Centers for Disease Control and Prevention





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

Pink Book Webinar Series 2019

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Varicella Disease

Varicella Zoster Virus

- Herpes virus (DNA)
- Primary infection results in varicella (chickenpox)
- 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 (10–21 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

Varicella Complications

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



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

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

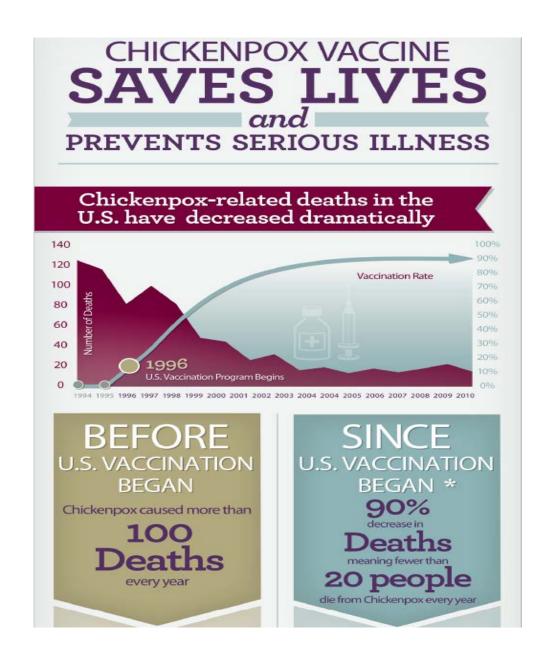
Varicellacontaining Vaccines

Vaccines for the Prevention of Varicella (Chickenpox)

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

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



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 and Clinical Considerations

Acceptable Evidence of Varicella Immunity

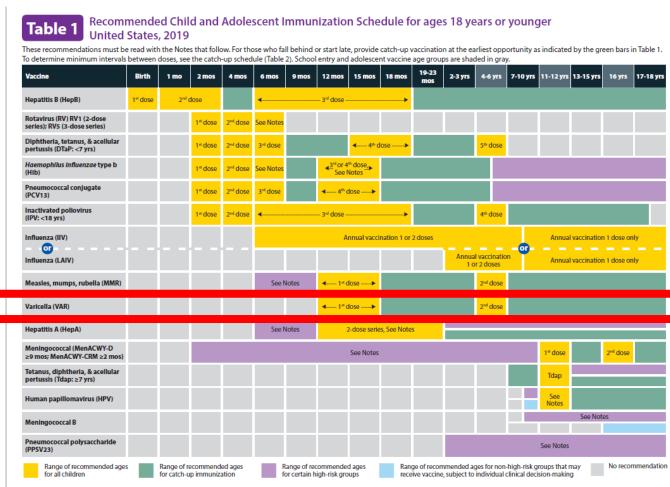
- Written documentation of age-appropriate vaccination
- Laboratory evidence of immunity or laboratory confirmation of varicella disease
- U.S.-born before 1980*
- Health care provider diagnosis or verification of varicella disease
- History of herpes zoster based on health care provider diagnosis

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

ACIP Immunization Recommendations: Young 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 12 years of age and younger



ACIP Immunization Recommendations: Adolescents and Adults

- Assess all persons 13 years of age and older for evidence of varicella immunity
- Administer 2 doses separated by at least 4 weeks to those without evidence of immunity

- 2nd dose recommended for persons of any age who have only received 1 dose
 - Do not repeat 1st dose because of extended interval between doses

Varicella Vaccination and Health Care Personnel

- Assess all health care personnel for evidence of immunity
- Vaccination is recommended for all susceptible health care personnel
 - Give 2 doses, 4 weeks apart to susceptible persons

- Prevaccination serologic screening might be cost-effective
- Postvaccination testing NOT recommended

Varicella Serology and Post Vaccination

- CDC and ACIP do NOT recommend antibody testing AFTER varicella vaccination
 - Commercially available laboratory tests for varicella antibody are usually not sufficiently sensitive to detect vaccine—induced antibody
 - Even though they are generally sensitive to deduce antibodies resulting from varicella zoster virus infection
- Documented receipt of 2 doses of varicella vaccine SUPERSEDES results of subsequent serologic testing

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

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

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
- 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 age 15 months through 12 years
- For the first dose at age 48 months or older

Zoster Disease

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

Postherpetic neuralgia (PHN)

 Dissemination with generalized skin eruptions and involvement of the central nervous system, lungs, liver, and pancreas

Ophthalmic zoster

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



Zoster involving the ophthalmic division of the trigeminal nerve

Zoster Vaccines

Vaccines for Prevention of Zoster (Shingles)

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

^{*}Zostavax is FDA-approved for persons 50 years of and older

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

Zoster Vaccine: Zostavax (ZVL)

Storage:

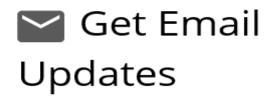
- Lyophilized vaccine: In the freezer between -50°C and -15°C (-58°F and +5°F)
- Diluent: At room temperature (68°F to 77°F, 20°C to 25°C) or in the refrigerator (36°F to 46°F, 2°C to 8°C)
- Preparation: Reconstitute the vaccine with the diluent supplied by the manufacturer just before administering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

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 2019
- GSK increased the U.S. supply during 2018 and plans to make even more doses available in 2019



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Clinical Considerations

ACIP Zoster Immunization Recommendations

- Administer 2 doses of Shingrix, 2 to 6 months apart, for adults
 50 years of age and older
- Shingrix is preferred to Zostavax for persons 60 years and older
- Whether or not they report a:
 - History of zoster disease
 - Prior dose of Zostavax or varicella vaccine
 - Separate varicella-containing vaccines and Shingrix by at least 8 weeks
 - History of chronic medical condition, unless a contraindication or precaution exists

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

- ACIP considers people born in the United States prior to 1980 immune to 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

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 2nd (last) dose of varicella and 1st 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 administering RZV to persons on moderate to high doses of immunosuppressive therapy

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

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

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

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



Resources

Vaccine Information Statements

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

VACCINE INFORMATION STATEMENT

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 virus causes symptoms that can include fever, cough.

Meades can lead to ear infections, diarrhea, and infection of the

Mumps virus causes fever, headache, muscle aches, tirednes

ears on one or both sides.

loss of appetite, and swollen and tender salivary glands under the

Mumps can lead to deafness, swelling of the brain and/or spinal

Rubella can cause arthritis in up to balf of teepage and adult

If a woman gets rubella while she is pregnant, she could have a

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

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

doesn't even require personal contact. You can get measles by

entering a room that a person with measles left up to 2 hours

Vaccines and high rates of vaccination have made these disease

These diseases can easily spread from person to person. Measles

and infections of the blood, bones, or joints. Rarely, varicella can

miscarriage or her baby could be born with serious birth defects

the testicles or ovaries, and, very rarely, death,

Rubella (also known as German Measles)

1 What is shingles?

Shinoles (also called hernes 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

A shingles rash usually appears body and heals within 2 to 4 w pain, which can be severe. Oth fever, headache, chills, and ups a shingles infection can lead t



long after the rash has cleared is called post-herpetic neural Shingles is far more common and older than in younger peop immune system is weakened b cancer or by drugs such as stere At least 1 million people a year

2 Shingles vaccine (live)

A live shingles vaccine was approved by FDA in 2006. In a clinical trial, the vaccine reduced the risk of shinoles 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.

VACCINE INFORMATION STATEMENT

MMRV (Measles, Mumps, Rubella, and

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis Varicella) Vaccine: What You Need to Know

on one side of the face or weeks. Its main pset stomach. \

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

in your body and can cause shingles later in life.

mation (

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chickenpox (varicella), MMRV is not licensed for red up. This long-

people 13 years of age or older. There are separate chickenpox vaccines. Your health care provider car ple, and the ri on in people as steroids or che

r in the United

Some people should not get this vaccine

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

2 MMRV Vaccine

First dose: 12 through 15 months of age

give you more information.

outbreak situations.

years of age. Two doses are usually recommended:

MMRV vaccine may be given to children 12 months through 12

A third dose of MMR might be recommended in certain mumps

There are no known risks to getting MMRV vaccine at the same

Instead of MMRV, some children 12 months

through 12 years of age might get 2 separate

shots: MMR (measles, mumps and rubella) and

Vaccine Information Statements for MMR and

- · 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
- cancer or HIV/AIDS) or medical treatments (such as radiation
- Has a history of seizures, or has a parent, brother, or sister
- · Has a parent, brother, or sister with a history of immune
- Has ever had a condition that makes them bruise or bleed Is pregnant or might be pregnant. MMRV vaccine should no
- · Is taking salicylates (such as aspirin). People should avoid



VACCINE INFORMATION STATEMENT

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

2 Shingles vaccine (recombinant) 1 Why get vaccinated?

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 rec

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

Varicella (Chickenpox) Vaccine: What You Need to Know

iojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

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 neonle with weakened immune syste

- Chickenpox causes an itchy rash that usually lasts about a week. It can also cause
- loss of appetite
 headache
- skin infections
- infection of the lungs (pne inflammation of blood wessels
- swelling of the brain and/or spinal cord coverings
- 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

Children who get chickenpox usually miss at least 5 or

Some people who get chickenpox get a painful rash called 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

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

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

Some people should not get this vaccine 3

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 chickenpox vaccine, or has a severe allerey 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
- · 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 · Has recently had a blood transfusion or received other
- blood products. You might be advised to postpone



There is a VIS for:

- RZV (Shingrix)
- Var (Varicella)
- MMRV (ProQuad)
- ZVL (Zostavax)
- Give the parent or patient the appropriate VIS for the product that will be administered

Varicella and Zoster Vaccine Resources and References

Resources and references are available on the webinar web page

COURSE RESOURCES

Epidemiology and Prevention of Vaccine-Preventable Diseases

Varicella

- Ask the Experts-Varicella FAQs: www.immunize.org/askexperts/experts var.asp
- CDC Varicella Disease and Vaccination: www.cdc.gov/chickenpox/hcp/index.html
- Chickenpox Infographic: www.cdc.gov/chickenpox/vaccine-infographic.html
- Standing Orders for Administering Varicella Vaccine:
 - Children and Teens: www.immunize.org/catg.d/p3080a.pdf
 - Adults: www.immunize.org/catg.d/p3080.pdf

Zoster

- Ask the Experts-Zoster FAQs: www.immunize.org/askexperts/experts zos.asp
- CDC Zoster Disease: www.cdc.gov/shingles/about/index.html
- CDC Zoster Vaccination: www.cdc.gov/vaccines/vpd/shingles/hcp/index.html
- Shingrix Fact Sheet: <u>www.cdc.gov/shingles/downloads/shingles-factsheet-hcp.pdf</u>
- Standing Orders for Administering Zoster Vaccine: www.immunize.org/catg.d/p3092.pdf