



# **Varicella (Chickenpox) and Zoster (Shingles) Disease Varicella and Zoster Vaccines**

## **Pink Book Webinar Series 2018**

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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 (Chickenpox) Clinical Features

- Incubation period 14 to 16 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

# Varicella Complications

- Bacterial infection of lesions
- Hemorrhagic varicella
- CNS manifestations
- Pneumonia (primary viral or secondary bacterial)
- Congenital varicella
- Perinatal varicella
- Prevacine era:
  - Hospitalization ~3 per 1,000 cases or 1,000/year
  - Death ~ 1 per 60,000 cases or 100/year



**Varicella with a secondary bacterial infection**

# 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

# Varicella Epidemiology

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



# Herpes Zoster (Shingles)

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

# 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



**Zoster involving the ophthalmic division of the trigeminal nerve**

# Herpes Zoster

- **Approximately 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**

# ACIP Recommendations: Varicella

# Vaccines for the Prevention of Varicella (Chickenpox)

<b>Product</b>	<b>ACIP Recommended Age Indications</b>	<b>ACIP Abbreviation</b>
Varivax	12 months and older	VAR
ProQuad	12 months through 12 years	MMRV

# Varicella-Containing Vaccines: Varivax (Var) and ProQuad (MMRV)

## ■ Storage:

- Lyophilized vaccine: In the freezer between -50°C and -15°C (-58°F and +5°F)
- Diluent: At room temperature (68°F to 77°F, 20°C to 25°C) or in the refrigerator (36°F to 46°F, 2°C to 8°C)

## ■ Preparation: Reconstitute the vaccine with the diluent supplied by the manufacturer just before administering

## ■ Administration: Subcut injection

- Site: Fatty tissue of the anterolateral thigh or upper outer triceps of the arm
- Needle length and gauge: 5/8-inch, 23- to 25-gauge needle

# Varicella Vaccine

## Immunogenicity and Efficacy

- **In a pre-licensure clinical trial, 2 doses of vaccine were:**
  - 98% effective at preventing any form of varicella
  - 100% effective against severe varicella
  
- **In post-licensure studies, 2 doses of vaccine were:**
  - 88% to 98% effective at preventing all varicella



# 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\***
- **Health care provider diagnosis or verification of varicella disease**
- **History of herpes zoster based on health care provider diagnosis**

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

# Varicella Vaccination and 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 Vaccination and 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 Vaccination and Health Care Personnel

- Vaccination is recommended for all susceptible health care personnel
- Prevaccination serologic screening probably cost-effective
- Postvaccination testing not necessary or recommended
- Give 2 doses, 4 weeks apart to susceptible persons

# Varicella Vaccine and Immunocompromised Persons

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

# Varicella and MMRV Vaccine Contraindications

- Severe allergic reaction to a vaccine component or following a prior dose
- Pregnancy or planned pregnancy within 4 weeks\*
- Immunosuppression
- Family history of altered immunocompetence

\*ACIP off-label recommendation

*MMWR* 2007;56(RR-04)

General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) Contraindications and Precautions section [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html), accessed 08/12/2018

# Varicella and MMRV Vaccine Precautions

- **Moderate or severe acute illness with or without fever**
- **Recent blood product**
  - Varicella or MMRV vaccines should not be administered for 3–11 months after receipt of antibody-containing blood products
- **Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination**
  - Avoid use of these antiviral drugs for 14 days after vaccination)
- **Use of aspirin or aspirin-containing products**

MMWR 2007;56(RR-04)\

General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) Contraindications and Precautions section [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html), accessed 08/12/2018

# Varicella-Containing Vaccines 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**



# Varicella Adverse Reactions

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

# Adverse Reactions

## MMRV and MMR + VAR

- Fever is more common in the 5–12 days after vaccination with MMRV (22%) than with MMR + VAR (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 + VAR at the same visit (4 per 10,000 vaccinated)
- Merck postlicensure surveillance has identified a similar trend

# MMRV Vaccine

- For the first dose of measles, mumps, rubella, and varicella vaccines at age 12–47 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

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

# 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

# ACIP Recommendations: Zoster

# Vaccines for Prevention of Zoster (Shingles)

<b>Product (ACIP Abbreviation)</b>	<b>Type</b>	<b>ACIP Age Recommendations</b>
<b>Zostavax (ZVL)</b>	Live, attenuated	60 years of age and older*
<b>Shingrix (RZV)</b>	Inactivated, adjuvanted	50 years of age and older

\*Zostavax is FDA-approved for persons 50 years of age and older

# Zoster Vaccine: Shingrix (RZV)

- **Storage:** Store vaccine AND diluent in the refrigerator between 2°C and 8°C (36°F and 46°F)
- **Preparation:** Reconstitute the vaccine with the diluent (adjuvant) supplied by the manufacturer just before administering
  - If not used immediately, the reconstituted vaccine may be stored in the refrigerator and use it within 6 hours of reconstitution
  - If not used,
- **Schedule:** 2 doses, 2 to 6 months apart
- **Route:** IM Injection
  - Site: Deltoid or the thigh may be used if necessary
  - Needle gauge and length: 23- to 25-gauge needle, length varies by age/weight
- **RZV may be administered during the same clinical encounter as other vaccines**



# Vaccine Supply: Shingrix

- Due to high levels of demand for GSK's Shingrix vaccine, GSK has implemented order limits and providers have experienced shipping delays
- Order limits and shipping delays will continue throughout 2018
- GSK has increased the U.S. supply available for 2018 and plans to release doses to all customer types on a consistent and predictable schedule for the rest of 2018
- Overall, the supply of Shingrix during 2018 is sufficient to support the vaccination of more patients during 2018 than were vaccinated against shingles during 2017

# Zoster Vaccine: Zostavax (ZVL)

- **Storage:**
  - Lyophilized vaccine: In the freezer between -50°C and -15°C (-58°F and +5°F)
  - Diluent: At room temperature (68°F to 77°F, 20°C to 25°C) or in the refrigerator (36°F to 46°F, 2°C to 8°C)
- **Preparation: Reconstitute the vaccine with the diluent supplied by the manufacturer just before administering**
- **Schedule: 1 dose**
- **Administration: Subcut injection**
  - Site: Fatty tissue of the upper outer triceps of the arm
  - Needle length and gauge: 5/8-inch, 23- to 25-gauge needle

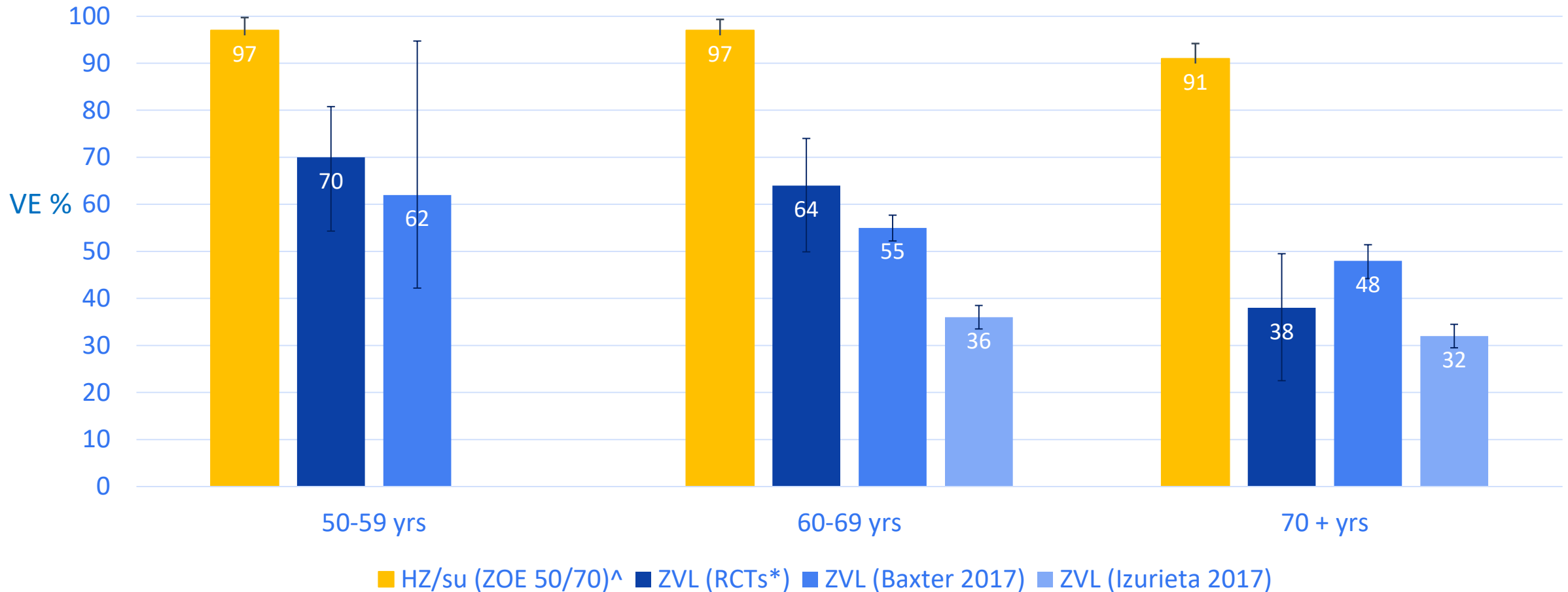
# Live Zoster Vaccine (ZVL) Efficacy

- **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

# RZV Vaccine Efficacy

- **Efficacy for the prevention of zoster:**
  - 96.6% in adults age 50 to 59 years
  - 97.4% in adults age 60 to 69 years
  - 91.3% in adults age 70 years and older
- **The efficacy for the prevention of postherpetic neuralgia (PHN) was:**
  - 91.2% in adults age 50 years and older
  - 88.8% in adults age 70 years and older

# Vaccine Efficacy and Effectiveness against HZ for HZ/su and ZVL, by Age Group, During the First 4<sup>‡</sup> Years Following Vaccination



<sup>‡</sup> Median follow-up may be less than 3 yrs: Schmader 2012= 1.3 yrs  
<sup>^</sup>ZOE 50/70= 50-59 and 60-69yr: Lal 2015, 70+yr: Cunningham 2016  
<sup>\*</sup>RCTs= 50-59 yrs: Schmader 2012, 60-69 and 70+ yrs: Oxman 2005,

# ACIP Zoster Immunization Recommendations

- **Administer 2 doses of Shingrix to immunocompetent persons 50 years of age and older**
  - Regardless of previous history of:
    - Vaccination with varicella-containing vaccines—Varivax or Zostavax
    - Zoster disease
- **Shingrix is preferred to Zostavax for persons 60 years and older**
  - Separate varicella-containing vaccines and Shingrix by at least 8 weeks

# **Zoster Vaccination: Patients Who Do Not Report A Prior Episode of Varicella**

- **When vaccinating adults 50 years of age and older, there is no need to:**
  - Screen for a history of varicella (chickenpox) infection OR
  - Conduct laboratory testing for serologic evidence of prior varicella infection
- **More than 99% of adults age 50 years and older worldwide have been exposed to varicella zoster virus**
- **ACIP considers people born in the United States prior to 1980 immune to varicella**

# Zoster Vaccine and Serology

- **If tested and varicella-negative:**
  - Administer 2 doses of single-antigen varicella vaccine (Varivax) separated by at least 4 weeks
  - Followed by 2 doses of RZV, separated by 2–6 months
    - Separate the 2<sup>nd</sup> (last) dose of varicella and 1<sup>st</sup> dose of RZV by at least 8 weeks



# RZV Contraindications and Precautions

- **History of severe allergic reaction, such as anaphylaxis, to any component of a vaccine or after a previous dose of Shingrix**
- **Moderate to severe illness, including an acute episode of herpes zoster**
  - Shingrix is not a treatment for herpes zoster or postherpetic neuralgia (PHN)
- **Shingrix has not been studied in pregnant women or women who are breastfeeding. Providers should consider delaying Shingrix vaccination for these women**

# RZV and Immunosuppressive Therapy

- **Administer RZV to persons:**
  - Taking low-dose immunosuppressive therapy (e.g., <20 mg/day of prednisone or equivalent or using inhaled or topical steroids)
  - Anticipating immunosuppression
  - Who have recovered from an immunocompromising illness
- **ACIP has not yet made recommendations regarding use RZV in these patients**
  - Persons on moderate to high doses of immunosuppressive therapy were excluded from RZV efficacy studies

# Zostavax (ZVL) Contraindications

- **History of a life-threatening or severe allergic reaction to gelatin, the antibiotic neomycin, or any other component of ZVL**
- **A weakened immune system because of:**
  - HIV/AIDS or another disease that affects the immune system
  - Treatment with drugs that affect the immune system
  - Cancer treatment such as radiation or chemotherapy
  - Cancer affecting the bone marrow or lymphatic system, such as leukemia or lymphoma
- **Women who are or might be pregnant**
  - Women should not become pregnant until at least 4 weeks\* after getting ZVL

\*ACIP off-label recommendation  
MMWR 2008;57(RR-5)

# Zostavax (ZVL) 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**

# Zostavax (ZVL) Adverse Reactions

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

# RZV (Shingrix) Adverse Reactions

<b>Local reactions</b>	<b>49%</b>
<b>Local reactions—Grade 3</b>	<b>9.4%</b>
<b>Systemic reactions (headache, malaise, fatigue)</b>	<b>45–78%</b>
<b>Systemic reactions (headache, malaise, fatigue)—Grade 3</b>	<b>11%</b>

# Adverse Reactions after Shingrix

- **Educate patients regarding:**
  - Potential adverse reactions, including injection site and systemic reactions
  - **The need for a second dose—even if s/he has an adverse reaction**
- **Offer comfort measures and strategies**



# Vaccine Information Statements

## VACCINE INFORMATION STATEMENT

### Live Zoster (Shingles) Vaccine, ZVL: What You Need to Know

#### 1 What is shingles?

Shingles (also called herpes zoster, or just zoster) is a painful skin rash, often with blisters. Shingles is caused by the varicella zoster virus, the same virus that causes chickenpox. After you have chickenpox, the virus stays in your body and can cause shingles later in life.

You can't catch shingles from another person. However, a person who has never had chickenpox (or chickenpox vaccine) could get chickenpox from someone with shingles.

A shingles rash usually appears on one side of the body and heals within 2 to 4 weeks. The pain, which can be severe, often includes fever, headache, chills, and upset stomach. A shingles infection can lead to problems, blindness, brain inflammation, or death.



For about 1 person in 5, severe pain called post-herpetic neuralgia occurs long after the rash has cleared up. Shingles is far more common in older people than in younger people. It is also more common in people whose immune system is weakened by cancer or by drugs such as steroids. At least 1 million people a year get shingles.

#### 2 Shingles vaccine (live)

A live shingles vaccine was approved by FDA in 2006. In a clinical trial, the vaccine reduced the risk of shingles by about 50% in people 60 and older. It can reduce the likelihood of PHN, and reduce pain in some people who still get shingles after being vaccinated.

The recommended schedule for live shingles vaccine is a single dose for **adults 60 years of age and older**.

#### Some people should not get this vaccine

Tell the person who is giving your child the vaccine if your child:

- Has any severe, life-threatening allergies. A person who has ever had a life-threatening allergic reaction after a dose of MMRV vaccine, or has a severe allergy to any part of this vaccine, may be advised not to be vaccinated. Ask your health care provider if you want information about vaccine components.

- Has a weakened immune system due to disease (such as cancer or HIV/AIDS) or medical treatments (such as radiation, immunotherapy, steroids, or chemotherapy).

- Has a history of seizures, or has a parent, brother, or sister with a history of seizures.

- Has a parent, brother, or sister with a history of immune system problems.

- Has ever had a condition that makes them bruise or bleed easily.

- Is pregnant or might be pregnant. MMRV vaccine should not be given during pregnancy.

- Is taking salicylates (such as aspirin). People should avoid using salicylates for 6 weeks after getting a vaccine that contains varicella.

## VACCINE INFORMATION STATEMENT

### Recombinant Zoster (Shingles) Vaccine, RZV: What You Need to Know

#### 1 Why get vaccinated?

Shingles (also called herpes zoster, or just zoster) is a painful skin rash, often with blisters. Shingles is caused by the varicella zoster virus, the same virus that causes chickenpox. After you have chickenpox, the virus stays in your body and can cause shingles later in life.

You can't catch shingles from another person. However, a person who has never had chickenpox (or chickenpox vaccine) could get chickenpox from someone with shingles.

A shingles rash usually appears on one side of the face or body and heals within 2 to 4 weeks. The pain, which can be severe, often includes fever, headache, chills, and upset stomach. A shingles infection can lead to problems, blindness, brain inflammation, or death.

A shingles rash usually appears on one side of the face or body and heals within 2 to 4 weeks. The pain, which can be severe, often includes fever, headache, chills, and upset stomach. A shingles infection can lead to problems, blindness, brain inflammation, or death.

#### 2 Shingles vaccine (recombinant)

Recombinant shingles vaccine was approved by FDA in 2017 for the prevention of shingles. In clinical trials, it was more than 90% effective in preventing shingles. It can also reduce the likelihood of PHN.

Two doses, 2 to 6 months apart, are recommended for **adults 50 and older**.

This vaccine is also recommended for people who have already gotten the live shingles vaccine (Zostavax). There is no live virus in this vaccine.

## VACCINE INFORMATION STATEMENT

### Varicella (Chickenpox) Vaccine: What You Need to Know

#### 1 Why get vaccinated?

Varicella (also called chickenpox) is a very contagious viral disease. It is caused by the varicella zoster virus. Chickenpox is usually mild, but it can be serious in infants under 12 months of age, adolescents, adults, pregnant women, and people with weakened immune systems.

Chickenpox causes an itchy rash that usually lasts about a week. It can also cause:

- fever
- tiredness
- loss of appetite
- headache

More serious complications can include:

- skin infections
- infection of the lungs (pneumonia)
- inflammation of blood vessels
- swelling of the brain and/or spinal cord coverings (encephalitis or meningitis)
- blood stream, bone, or joint infections

Some people get so sick that they need to be hospitalized. It doesn't happen often, but people can die from chickenpox. Before varicella vaccine, almost everyone in the United States got chickenpox, an average of 4 million people each year.

Children who get chickenpox usually miss at least 5 or 6 days of school or childcare.

Some people who get chickenpox get a painful rash called shingles (also known as herpes zoster) years later.

Chickenpox can spread easily from an infected person to anyone who has not had chickenpox and has not gotten chickenpox vaccine.

#### 2 Chickenpox vaccine

Children 12 months through 12 years of age should get 2 doses of chickenpox vaccine, usually:

- First dose: 12 through 15 months of age
- Second dose: 4 through 6 years of age

People 13 years of age or older who didn't get the vaccine when they were younger, and have never had chickenpox, should get 2 doses at least 28 days apart.

A person who previously received only one dose of chickenpox vaccine should receive a second dose to complete the series. The second dose should be given at least 3 months after the first dose for those younger than 13 years.

and at least 28 days after the first dose for those 13 years of age or older.

There are no known risks to getting chickenpox vaccine at the same time as other vaccines.

This is a combination vaccine called MMRV that contains both chickenpox and MMR vaccines. MMRV is an option for some children 12 months through 12 years of age. There is a separate Vaccine Information Statement for MMRV. Your health care provider can give you more information.

#### 3 Some people should not get this vaccine

Tell your vaccine provider if the person getting the vaccine:

- Has any severe, life-threatening allergies. A person who has ever had a life-threatening allergic reaction after a dose of this vaccine, or has a severe allergy to any part of this vaccine, may be advised not to be vaccinated. Ask your health care provider if you want information about vaccine components.

- Is pregnant, or thinks she might be pregnant. Pregnant women should wait to get chickenpox vaccine until after they are no longer pregnant. Women should avoid getting pregnant for at least 1 month after getting chickenpox vaccine.

- Has a weakened immune system due to disease (such as cancer or HIV/AIDS) or medical treatments (such as radiation, immunotherapy, steroids, or chemotherapy).

- Has a parent, brother, or sister with a history of immune system problems.

- Is taking salicylates (such as aspirin). People should avoid using salicylates for 6 weeks after getting varicella vaccine.

- Has recently had a blood transfusion or received other blood products. You might be advised to postpone chickenpox vaccination for 3 months or more.

- Has tuberculosis.

## VACCINE INFORMATION STATEMENT

### MMRV (Measles, Mumps, Rubella, and Varicella) Vaccine: What You Need to Know

#### 1 Why get vaccinated?

Measles, mumps, rubella, and varicella are viral diseases that can have serious consequences. Before vaccines, these diseases were very common in the United States, especially among children. They are still common in many parts of the world.

**Measles**

- Measles virus causes symptoms that can include fever, cough, runny nose, and red, watery eyes, commonly followed by a rash that covers the whole body.

- Measles can lead to ear infections, diarrhea, and infection of the lungs (pneumonia). Rarely, measles can cause brain damage or death.

**Mumps**

- Mumps virus causes fever, headache, muscle aches, tiredness, loss of appetite, and swollen and tender salivary glands under the ears on one or both sides.

- Mumps can lead to deafness, swelling of the brain and/or spinal cord covering (encephalitis or meningitis), painful swelling of the testicles or ovaries, and, very rarely, death.

**Rubella (also known as German Measles)**

- Rubella virus causes fever, sore throat, rash, headache, and eye irritation.

- Rubella can cause arthritis in up to half of teenage and adult women.

- If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

**Varicella (also known as Chickenpox)**

- Chickenpox causes an itchy rash that usually lasts about a week, in addition to fever, tiredness, loss of appetite, and headache.

- Chickenpox can lead to skin infections, infection of the lungs (pneumonia), inflammation of blood vessels, swelling of the brain and/or spinal cord covering (encephalitis or meningitis) and infections of the blood, bones, or joints. Rarely, varicella can cause death.

- Some people who get chickenpox get a painful rash called shingles (also known as herpes zoster) years later.

These diseases can easily spread from person to person. Measles doesn't even require personal contact. You can get measles by entering a room that a person with measles left up to 2 hours before.

Vaccines and high rates of vaccination have made these diseases much less common in the United States.



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



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

- There is a VIS for:
  - ZVL (Zostavax)
  - RZV (Shingrix)
  - Var (Varicella)
  - MMRV (ProQuad)

- Give the parent or patient the appropriate VIS for the product that will be administered



# Real-Life Shingrix Administration Errors

- Notes from the Field: Vaccine Administration Errors Involving Recombinant Zoster Vaccine
- 13 (8%) of the 155 reports to VAERS regarding Shingrix documented a vaccine administration error

Morbidity and Mortality Weekly Report

## Notes from the Field

### Vaccine Administration Errors Involving Recombinant Zoster Vaccine — United States, 2017–2018

Tom T. Shimabukuro, MD<sup>1</sup>; Elaine R. Miller, MPH<sup>1</sup>; Raymond A. Strikas, MD<sup>2</sup>; Beth F. Hibbs, MPH<sup>1</sup>; Kathleen Dooling, MD<sup>3</sup>; Ravi Goud, MD<sup>4</sup>; Maria V. Cano, MD<sup>1</sup>

Two vaccines for the prevention of herpes zoster (shingles) are licensed for use in the United States and recommended by the Advisory Committee on Immunization Practices (ACIP). Zoster vaccine live (ZVL; Zostavax, Merck), licensed in 2006,<sup>\*</sup> is a live attenuated virus vaccine administered as a single subcutaneous (SQ) dose. Although the Food and Drug Administration (FDA) approved ZVL for adults aged ≥50 years, ACIP recommends ZVL for immunocompetent adults aged ≥60 years (1). Recombinant zoster vaccine (RZV; Shingrix, GlaxoSmithKline), licensed October 2017,<sup>†</sup> is also approved by the FDA for adults

also described vaccination of a person aged 48 years (inappropriate age), and two described patients receiving the vaccine information statement for ZVL instead of RZV and not being instructed to return for the second RZV dose. The remaining four reports included 1) administration of RZV instead of the intended varicella (Varivax) vaccine to a person of unreported age, 2) administration of RZV after incorrect frozen storage, 3) administration of RZV to a person aged 39 years, and 4) administration of only the adjuvant component without reconstitution with the vaccine antigen. Vaccine administration errors occurred in a pharmacy (nine reports), a health care provider's office (two), and unknown sites (two). CDC also received 13 public inquiries concerning RZV administration errors or questions asked to avoid errors. Topics included SQ administration (five), reconstitution (five), incorrect interval or schedule (two), and administration of previously frozen vaccine (one).

# Shingrix Vaccine Administration Errors

- **Vaccine administration errors reported to VAERS include:**
  - **Wrong route:** Subcut route rather than the IM
  - **Wrong age:** Administered to persons less than 50 years of age
  - **Wrong vaccine:** Shingrix instead of varicella (Varivax) vaccine
  - **Improper storage:** Administered after frozen storage
  - **Wrong preparation:** Administered the adjuvanted diluent only
  - **Wrong schedule:** Interval violations between doses of Shingrix or a previous dose of varicella-containing vaccine
- **Other errors we have heard about:**
  - Staff unaware of the need for a second dose
  - Staff thinks Zostavax can count toward completing the 2-dose Shingrix series

# Varicella and Zoster Vaccine Resources and References

- Resources and references are available on the webinar web page

## Varicella and Zoster Vaccines Resources and References

### 2018 PINK BOOK WEBINAR SERIES

#### ACIP recommendations

- Current ACIP varicella vaccine recommendations [www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/varicella.html](http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/varicella.html)
- Current ACIP MMRV recommendations [www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mmr.html](http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mmr.html)
- Current ACIP zoster vaccine recommendations [www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/shingles.html](http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/shingles.html)
- ACIP Update on the use of herpes zoster vaccine [www.cdc.gov/mmwr/volumes/67/wr/mm6703a5.html](http://www.cdc.gov/mmwr/volumes/67/wr/mm6703a5.html)

#### Manufacturer's vaccine package inserts (PI)

- VAR (Varivax), Merck & Co., Inc. [www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm200582.htm](http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm200582.htm)
- MMRV (ProQuad), Merck & Co., Inc. [www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094051.htm](http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094051.htm)
- RZV (Shingrix), GlaxoSmithKline, Biologicals [www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm581605.pdf](http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm581605.pdf)
- ZVL (Zostavax) Merck & Co., Inc. [www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm132831.pdf](http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm132831.pdf)

#### Schedule

- 2018 Recommended immunization schedule for persons aged 18 years and younger [www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html](http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html)
- 2018 Recommended immunization schedule for adults 19 years and older [www.cdc.gov/vaccines/schedules/hcp/adult.html](http://www.cdc.gov/vaccines/schedules/hcp/adult.html)

#### Disease

- Chickenpox disease webpage [www.cdc.gov/chickenpox/about/](http://www.cdc.gov/chickenpox/about/)
- Information you need to know [www.vaccineinformation.org/chickenpox/](http://www.vaccineinformation.org/chickenpox/)
- Shingles (Herpes Zoster) [www.cdc.gov/shingles/hcp/index.html](http://www.cdc.gov/shingles/hcp/index.html)

#### Information for health care personnel

- *Epidemiology and Prevention of Vaccine-Preventable Diseases: Varicella chapter* [www.cdc.gov/vaccines/pubs/pinkbook/chapters.html](http://www.cdc.gov/vaccines/pubs/pinkbook/chapters.html)
- Ask the Experts: varicella questions [www.immunize.org/askexperts/experts\\_var.asp](http://www.immunize.org/askexperts/experts_var.asp)
- Ask the Experts: zoster questions [www.immunize.org/askexperts/experts\\_zos.asp](http://www.immunize.org/askexperts/experts_zos.asp)
- CDC Zoster Fact Sheet [www.cdc.gov/shingles/downloads/shingles-factsheet-hcp.pdf](http://www.cdc.gov/shingles/downloads/shingles-factsheet-hcp.pdf)
- MMR & varicella vaccines or MMRV vaccine: discussing options with parents [www.cdc.gov/vaccines/vpd/mmr/hcp/vacopt-factsheet-hcp.html](http://www.cdc.gov/vaccines/vpd/mmr/hcp/vacopt-factsheet-hcp.html)
- *You Call the Shots: Varicella* [www.cdc.gov/vaccines/ed/youcalltheshots.html](http://www.cdc.gov/vaccines/ed/youcalltheshots.html)
- *You Call the Shots: Zoster* [www.cdc.gov/vaccines/ed/youcalltheshots.html](http://www.cdc.gov/vaccines/ed/youcalltheshots.html)
- You call the Shots: Zoster job aid [www.cdc.gov/vaccines/hcp/infographics/you-call-the-shots-intramuscular-shingrix-vaccination.html](http://www.cdc.gov/vaccines/hcp/infographics/you-call-the-shots-intramuscular-shingrix-vaccination.html)
- Varicella information [www.immunize.org/varicella/](http://www.immunize.org/varicella/)
- Zoster information [www.immunize.org/zoster/](http://www.immunize.org/zoster/)