

Varicella Disease, Varicella and Zoster Vaccines

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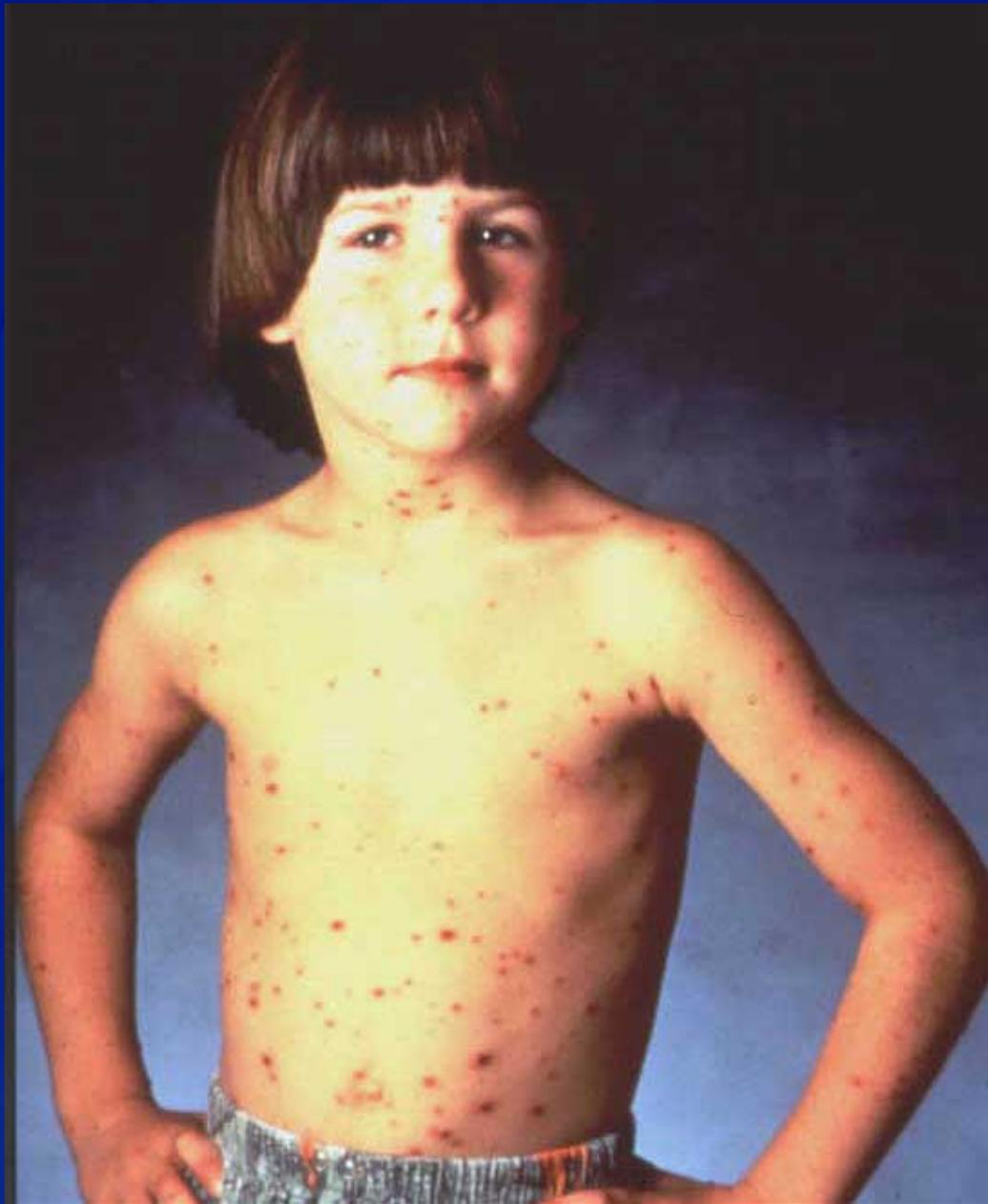


Varicella Zoster Virus

- ❑ Herpes virus (DNA).
- ❑ Primary infection results in varicella (chickenpox).
- ❑ Recurrent infection results in herpes zoster (shingles).
- ❑ Short survival in environment.

Varicella Pathogenesis

- ❑ Respiratory transmission of virus.
- ❑ Replication in nasopharynx and regional lymph nodes.
- ❑ Primary viremia 4 to 6 days after infection.
- ❑ Multiple tissues, including sensory ganglia, infected during viremia.



Varicella Clinical Feature

- ❑ Incubation period 14 to 16 days (range 10 to 21 days).
- ❑ Mild prodrome for 1 to 2 days (adults).
- ❑ Rash generally appears first on the head; most concentrated on the trunk.
- ❑ Successive crops over several days with lesions present in several stages of development.

Herpes Zoster (Shingles)

- ❑ Reactivation of varicella zoster virus.
- ❑ Associated with:
 - Aging.
 - Immunosuppression.
 - Intrauterine exposure.
 - Varicella disease younger than 18 months of age.



Herpes zoster

Varicella Complications

□ Complications include:

- Bacterial infection of lesions.
- Hemorrhagic varicella.
- CNS manifestations.
- Pneumonia (primary viral or secondary bacterial).
- Congenital varicella.
- Perinatal varicella.

□ Pre-vaccine era:

- Hospitalization ~3 per 1,000 cases or 11,000/year.
- Death ~ 1 per 60,000 cases or 100/year.



Varicella with secondary bacterial infection

Groups at Increased Risk of Complications of Varicella

- ❑ Persons older than 15 years.
- ❑ Infants younger than 1 year.
- ❑ Immunocompromised persons.
- ❑ Newborns of women with rash onset within 5 days before to 48 hours after delivery.

Complications of Herpes Zoster

- ❑ Dissemination with generalized skin eruptions and involvement of the central nervous system, lungs, liver, and pancreas.
- ❑ Postherpetic neuralgia (PHN).
- ❑ Ophthalmic zoster.



Varicella Epidemiology

Reservoir	Human
Transmission	Person to person – respiratory tract secretions Direct contact with lesions
Temporal Pattern	Peak in late winter and spring (U.S.)
Communicability	1 to 2 days before until lesions have formed crusts May be longer in immunocompromised

Herpes Zoster

- ❑ 500,000 to 1 million episodes occur annually in the United States.
- ❑ Lifetime risk of zoster estimated to be 32%.
- ❑ 50% of persons living until age 85 will develop zoster.

Varicella-containing Vaccines

Product	FDA Age Indications	ACIP Abbreviation
Varivax	12 months and older	VAR
Proquad	12 months through 12 years	MMRV
Zostavax	50 years and older	HZV

Varicella Vaccine Immunogenicity and Efficacy

- ❑ **Detectable antibody:**
 - 97% of children 12 months through 12 years following 1 dose.
 - 99% of persons 13 years and older after 2 doses.

- ❑ **1 dose of varicella vaccine is**
 - 70%-90% effective against any varicella disease.
 - 95%-100% effective against severe varicella disease.

Varicella Breakthrough Infection

- ❑ Breakthrough infection is significantly milder, with fewer lesions (but transmissible).
- ❑ No consistent evidence that risk of breakthrough infection increases with time since vaccination.
- ❑ Risk of breakthrough varicella 2.5 times higher if varicella vaccine administered less than 30 days following MMR.
- ❑ No increased risk if varicella vaccine given simultaneously or more than 30 days after MMR.

Herpes Zoster Vaccine Efficacy

- ❑ Vaccine recipients 60 to 80 years of age had 51% fewer episodes of zoster.
 - Efficacy declines with increasing age.
 - Significantly reduces the risk of postherpetic neuralgia.
 - Reduces the risk of zoster 69.8% in persons 50 through 59 years of age.

Figure 1. Recommended immunization schedule for persons aged 0 through 18 years – United States, 2015.

(FOR THOSE WHO FALL BEHIND OR START LATE, SEE THE CATCH-UP SCHEDULE [FIGURE 2]).

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are shaded.

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	16–18 yrs
Hepatitis B ¹ (HepB)	1 st dose	← 2 nd dose →		← 3 rd dose →						Range of recommended ages for catch-up immunization						
Rotavirus ² (RV) RV1 (2-dose series); RV5 (3-dose series)			1 st dose	2 nd dose	See footnote 2											
Diphtheria, tetanus, & acellular pertussis ³ (DTaP: <7 yrs)			1 st dose	2 nd dose	3 rd dose	Range of recommended ages for catch-up immunization			← 4 th dose →	Range of recommended ages for catch-up immunization		5 th dose				
Tetanus, diphtheria, & acellular pertussis ³ (Tdap: ≥7 yrs)														(Tdap)	Range of recommended ages for catch-up immunization	
Haemophilus influenzae type b ⁴ (Hib)			1 st dose	2 nd dose	See footnote 5		← 3 rd or 4 th dose → See footnote 5		Range of recommended ages for catch-up immunization							
Pneumococcal conjugate ⁶ (PCV13)			1 st dose	2 nd dose	3 rd dose	Range of recommended ages for catch-up immunization			← 4 th dose →	Range of recommended ages for certain high-risk groups						
Pneumococcal polysaccharide ⁶ (PPSV23)											Range of recommended ages for certain high-risk groups					
Inactivated poliovirus ⁷ (IPV: <18 yrs)			1 st dose	2 nd dose	← 3 rd dose →				Range of recommended ages for catch-up immunization		4 th dose	Range of recommended ages for catch-up immunization				
Influenza ⁸ (IV; LAIV) 2 doses for some: See footnote 8					Annual vaccination (IV only) 1 or 2 doses						Annual vaccination (LAIV or IIV) 1 or 2 doses		Annual vaccination (LAIV or IIV) 1 dose only			
Measles, mumps, rubella ⁹ (MMR)					See footnote 9		← 1 st dose →		Range of recommended ages for catch-up immunization			2 nd dose	Range of recommended ages for catch-up immunization			
Varicella ¹⁰ (VAR)							← 1 st dose →		Range of recommended ages for catch-up immunization			2 nd dose	Range of recommended ages for catch-up immunization			
Hepatitis A ¹¹ (HepA)							← 2-dose series, See footnote 11 →			Range of recommended ages for certain high-risk groups						
Human papillomavirus ¹² (HPV2: females only; HPV4: males and females)														(3-dose series)	Range of recommended ages for catch-up immunization	
Meningococcal ¹³ (Hib-MenCY ≥ 6 weeks; MenACWY-D ≥ 9 mos; MenACWY-CRM ≥ 2 mos)			See footnote 13									Range of recommended ages for certain high-risk groups		1 st dose	Range of recommended ages for catch-up immunization	

Range of recommended ages for all children

Range of recommended ages for catch-up immunization

Range of recommended ages for certain high-risk groups

Range of recommended ages during which catch-up is encouraged and for certain high-risk groups

Not routinely recommended

This schedule includes recommendations in effect as of January 1, 2015. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (<http://www.vaers.hhs.gov>) or by telephone (800-822-7967). Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (<http://www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm>) or by telephone (800-CDC-INFO [800-232-4636]).

This schedule is approved by the Advisory Committee on Immunization Practices (<http://www.cdc.gov/vaccines/acip>), the American Academy of Pediatrics (<http://www.aap.org>), the American Academy of Family Physicians (<http://www.aafp.org>), and the American College of Obstetricians and Gynecologists (<http://www.acog.org>).

NOTE: The above recommendations must be read along with the footnotes of this schedule.

Recommended Adult Immunization Schedule—United States - 2015

Note: These recommendations must be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

Figure 1. Recommended adult immunization schedule, by vaccine and age group¹

VACCINE ▼	AGE GROUP ►	19-21 years	22-26 years	27-49 years	50-59 years	60-64 years	≥ 65 years
Influenza ²		1 dose annually					
Tetanus, diphtheria, pertussis (Td/Tdap) ^{3,4}		Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs					
Varicella ⁴		2 doses					
Human papillomavirus (HPV) Female ⁵		3 doses					
Human papillomavirus (HPV) Male ⁵		3 doses					
Zoster ⁶						1 dose	
Measles, mumps, rubella (MMR) ⁷		1 or 2 doses					
Pneumococcal 13-valent conjugate (PCV13) ⁸		1-time dose					
Pneumococcal polysaccharide (PPSV23) ⁸		1 or 2 doses					1 dose
Meningococcal ⁹		1 or more doses					
Hepatitis A ¹⁰		2 doses					
Hepatitis B ¹¹		3 doses					
<i>Haemophilus influenzae</i> type b (Hib) ¹²		1 or 3 doses					

*Covered by the Vaccine Injury Compensation Program

For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; zoster vaccine recommended regardless of prior episode of zoster

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indication)

No recommendation

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.

Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 8:00 a.m. - 8:00 p.m. Eastern Time, Monday - Friday, excluding holidays.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), American College of Obstetricians and Gynecologists (ACOG) and American College of Nurse-Midwives (ACNM).

Figure 2. Vaccines that might be indicated for adults based on medical and other indications¹

VACCINE ▼	INDICATION ►	Pregnancy	Immuno-compromising conditions (excluding human immunodeficiency virus [HIV]) ^{4,6,7,8,13}	HIV infection CD4+ T lymphocyte count ^{4,6,7,8,13}		Men who have sex with men (MSM)	Kidney failure, end-stage renal disease, receipt of hemodialysis	Heart disease, chronic lung disease, chronic alcoholism	Asplenia (including elective splenectomy and persistent complement component deficiencies) ^{8,12}	Chronic liver disease	Diabetes	Healthcare personnel
			< 200 cells/µL	≥ 200 cells/µL								
Influenza ²			1 dose IIV annually			1 dose IIV or LAIV annually	1 dose IIV annually					1 dose IIV or LAIV annually
Tetanus, diphtheria, pertussis (Td/Tdap) ^{2,3}		1 dose Tdap each pregnancy	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs									
Varicella ⁴			Contraindicated				2 doses					
Human papillomavirus (HPV) Female ^{4,5}			3 doses through age 26 yrs				3 doses through age 26 yrs					
Human papillomavirus (HPV) Male ^{4,5}			3 doses through age 26 yrs				3 doses through age 21 yrs					
Zoster ⁶			Contraindicated				1 dose					
Measles, mumps, rubella (MMR) ⁷			Contraindicated				1 or 2 doses					
Pneumococcal 13-valent conjugate (PCV13) ⁸							1 dose					
Pneumococcal polysaccharide (PPSV23) ⁸							1 or 2 doses					
Meningococcal ⁹							1 or more doses					
Hepatitis A ¹⁰							2 doses					
Hepatitis B ¹¹							3 doses					
<i>Haemophilus influenzae</i> type b (Hib) ¹²			post-HSCT recipients only				1 or 3 doses					

¹Covered by the Vaccine Injury Compensation Program



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Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)



No recommendation

Varicella Vaccine Recommendations: Children

- ❑ **Routine recommendations:**
 - Dose 1 at 12-15 months of age.
 - Dose 2 at 4-6 years of age.
- ❑ **Minimum interval between doses is 3 months for children younger than 13 years of age.**

Varicella Vaccine Recommendations: Adolescents and Adults

- ❑ All persons 13 years of age and older without evidence of varicella immunity.
 - 2 doses separated by at least 4 weeks.
- ❑ Do not repeat first dose because of extended interval between doses.
- ❑ Second dose recommended for persons of any age who have only received 1 dose.

Varicella and HCP

- ❑ Recommended for all susceptible healthcare workers.
- ❑ Pre-vaccination serologic screening probably cost-effective.
- ❑ Post-vaccination testing not necessary or recommended.
- ❑ Give 2 doses, 4 weeks apart to susceptible persons.

Acceptable Evidence of Varicella Immunity

- ❑ Written documentation of age-appropriate vaccination.
- ❑ Laboratory evidence of immunity or laboratory confirmation of varicella disease.
- ❑ U.S.-born before 1980*.
- ❑ Healthcare provider diagnosis or verification of varicella disease.
- ❑ History of herpes zoster based on healthcare provider diagnosis.

*Birth year immunity criterion does not apply to healthcare personnel or pregnant women. *MMWR* 2007;56(RR-4):16-17

Varicella Vaccine

Post Exposure Prophylaxis

- ❑ Varicella vaccine is recommended for use in susceptible persons after exposure to varicella
 - 70%-100% effective if given within 72 hours of exposure
 - Not effective if administered more than 5 days after exposure but will produce immunity if not infected

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Zoster ⁶		Contraindicated		1 dose								
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Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)



No recommendation

ACIP Recommendations: Zoster Vaccine

- ❑ **Administer 1 dose of zoster vaccine to adults 60 years and older.**
 - Need for booster dose or doses not known at this time.
- ❑ **A history of herpes zoster should not influence the decision to vaccinate.**

Herpes Zoster Vaccine

- ❑ FDA approved for persons 50 years and older.
- ❑ ACIP does not recommend vaccination of persons younger than 60 years because of supply and lower risk of zoster in this age group.

Zoster Vaccine

- ❑ Persons 60 years of age and older can be assumed to be immune regardless of their recollection of chickenpox.
- ❑ It is not necessary to inquire about chickenpox before administering zoster vaccine.

Zoster Vaccine and Serology

- ❑ Do not perform serologic testing to verify varicella immunity prior to administering zoster.
 - If tested and seronegative ,the person should receive 2 doses of single antigen varicella vaccine (Varivax) separated by at least 4 weeks.
 - Zoster vaccine is not indicated for a person whose immunity is based on vaccination.

Zoster and Pneumococcal Polysaccharide (PPSV) Vaccines

- ❑ A reduced immune response to zoster vaccines was seen when PPSV23 and HZV were administered simultaneously.
- ❑ Subsequent study has shown simultaneous administration of HZV and PPSV23 does not effect zoster vaccine efficacy.

Zoster and Pneumococcal Polysaccharide Vaccines

- ❑ CDC has not changed vaccination recommendations for either vaccine.
- ❑ Administer zoster and PPSV at the same visit if the person is eligible for both vaccines.*

*Off-label ACIP recommendation

Varicella-Containing Vaccine Contraindications

- ❑ Severe allergic reaction to a vaccine component or following a prior dose.
- ❑ Pregnancy or planned pregnancy within 4 weeks.*
- ❑ Immunosuppression.

**ACIP off-label recommendation*

Varicella-containing Vaccines Immunocompromised Persons

- ❑ Single-antigen varicella vaccine may be administered to persons with isolated humoral immunodeficiency.
- ❑ Consider varicella vaccination for HIV-infected children with CD4 % of 15% or higher.
- ❑ Consider varicella vaccination for HIV-infected older children and adults with CD4 count of 200 or higher.

Varicella-containing Vaccine Precautions

- ❑ Moderate or severe acute illness.
- ❑ Recent blood product (varicella and MMRV).
 - Varicella or MMRV vaccine should not be administered for 3–11 months after receipt of antibody-containing blood products.

Varicella-containing Vaccine Precautions

- ❑ **MMRV only: 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.**

Zoster Vaccine Contraindications

- ❑ Severe allergic reaction to a vaccine component or following a prior dose.
- ❑ Pregnancy or planned pregnancy within 4 weeks.*
- ❑ Immunosuppression.

**ACIP off-label recommendation*

Zoster Vaccine Contraindications

Immunosuppression

- ❑ Leukemia, lymphoma, or other malignant neoplasm affecting the bone marrow or lymphatic system.
 - Persons whose leukemia or lymphoma is in remission and who have not received chemotherapy or radiation for at least 3 months can be vaccinated.*

**Off-label ACIP recommendation*

Zoster Vaccine Contraindications

Immunosuppression

- ❑ AIDS or other clinical manifestation of HIV infection.
 - Includes persons with CD4+ T-lymphocyte values less than 200 per mm³, or less than 15% of total lymphocytes.

Zoster Vaccine Contraindications

Immunosuppression

- ❑ **High-dose corticosteroid therapy**
 - 20 milligrams or more per day of prednisone or equivalent lasting 2 or more weeks.
 - Vaccination should be deferred for at least 1 month after discontinuation of therapy.

Zoster Vaccine Contraindications

Immunosuppression

- ❑ Hematopoietic cell transplant recipients
 - Experience is limited.
 - Assess the immune status of the recipient on a case-by-case basis.
 - If a decision is made to vaccinate, the vaccine should be administered at least 24 months after transplantation.

Zoster Vaccine Contraindications

Immunosuppression

- ❑ Preferred: Administer zoster vaccine before treatment with recombinant human immune mediators and immune modulators.
 - If not, assess the immune status of the recipient on a case-by-case basis.
- ❑ Vaccination should be deferred for at least 1 month after discontinuation of treatment.

Zoster Vaccine Precautions

- ❑ Moderate or severe acute illness.
- ❑ Current treatment with an antiviral drug active against herpes viruses.
 - Discontinue at least 24 hours before administration of zoster vaccine.
 - Should not be taken for at least 14 days after vaccination.
- ❑ Recent receipt of a blood product is NOT a precaution.

Varicella Vaccine Adverse Reactions

- ❑ **Local reactions (pain, erythema)**
 - 19% (children)
 - 24% (adolescents and adults)
- ❑ **Rash – 3%-4%**
 - May be maculopapular rather than vesicular
 - Average 5 lesions
- ❑ **Systemic reactions not common**

Zoster Following Vaccination

- ❑ Most cases in children
- ❑ Not all cases caused by vaccine virus
- ❑ Risk from vaccine virus less than from wild-type virus
- ❑ Usually a mild illness without complications such as postherpetic neuralgia

Adverse Reactions Following MMRV and MMR+VAR

- ❑ Fever is more common in the 5-12 days after vaccination following MMRV (22%) than following MMR+V (15%).
- ❑ Data from CDC Vaccine Safety Datalink sites indicate the rate of febrile seizures following MMRV (9 per 10,000 vaccinated) was approximately 2 times higher than among those receiving MMR+V at the same visit (4 per 10,000 vaccinated).
- ❑ Merck post-licensure surveillance has identified a similar trend.

MMRV Vaccine

- For the first dose of measles, mumps, rubella, and varicella vaccines at age 12 through 47 months, either MMR vaccine and varicella vaccine or MMRV vaccine may be used.
- Providers who are considering administering MMRV vaccine should discuss the benefits and risks of both vaccination options with the parents or caregivers.

MMRV Vaccine

- ❑ Unless the parent or caregiver expresses a preference for MMRV vaccine, CDC recommends that separate MMR vaccine and varicella vaccine should be administered for the first dose for children 12–47 months of age.

MMRV Vaccine

□ Administer MMRV

- For the second dose of measles, mumps, rubella, and varicella vaccines at ages 15 months through 12 years.
- For the first dose at age 48 months or older.

Herpes Zoster Vaccine Adverse Reactions

- ❑ Local reactions - 34% (pain, erythema).
- ❑ No increased risk of fever.
- ❑ No serious adverse reactions identified.

Storage and Handling Varicella-containing Vaccine

□ Lyophilized vaccine:

- Store frozen between -58°F and +5°F (-50°C and -15°C)
- Vaccine may be stored in the refrigerator between 36°F and 46°F, (2°C and 8°C) for up to 72 continuous hours after removal from freezer. Discard unused vaccine after 72 hours.
- Protect vaccine from light.

□ Diluent:

- Store diluent at room temperature or refrigerate.

□ Reconstitute:

- Using diluent supplied by the manufacturer.

Varicella Resources

- ❑ ACIP's Varicella Recommendations web page
www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/varicella.html
- ❑ CDC's Varicella Infection web page
www.cdc.gov/chickenpox/index.html
- ❑ CDC's Varicella Vaccination web page
www.cdc.gov/vaccines/vpd-vac/varicella/default.htm
- ❑ Immunization Action Coalition Varicella web page
www.immunize.org/varicella/
- ❑ Children's Hospital of Philadelphia Vaccine Education Center Varicella web page
www.chop.edu/service/vaccine-education-center/a-look-at-each-vaccine/varicella-chickenpox-vaccine.html

Zoster Resources

- ❑ ACIP's Zoster Recommendations web page
www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/shingles.html
- ❑ CDC's Zoster Infection web page
www.cdc.gov/shingles/index.html
- ❑ CDC's Zoster Vaccination web page
www.cdc.gov/vaccines/vpd-vac/shingles/default.htm
- ❑ Immunization Action Coalition Zoster web page
www.immunize.org/zoster/
- ❑ Children's Hospital of Philadelphia Vaccine Education Center Zoster web page
www.chop.edu/service/vaccine-education-center/a-look-at-each-vaccine/shingles-vaccine.html

ADDITIONAL SLIDES

Varicella Laboratory Diagnosis

- ❑ Isolation of varicella virus from clinical specimen
- ❑ Rapid varicella virus identification using real-time PCR (preferred, if available) or DFA
- ❑ Significant rise in varicella IgG by any standard serologic assay

Varicella Zoster Immune Globulin

- ❑ Used for post exposure prophylaxis for persons in whom varicella vaccine is contraindicated (pregnant women, immunosuppressed, etc.)
- ❑ Only VariZIG is currently available
- ❑ Updated recommendations for use published in July 2013[†]

[†] *MMWR* July 19, 2013 / 62(28);574-6

Herpes Zoster Vaccine

- ❑ **Herpes Zoster Vaccine (Zostavax)**
 - FDA approved for persons 50 years of age and older
 - Contains live varicella vaccine virus in much larger amount (14x) than standard varicella vaccine (Varivax)
- ❑ **Administer by subcutaneous injection**
- ❑ **ACIP abbreviation: HZV**