8 years who have received fewer than 2 influenza vaccine doses before July 1, 2021, or whose influenza vaccination history is unknown (administer dose 2 even if the child turns 9 between receipt of dose 1 and dose 2)
 - 1 dose for children age 6 months–8 years who have received at least 2 influenza vaccine doses before July 1, 2021
 - 1 dose for all persons age 9 years or older

ACIP Seasonal Influenza Vaccine Recommendations: Adult

Adult vaccine recommendations are found in the [Recommended Adult Immunization Schedule for ages 19 years or older](#).

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
Influenza inactivated (IIV) or Influenza recombinant (RIV4)	1 dose annually			
Influenza live, attenuated (LAIV4)				

Information from <https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html>

- ACIP recommends influenza vaccine be given annually for adults. Adult vaccine recommendations are found in the [Recommended Adult Immunization Schedule for ages 19 years or older](#). Influenza vaccine recommendation from Immunization Schedule can be found here.
- For adults 1 dose any influenza vaccine appropriate for age and health status annually
- For the 2021–22 season, see the 2021–22 ACIP influenza vaccine recommendations.

Vaccination Schedule by Product

Influenza vaccines — United States, 2021–22 influenza season*			
Trade name (manufacturer)	Presentations	Age indication	Route
IIV4 (standard-dose, egg-based vaccines†)			
Afluria Quadrivalent (Seqirus)	0.25-mL PFSS§	6 through 35 mos§	IM¶
	0.5-mL PFSS§	≥3 yrs§	IM¶
	5.0-mL MDV§	≥6 mos§ (needle/syringe) 18 through 64 yrs (jet injector)	IM¶
Fluarix Quadrivalent (GlaxoSmithKline)	0.5-mL PFS	≥6 mos	IM¶
FluLaval Quadrivalent (GlaxoSmithKline)	0.5-mL PFS	≥6 mos	IM¶
Fluzone Quadrivalent (Sanofi Pasteur)	0.5-mL PFS**	≥6 mos**	IM¶
	0.5-mL SDV**	≥6 mos**	IM¶
	5.0-mL MDV**	≥6 mos**	IM¶

Abbreviations: MDV = multidose vial; NAS = intranasal; PFS = prefilled syringe; SDV = single-dose vial. Special Character footnotes: *, †, §, **, ¶ (see following slides)

Package inserts for U.S.-licensed vaccines are available at <https://www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states>.

Availability and characteristics of specific products and presentations might change or differ from what is described in this table and in the text of this report

Information from Grohskopf LA, Alyanak E, Ferdinands JM, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2021–22 Influenza Season. MMWR Recomm Rep 2021;70(No. RR-5):1–28. DOI: <http://dx.doi.org/10.15585/mmwr.rr7005a1>

Influenza Vaccine by Product — United States, 2021–22 influenza season

- This table shows the different available IIV4 standard-dose egg-based vaccines for the 2021–2022 season with presentation, age indication, and route of administration.

Vaccine Schedule by Product (Continued)

Influenza vaccines — United States, 2021–22 influenza season*			
Trade name (manufacturer)	Presentations	Age indication	Route
ccIIV4 (standard-dose, cell culture–based vaccine)			
Flucelvax Quadrivalent (Seqirus)	0.5-mL PFS	≥6 months	IM¶
	5.0-mL MDV	≥6 months	IM¶
HD-IIV4 (high-dose, egg-based vaccine[†])			
Fluzone High-Dose Quadrivalent (Sanofi Pasteur)	0.7-mL PFS	≥65 yrs	IM¶
aIIV4 (standard-dose, egg-based[†] vaccine with MF59 adjuvant)			
Fluad Quadrivalent (Seqirus)	0.5-mL PFS	≥65 yrs	IM¶
RIV4 (recombinant HA vaccine)			
Flublok Quadrivalent (Sanofi Pasteur)	0.5-mL PFS	≥18 yrs	IM¶
LAIV4 (egg-based vaccine[†])			
FluMist Quadrivalent (AstraZeneca)	0.2-mL prefilled single-use intranasal sprayer	2 through 49 yrs	NAS

Abbreviations: MDV = multidose vial; NAS = intranasal; PFS = prefilled syringe; SDV = single-dose vial. Special Character footnotes: *, †, §, **, ¶ (see following slides)
 Package inserts for U.S.-licensed vaccines are available at <https://www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states>.
 Availability and characteristics of specific products and presentations might change or differ from what is described in this table and in the text of this report

Information from Grohskopf LA, Alyanak E, Ferdinands JM, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2021–22 Influenza Season. MMWR Recomm Rep 2021;70(No. RR-5):1–28. DOI: <http://dx.doi.org/10.15585/mmwr.rr7005a1>; <https://www.fda.gov/vaccines-blood-biologics/vaccines/flucelvax-quadrivalent>

Influenza Vaccine by Product — United States, 2021–22 influenza season (Continued)

- This table shows the different available vaccines for the 2021–2022 season with presentation, age indication, and route of administration for ccIIV4 (standard-dose, cell culture-based vaccine) HD-IIV4 (high-dose, egg-based vaccine); aIIV4 (standard-dose, egg-based vaccine with MF59 adjuvant); RIV4 (recombinant HA vaccine); and LAIV4 (egg-based vaccine[†]).

Vaccination Schedule by Product Footnote Description

- * Vaccination providers should consult FDA-approved prescribing information for 2021–22 influenza vaccines for the most complete and updated information, including (but not limited to) indications, contraindications, warnings, and precautions.
- † Although a history of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of egg-based IIV4s and LAIV4, ACIP recommends that persons with a history of egg allergy may receive any licensed, recommended influenza vaccine that is otherwise appropriate for their age and health status. Those who report having had reactions to egg involving symptoms other than urticaria (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent emesis) or who required epinephrine or another emergency medical intervention should be vaccinated in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health departments, and physician offices) supervised by a health care provider who is able to recognize and manage severe allergic reactions, if a vaccine other than cIIIV4 or RIV4 is used.

Information from <https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm>

[READ SLIDE]

Vaccination Schedule by Product Footnote Description

§ The dose volume for Afluria Quadrivalent is 0.25 mL for children aged 6 through 35 months and 0.5 mL for persons aged ≥ 3 years.

¶ IM-administered influenza vaccines should be given by needle and syringe only, with the exception of the MDV presentation of Afluria Quadrivalent, which may alternatively be given by the PharmaJet Stratis jet injector for persons aged 18 through 64 years only. Additional specific guidance regarding site selection and needle length for IM administration is available in the ACIP General Best Practice Guidelines for Immunization, available at <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>.

** Fluzone Quadrivalent is currently approved for ages 6 through 35 months at either 0.25 mL or 0.5 mL per dose; however, 0.25-mL prefilled syringes are not expected to be available for the 2021–22 influenza season. If a prefilled syringe of Fluzone Quadrivalent is used for a child in this age group, the dose volume will be 0.5 mL per dose.

Information from <https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm>

[READ SLIDE]

Timing of Vaccination

- Vaccination should occur before onset of influenza activity. Health care providers should offer vaccination by the end of October, if possible.
- To avoid missed opportunities for vaccination, providers should offer vaccination during routine health care visits and hospitalizations when vaccine is available.
- Vaccination soon after vaccine becomes available may also be considered for pregnant people during the third trimester
 - Vaccination of pregnant people reduces risk for influenza illness in their infants during the first months of life (a period during which they are too young to receive influenza vaccine)
- For nonpregnant adults, vaccination in July and August should be avoided unless there is concern that later vaccination might not be possible.

Information from <https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm>

[READ SLIDE]

Special Considerations: History of Guillain-Barré Syndrome

- Guillain-Barré syndrome (GBS) is an acute condition that results in temporary weakness and paralysis following infection with a virus or bacteria.
- In 1976, a small increased risk of GBS was noted after swine flu vaccination.
- Since then, there have been several studies to evaluate the risk of GBS following an influenza vaccine.
- CDC monitors for GBS during each influenza season.
- When there has been an increased risk, it has been in the range of 1-2 additional GBS cases per million influenza vaccine doses administered.
- It is for this reason, that history of GBS within 6 weeks of previous influenza vaccination, is a precaution of influenza vaccination.

Information from Centers for Disease Control and Prevention. *Guillain-Barré Syndrome and Vaccines*. <https://www.cdc.gov/vaccinesafety/concerns/guillain-barre-syndrome.html>; <https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html#Safety>; <https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm#recommendationsfortheuseofinfluenzavaccines,2021%E2%80%9322>

[READ SLIDE]

Special Considerations: Egg Allergies

- Persons with a history of egg allergy who have experienced only urticaria (hives) after exposure to egg should receive influenza vaccine.
 - Any influenza vaccine (i.e., any IIV4, RIV4, or LAIV4) can be used.
- Persons having had reactions to egg involving symptoms other than urticaria (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent vomiting) or who required epinephrine or another emergency medical intervention can similarly receive any influenza vaccine (i.e., any IIV4, RIV4, or LAIV4)
 - If a vaccine other than cIIIV4 or RIV4 is used, it should be administered in an inpatient or outpatient medical setting and be supervised by a health care provider who is able to recognize and manage severe allergic reactions.
- For egg-based IIV4s and LAIV4: A history of severe allergic reaction (e.g., anaphylaxis) to any influenza vaccine (i.e., any egg-based IIV, cIIIV, RIV, or LAIV of any valency) is a contraindication to future receipt of all egg-based IIV4s and LAIV4.

Information from <https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm#recommendationsfortheuseofinfluenzavaccines.2021%E2%80%93322>

- Most available influenza vaccines, with the exceptions of RIV4 (Flublok Quadrivalent, licensed for those aged ≥ 18 years) and cIIIV4 (Flucelvax Quadrivalent, licensed for those aged ≥ 6 months), are prepared by propagation of virus in embryonated eggs and might contain trace amounts of egg proteins, such as ovalbumin.
- For persons who report a history of egg allergy, ACIP recommends the following:
 - Persons with a history of egg allergy who have experienced only urticaria (hives) after exposure to egg should receive influenza vaccine. Any licensed, recommended influenza vaccine (i.e., any IIV4, RIV4, or LAIV4) that is otherwise appropriate for the recipient's age and health status can be used.
 - Persons who report having had reactions to egg involving symptoms other than urticaria (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent vomiting) or who required epinephrine or another emergency medical intervention can similarly receive any licensed, recommended influenza vaccine (i.e., any IIV4, RIV4, or LAIV4) that is otherwise appropriate for their age and health status.
 - If a vaccine other than cIIIV4 or RIV4 is used, the selected vaccine should be administered in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health departments, and physician offices). Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic reactions.
- All vaccine providers should be familiar with their office emergency plan and be certified in cardiopulmonary resuscitation.
- For egg-based IIV4s and LAIV4: A history of severe allergic reaction (e.g., anaphylaxis) to any influenza vaccine (i.e., any egg-based IIV, cIIIV, RIV, or LAIV of any valency) is a contraindication to future receipt of all egg-based IIV4s and LAIV4.

Special Considerations: Pregnancy

- Pregnant and postpartum people have been observed to be at higher risk for severe illness and complications from influenza, particularly during the second and third trimesters.
- Influenza vaccination during pregnancy is associated with reduced risk for respiratory illness and influenza among pregnant and postpartum people, as well as infants during the first several months of life.
- Influenza vaccine recommended for those who are pregnant or who might be pregnant or postpartum during the influenza season receive any licensed, recommended, and age-appropriate IIV4 or RIV4.
 - LAIV4 should not be used during pregnancy but can be used postpartum.

Information from Grohskopf LA, Alyanak E, Ferdinands JM, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2021–22 Influenza Season. MMWR Recomm Rep 2021;70(No. RR-5):1–28. DOI: <http://dx.doi.org/10.15585/mmwr.rr7005a1>

- Pregnant and postpartum people have been observed to be at higher risk for severe illness and complications from influenza, particularly during the second and third trimesters.
- Influenza vaccination during pregnancy is associated with reduced risk for respiratory illness and influenza among pregnant and postpartum people, as well as infants during the first several months of life.
- ACIP and the American College of Obstetricians and Gynecologists recommend that those who are pregnant or who might be pregnant or postpartum during the influenza season receive influenza vaccine.
- Influenza vaccine can be administered at any time during pregnancy, before and during the influenza season.
 - Any licensed, recommended, and age-appropriate IIV4 or RIV4 may be used.
 - LAIV4 should not be used during pregnancy but can be used postpartum.

Special Considerations: Older Adults

- Because of the vulnerability of older adults to influenza-associated severe illness, hospitalization, and death, efficacy and effectiveness of influenza vaccines in this population is an area of active research.
- There are regular influenza shots that are approved for use in people 65 years and older and there also are two vaccines designed specifically for this age group (high dose influenza vaccine and adjuvanted influenza vaccine).
 - No preference is expressed for any one vaccine type. Vaccination should not be delayed if a specific vaccine is not readily available. For persons aged ≥ 65 years, any age-appropriate IIV4 formulation (standard dose or high dose, nonadjuvanted or adjuvanted) or RIV4 is an acceptable option.
- Individuals 50 years of age and older should not receive LAIV.

Information from <https://www.cdc.gov/flu/highrisk/65over.htm>;

<https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm#recommendationsfortheuseofinfluenzavaccines,2021%E2%80%9322>

[READ SLIDE]

Special Considerations: Immunocompromised Persons

- Persons with immunocompromising conditions should receive an age-appropriate IIV4 or RIV4.
 - Immunocompromising conditions include but are not limited to persons with congenital and acquired immunodeficiency states, persons who are immunocompromised due to medications, and persons with anatomic and functional asplenia.
- ACIP recommends that LAIV4 not be used for these groups because of the uncertain but biologically plausible risk for disease attributable to the live vaccine virus.
- Timing of vaccination with IIV4 or RIV4 might be a consideration (e.g., vaccinating during some period either before or after an immunocompromising intervention).

Information from <https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm#recommendationsfortheuseofinfluenzavaccines,2021%E2%80%9322>

[READ SLIDE]

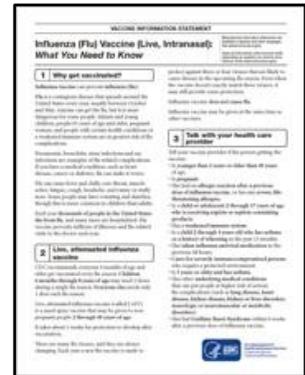
COMMUNICATIONS

CDC Seasonal Influenza Vaccine Information Statement (VIS)

- Federal law requires that a VIS be provided to a patient, parent, or legal representative before each dose of certain vaccines, including Influenza (both Inactivated and Live, Intranasal vaccines)
- VISs explain both the benefits and risks of the vaccine the patient is receiving.
- Current VISs [Vaccine Information Statement | Current VISs | CDC](#)



Influenza, inactivated



Influenza, live

Information from vaccine information statements www.cdc.gov/vaccines/hcp/vis/; foreign language versions <https://www.immunize.org/vis/>

- All public and private vaccine providers are required by the National Childhood Vaccine Injury Act to give the appropriate VIS to the patient (or their parent or legal representative) prior to every dose of certain vaccines. VISs have been translated into about 40 languages. These can be found on the website of CDC's partner, immunize.org. You can access the website by clicking on the image on the right of the slide. Additional resources on the use of VISs are listed in the resources and references slides at the end of this presentation.

CDC Vaccine Information Statement (VIS)

How to provide a VIS prior to vaccination:

- Paper copies of the VIS can be printed and given to patients prior to vaccination.
- Permanent, laminated office copies may be given to patients to read prior to vaccination.
- Patients may view VISs on a computer monitor or other video display.
- Patients may read the VIS on their phone or other digital device by downloading the pdf file from CDC's website.
- Patients may be given a copy of a VIS during a prior visit, or told how to access it through the internet, so they can read it in advance. These patients must still be offered a copy to read during the immunization visit, as a reminder.

Always offer the parent or legal representative an opportunity to ask questions about the vaccine you are administering.

Patients must still be offered a copy of the VIS to take away following the vaccination. The patient may decline.

Information from <https://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html>

- The appropriate VIS must be given **prior** to the vaccination, and must be given prior to **each dose** of a multi-dose series. It must be given **regardless of the age** of the recipient.
 - Paper copies of the VIS can be printed and given to the parent or legal representative.
 - Permanent, laminated office copies may be given to the parent or legal representative to read.
 - Parents or legal representatives may view VISs on a computer monitor or other video display.
 - Providing the VIS as an attachment or weblink contained within an email sent to the parent/legal representative.
 - Parents or legal representatives may read the VIS on their phones or other digital devices by downloading the pdf file from CDC's website.
 - Parents or legal representatives may be given a copy of a VIS during a prior visit or told how to access it through the internet so they can read it in advance. These patients must still be offered a copy to read as a reminder during the immunization visit.
- Always offer the parent or legal representative an opportunity to ask questions about the vaccine you are administering.
- Providers can make VISs available to the parent or legal representative on paper or in electronic form. The parent or legal representative must be offered a copy of the VIS to take home, but they may decline.
- If the parent/legal representative is not present, provision of the VIS prior to vaccination must be coupled with a method to verify parent/legal representative receipt of the VIS, in addition to parent/legal representative consent to vaccination in compliance with the applicable state medical consent law.

How to Communicate Vaccine Benefits to Vaccine Hesitant Individual

- Avoid assumptions about the patient's position on vaccines
- Ask open ended questions to foster good discussion
- Recommend the vaccine
- Leverage science and personal anecdote when talking to patients



Information from <https://www.cdc.gov/vaccines/hcp/conversations/talking-with-parents.html#parents-refuse-vaccination>; <https://www.cdc.gov/washington/testimony/2019/t20190227.htm> <https://www.medscape.com/viewarticle/882865>; <https://www.cdc.gov/flu/fluview/coverage-1920estimates.htm>. Media clip: <https://youtu.be/HQHnmrBKrpw>

- While confidence in vaccines remains consistently high at the national level, there are pockets of people who are vaccine-hesitant, who delay or refuse to vaccinate themselves and/or their children. The World Health Organization named vaccine hesitancy as one of the top ten threats to global health in 2019.
- The Centers for Disease Control and Prevention (CDC) analyzed data from two telephone surveys, the National Immunization Survey-Flu (NIS-Flu) and the Behavioral Risk Factor Surveillance System (BRFSS), to estimate flu vaccination coverage for the U.S. population during the 2018–19 flu season. Vaccination coverage varied by state, ranging from 46.0%–81.1% among children and from 33.9%–56.3% among adults. CDC estimated that increasing coverage by five percentage points could have prevented another 4,000 to 11,000 hospitalizations, depending on the severity of the season.
- Vaccine hesitancy, in general, is rooted in misinformation about the risk of disease and the safety and efficacy of vaccines. However, the specific issue fueling the hesitancy often varies by community. For some, it could be that, fewer and fewer doctors, other healthcare providers, and parents/patients have witnessed the serious and sometimes life-threatening consequences of Vaccine-preventable diseases. Parents/patients may wonder if vaccines are really necessary, and they may believe that the risks of temporary discomfort vaccinating themselves or their children may cause a vaccine may cause outweigh the benefits of protecting them from infection. For some, they question whether vaccines are safe, or whether they contain harmful ingredients. Others have religious beliefs that dissuade them from seeking medical care, including vaccination.
- When talking to individuals who may be hesitant about vaccine, it is important to delay assumptions about the individuals' position on vaccines. In reserving judgment from conversation, you can foster more trust in the relationship with the individual.
- Asking open ended questions is important way to foster good discussion with balanced answers to questions. It is important to acknowledge concerns but give correct information about vaccines as well.
- As a trusted source of health information for individual and their families, a nurse's recommendation is important – stating your confidence in the safety and efficacy of vaccines.
- Some individuals respond better to information about the science whereas others may respond better to personal anecdote from yourself or your practice.
- These are a few key strategies that can be used to foster good discussion with vaccine hesitant parents. You can find a short clip here with other great techniques that can be used to talk about vaccines with parents.

Seasonal Influenza Communication Resources

- CDC Influenza Communication Resource Center provides:
 - Toolkits
 - Seasonal Flu Vaccine Campaign Toolkit
<https://www.cdc.gov/flu/resource-center/toolkit/index.htm>
 - Health Care Professional Fight Flu Toolkit
<https://www.cdc.gov/flu/professionals/vaccination/prepare-practice-tools.htm>
 - Print materials
 - Infographics
 - Digital Media/Videos
 - Social Media Images and Messages

Information from <https://www.cdc.gov/flu/resource-center/index.htm> <https://www.cdc.gov/flu/professionals/vaccination/prepare-practice-tools.htm>

- CDC's seasonal flu vaccination campaign materials are available to assist partners in communicating about the importance of vaccination. This digital toolkit includes details on events/activities, sample social media and newsletter content, graphics, web assets, and media prep material. This material is downloadable, shareable, and some of the material is customizable.
- CDC encourages partner organizations to use these messages on their social media platforms to encourage flu vaccination

LEGAL/ETHICAL ISSUES

Legal and Ethical Considerations

State seasonal influenza vaccination requirements

- As of August 2020, there were 7 states in the U.S. that required influenza vaccination for childcare and/or school entry.
- Influenza immunization requirements for health care personnel and patients of health care facilities varies by state and facility.
- Eleven states establish flu vaccination requirements for ambulatory care facility healthcare workers. These laws establish requirements based on the ambulatory care facility type and the type of vaccination requirements and, in some states, authorize certain vaccination exemptions.

Information from <https://www.cdc.gov/vaccines/imz-managers/laws/index.html>; <https://www.immunize.org/laws/>;
https://www.immunize.org/laws/flu_childcare.asp

[READ SLIDE]

Legal and Ethical Considerations for Routine Immunizations*

Vaccine exemptions

- All states provide medical exemptions to vaccination.
- Some states offer religious and/or philosophical exemptions.
- Some states require these exemptions be sworn or affirmed through signed, notarized affidavits.
- Children with vaccine exemptions may be excluded from childcare facilities or school during an outbreak of a vaccine-preventable disease.

*May not apply to COVID vaccines

Information from <https://www.cdc.gov/vaccines/imz-managers/laws/index.html> .

[READ SLIDE]

Legal and Ethical Considerations

National Childhood Vaccine Injury Act (NCVIA)

- Passed by Congress in 1986
- Established Vaccine Adverse Event Reporting System (VAERS) to collect reports of vaccine adverse events
- Initiated the National Vaccine Injury Compensation Program (VICP) to compensate individuals who experience certain health events following receipt of a VICP-covered vaccine

Information from <https://www.hrsa.gov/vaccine-compensation/about/index.html>; <https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html>; <https://www.hrsa.gov/vaccine-compensation/index.html>

- Unsubstantiated vaccine injury claims caused a risk to the vaccine supply in the past because fear of lawsuits drove many manufacturers out of the vaccine business. In response, Congress passed the National Childhood Vaccine Injury Act in 1986. This law established the Vaccine Adverse Event Reporting System, which collects reports of vaccine adverse events, and includes a reporting table for the National Vaccine Injury Compensation Program. This program was also initiated by the law to compensate individuals who experience certain health events following vaccination. The VAERS reporting table complements the Health Resources and Services Administration Injury Table, outlining distinct outcomes that are compensable, along with the time period when the outcome occurred following vaccination.

Legal and Ethical Considerations

Consent for vaccines

- There is no federal requirement for informed consent relating to immunization.
- Individual states may have laws outlining consent requirements.
- Health care systems/facilities also may have consent policies.

Information from <https://www.cdc.gov/vaccines/imz-managers/laws/index.html>

[READ SLIDE]

VACCINE STORAGE AND HANDLING

Vaccine Storage and Handling

Preparation

- Prepare vaccine just prior to administration.

Storage

- Influenza vaccines should be protected from light and stored at temperatures that are recommended in the package insert.
 - Influenza vaccines (IIV, RIV and LAIV) should be maintained at refrigerator temperature between 2°C and 8°C (36°F and 46°F).
 - LAIV sprayers must be kept in the carton until use in order to protect from light.
 - Vaccine that has frozen should be discarded.
- [2021 Vaccine Storage and Handling Toolkit](#)
- [2021– 2022 Influenza Season Vaccine Labels](#)

Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. <https://www.cdc.gov/vaccines/vpd/flu/hcp/index.html>; <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/storage.html>; <https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm#storageandhandlingofinfluenzavaccines>

It is important to follow best practices when storing and handling vaccines.

Preparation

- Prepare vaccine just prior to administration.

Storage

- Influenza vaccines should be protected from light and stored at temperatures that are recommended in the package insert.
 - Influenza vaccines (IIV, RIV and LAIV) should be maintained at refrigerator temperature between 2°C and 8°C (36°F and 46°F).
 - LAIV sprayers must be kept in the carton until use in order to protect from light.
 - Vaccine that has frozen should be discarded.
- For complete information on best practices and recommendations please refer to CDC's [Vaccine Storage and Handling Toolkit](#), referenced at the end of the presentation in the References and Resources section.

Vaccine Storage and Handling

Keys to vaccine storage

- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management
- Well-trained staff



[“Keys to Storing and Handling Your Vaccine Supply” Video](#)

Information from Centers for Disease Control and Prevention. *Pink Book Webinar Series*, 2019; https://www2.cdc.gov/vaccines/ed/pinkbook/2019/downloads/PB5/SHVA_webinar_7-17-19.pdf; <https://www.cdc.gov/vaccines/vpd/rotavirus/hcp/storage-handling.html>; video <https://www2.cdc.gov/vaccines/ed/shvideo/>; <https://www.youtube.com/watch?v=VCzO8Zod8DI>

- Proper vaccine storage and handling are important factors in ensuring vaccine potency, thereby preventing many common vaccine-preventable diseases. Yet, each year, storage and handling errors result in revaccination of many patients and significant financial loss due to wasted vaccines. Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease. Patients can lose confidence in vaccines and providers if they require revaccination because the vaccines they received may have been compromised.
- The following are necessary to protect a vaccine inventory:
 - 1) Reliable storage and temperature monitoring equipment
 - 2) Accurate vaccine inventory management
 - 3) Well-trained staff
- The “Keys to Storing and Handling Your Vaccine Supply” video linked on the right, is designed to decrease vaccine storage and handling errors and preserve the nation’s vaccine supply by demonstrating to immunization providers the recommended best practices for storage and handling of vaccines. Additional resources on storage and handling are listed in the resources and references slides at the end of this presentation.

VACCINE ADMINISTRATION

Before Vaccine Administration

- Assess for needed vaccines by reviewing the immunization history.
 - Accept only written (including electronic), dated medical records.*
 - Compare to recommended vaccination schedule.
- Screen for contraindications and precautions.
- Discuss vaccine benefits, risks, and vaccine-preventable diseases using VISs and other reliable resources.
- Provide after-care instructions.

*Self-reported doses of influenza and pneumococcal polysaccharide (PPSV23) vaccines are acceptable.

Information from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021; <https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html>

- The patient's immunization status should be reviewed at every health care visit. Using the patient's immunization history, health care personnel should assess for all routinely recommended vaccines, as well as any vaccines indicated based on health status, occupation, or other risk factors such as travel. Use the current immunization schedule based on the age of the patient to determine all vaccines that are needed.
- The immunization history may be obtained by using information from immunization information systems, current and previous medical records, and personal vaccination record cards. Providers should only accept written (including electronic), dated records as evidence of vaccination.
- Before administering any vaccine, patients should be screened for contraindications and precautions, even if the patient has previously received that vaccine. The patient's health status may change from one visit to the next or recommendations regarding contraindications and precautions may have changed. Using a standardized, comprehensive screening tool helps staff assess patients correctly and consistently. Staff should be knowledgeable about contraindications and precautions to vaccination and only valid contraindications should be followed.
- Health care personnel should assess the level and type of information each patient or parent needs—for example, not everyone wants the same level of medical or scientific information about vaccines. Health care personnel need to be ready to answer questions. Fortunately, there are many resources available to help providers stay up to date on vaccine-related information, including vaccine information statements.
- Parent/patient education should also include a discussion of comfort and care strategies after vaccination. After-care instructions should include information for dealing with common side effects such as injection site pain, fever, and fussiness (especially in infants). After-care instructions should also include information on when to seek medical attention and when to notify the health care provider about any concerns that arise following vaccination.

Concurrent Administration of Seasonal Influenza Vaccine With Other Vaccines

- Inactivated and recombinant influenza vaccines may be administered concurrently or sequentially with other live or inactivated vaccines. Injectable vaccines given simultaneously should be administered at separate anatomic sites.
- LAIV4 may be administered simultaneously with other inactivated or live vaccines. If not given simultaneously, then LAIV4 and other live vaccine should be spaced at least 4 weeks apart.
- Current guidance for the use of COVID-19 vaccines states that COVID-19 vaccines may be administered with other vaccines. Providers should refer to current CDC and Advisory Committee on Immunization Practices (ACIP) recommendations and guidance for the use of COVID-19 vaccines.

Information from Centers for Disease Control and Prevention. *Seasonal Influenza Vaccine Safety: A Summary for Clinicians*.
https://www.cdc.gov/flu/professionals/vaccination/vaccine_safety.htm; https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm?s_cid=rr7005a1_w#T2_down

[READ SLIDE]

Contraindications and Precautions

- **Egg-Based Inactivated Influenza Vaccines (Egg-Based IIV4s)**
 - Contraindications
 - History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine. However, ACIP makes an exception for allergy to egg (see Special Considerations - Egg Allergy Slide).
 - Severe allergic reaction to a previous dose of any influenza vaccine (i.e., any egg-based IIV, cIIIV, RIV, or LAIV)
 - Precautions
 - Moderate or severe acute illness with or without fever
 - Individuals who were hospitalized with an acute illness but now are well enough to be discharged can be vaccinated
 - History of Guillain Barré syndrome within 6 weeks of a previous dose of an influenza vaccine

Information from Centers for Disease Control and Prevention. *Seasonal Influenza Vaccine Safety: A Summary for Clinicians*.
https://www.cdc.gov/flu/professionals/vaccination/vaccine_safety.htm; https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm?s_cid=rr7005a1_w#T2_down

- Screen for contraindications and precautions before administering vaccines.
- [READ SLIDE]
- Additional resources for screening for vaccine contraindications and precautions are listed in the resources and references slides at the end of this presentation.

Contraindications and Precautions (Continued)

■ Cell Culture-based Inactivated Influenza Vaccine (ccIIV4)

– Contraindications

- History of severe allergic reaction (e.g., anaphylaxis) to a previous dose of any ccIIV or any component of ccIIV4

– Precautions

- Moderate or severe acute illness with or without fever
 - Individuals who were hospitalized with an acute illness but now are well enough to be discharged can be vaccinated
- History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine
- History of severe allergic reaction to a previous dose of any other influenza vaccine (i.e., any egg-based IIV, RIV, or LAIV)

Information from Centers for Disease Control and Prevention. *Seasonal Influenza Vaccine Safety: A Summary for Clinicians*.
https://www.cdc.gov/flu/professionals/vaccination/vaccine_safety.htm; https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm?s_cid=rr7005a1_w#T2_down

[READ SLIDE]

Contraindications and Precautions (Continued)

- **Recombinant Influenza Vaccine (RIV4)**
 - Contraindications
 - History of severe allergic reaction (e.g., anaphylaxis) to a previous dose of any RIV or any component of RIV4
 - Precautions
 - Moderate or severe acute illness with or without fever
 - Individuals who were hospitalized with an acute illness but now are well enough to be discharged can be vaccinated
 - History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine
 - History of severe allergic reaction to a previous dose of any other influenza vaccine (i.e., any egg-based IIV, cclIV, or LAIV)

Information from Centers for Disease Control and Prevention. *Seasonal Influenza Vaccine Safety: A Summary for Clinicians*.
https://www.cdc.gov/flu/professionals/vaccination/vaccine_safety.htm; https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm?s_cid=rr7005a1_w#T2_down

[READ SLIDE]

Contraindications and Precautions (Continued)

▪ Live Attenuated Influenza Vaccine (LAIV4)

– Contraindications

- Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or to a previous dose of any influenza vaccine (i.e., any egg-based IIV, cIIIV, RIV, or LAIV of any valency; However, ACIP makes an exception for allergy to egg (see Special Considerations - Egg Allergy Slide);
- Children and adolescents receiving concomitant aspirin or salicylate-containing medications, because of the potential risk for Reye syndrome;

Information from Centers for Disease Control and Prevention. *Seasonal Influenza Vaccine Safety: A Summary for Clinicians*.
https://www.cdc.gov/flu/professionals/vaccination/vaccine_safety.htm; https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm?s_cid=rr7005a1_w#T2_down

[READ SLIDE]

Contraindications and Precautions (Continued)

- **Live Attenuated Influenza Vaccine (LAIV4)**

- Contraindications (continued)

- Children aged 2 through 4 years who have received a diagnosis of asthma or whose parents or caregivers report that a health care provider has told them during the preceding 12 months that their child had wheezing or asthma or whose medical record indicates a wheezing episode has occurred during the preceding 12 months
 - Children and adults who are immunocompromised due to any cause, including but not limited to immunosuppression caused by medications, congenital or acquired immunodeficiency states, HIV infection, anatomic asplenia, or functional asplenia (such as that due to sickle cell anemia)

Information from Centers for Disease Control and Prevention. *Seasonal Influenza Vaccine Safety: A Summary for Clinicians*.

https://www.cdc.gov/flu/professionals/vaccination/vaccine_safety.htm; https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm?s_cid=rr7005a1_w#T2_down

[READ SLIDE]

Contraindications and Precautions (Continued)

- **Live Attenuated Influenza Vaccine (LAIV4)**
 - Contraindications (continued)
 - Close contacts and caregivers of severely immunosuppressed persons who require a protected environment;
 - Persons with active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, or ear or any other cranial CSF leak;
 - Persons with cochlear implants, because of the potential for CSF leak, which might exist for some period after implantation (providers might consider consulting with a specialist concerning the risk for persistent CSF leak if an age-appropriate inactivated or recombinant vaccine cannot be used);

Information from Centers for Disease Control and Prevention. *Seasonal Influenza Vaccine Safety: A Summary for Clinicians*.
https://www.cdc.gov/flu/professionals/vaccination/vaccine_safety.htm; https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm?s_cid=rr7005a1_w#T2_down

[READ SLIDE]

Contraindications and Precautions (Continued)

- **Live Attenuated Influenza Vaccine (LAIV4)**
 - Contraindications (continued)
 - Pregnancy; and
 - Receipt of influenza antiviral medication within the previous 48 hours for oseltamivir and zanamivir, previous 5 days for peramivir, and previous 17 days for baloxavir. The interval between influenza antiviral receipt and LAIV4 for which interference might potentially occur might be further prolonged in the presence of medical conditions that delay medication clearance (e.g., renal insufficiency).

Information from Centers for Disease Control and Prevention. *Seasonal Influenza Vaccine Safety: A Summary for Clinicians*.
https://www.cdc.gov/flu/professionals/vaccination/vaccine_safety.htm; https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm?s_cid=rr7005a1_w#T2_down

[READ SLIDE]

Contraindications and Precautions (Continued)

▪ Live Attenuated Influenza Vaccine (LAIV4)

– Precautions

- Moderate or severe acute illness with or without fever
 - Individuals who were hospitalized with an acute illness but now are well enough to be discharged can be vaccinated
- History of Guillain-Barré syndrome within 6 weeks after receipt of any influenza vaccine;
- Asthma in persons aged ≥ 5 years; and
- Other underlying medical condition (other than those listed under contraindications) that might predispose to complications after wild-type influenza virus infection (e.g., chronic pulmonary, cardiovascular [except isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders [including diabetes mellitus])

Information from Centers for Disease Control and Prevention. *Seasonal Influenza Vaccine Safety: A Summary for Clinicians*.

https://www.cdc.gov/flu/professionals/vaccination/vaccine_safety.htm; https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm?s_cid=rr7005a1_w#T2_down

[READ SLIDE]

Vaccine Supplies



Children: Birth Through 18 Years of Age



Adults: 19 Years and Older

Information and videos from <https://www.youtube.com/watch?v=odQTVg7s3HA> and <https://www.youtube.com/watch?v=SsCxncrsKM>

[PLAY VIDEOS]

Vaccine Preparation

- Wash your hands.
- Use designated, clean preparation area.
- Prepare your own vaccines.
- Prepare vaccine only when ready to administer.
- Verify vaccine matches the standing or provider's order
- Check expiration date on the vaccine.
- Always follow the vaccine manufacturers' directions, located in the package insert.

Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021.. <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>;
https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html#anchor_1604346392751

- Preparing vaccine properly is critical to maintaining the integrity of the vaccine during transfer from the manufacturer's vial to the syringe and, ultimately, to the patient. CDC recommends preparing and drawing up vaccines just before administration. When preparing vaccines:
 - Follow strict aseptic medication preparation practices.
 - Wash your hands BEFORE preparing vaccines.
 - Use a designated clean medication area that is not adjacent to any area where potentially contaminated items are placed.
 - Prepare your own vaccines.
 - Prepare vaccine only when ready to administer.
 - Check expiration date on the vaccine.
 - Always follow the vaccine manufacturer's directions, located in the package insert.
- Additional resources on vaccine preparation are listed in the resources and references slides at the end of this presentation.

Pediatric Vaccine Administration Technique

- Infants and toddlers best held in parent's arms.
- Children best held in parent's lap.



"Comfort and Restraint Techniques" Video

Information from <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>;

Video link <https://youtu.be/r1dGpTCgerE>;

[PLAY VIDEO]

- When administering vaccines to young children, Determine the best position and/or type of comforting restraint by considering the patient's age, activity level, administration route and site, safety, and comfort. Parents and guardians play an important role when children receive vaccines. They can soothe and comfort the child, making them feel safe and secure. Parent participation has been shown to increase the child's comfort and reduces the child's perception of pain. Engage the parent or guardian in the process. Instruct parents/guardians to hold infants and children in a position comfortable for the child and parent, so that one or more limbs are exposed for injections. A parent's embrace during vaccination offers several benefits.
 - A comforting hold:
 - Avoids frightening children by embracing them rather than overpowering them
 - Allows the health care provider steady control of the limb and the injection site
 - Prevents children from moving their arms and legs during injections
 - Encourages parents to nurture and comfort their child
- While definitive guidelines for positioning patients during vaccination have not been established, some techniques have been suggested. Research shows that children age 3 years and older are less fearful and experience less pain when receiving an injection if they are sitting up rather than lying down. The exact mechanism behind this phenomenon is unknown. It may be that the child's anxiety level is reduced, which, in turn, reduces the child's perception of pain.

Vaccine Administration Route: Influenza Vaccines

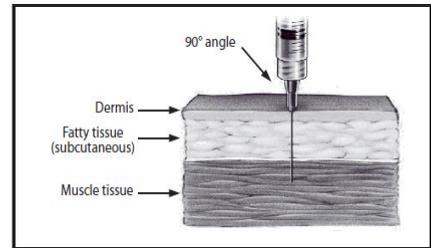
- Intramuscular Route
 - Inactivated Influenza vaccines (IIVs)
 - Recombinant influenza vaccine (RIVs)
- Intranasal Route
 - Live attenuated influenza vaccine (LAIV4)

Information from Centers for Disease Control and Prevention. <https://www.cdc.gov/flu/professionals/acip/2020-2021/acip-table.htm>

[READ SLIDE]

Vaccine Administration: Intramuscular Injections

- 22–25 gauge
- Use a needle length appropriate for the patient’s age, size, and site.
 - Children: 5/8–1.25-inches (based on age and injection site)
 - Adults: 1–1.5-inches (based on weight)*
- Aspiration before injection of vaccines or toxoids (i.e., pulling back on the syringe plunger after needle insertion but before injection) is not recommended.
- In infants and children younger than 3 years of age, the vastus lateralis muscle is the preferred site. In persons age 3 years and older, the deltoid muscle is the preferred site.



*Some experts recommend a 5/8-inch needle for men and women who weigh <60 kg, if used, skin must be stretched tightly (do not bunch subcutaneous tissue).

Information from <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html>; video source <https://www.youtube.com/watch?v=PqSuCPnPeYE>; image source Adapted from California Immunization Branch.

- When administering intramuscular injections, select a needle that is 22- through 25-gauge.
- Vaccines must reach the desired tissue for an optimal immune response and to reduce the likelihood of injection site reactions. Therefore, when choosing needle length, select a needle long enough to reach the muscle tissue but not so long as to reach any underlying bone, nerves, or blood vessels.
- Use a needle length appropriate for the patient’s age, size, and site.
 - Children: 5/8–1.25-inches (based on age and injection site)
 - Adults: 1–1.5-inches (based on weight) *Some experts recommend a 5/8-inch needle for men and women who weigh <60 kg, if used, skin must be stretched tightly (do not bunch subcutaneous tissue).*
- Aspiration before injection of vaccines or toxoids (i.e., pulling back on the syringe plunger after needle insertion but before injection) is not recommended because no large blood vessels are present at the recommended injection sites, and a process that includes aspiration might be more painful for infants.
- In infants and children younger than 3 years of age, the vastus lateralis muscle is the preferred site. In persons age 3 years and older, the deltoid muscle is the preferred site. Insert the needle at a 90-degree angle.
- Additional resources on administering IM injections are listed in the resources and references slides at the end of this presentation.

Vaccine Administration: Intranasal

- Manufacturer filled nasal sprayer used to administer vaccine
- Dose divider clip separates vaccine dose equally
- Vaccine administered into each nostril



Information and video clip from Centers for Disease Control and Prevention. Live, Attenuated Influenza Vaccine. <https://youtu.be/FUaptzVvRmU>

- When administering Live Attenuated Influenza Vaccine intranasal vaccine, use the manufacturer filled nasal sprayer. LAIV is intended for intranasal administration only and should never be administered by injection. LAIV is supplied in a prefilled single-use sprayer containing 0.2 mL of vaccine. 0.1 mL (i.e., half of the total sprayer contents) is sprayed into the first nostril while the recipient is in the upright position. An attached dose-divider clip is removed from the sprayer to administer the second half of the dose into the other nostril. If the vaccine recipient sneezes after administration, the dose should not be repeated.
- For step-by-step guidance on live, attenuated influenza vaccine administration, click on the short video clip on this slide.

DOCUMENTATION

Documenting Vaccinations

All vaccinations should be documented in the patient's permanent medical record. Federal law requires documentation of:

- Vaccine manufacturer
- Vaccine lot number
- Date of administration
- Name and title of the person who administered the vaccine and the address of the facility where the permanent record will reside
- Edition date of the vaccine information statement and the date it was provided to the patient, parent, or legal guardian



Information from <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; Video from <https://www.youtube.com/watch?v=xlyqUgKGFpk>

- Accurate and timely documentation can help prevent administration errors and curtail the number and cost of excess vaccine doses administered. In addition, preventing excess doses of vaccines may decrease the number of adverse reactions. All vaccines administered should be fully documented in the patient's permanent medical record. Health care providers who administer vaccines covered by the National Vaccine Injury Compensation Program are required to document the following information in the patient's permanent record:
 - Vaccine manufacturer
 - Vaccine lot number
 - Date of administration
 - Name and title of the person who administered the vaccine and the address of the facility where the permanent record will reside
 - Edition date of the VIS distributed, and the date provided
- This federal law applies to all routinely recommended childhood vaccines, even for doses of the vaccine that are administered to adults. The law applies to the on-point provider, who is not liable for previous lack of documentation.
- The video on the right contains more detail about documenting vaccinations.
- Additional resources for documenting vaccinations after administration are listed in the resources and references slides at the end of this presentation.

Documentation: Best Practice Guidelines

- Best practice guidelines also include documenting:
 - Route
 - Dosage (amount)
 - Anatomic site
 - Expiration date
- Provide personal immunization record that includes the vaccinations and administration dates.
- Update medical records to include:
 - Adverse events after vaccination
 - Serologic test results related to vaccine-preventable diseases

Information from Centers for <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>; <https://www2.cdc.gov/vaccines/ed/vaxadmin/va/index.html>

- Medication administration best practices also include documenting the route, dosage (amount), anatomic site, and vaccine expiration date. The patient or parent/guardian should be provided with a personal immunization record that includes the vaccinations and date administered. Providers should update patients' permanent medical records to reflect any documented episodes of adverse events after vaccination and any serologic test results related to vaccine-preventable diseases (e.g., those for rubella screening).

Reporting Vaccine Adverse Events

Vaccine Adverse Event Reporting System (VAERS): A passive surveillance system to monitor adverse events following vaccination

Health care providers are required by law to report:

- Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine
- Any adverse event listed in [the VAERS Table of Reportable Events Following Vaccination](#) that occurs within the specified time period after vaccination

Health care providers are encouraged to report:

- Any adverse event after the administration of a vaccine
- Vaccine administration errors

Information from <https://vaers.hhs.gov/reportevent.html>

- Severe, life-threatening anaphylactic reactions following vaccination are rare.
- Report significant adverse events that occur after vaccination of adults and children to VAERS, even if you are not sure whether the vaccine caused the adverse event.
- VAERS accepts all reports, including reports of vaccine administration errors.
- **Health care professionals are required by law to report:**
 - Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine
 - Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination within the specified time period
- **Health care providers are encouraged to report:**
 - Any adverse event after the administration of a vaccine
 - Vaccine administration errors

Reporting Adverse Events

VAERS Table of Reportable Events Following Vaccination*	
Vaccine/Toxoid	Event and interval** from vaccination
Seasonal influenza--trivalent inactivated influenza, quadrivalent inactivated influenza, live attenuated influenza-IIV, IIV3, IIV4, RIV3, cclIIV3, LAIV4	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Guillain-Barré Syndrome (42 days) E. Any acute complication or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

* Effective date: March 21, 2017. Table reflects what is reportable by law to VAERS. **Represents the onset interval between vaccination and the adverse event.

Information from https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

- Providers should report all adverse events after vaccination to VAERS. This table reflects conditions reportable by law, but providers should report any adverse event that concerns them.
- * Effective date: March 21, 2017. The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturer package insert. In addition, healthcare professionals are encouraged to report any clinically significant or unexpected events (even if not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET. Manufacturers are also required by regulation (21CFR 600.80) to report to the VAERS program all adverse events made known to them for any vaccine. Note that the RET differs from the Vaccine Injury Table (VIT) regarding timeframes of adverse events. Timeframes listed on the RET reflect what is required for reporting, but not what is required for compensation. To view timeframes for compensation, please see the VIT at <https://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf>
- **Represents the onset interval between vaccination and the adverse event. For a detailed explanation of terms, see the Vaccine Injury Table at <https://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf>

VACCINE SAFETY

Vaccine Safety

- Hundreds of millions of Americans have safely received influenza vaccines for more than 50 years and the body of scientific evidence overwhelmingly supports their safety.
- The safety of influenza vaccines is monitored by CDC and FDA. Certain safety outcomes are commonly evaluated, including Guillain-Barré Syndrome, maternal and infant safety, and febrile seizures.



Information from Centers for Disease Control and Prevention. Influenza Vaccines. <https://www.cdc.gov/vaccinesafety/vaccines/flu-vaccine.html>.
Image source <https://www.cdc.gov/vaccinesafety/vaccines/flu-vaccine.html>

- Findings from vaccine safety monitoring systems and scientific studies have shown that the flu vaccines have been safe for hundreds of millions of Americans who received flu vaccines for more than 50 years. The body of scientific evidence overwhelmingly supports the safety of influenza vaccines.
- The CDC and FDA closely monitor the safety of flu vaccines. Certain safety outcomes are commonly evaluated, including Guillain-Barré Syndrome, maternal and infant safety, and febrile seizures.

Seasonal Influenza Vaccine Adverse Reactions*

- **Egg-Based IIV4s, cclIV4, RIV4**
 - Injection site reactions that include soreness, redness and swelling
 - Fever
 - Muscle aches
 - Headache
 - Fatigue
- **LAIV in children:**
 - Runny nose
 - Wheezing
 - Headache
 - Vomiting
 - Muscle aches
 - Fever
- **LAIV in adults:**
 - Runny nose
 - Headache
 - Sore throat
 - Cough

*For additional information https://www.cdc.gov/flu/professionals/vaccination/vaccine_safety.htm

Information from <https://www.cdc.gov/vaccinesafety/vaccines/flu-vaccine.html>; https://www.cdc.gov/flu/professionals/vaccination/vaccine_safety.htm ;
<https://www.cdc.gov/vaccines/hcp/vis/vis-statements/fluive.pdf>; <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/flu.pdf>

- Inactivated influenza vaccine and recombinant influenza vaccine may cause pain, redness, and swelling at the injection site as well as fever, headache, malaise, and myalgias. These side effects may affect your ability to do daily activities, but they should go away in a few days. Some people have no side effects.
- The most common adverse reactions to live, attenuated influenza vaccine are runny nose or nasal congestion in all ages, fever >100°F in children 2-6 years of age, and sore throat in adults.
- Runny nose or nasal congestion, wheezing, and headache can happen after live, attenuated influenza vaccination. Vomiting, muscle aches, fever, sore throat, and cough are other possible side effects. If these problems occur, they usually begin soon after vaccination and are mild and short-lived. As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death ([Vaccine Information Statement: Attenuated Influenza Vaccine, Live, Intranasal \(cdc.gov\)](#)).

Seasonal Influenza Vaccine Adverse Reactions (Continued)

- Vaccines can be associated with allergic (immediate hypersensitivity) reactions that range in severity from mild reactions to anaphylaxis.
- IIV has been associated with febrile seizures in young children, particularly when given together with 13-valent pneumococcal conjugate vaccine (PCV13) and diphtheria, tetanus and pertussis (DTaP) vaccines.
- Safety monitoring of seasonal IIV over the course of many years has not detected a clear link to Guillain-Barré syndrome (GBS). However, if there were a risk of GBS from IIV, it would be no more than 1 or 2 additional cases per million people vaccinated.
 - Even though GBS following influenza illness is rare, studies suggest that the risk of developing GBS after having influenza is higher than the potential risk of developing GBS after influenza vaccination.
- Vaccine reactions can include syncope, or fainting.

Information from <https://www.cdc.gov/vaccinesafety/vaccines/flu-vaccine.html>; https://www.cdc.gov/flu/professionals/vaccination/vaccine_safety.htm

[READ SLIDE]

NURSING CONSIDERATIONS

Nursing Considerations

	Reaction to Vaccine	Supportive Treatment Recommendation
Mild to Moderate	<p>Injection reactions: Soreness, redness, swelling and fever</p> <p>Intranasal reactions: runny nose, headache, sore throat, cough</p>	<p>Usually self limiting;</p> <p>For injection reactions: Cool, damp cloth to help reduce redness, soreness, and/or swelling at the injection site, antipyretics can be used for fever and localized discomfort.</p>
Severe	<p>Anaphylaxis:</p> <p>Hoarseness, wheezing, airway constriction, difficulty breathing, pale or mottled skin, hypotension, altered mental status, fever, generalized hives</p>	<p>Call 911, administer CPR, provide epinephrine or equivalent (e.g., EpiPen), immediately transfer to hospital</p>

Information from Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. www.cdc.gov/vaccines/pubs/pinkbook/index.html; <https://www.cdc.gov/vaccines/parents/by-age/months-1-2.html>; <https://www.cdc.gov/vaccines/covid-19/downloads/recognizing-responding-to-anaphylaxis-508.pdf>

Supportive Treatment

Mild to moderate reaction

- Injection reactions: Soreness, redness, swelling and fever
- Intranasal reactions: runny nose, headache, sore throat, cough
- Treatment: Usually self-limiting; Cool, damp cloth to help reduce redness, soreness, and/or swelling at the injection site. Evidence does not support use of antipyretics before or at the time of vaccination. However, they can be used for the treatment of fever and local discomfort that might occur following vaccination.

Severe reaction (anaphylaxis)

- Anaphylaxis:
 - These signs and symptoms can include, but are not limited to, hoarseness, wheezing, airway constriction, difficulty breathing, pale or mottled skin, hypotension, altered mental status, fever, generalized hives
- Each staff member should know their role in the event of an emergency and all vaccination providers should be certified in cardiopulmonary resuscitation (CPR).
- Epinephrine and equipment for maintaining an airway should be available for immediate use. After the patient is stabilized, arrangements should be made for immediate transfer to an emergency facility for additional evaluation and treatment.

Nursing Considerations

Vaccinate with Confidence

- CDC's strategic framework to strengthen vaccine confidence and prevent outbreaks of vaccine-preventable diseases in the United States
- Key priorities:
 - Protect communities.
 - Empower families.
 - Stop myths.



Child vaccination coverage remains high nationally, and most parents are confident in the safety and effectiveness of vaccines. However, the spread of myths and misinformation has put some communities at risk. When misleading information circulates, vaccination coverage can fall and increase the risk for outbreaks of vaccine-preventable diseases.

A New Approach

Vaccinate with Confidence is CDC's strategic framework to strengthen vaccine confidence and prevent outbreaks of vaccine-preventable diseases in the United States.

Vaccinate with Confidence will strengthen public trust in vaccines by advancing three key priorities:

Protect Communities
Vaccination rates remain strong nationally, but pockets of under-vaccination persist in some locations, putting communities at risk for outbreaks. CDC will support states, cities, and counties to find these communities and take steps to protect them.

Empower Families
Trust in vaccines is not built through a top-down approach, but through millions of conversations between parents, doctors, nurses, pharmacists, and community members. CDC will expand resources for health care professionals to support effective vaccine conversations.

Stop Myths
To stop misinformation from eroding public trust in vaccines, CDC will work with local partners and trusted messengers to improve confidence in vaccines among at-risk groups; establish partnerships to contain the spread of misinformation; and reach critical stakeholders to provide clear information about vaccination and the critical role it plays in protecting the public.



Image courtesy of the American Academy of Pediatrics and CDC programs.

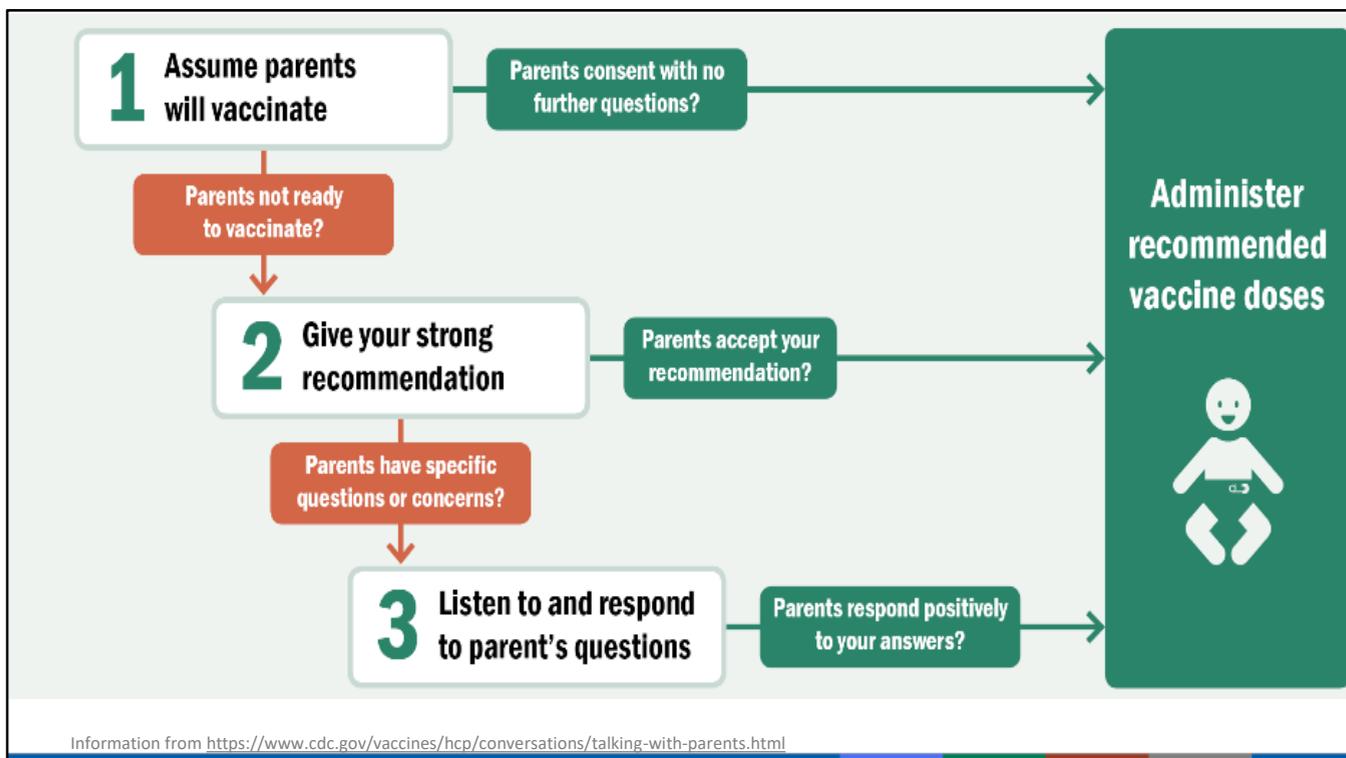


U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

[Vaccinate with Confidence fact sheet](#)

Information from <https://www.cdc.gov/vaccines/partners/vaccinate-with-confidence.html>.

- *Vaccinate with Confidence* is CDC's strategic framework to strengthen vaccine confidence and prevent outbreaks of vaccine-preventable diseases in the United States. This slide contains links to the Vaccinate with Confidence web page and fact sheet.
- *Vaccinate with Confidence* will strengthen public trust in vaccines by advancing three key priorities:
 - Protect communities.
 - Empower families.
 - Stop myths.
- *Protect communities*: Vaccination coverage remains strong nationally, but pockets of undervaccination persist in some locations, putting communities at risk for outbreaks. CDC will support states, cities, and counties to find these communities and take steps to protect them.
- *Empower families*: Trust in vaccines is not built through a top-down approach, but through millions of conversations between parents, doctors, nurses, pharmacists, and community members. CDC will expand resources for health care professionals to support effective vaccine conversations.
- *Stop myths*: To stop misinformation from eroding public trust in vaccines, CDC will work with local partners and trusted messengers to improve confidence in vaccines among at-risk groups, establish partnerships to contain the spread of misinformation, and reach critical stakeholders to provide clear information about vaccination and the critical role it plays in protecting the public.



- Doctors, nurses, physician assistants, and office staff all play a key role in establishing and maintaining a practice-wide commitment to communicating effectively about vaccines and maintaining high vaccination rates. You can all answer parents' questions, provide educational materials, and ensure that families make and keep vaccine appointments.
- Parents consider their child's healthcare professionals to be their most trusted source of information when it comes to vaccines. This is true even for parents who are vaccine-hesitant or who have considered delaying one or more vaccines. Therefore, you have a critical role in helping parents choose vaccines for their child.
- With all you do, you may feel that long vaccine conversations are stressful when you also need to check physical and cognitive milestones and have a full schedule of patients. Because of this, we designed this resource to guide you with conversational techniques and resources for discussing vaccines with parents.

VACCINE RESOURCES AND REFERENCES

Here is a list of vaccine resources and references.

Vaccine Resources and References

ACIP recommendations

- Current ACIP Influenza Recommendations
<https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm>
- General Best Practice Guidelines for Immunization
www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

Disease

- CDC Influenza <https://www.cdc.gov/flu/index.htm>
- Ask the Experts–Influenza FAQs:
https://www.immunize.org/askexperts/experts_inf.asp

Vaccine Resources and References

Manufacturer's vaccine package inserts (PIs)

- Fluzone® Quadrivalent, Sanofi Pasteur:
<https://www.fda.gov/media/119856/download>
- Afluria®, Seqirus <https://www.fda.gov/media/81559/download>
- Flud® , Seqirus <https://www.fda.gov/media/81559/download>
- Flud® Quadrivalent, Seqirus <https://www.fda.gov/media/135432/download>
- Flublok Quadrivalent®, Protein Sciences Corporation
<https://www.fda.gov/media/123144/download>
- Flucelvax® Quadrivalent, Seqirus: <https://www.fda.gov/media/115862/download>
- Flulaval® Quadrivalent, ID Biomedical Corporation of Quebec
<https://www.fda.gov/media/115785/download>

Vaccine Resources and References

Manufacturer's vaccine package inserts (PIs)

- Flumist® Quadrivalent, Medimmune <https://www.fda.gov/media/83072/download>
- Fluzone® High Dose Quadrivalent, Sanofi Pasteur
<https://www.fda.gov/media/119870/download>

Immunization schedules

- [Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger](#)
- [Catch-up Immunization Schedule](#)

Vaccine Resources and References

Communications

- Current vaccine information statements (VISs) <https://www.cdc.gov/vaccines/hcp/vis/current-vis.html>
- Instructions for Using VISs <https://www.cdc.gov/vaccines/hcp/vis/about/required-use-instructions.html>
- Translated VISs <https://www.immunize.org/vis/?f=9>
- Talking to Parents about Vaccines: <https://www.cdc.gov/vaccines/hcp/conversations/conv-materials.html>
- HCP Fight Flu Toolkit: <https://www.cdc.gov/flu/professionals/vaccination/prepare-practice-tools.htm>

Vaccine Resources and References

Vaccine storage and handling

- Vaccine Storage and Handling Toolkit
<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>
- “Keys to Storing and Handling Your Vaccine Supply”
<https://www.youtube.com/watch?v=VCzO8Zod8DI>

Vaccine administration

- Immunization Action Coalition Clinic Tools Screening for Vaccine Contraindications and Precautions <https://www.immunize.org/clinic/screening-contraindications.asp>
- Standing Orders for Administering Influenza Vaccine to Adults
<https://www.cdc.gov/flu/professionals/vaccination/prepare-practice-tools.htm>
- CDC Vaccine Administration Resource Library
<https://www.cdc.gov/vaccines/hcp/admin/resource-library.html>

Vaccine Resources and References

Documentation

- Documentation of Vaccinations After Administration
<https://www.youtube.com/watch?v=xlyqUgKGFPk>

Safety

- Seasonal Influenza Vaccine Safety: A Summary for Clinicians
https://www.cdc.gov/flu/professionals/vaccination/vaccine_safety.htm
- Safety Information Influenza (Flu) Vaccines
<https://www.cdc.gov/vaccinesafety/vaccines/flu-vaccine.html>

ABBREVIATIONS

Influenza Vaccine Abbreviations

- IIV, RIV, and LAIV denote vaccine categories; numeric suffix denotes number of antigens in the vaccine
 - **IIV** = Inactivated Influenza Vaccine (formerly called TIV)
 - **IIV3** = Trivalent Inactivated Influenza Vaccine
 - **IIV4** = Quadrivalent Inactivated Influenza Vaccine
 - **RIV** = Recombinant Influenza Vaccine
 - **RIV3** = Trivalent Recombinant Influenza Vaccine
 - **RIV4** = Quadrivalent Recombinant Influenza Vaccine
 - **LAIV** = Live Attenuated Influenza Vaccine
 - **LAIV4** = Quadrivalent Live Attenuated Influenza Vaccine
- **SD** = standard dose (e.g., **SD-IIV3** and **SD-IIV4**)
- **HD** = high dose (e.g., **HD-IIV3**)
- **a** = adjuvanted (e.g., **aIIV3**)
- **cc** = cell-culture-based (e.g., **ccIIV4**)
- **IM** = Intramuscular
- **NAS** = intranasal

GLOSSARY

Glossary

- **Active immunity:** Protection against disease through antibodies produced by the body's own immune system.
- **Adjuvant:** An ingredient of a vaccine that helps create a stronger immune response in the patient's body.
- **Adverse reaction:** An undesirable medical condition that has been demonstrated to be caused by a vaccine. Evidence for the causal relation is usually obtained through randomized clinical trials, controlled epidemiologic studies, isolation of the vaccine strain from the pathogenic site, or recurrence of the condition with repeated vaccination (i.e., rechallenge); synonyms include side effect and adverse effect.
- **Anaphylaxis:** a severe and sometimes fatal allergic reaction characterized by hives, itching, respiratory difficulty, and shock; this condition requires immediate medical attention.
- **Antibody:** A special protein made by the body in response to antigens (foreign substances such as bacteria or viruses). Antibodies bind with antigens on microorganisms to protect the body against infection.

Glossary (continued)

- **Antigen:** A foreign substance (e.g., bacterium or virus) in the body that is capable of causing disease. The presence of antigens in the body triggers an immune response, usually the production of antibodies.
- **Antigenic drift:** Small changes in the genes of the viruses that can lead to changes in surface proteins of virus.
- **Antigenic shift:** Abrupt, major change in an influenza A virus, resulting in new surface proteins of virus.
- **Antipyretics:** Fever-reducing medications.
- **Contraindication:** A condition that increases the likelihood of a serious adverse reaction to a vaccine for a patient with that condition. If the vaccine is administered in the presence of that condition, the resulting adverse reaction could seriously harm the recipient.

Glossary (continued)

- **Guillain-Barré syndrome (GBS):** A rare, autoimmune disorder in which a person's own immune system damages the nerves, causing muscle weakness and sometimes paralysis. GBS can cause symptoms that last for a few weeks to several years. Most people recover fully, but some have permanent nerve damage. Some people have died of GBS.
- **Immunity:** protection against a disease or an infection, usually associated with antibodies or certain cells in the blood that counteract microbes or toxin. Immunity can come from infection with a disease or from vaccination.
- **Immunogenicity:** the ability of a particular substance to provoke an immune response.
- **Inactivated vaccine:** A vaccine in which the antigen is inactivated with heat and/or chemicals. The antigen in the vaccine is not alive and cannot replicate. These vaccines cannot cause disease from infection, even in an immunodeficient person. Inactivated vaccines always require multiple doses.
- **Incubation period:** The length of time between entry of an infectious agent into the body and the beginning of disease symptoms.

Glossary (continued)

- **Informed consent:** Process by which a patient or parent makes a voluntary decision about a procedure or intervention after being fully informed by a health care provider about the risks and benefits of the procedure or intervention; some states have informed consent laws for vaccination.
- **Informed refusal:** Refusal of a recommended medical treatment, such as vaccination, based on an understanding of the facts and implications of not following the recommended treatment.
- **Malaise:** a general feeling of tiredness or fatigue.
- **Medical exemption from vaccination:** Some people may be at risk for an adverse reaction because of an allergy to one of the vaccine components or a medical condition. This is referred to as a medical exemption.
- **Myalgia:** muscle pains.
- **Pandemic:** Event in which a disease spreads across several countries and affects a large number of people; a global disease outbreak.
- **Passive Immunity:** Protection against disease through antibodies produced by another human or animal. Passive immunity is effective, but protection diminishes with time (usually within several weeks or months).

Glossary (continued)

- **Pathogenesis:** The pathologic, physiologic, or biochemical mechanism resulting in the development of a disease or morbid process.
- **Philosophical exemption:** exemption from vaccination laws for people who have personal or moral beliefs against vaccinations. Criteria for granting this exemption varies by state.
- **Precaution:** A condition in a recipient that might increase the risk for a serious adverse reaction, might cause diagnostic confusion, or might compromise the ability of the vaccine to produce immunity.
- **Recombinant:** of or resulting from new combinations of genetic material or cells; the genetic material produced when segments of DNA from different sources are joined to produce recombinant DNA.
- **Religious exemption:** Some people may decline vaccination because of a religious belief. This is referred to as a religious exemption. Criteria for granting this exemption varies by state.

Glossary (continued)

- **Reservoir:** Habitat in which an infectious agent normally lives, grows, and multiplies; reservoirs include humans, animals, and the environment.
- **Temporal pattern:** Occurrence of health-related events by time.
- **Subtype:** subdivision of a type of a microorganism.
- **Vaccine effectiveness:** The ability of a vaccine to provide protection against disease when used under field conditions (e.g., use of the vaccine in routine practice).
- **Vaccine efficacy:** The ability of a vaccine to provide protection against disease under ideal circumstances (e.g., during a clinical trial).
- **Zoonotic diseases:** (also known as zoonoses) are caused by germs that spread between animals and people.