

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

About This Presentation

This publication was designed to help prelicensure nursing faculty incorporate appropriate elements of the <u>IRUN Curriculum Framework</u> into their existing curricula. This content is also available in a PowerPoint file located on the <u>IRUN web page</u>.

Please submit questions or comments about this publication via the IRUN web page.

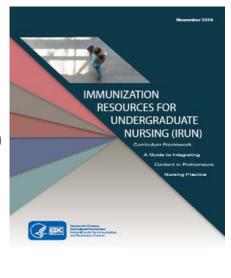
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Immunization Resources for Undergraduate Nursing (IRUN) Curriculum Framework Topics

- 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 Hepatitis A and the corresponding vaccine recommendations.
- 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 varicella.
- Describe barriers to vaccination and strategies to increase vaccination coverage for varicella disease.
- Describe the varicella vaccine, including immunogenicity, indications, contraindications, and precautions for vaccination.
- Discuss the importance of appropriate spacing and timing of varicella vaccine doses.

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

Learning Objectives (continued)

- Describe correct varicella vaccine and diluent storage and handling.
- Define the steps for proper varicella vaccine administration.
- Describe proper varicella vaccine documentation and adverse event reporting practices.
- Explain the nurse's role in preventing varicella infection through immunization.
- Locate resources relevant to current varicella vaccine recommendations.

PUBLIC HEALTH PERSPECTIVE

Global Impact of Varicella

- Occurs worldwide
- In 2014, WHO estimated approximately 4.2 million varicella cases resulted in severe complications and around 4200 resulted in death annually in the world.

Information from: Varicella and herpes Zoster vaccines. WHO position paper, June 2014. Wkly Epidemiol Rec. 2014;89:265–287.

Impact of Varicella in the United States

- Varicella was a universal childhood disease in the United States causing approximately 4 million cases and 105 deaths annually in the prevaccine era
- Since U.S. began vaccinating against varicella in 1995, the following have occurred:
 - 90% decrease in deaths related to varicella, meaning fewer than 20 people die from varicella (chickenpox) every year
 - 84% fewer hospitalizations, meaning fewer than 1,700 people are hospitalized for varicella (chickenpox) every year
 - 92% fewer cases of varicella (chickenpox), meaning fewer than
 350,000 people get varicella (chickenpox) every year

Information from: https://www.cdc.gov/chickenpox/vaccine-infographic.html

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.

Information from Hill HA, Yankey D, Elam-Evans LD, Singleton JA, Sterret N. Vaccination Coverage by Age 24 Months Among Children Born in 2017 and 2018 — National Immunization Survey-Child, United States, 2018–2020. MMWR Morb Mortal Wkly Rep 2021;70:1434–1440. DOI: https://www.cdc.gov/mmwr/volumes/70/wr/mm7041a1.htm

 Strategies to increase vaccination coverage in our communities cannot be developed without a thorough understanding of what barriers exist, preventing 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. In 2017–2019, vaccination coverage among children enrolled in Medicaid or with no health insurance was lower than that among children who were privately insured.

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: https://www.cdc.gov/vaccines/programs/vfc/about/index.html; https://www.cdc.gov/vaccines/programs/vfc/about/index.html; Image from: https://www.cdc.gov/vaccines/programs/vfc/index.html; Image from: https://www.cdc.gov/vaccines/programs/vfc/index.

- 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, birth through 18 years of age.
- Children living below and up to a certain percentage above the poverty level are eligible for Medicaid and are entitled to vaccines through the VFC program.
- Uninsured children, American Indians and Alaska natives are eligible for VFC benefits.
- And finally, underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement.
 - Underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-¬eligible for non-covered vaccines only); A child whose insurance has a fixed dollar limit or cap for vaccines (VFC-eligible once fixed dollar amount or cap is reached).
- 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 in collaboration with state and local public health partners are engaged in activities to reduce barriers to vaccination coverage. Educating immunization providers and eligible communities about the VFC program and enrolling immunization providers who serve these communities in the VFC program are ongoing immunization program activities.

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: <u>https://www.cdc.gov/vaccines/pubs/pinkbook/strat.html</u>; <u>https://www.cdc.gov/vaccines/pubs/pinkbook/index.html</u>; <u>https://www.cdc.gov/vaccines/pubs/pinkbook/index.html</u>; <u>https://www.cdc.gov/vaccines/programs/iqip/index.html</u>; <u>https://www.cdc.gov/vaccines/hcp/admin/reminder-sys.html</u>

- 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 United States, 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 (continued)

- 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: https://www.cdc.gov/vaccines/programs/igip/at-a-glance.html; https://www.cdc.gov/vaccines/programs/igip/at-a-glance.html; https://www.cdc.gov/vaccines/programs/igip/at-a-glance.html; https://www.cdc.gov/vaccines/programs/igip/at-a-glance.html; https://www.cdc.gov/vaccines/programs/igip/at-a-glance.html; https://www.cdc.gov/vaccines/programs/igip/at-a-glance.html

- The Immunization Quality Improvement for Providers process and strategies promotes and supports implementation of provider-level strategies designed to help increase ontime 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.

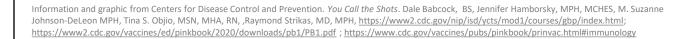
Information from https://www.cdc.gov/vaccines/pubs/pinkbook/strat.html; https://www.cdc.gov/vaccines/programs/iis/index.html; https://www.cdc.gov/vaccines/programs/iis/about.html

- 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

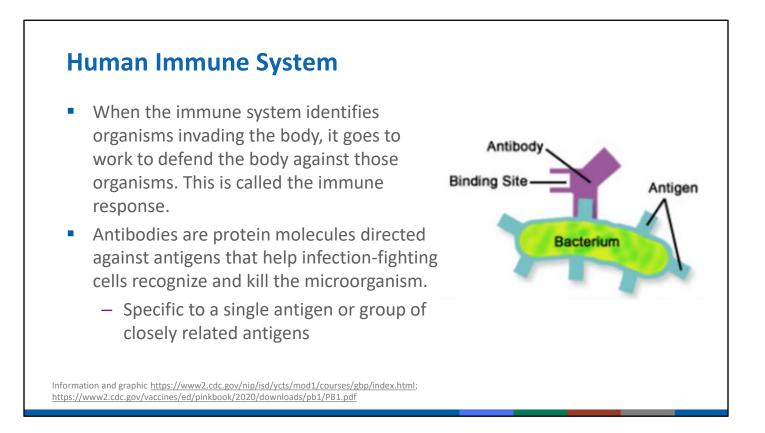
- Complex network of interacting cells and proteins whose purpose is to identify and eliminate foreign substances called antigens on the surface of organisms like bacteria or viruses.
- Antigens chosen for vaccination can either be live or inactivated.



Antigens

Bacterium

- 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 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.



- 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, which are substances that can stimulate the immune system. 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).

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, <u>https://www2.cdc.gov/nip/isd/ycts/mod1/courses/gbp/index.html</u>; Media files from 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 (vaccineinduced 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 disease for up to a year. Protection is better against some disease (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
 - Age, coexisting diseases, nutritional factors, genetics
- 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.

Varicella Immunity

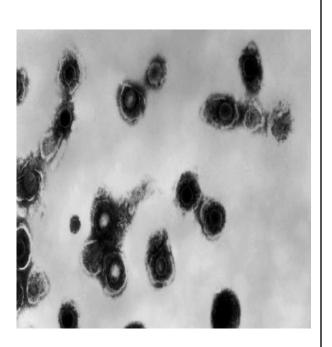
- Recovery from primary varicella infection usually results in lifelong immunity
- In otherwise healthy persons, a second occurrence of varicella is uncommon
 - It is more common in immunocompromised persons
- As with other viral diseases, re-exposure to natural (wild) varicella may lead to reinfection that boosts antibody titers without causing clinical illness or detectable viremia.

Information from https://www.cdc.gov/vaccines/pubs/pinkbook/varicella.html

VACCINE-PREVENTABLE DISEASES

Varicella Virus

- DNA virus; a member of herpesvirus group
- Primary infection results in varicella (chickenpox)
- Reactivation of latent infection results in herpes zoster (shingles)



Information from https://www.cdc.gov/vaccines/pubs/pinkbook/varicella.html Image source: https://wwwnc.cdc.gov/eid/article/21/4/et-2104-f1

- Varicella Zoster Virus, DNA virus, is a member of the herpesvirus group.
- The primary (first) infection results in varicella (chickenpox).
- It can cause an itchy, blister-like rash. The rash first appears on the chest, back, and face, and then spreads over the entire body, causing between 250 and 500 itchy blisters. Chickenpox can be serious, especially in babies, adolescents, adults, pregnant women, and people with bodies that have a lowered ability to fight germs and sickness (weakened immune system). The best way to prevent chickenpox is to get the chickenpox vaccine.
- Like other herpesviruses, the varicella virus persists in the body as a latent infection after the primary (first) infection.
- Latent infection can reactivate resulting in herpes zoster (shingles).

Varicella Pathogenesis

- Enters through respiratory tract and conjunctiva
- Replication in nasopharynx and regional lymph nodes
- Primary viremia 4 to 6 days after infection
- Cultured from an infected person from 5 days before to 1 to 2 days after the appearance of the rash.

Information from https://www.cdc.gov/vaccines/pubs/pinkbook/varicella.html

Varicella Epidemiology

Reservoir	Human
Transmission	Person-to-person Direct contact with vesicular fluid and/or inhalation of aerosolized droplets
Temporal pattern	Winter and Spring
Communicability	1 to 2 days before onset of rash and until all lesions have formed crusts

- Reservoir: The virus that causes both varicella (chickenpox) and zoster (shingles), is an exclusively human pathogen. No animal or insect source or vector is known to exist.
- Transmission: Varicella is transmitted from person-to-person by direct contact with vesicular fluid and/or by inhalation of aerosolized respiratory tract droplets.
- Temporal Pattern: In temperate areas, varicella has a distinct seasonal fluctuation, with the highest incidence occurring in winter and early spring. However, high rates of vaccination coverage in the United States have eliminated discernible seasonality of varicella.
- Communicability: The period of communicability extends from 1 to 2 days before the onset of rash until all lesions have formed crusts. The virus has not been isolated from crusted lesions. Isolation guidance for infected persons is to restrict contact with others until no new lesions appear within a 24-hour period and all lesions are crusted. Varicella is highly contagious. Zoster is much less infectious than varicella, i.e., about 1/5 as infectious as varicella.

Varicella Clinical Signs and Symptoms

- Incubation period ranges 10 to 21 days (average 14 to 16 days)
- Initial prodromal stage slight fever, malaise
- Rash begins as macule then vesicle and erupts
- Rash generally appears first on the head; most concentrated on the trunk.
- Rash is extremely pruritic
- Lifetime immunity typically results following recovery

- The incubation period for varicella ranges from 10 to 21 days with an average of 14 to 16 days after exposure.
- In individuals who have not received varicella vaccine, the rash is generalized and pruritic and progresses rapidly (within 24 hours) from macules to papules to vesicular lesions before crusting. The rash usually appears first on the scalp, face or trunk, and then spreads to the extremities; the highest concentration of lesions is on the trunk.
- Recovery from primary varicella infection usually results in lifetime immunity. In otherwise healthy persons, a second occurrence of varicella is uncommon; it is more common in immunocompromised persons.

Varicella Complications

- Secondary bacterial infection of skin lesions
- Pneumonia
- Central nervous system manifestations
 - Meningitis
 - Encephalitis
 - Seizures
 - Coma
 - Cerebella ataxia

- Acute varicella is generally mild and self-limited, but it may be associated with complications.
- Secondary bacterial infections of skin lesions with Staphylococcus or Streptococcus are the most common cause of hospitalization and outpatient medical visits and can lead to death.
- Pneumonia following varicella is usually viral but may be bacterial. Primary pneumonia is uncommon among immunocompetent children but is the most common complication in adults. Secondary bacterial pneumonia is more common in children younger than age 1 year.
- Central nervous system manifestations of varicella range from meningitis to encephalitis. Encephalitis is an infrequent complication of varicella (1 per 50,000 cases of varicella in unvaccinated children) and may lead to seizures and coma. Diffuse cerebral involvement is more common in adults than in children. Involvement of the cerebellum, with resulting cerebellar ataxia, is the most common central nervous system manifestation (1 per 4,000 cases of varicella in unvaccinated children) and generally has a good outcome.
- Rare complications of varicella include meningitis, transverse myelitis, Guillain-Barré syndrome, thrombocytopenia, hemorrhagic varicella, purpura fulminans, glomerulonephritis, myocarditis, arthritis, orchitis, uveitis, iritis, and hepatitis.

Persons at Risk of Varicella Complications

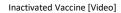
- Certain populations are at increased risk for complications of varicella (chickenpox):
 - Individuals age < 1 year
 - Individuals age > 15 years
 - Immunocompromised persons
 - Newborns of women with rash onset within 5 days before to 48 hours after delivery

- The risk of complications from varicella varies with age. Complications are infrequent among healthy children. They occur much more frequently in persons younger than age 1 year and older than age 15 years.
- Immunocompromised persons have a high risk of disseminated disease (up to 36% in one report). These persons may have multiple organ system involvement, and the disease may become fulminant and hemorrhagic.
- The onset of varicella in pregnant women from 5 days before to 2 days after delivery results in severe varicella infection in an estimated 17%–30% of their newborn infants. These infants are exposed to varicella without sufficient maternal antibody to lessen the severity of disease. The risk for neonatal death has been estimated to be 31% among infants whose mothers had onset of rash <5 days before giving birth.</p>

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





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 to a live, attenuated vaccine is virtually identical to that produced by a natural infection because the immune system does not differentiate between an infection with a weakened vaccine virus and an infection with a wild virus.
- 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 vaccines and live, attenuated vaccines.
- Varicella vaccines are live vaccines.

Varicella vaccine

- The first live attenuated varicella vaccine was developed in 1974.
- It was derived from wild type varicella zoster virus isolated from a child.
- In United States, routine varicella vaccination in childhood began in 1995.
- In 2014, WHO recommended that countries where varicella is a significant public health burden should consider introducing routine vaccination in childhood.

Information from https://www.cdc.gov/vaccines/pubs/pinkbook/varicella.html

Varicella Vaccine Characteristics

- A live attenuated vaccine
- Derived from the Oka strain of a wild varicella zoster virus
- Types of varicella vaccine
 - Varivax[®]: single-antigen vaccine
 - ProQuad[®]: combination vaccine containing measles, mumps, rubella, and varicella antigens
- Both vaccine types contain gelatin and neomycin

Information from https://www.cdc.gov/vaccines/pubs/pinkbook/varicella.html

Varicella Vaccine Type

Product	ACIP Recommended Age Indications	ACIP Abbreviation
Varivax®	12 months and older	VAR
ProQuad [®]	12 months through 12 years	MMRV

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 A meta-analysis of postlicensure estimates found the effectiveness of 1 dose of varicella vaccine to be 82% against any clinical varicella and 98% against severe disease. Two doses of vaccine demonstrated 92% effectiveness against any clinical varicella.

IMMUNIZATION SCHEDULES

Advisory Committee on Immunization Practices (ACIP)

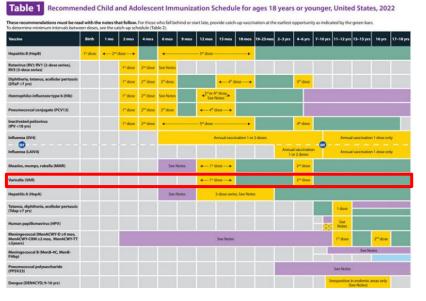
- A group of medical and public health experts who develop recommendations on the use of vaccines in the civilian population of the United States
- Provides guidance on use of vaccines and other biologic products to U.S.
 Department of Health and Human Services, CDC, and the U.S. Public
 Health Service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

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

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 the standard of care in the U.S. The ACIP recommendations stand as public health guidance for the safe use of vaccines and related biological products. The ACIP holds three meetings each year at the Centers for Disease Control and Prevention (CDC) headquarters in Atlanta, Georgia, to review scientific data and vote on vaccine recommendations. Meetings are open to the public and available online via live webcast.

ACIP Varicella Vaccine Recommendations: Pediatric

Recommendations for routine childhood vaccination are found in the <u>Recommended Child and</u> <u>Adolescent Immunization</u> <u>Schedule for ages 18 years</u> <u>or younger</u>.



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

ACIP Varicella Vaccine Recommendations: Children and Adolescents

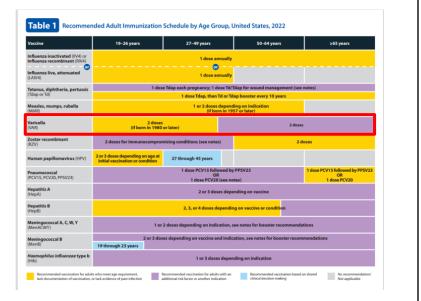
- First dose at age 12–15 months
 - Minimum age is 12 months
 - In children aged 12–47 months, administer MMR and VAR separately unless parents express a preference for MMRV
- Second dose at age 4–6 years
- Minimum interval between doses
 - 3 months for ages 12 months-12 years
 - 4 weeks for ages 13 years and older (VAR only)

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

- The ACIP varicella vaccine recommendations for children and adolescents includes a 2-dose series beginning at age 12 months of age and again at 4 to 6 years
- The minimum age for dose 1 is 12 months. Doses given before 12 months of age should not be counted as valid.
- For dose 1, children aged 12–47 months should receive MMR and varicella vaccines separately unless parents express a preference for MMRV. Providers who are considering administering MMRV vaccine should discuss the benefits and risks of both vaccination options with the parents or caregivers.
- MMRV is the preferred vaccine for dose 1 in children aged 48 months through 12 years, and for dose 2 in all age eligible children.
- The minimum interval between dose 1 and 2 is 3 months in children aged 12 months to 12 years, and 4 weeks in persons aged 13 years and older.
- If dose 2 of varicella vaccine is inadvertently administered at least 4 weeks after dose 1, it can be counted as valid.
- People who received 2 doses of either varicella vaccine using the recommended intervals are considered protected for life.

ACIP Varicella Vaccine Recommendations: Adult

Recommendations for routine vaccinations in adult is found in the <u>Recommended Adult</u> <u>Immunization Schedule</u> (cdc.gov)



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

ACIP Varicella Vaccine Recommendations: Adults

- Adults born in 1980 or later without acceptable evidence of immunity to varicella should receive 2 doses of VAR
- A routine second dose of VAR vaccine at least 28 days after the first dose is recommended for adults
- Do not repeat first dose because of extended interval between doses
- Second dose recommended for adults of any age who have only received 1 dose

Information from https://www.cdc.gov/vaccines/pubs/pinkbook/varicella.html

[ACIP Varicella Vaccine Recommendations: Adults]

- Because serologic evidence of VZV infection has been documented in 96%–97% of U.S.-born adults age 20–29 years and in 97%–99% of adults age 30 years or older tested during 1998–1999, individuals who were born in the United States before 1980 are considered to have evidence of immunity to varicella except for health-care personnel because of the risk of exposing high-risk patients if serologic or vaccine documentation not present.
- Adults born in 1980 or later in the United States without acceptable evidence of immunity to varicella should receive 2 doses of VAR. The second dose should be administered at least 28 days after the first dose and is recommended for adults of any age who have received only received 1 dose.

Acceptable Evidence of Varicella Immunity

- Documentation of age-appropriate vaccination
- Laboratory evidence of immunity
- Laboratory confirmation of disease⁺
- Birth in the U.S. before 1980* (Exception: Health care personnel, pregnant women, and immunocompromised persons)
- Health care provider diagnosis or verification of varicella disease
- History of herpes zoster based on health care provider diagnosis or verification of disease history

⁺Commercial assays can be used to assess disease-induced immunity, but they lack sensitivity to always detect vaccine-induced immunity

*Birth year immunity criterion does not apply to health care personnel or pregnant women

Information from https://www.cdc.gov/vaccines/pubs/pinkbook/varicella.html

- Serologic testing of children prior to vaccination is not warranted because most children between age 12 months and 12 years without a clinical history of varicella are not immune. Commercial serological assays can be used to assess disease-induced immunity induced by wild type infection, but they lack sensitivity to always detect vaccine-induced immunity.
- Persons with a clinician-diagnosed or verified history of typical varicella or herpes zoster can be assumed to be immune to varicella. A prior history of varicella is not a contraindication to varicella vaccination, so when in doubt as to history, varicella vaccine should be administered.

COMMUNICATIONS

CDC Varicella 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 varicella.
- VISs explain both the benefits and risks of the vaccine the patient is receiving.
- Current VISs Vaccine Information Statement Current VISs CDC

•	Federal law requires that a VIS be provided to a patient, parent, or legal representative	VACCINE INFORMA Varicella (Chickenpox) What You Need to Know	Many vaccine information statements are
	before each dose of certain vaccines, including varicella.	 Why get vaccinated? Varietilia vaccine can prevent varietilia. Varietilia, also alled "bidregent," causes an itchy print that unaphysical social vaccine. It can be assess that the one of the social vaccine in the social cash to akin infections, portunnomia, inflammatian of the biodregents, welling of the binatediaterum, and the biodregent and bidregent of the biodregent act a quantification ald" values," also become an et a quantification ald "values," also become an et a quantification alde "values," also become an 	Talk with your health are provider The service intermediate of the person getting the service intermediate of the person getting the service intermediate of the service of the service description of the service of the service of the service representation of the service of the service of the service the service of the service
1	VISs explain both the benefits and risks of the vaccine the patient is receiving.	propagation provides and provid	 Has tubercalosis Has gotten any other vaccines in the past 4 weeks In some cases, your health care provider may decide to postpone variella vaccination until a future visit. People with minor illnesses, such as a cold, may be
	Current VISs Vaccine Information Statement	2. Varicella vaccine Children need 2 doses of varicella vaccine, usually: • First dose, age 12 through 15 months	vaccinated. People who are moderately or severely ill should usually wait until they recover before getting varicella vaccine. Your bealth care provider can give you more information.
	Current VISs CDC	 Second doses age 4 through by yars Other children, a biddersatt, and addustales need 2 doses of varicella vaccine if they are not already immune to chickepose. Varicella vaccine may be given at the same time as other vaccines. Also, a child between 15 months and 12 years of age might needers varicella vaccine vaccine in a single which, known as MMRW. Your builth care provider can give you more information. 	U.S. Described of
Inf	ormation from: <u>https://www.immunize.org/vis/vis_chickenpox.asp;</u> foreign language versions <u>https://w</u>	ww.immunize.org/vis/	Control of Pression

 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, the Immunization Action Coalition. 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) (continued)

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; <a href="https://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.ht

Talking to Parents/Patients Who are Vaccine Hesitant

- 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



What do you say to parents who decline or refuse vaccines?

#HowIRecommend

Information from https://www.cdc.gov/washington/testimony/2019/t20190227.htm ; https://www.medscape.com/viewarticle/882865 Media clip https://www.youtube.com/watch?v=HQHnmrBKrpw&list=UUiMg06DjcUk5FRiM3g5sqoQ&index=223

- 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.
- 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.

LEGAL/ETHICAL ISSUES

Legal and Ethical Considerations

State vaccination requirements

- As of 2021, 50 states in the U.S. require varicella vaccination for childcare and school entry.
- Healthcare professionals working in institutions are required to have any of the following:
 - Documented evidence of immunity
 - Receipt of 2 doses of varicella without documented immunity

Information from https://www.cdc.gov/shingles/hcp/hc-settings.html; https://www.immunize.org/laws/

State vaccination requirements

- As of 2021, 50 states in the U.S. require varicella vaccination for childcare and school entry.
- Recommendations for healthcare institutions to prevent varicella and nosocomial spread
 - Have documented evidence of immunity for all healthcare personnel readily available at the healthcare personnel's work location
 - Alert healthcare personnel without evidence of immunity to varicella about the risks of possible infection and offer those without evidence of immunity 2 doses of varicella vaccine, administered 4 to 8 weeks apart, when they begin employment
 - Establish protocols and recommendations for screening and vaccinating healthcare personnel and for managing healthcare personnel after exposures in the workplace

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 child care 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

Legal and Ethical Considerations (continued)

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.cdc.gov/vaccines/imz-managers/laws/index.html; https://www.cdc.gov/vaccinesafety/concerns/concerns-history.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 (continued)

- 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

VACCINE STORAGE AND HANDLING

Vaccine Storage and Handling: Varicella-Containing Vaccine

Varivax[®] (VAR) and ProQuad[®] (MMRV)

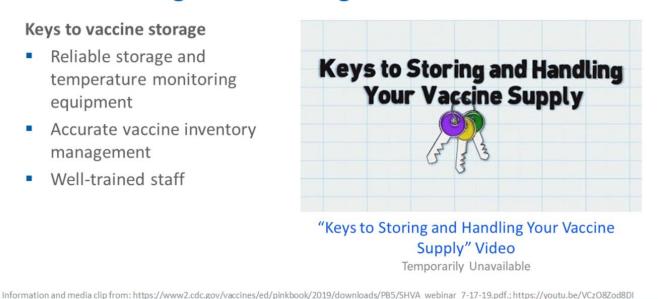
- Storage:
 - Vaccine: In the freezer between -50°C and -15°C (-58°F and +5°F)
 - Diluent: At room temperature between 20°C to 25°C (68°F to 77°F) or in the refrigerator at 2°C to 8°C (36°F to 46°F)
- Preparation: Reconstitute the vaccine with the diluent supplied by the manufacturer immediately prior to administering

Information from https://www.cdc.gov/vaccines/vpd/varicella/hcp/storage-handling.html; https://www.dir.iwk.nshealth.ca/Content/resources/Subcutaneous%20and%20IM%20Injections.pdf

Vaccine Storage and Handling

Keys to vaccine storage

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



 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:
 - Reliable storage and temperature monitoring equipment
 - Accurate vaccine inventory management
 - 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; <u>https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html</u>

- 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.
- You can find a patient's immunization history by using information from immunization information systems, current and previous medical records, and personal vaccination record cards.
- 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 should only follow valid contraindications.
- 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.

Varicella and MMRV Vaccine Contraindications*

- Severe allergic reaction to vaccine component or following a prior dose
- Immunosuppression due to leukemia, lymphoma, generalized malignancy, immune deficiency disease, or immunosuppressive therapy
- Family history of congenital or heredity immunodeficiency in first-degree relatives
- HIV infection
 - Contraindicated for MMRV; VAR depending on CD4 count and percentages
- Hematopoietic stem cell transplant (wait at least 24 months)
- Pregnancy
- * Conditions under which vaccines should not be administered

Information from https://www.cdc.gov/vaccines/pubs/pinkbook/varicella.html

Varicella-Containing Vaccines Precautions*

- Moderate or severe acute illness with or without fever
- Receipt of blood products (wait 3 to 11 months to vaccinate)
- Need for tuberculosis testing
 - MMRV may suppress the positive response to TB testing in a person who has tuberculosis (TB). This suppression may result in a false negative test in a person who is infected with TB. Recommendations are to administer both the PPD test and MMRV in the same visit or delay testing for TB for at least 4 weeks after MMRV vaccination.
- Receipt of specific antiviral drugs (i.e., acyclovir, famciclovir, or valacyclovir)
 24 hours before vaccination
- Simultaneous use of aspirin or aspirin-containing products

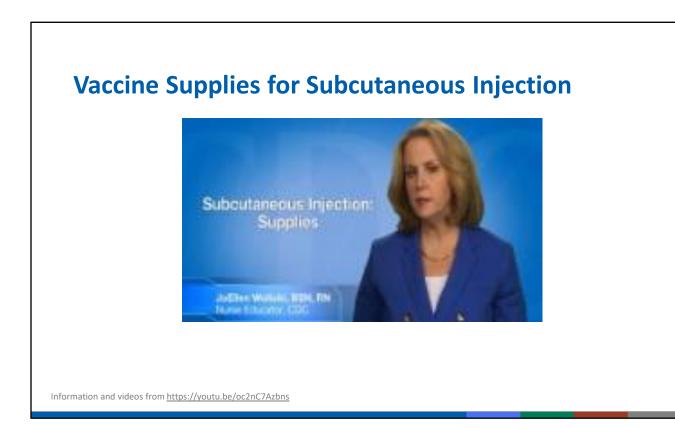
* Vaccinations should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction.

 $Information \ from \ \underline{https://www.cdc.gov/vaccines/pubs/pinkbook/varicella.html}$

MMRV Vaccine Precautions

- History of thrombocytopenia or thrombocytopenia purpura
- Personal or family (i.e., sibling or parent) history of seizures of any etiology
 - These children generally should be vaccinated with separate MMR and varicella vaccines.
 - Providers who are considering administering MMRV vaccine should discuss the benefits and risks of both vaccination options with the parents or caregivers.
- For dose 1 in children aged 12–47 months, administer MMR and varicella vaccines separately. MMRV may be used if parents or caregivers express a preference.

 $Information \ from \ \underline{https://www.cdc.gov/vaccines/pubs/pinkbook/varicella.html}$



[PLAY VIDEO]

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 and diluent (if needed).
- Always follow vaccine manufacturers' directions, located in the package.

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

 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:

READ SLIDE

 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 from https://www.youtube.com/watch?v=r1dGpTCgerE&feature=emb_logo

- 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:
 - o Avoids frightening children by embracing them rather than overpowering them
 - $\circ\;$ Allows the health care provider steady control of the limb and the injection site
 - o Prevents children from moving their arms and legs during injections
 - o 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: Subcutaneous Injections

Vaccine dose

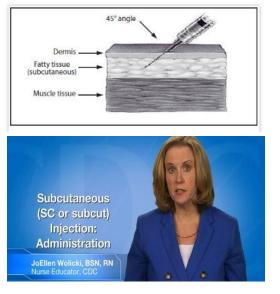
• 0.5ml

Needle Size

- 5/8 inch
- 23–25 gauge

Site

 12 months of age and older: Upperouter triceps area



Information from www.youtube.com/watch?v=R5jd4SDEcsA

- The recommended dose for varicella and MMRV vaccine is 0.5ml administered subcutaneously.
- Subcutaneous injections are administered at a 45-degree angle, usually into the anterolateral aspect of the thigh for infants younger than 12 months and in the upperouter triceps area of persons 12 months of age or older. Subcutaneous injections may be administered into the upper-outer triceps area of an infant if necessary. A ⁵/₄-inch, 23- to 25-gauge needle should be inserted into the subcutaneous tissue.
- Additional resources on administering subcutaneous injections are listed in the resources and references slides at the end of this presentation.
- [PLAY VIDEO]

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
 - o 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)
 - 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), 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 <u>the VAERS Table of Reportable Events Following</u> <u>Vaccination</u> 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, 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 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 (continued)

VAERS Table of Reportable Events Following Varicella Vaccination

Vaccine/Toxoid	Adverse Event
Varicella vaccine in any combination- VAR, MMRV	 A. Anaphylaxis or anaphylactic shock (7 days) B. Disseminated varicella vaccine-strain viral disease. Vaccine-strain virus identified (time interval unlimited) If strain determination is not done or if laboratory testing is inconclusive (42 days) C. Varicella vaccine-strain viral reactivation (time interval unlimited) D. Shoulder Injury Related to Vaccine Administration (7 days) E. Vasovagal syncope (7 days) F. Any acute complication or sequelae (including death) of above events G. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (see package insert)

This table shows adverse events from the VAERS Table of Reportable Events following varicella vaccination. By law, healthcare providers are required to report these adverse events if they occur within the time period noted in the table. In addition to these adverse events, healthcare providers are encouraged to report any adverse event that concerns them.

VACCINE SAFETY

Varicella-containing Vaccines Adverse Reactions

- Injection-site reactions
 - Pain, soreness, erythema, swelling, and varicella-like rash
- Systemic reactions
 - Fever, varicella-like rash
 - Measles-like rash for MMRV only
- Febrile seizures
 - One additional febrile seizure per 2,300 to 2,600 children aged 12 through 23 months after the first dose of MMRV vaccine, compared with children who received the first dose of MMR vaccine and VAR vaccine as separate injections at the same visit.
- Herpes zoster
 - Less common after vaccination compared to wild-type varicella disease

Information from https://www.cdc.gov/vaccines/pubs/pinkbook/varicella.html#vaccine-safety

- Adverse reactions (i.e., caused by the vaccine) after varicella vaccination include injection-site reactions (such as pain, tenderness, swelling) and redness and systemic reactions (e.g, fever). Varicella-like rash can occur at the injection site or be generalized. Persons who received MMRV can also develop a measles-like rash.
- Young children who develop fever after MMRV vaccination may have febrile seizures. After dose 1 MMRV in children aged 12–23 months, an estimated one additional febrile seizure per 2,300 to 2,600 children occurs compared with children who received the first dose of MMR vaccine and VAR vaccine as separate injections at the same visit.
- Herpes zoster can also occur after receipt of a varicella-containing vaccine, but this is less common compared with the occurrence of herpes zoster after wild-type varicella infection

Varicella-containing Vaccines Adverse Reactions

Severe adverse reactions

- Pneumonia, hepatitis, and severe disseminated varicella infection
- All severe reactions occurred in immunocompromised persons or in persons who had other serious medical conditions that were undiagnosed at the time of vaccination.

Information from https://www.cdc.gov/vaccines/pubs/pinkbook/varicella.html#vaccine-safety

- Severe adverse reactions after varicella vaccination are pneumonia, hepatitis, and severe disseminated varicella infection.
- All severe reactions occurred in immunocompromised persons or in persons who had other serious medical conditions that were undiagnosed at the time of vaccination.

NURSING CONSIDERATIONS

Nursing Considerations

	Reaction Following Vaccine Administration	Supportive Treatment Recommendation
Mild to Moderate	 Most common: Pain or redness at injection side Fever Headache Tiredness Nausea Vomiting Loss of appetite 	 Usually, self-limiting Cool, damp cloth to help reduce redness, soreness, and/or swelling at the injection site Antipyretics or analgesics may be indicated for supportive care. Encourage rest and hydration and refer to provider if reactions persist or worsen
Severe	Anaphylaxis; Hoarseness, wheezing, airway constriction, difficulty breathing, pale or mottled skin, hypotension, altered mental status, fever, redness, rash	Call 911, administer CPR, provide epinephrine or equivalent (e.g., EpiPen), immediate transfer to hospital

Mild to moderate reaction

- Reactions: Pain or redness at injection side, Fever, Headache, Tiredness, Nausea, Vomiting, Loss
 of appetite
- Supportive Treatment: The side effects are usually, self-limiting. However, supportive treatment can be recommended to alleviate side effects. 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. Encourage rest and hydration and refer to provider if reactions persist or worsen

Severe reaction (anaphylaxis)

- Severe, life-threatening, anaphylactic reactions following vaccination are rare. Facilities must have in place and staff should be familiar with procedures for managing a severe reaction. Staff should be familiar with the signs and symptoms of anaphylaxis, which usually begin within minutes of vaccination.
- 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, redness, rash. 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, they should immediately be transferred to an emergency facility for additional evaluation and treatment.

Nursing Considerations

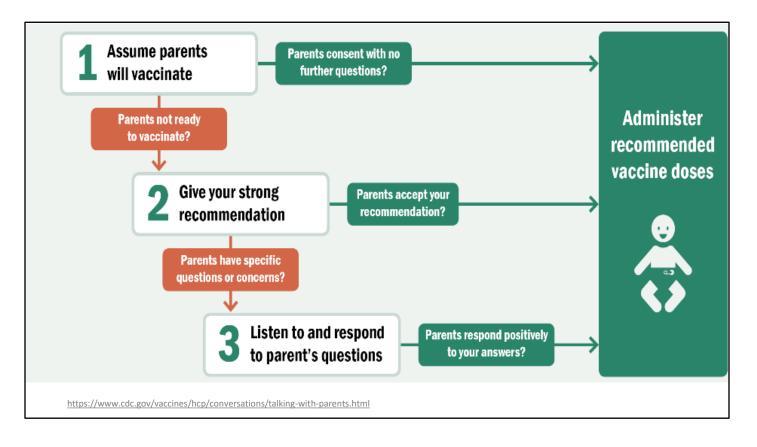
Vaccinate with Confidence

- 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.



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.
 - o 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 atrisk 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 vaccinehesitant 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

Vaccine Resources and References

ACIP recommendations

- Current ACIP varicella recommendations https://www.cdc.gov/vaccines/vpd/varicella/hcp/recommendations.html
- ACIP General Best Practice Guidelines for Immunization www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

Disease

- CDC Varicella <u>https://www.cdc.gov/vaccines/vpd/varicella/index.html</u>
- Ask the Experts–Varicella FAQs: <u>https://www.immunize.org/askexperts/experts_var.asp</u>

Manufacturer's vaccine package inserts (PIs)

- ProQuad package insert <u>www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/uc</u> <u>m123793.pdf</u>
- Varivax package insert www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UC M142812.pdf

Immunization Strategies

- Immunization Information Systems <u>https://www.cdc.gov/hpv/hcp/index.html</u>
- Immunization Quality Improvement for Providers <u>https://www.cdc.gov/vaccines/programs/iqip/at-a-glance.html</u>
- Comprehensive Clinic Assessment Software Application <u>https://www.cdc.gov/vaccines/programs/cocasa/index.html</u>

Immunization schedules

- Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#birth-15
- Recommended Adult Immunization Schedule for ages 19 years or older https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html
- Catch-Up Immunization Schedule https://www.cdc.gov/vaccines/schedules/hcp/imz/catchup.html

Communications

- Current vaccine information statements (VISs) <u>https://www.cdc.gov/vaccines/hcp/vis/current-vis.html</u>
- Instructions for Using VISs <u>https://www.cdc.gov/vaccines/hcp/vis/about/required-use-instructions.html</u>
- Translated VISs <u>https://www.immunize.org/vis/?f=9</u>
- Talking to Parents about Vaccines: <u>https://www.cdc.gov/vaccines/hcp/conversations/conv-materials.html</u>

Vaccine storage and handling

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

Vaccine Administration

 Immunization Action Coalition Clinic Tools Screening for Vaccine Contraindications and Precautions https://www.immunize.org/clinic/screening-contraindications.asp

Vaccine Administration

- Vaccine Administration for Healthcare Professionals <u>https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html</u>
- Standing Orders for Administering <u>https://www.immunize.org/standing-orders/</u>
- CDC Vaccine Administration Resource Library https://www.cdc.gov/vaccines/hcp/admin/resource-library.html
- You Call the Shots Module- Vaccine Administration <u>https://www2.cdc.gov/vaccines/ed/vaxadmin/va/ce.asp</u>

Vaccine Administration

- Subcutaneous (SC or Subcut) Injections: Supplies <u>https://www.youtube.com/watch?v=oc2nC7Azbns</u>
- Subcutaneous (SC or Subcut) Injection: Administration <u>https://www.youtube.com/watch?v=R5jd4SDEcsA</u>
- Subcutaneous (SC or Subcut) Injections: Sites <u>https://www.youtube.com/watch?v=ylhdvNZBWN0</u>

Documentation

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

Safety

- <u>https://www.cdc.gov/vaccinesafety/vaccines/hpv/hpv-safety-faqs.html#A10</u>
- <u>https://www.cdc.gov/vaccinesafety/vaccines/hpv-vaccine.html</u>

GLOSSARY

Glossary

- Active immunity: Protection against disease through antibodies produced by the body's own immune system.
- 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.
- 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.

Glossary (continued)

- 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.
- 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.
- 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.
- 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.
- Pandemic: Event in which a disease spreads across several countries and affects a large number of people.

Glossary (continued)

- 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).
- 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.
- 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.
- **Reservoir:** Habitat in which an infectious agent normally lives, grows, and multiplies; reservoirs include humans, animals, and the environment.

Glossary (continued)

- **Temporal pattern:** Occurrence of health-related events by time.
- Vaccine effectiveness: A measure of how well vaccines work in the real world.
- Vaccine efficacy: The extent to which a vaccine provides a beneficial result under ideal conditions. The efficacy of a new vaccine is measured in phase III clinical trials by giving one group of people a vaccine and comparing the incidence of disease in that group to another group of people who do not receive the vaccine.