OREGON HEALTH AUTHORITY

IMMUNIZATION PROTOCOL FOR PHARMACISTS

Varicella (Varivax®) [1] MMRV (ProQuad ®)[2] and Zoster (Zostavax®) [3] vaccines

01-01-2016:

- Vaccination age changed to clients ≥7 years of age

I. OREGON IMMUNIZATION PHARMACY PROTOCOL:

1. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
2. Screen clients ≥7 years of age for contraindications to varicella-containing vaccine.
3. Screen clients ≥60 years for contraindications to zoster vaccine.
4. Provide a current Vaccine Information Statement (VIS) and answer any questions.
5. Record all required data elements in the client's permanent health record.
6. **Varivax® or ProQuad ®: Give** a single 0.5mL dose **SQ** according to recommendations and appropriate schedules.

OR

7. **Zostavax®**: Give **0.65mL** dose **SQ** according to recommendations and appropriate schedule.
8. Can administer varicella-containing vaccine simultaneously with all routine childhood and adult immunizations according to age and immunization status of recipient.
9. If varicella is not given simultaneously with another live virus vaccine, administer at least 28 days apart.
10. Do not give immune globulin, including VARIZIG® concurrently with varicella-containing vaccine. Check package inserts for guidance.
11. A PPD tuberculin skin test can be given simultaneously with varicella. If not given simultaneously see Section VI-C, page 8 for directions. [3]
12. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

Immunizing Pharmacist Signature Date

For multiple signatures see: *1.usa.gov/PharmacyImmunizationProtocols*

II. LICENSED VACCINES

II. A. LICENSE SINGLE-ANTIGEN VARICELLA VACCINE				
Product Name	**PFU***	**Vaccine Components**	**Acceptable Age Range**	**Thimerosal**
Varivax®◊	1,350	Reconstituted Live attenuated varicella virus	≥12 months of age	No
II. B. LICENSE VARICELLA COMBINATION VACCINE				
ProQuad®§§ ‡‡ (Merck)	9,772 PFU	Reconstituted Live attenuated: Measles§ Mumps‡ Rubella** Varicella◊◊	12 months–12 years	No
II. C. LICENSED SINGLE-ANTIGEN VARICELLA ZOSTER VACCINE				
Zostavax®***	19,400	Reconstituted Live attenuated varicella virus	≥60 years of age	No

*Plaque Forming Units[1, 2, 3]

◊Varivax® is a lyophilized preparation containing sucrose, phosphate, glutamate and processed gelatin as stabilizers.[1]

§ M-M-R® II contains a sterile, lyophilized preparation of ATTENUVAX®, a more attenuated line of measles virus, derived from Enders' attenuated Edmonston strain and grown in cell cultures of chick embryo.

‡MUMPSVAX®, the Jeryl Lynn strain of mumps virus, is grown in cell cultures of chick embryo.

**MERUVAX®, the Wistar RA 27/3 strain of live attenuated rubella virus, is grown in human diploid cell culture.

◊◊ Oka/Merck strain of varicella-zoster virus propagated in MRC-5 cells.

§§MMRV vaccine must be stored frozen at an average temperature ≤ 5°F (≤ 15°C) and the diluent should be stored separately at room temperature.

‡‡ MMRV, like Varicella vaccine, must be given within 30 minutes of reconstitution.

***Zostavax ® is a lyophilized preparation containing sucrose, phosphate, glutamate (MSG), neomycin, porcine gelatin and bovine calf serum. No preservatives.[3]

III. VACCINE SCHEDULE:

A. SCHEDULE FOR VARIVAX®

VARIVAX® Dose and Route: 0.5mL SQ			
1. VARIVAX® for Persons ≤13 years of age (2 doses):			
Dose	**Recommended Minimum Age*◊**		**Recommend Age**
1	12 months		12–15 months
2	15 months§		4–6 years
2. VARIVAX® for Persons ≥13 years of age (2 doses)			
Dose	**Minimum Spacing*◊**		**Recommended Age**
1			13 years
2	28 days		
3. VARIVAX® for Immunocompromised persons‡ (2 doses)			
Dose	**Recommended Minimum Age◊**	**Minimum Spacing*◊**	**Recommended Age**
1	12 months		15 months
2	15 months‡	3 months	

*For retrospective checking, doses that violate the minimum spacing or age by 4 or fewer days do not need to be repeated. However, live parenteral vaccines that are not administered simultaneously should be separated by at least 28 days. Simultaneous administration is defined as: two or more vaccines administered at the same visit or on the same day.[4]

◊When an invalid dose needs to be repeated, the repeat dose should be spaced after the invalid dose by at least 28 days.[4]

§While 15 months is the recommended minimum age for the 2nd dose (allowing for a 3 month interval between dose one and two), If the second dose is administered at least 28 days following the first dose, the second dose is considered valid and does not need to be repeated.[4]

‡With the consultation and written order from the personal physician, persons with impaired humoral immunity may now be immunized. Consider varicella vaccination for asymptomatic HIV-infected children with CD4 T-lymphocyte percentages ≥ 15%. These children should

receive 2 doses of vaccine with a 3- month interval between doses. Doses separated by <3 months are invalid for persons with altered immunocompetence. [4]

III. B. SCHEDULE FOR PROQUAD®

PROQUAD® Dose and Route: 0.5mL SC			
Dose	**Minimum Age**	**Minimum Spacing**	**Recommended Age§**
1*	12 months		12–15 months*
2◊§	15 months‡**	3 months from dose #1 to dose #2‡	4–6 years◊◊

* For the 1st dose of measles, mumps, rubella, and varicella vaccines at age 12–47 months, use MMR and varicella vaccines separately unless the parent or caregiver expresses a preference for MMRV. A personal or family history of seizures of any etiology is a precaution for MMRV vaccination (Section VII, pages 10–11)[5]

◊ MMRV is NOT recommended for persons with HIV infection regardless of degree of immunosuppression because it has not been studied in this population.[6, 7]

§ For the second dose of measles, mumps, rubella, and varicella vaccines (15 months–12 years) and for the 1st dose at age ≥48 months, use of MMRV generally is preferred over separate injections of its equivalent component vaccines. Considerations should include provider assessment, patient preference, and the potential for adverse events.[5]

‡MMRV may be used in children 12 months–12 years of age if a second dose of measles, mumps and rubella vaccine is to be administered and if no MMR is available at the time the second dose of MMR is indicated.[6]

**Although 15 months is the recommended minimum age for the 2nd dose (allowing for a 3-month interval between doses one and two), if the second dose is administered at least 28 days, with the first dose administered at age ≥12 months, following the first dose, the second dose is considered valid and does not need to be repeated.[8]

◊◊If MMRV is inadvertently given to a patient age 13 years and older, it may be counted towards completion of the MMR and varicella vaccine series and does not need to be repeated. [8]

III. C. SCHEDULE FOR ZOSTAVAX® VACCINE

Zoster Vaccine: 0.65mL SQ**			
Dose	**Minimum Age**	**Minimum Spacing**	**Recommended Age§**
1	≥60 years of age		

** Duration of protection beyond 5 years is uncertain. The need for revaccination has not been defined.[3]

IV. A. RECOMMENDATIONS FOR VARIVAX®:[4, 5, 7, 9, 10]

1. All children 12 months to 13 years of age without contraindications or evidence of varicella immunity (see immunity criteria Section V, page 7) should be vaccinated with two doses of varicella-containing vaccine.

- HIV-infected children ≥12 months of age in CDC clinical class N, A, or B with CD4+ T-lymphocyte counts ≥15% and without evidence of varicella immunity should receive two doses of **single antigen varicella** vaccine at a minimum interval of 3 months apart. (Must have written prescription from primary care provider for vaccine.)[4]
- HIV infected persons who are receiving regular doses of IGIV might not respond to varicella vaccine or MMR vaccine. Varicella and MMR vaccines should be considered 14 days before the next scheduled dose of IGIV.[4]
- HSCT: Physicians should assess the immune status of each recipient on a case-by-case basis and determine a risk for infection before using the vaccine. A 2–dose series of varicella should be administered 24 months after HSCT to varicella-seronegative patients with neither graft-versus-host disease (GVHD) nor ongoing immunosuppression and 8–11 months after the last dose of IGIV.[7]
- Antiviral Use: Antivirals should be discontinued at least 24 hours before administration of varicella-containing vaccine and delay resumption for at least 14 days after vaccination.[4]

2. All persons ≥13 years of age without contraindications or evidence of immunity should be vaccinated with two doses of Varicella vaccine, including these persons[9]:

- Persons who are susceptible due to no evidence of varicella immunity.
- Persons who have close contact with persons at high risk for serious complications, e.g.,
  a. Healthcare workers
  b. Family contacts of immunocompromised persons[4]

- Persons who live or work in environments where transmission of varicella zoster virus is likely, such as[9]
  a. Teachers
  b. Day care employees
  c. Residents and staff of institutional settings
  d. College students
  e. Inmates and staff of correctional institutions
  f. Military personnel
  g. Adolescents and adults who live in households with children
- Non-pregnant women of childbearing age. Women should be asked if they are pregnant and advised to avoid pregnancy for one month following each dose of vaccine.[5]
- Susceptible postpartum women. Upon completion or termination of a pregnancy, women who do not have evidence of varicella immunity should receive the 1st dose of varicella vaccine before discharge from the healthcare facility. The 2nd dose should be administered 4–8 weeks later (at the postpartum or other healthcare visit). [10]
- Susceptible international travelers.

3. **Outbreak Control**
   During a varicella outbreak, persons who have received one dose of varicella vaccine should receive a second dose, provided the appropriate vaccination interval has elapsed since the first dose: 3 months for persons aged 12 months through 12 years and at least 4 weeks for persons aged 13 years of age and older. [9]

IV. B. RECOMMENDATIONS FOR PROQUAD® [5]

•**For the first dose** of measles, mumps, rubella, and varicella vaccines at age 12--47 months, either measles, mumps, and rubella (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 MMR vaccine and varicella vaccine should be administered for the first dose in this age group.

•**For the second dose** of measles, mumps, rubella, and varicella vaccines at any age (15 months--12 years) **and for the first dose at age ≥48 months**, use of MMRV vaccine generally is preferred over separate injections of its equivalent component vaccines (i.e., MMR vaccine and varicella vaccine). Considerations should include provider assessment, patient preference, and the potential for adverse events.

•**A personal or family (i.e., sibling or parent) history of seizures of any etiology** is a precaution for MMRV vaccination. Children with a personal or family history of seizures of any etiology generally should be vaccinated with MMR vaccine and varicella vaccine.

IV. C. RECOMMENDATIONS FOR ZOSTAVAX® [11, 12]:

1. Adults ≥60 years of age whether or not they report a prior episode of herpes zoster.* ◊ §
   - Persons with chronic medical conditions may be vaccinated unless a contraindication or precaution exists for this condition.
   - Immunocompetent persons ≥60 years of age, without a history of zoster vaccination and anticipating initiation of immunosuppressive treatment, should receive 1 dose of zoster vaccine at the first possible clinical encounter while their immunity is intact. Zoster vaccine should be administered at least 14 days before initiation of immunosuppressive therapy, although some experts advise waiting 1 month after zoster vaccination to begin immunosuppressive therapy if delay is possible.[11]

* Zostavax® is not indicated for the treatment of zoster or post–herpetic neuralgia (PHN).

◊ Zoster vaccine can be administered with other indicated vaccines during the same visit. (e.g., Td, Tdap, PCV–13 or PPSV23 and Influenza).

§ Although the safety and efficacy of zoster vaccine has not been assessed in persons with a history of zoster, different safety concerns are not expected in this group.

V. EVIDENCE OF VARICELLA IMMUNITY[13]: Any of the following:

A. Documentation of age-appropriate vaccination:
   1. Preschool-aged children ≥12 months of age: one dose
   2. School aged children, adolescents, and adults: two doses *

B. Laboratory evidence of immunity ◊

C. Born in the US before 1980 §

D. A healthcare provider diagnosis of varicella or healthcare provider verification of history of varicella disease ‡

E. History of herpes zoster based on healthcare provider diagnosis

* For children who have received their first dose before age 13 years with an interval between the two doses of at least 28 days, the second dose is considered valid.[4]

◊Commercial assays can be used to assess disease-induced immunity, but they lack adequate sensitivity to detect reliably vaccine-induced immunity (may be false negative).[13]

§For healthcare providers and pregnant women, birth before 1980 should not be considered evidence of immunity.[13]

‡Verification of history (by parent or adult report) or diagnosis of typical disease can be done by any healthcare provider. For those with history of atypical or mild disease, assessment by a physician is recommended, accompanied by:

a) epi link to varicella case or
b) evidence of lab confirmation at time of acute disease. When such documentation is lacking, a person should not be considered as having a valid history of disease, because other diseases may mimic atypical varicella.[9, 13]

VI. CONTRAINDICATIONS: Varivax® Proquad® and Zostavax®

A. Allergies to vaccine components:
Do not give a varicella-containing vaccine to any person with a history of anaphylactic reaction (hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) to the vaccine or an excipient of the vaccine, e.g., gelatin or neomycin. However, contact dermatitis reaction to neomycin is not a contraindication.[2, 3, 13]

C. Varicella-containing vaccine is not recommended for persons who have untreated active tuberculosis.[4] However, TB skin testing (TST) is not required prior to administering varicella vaccine.

- A TST may be given before varicella vaccine is administered or on the same day.
- If a TST is needed after varicella vaccine has been given, wait ≥ 4 weeks to place a TST. Varicella vaccine may temporarily suppress reactivity to a tuberculin test, resulting in falsely negative results.[4, 13]

D. Do not give a varicella-containing vaccine to individuals with immunosuppression due to: [9]

- Leukemia[13]
- Lymphoma or generalized malignancy[13]
- Immune deficiency disease[13]
- Immunosuppressive therapy (e.g., large daily doses of steroids)*◊ [4, 13]
- Cellular immunodeficiency; except those with isolated humoral immunodeficiency (e.g., hypogammaglobulinemia and agammaglobulinemia) may be vaccinated.[13]
- HIV infection or AIDS diagnosis or other clinical manifestations of HIV infections[13§]

E. Pregnancy: [9]

- Do not vaccinate pregnant women with a varicella-containing vaccine.
- Non-pregnant women being vaccinated should avoid becoming pregnant for 4 weeks following each dose.
- If a pregnant woman is inadvertently vaccinated, this administration should be reported to VAERS.
- The manufacturer, in collaboration with CDC, has established a Varicella Vaccination in Pregnancy registry to monitor the maternal-fetal outcomes of pregnant women inadvertently given varicella vaccine. The telephone number for the Registry is 800-986-8999.[9]

* Treatment with <2mg/kg/day, alternate day, topical, replacement, or aerosolized steroid preparations is not a contraindication to varicella-containing vaccine.[9]

◊ Persons whose immunosuppressive therapy with steroids has been discontinued for 1 month (3 months for chemotherapy) may be vaccinated.[9]

§ Vaccination should be considered for children with asymptomatic or mildly symptomatic HIV infection (CDC class N, A. or B with CD4+ T-lymphocyte counts of ≥15%). They should receive 2 doses of varicella vaccine separated by 3 months.[9]

VII. PRECAUTIONS AND WARNINGS

A. Receipt of blood products: [1, 2, 3, 9, 4]

- Varicella vaccines should not be administered for 3--11 months, (depending on the dosage and content of IG), after administration of blood (except washed red blood cells), plasma, or IG. [13] See Section VII F on page 12.[14]

- Immune globulin should not be given for 3 weeks following vaccination unless the benefits exceed those of the vaccine. In such cases, the vaccinees should either be revaccinated or tested for immunity at least 3 months later (depending on the antibody-containing product administered) and revaccinated if seronegative.[9]

B. Family History of Immunodeficiency[1]:

- Vaccination with varicella-containing vaccine should be deferred in patients with a family history of congenital or hereditary immunodeficiency until the patient's immune status has been evaluated and the patient has been found to be immunocompetent.[9, 13]

C. **Transmission of varicella-containing vaccine virus**[1] may occur rarely between healthy vaccinees who develop a varicella-like rash and healthy susceptible contacts. Transmission of vaccine virus from a mother who did not develop a varicella-like rash to her newborn infant has been reported.
Vaccinated persons with varicella with <50 lesions were only one third as contagious as unvaccinated persons with varicella. However, vaccinated persons with varicella who had ≥50 lesions were as contagious as unvaccinated persons with varicella. Vaccinated persons with varicella tend to have milder disease, and, although they are less contagious than unvaccinated persons with varicella, they might not receive a diagnosis and be isolated.[13]
Due to the concern for transmission of varicella-containing vaccine virus, vaccine recipients should attempt to avoid whenever possible close association with susceptible high-risk individuals.
Susceptible high-risk individuals include:
- Immunocompromised individuals;
- Pregnant women without documented history of varicella or laboratory evidence of prior infection;
- Newborn infants of mothers without documented history of varicella or laboratory evidence of prior infection and all newborn infants born at <28 weeks gestation regardless of maternal varicella immunity.

D. **Salicylate Therapy**[1]**:** Avoid use of salicylates (aspirin) or salicylate-containing products in children and adolescents 12 months through 17 years of age for six weeks[13] following vaccination with varicella-containing vaccine because of the association of Reye syndrome with aspirin therapy and wild-type varicella infection.

E. Defer a varicella-containing vaccination during moderate or severe acute illness. Minor illnesses: such as otitis media, upper respiratory infection, diarrhea, or concurrent antibiotic therapy are NOT contraindications to varicella vaccine. Routine physical exams or routine temperature taking are not prerequisites for vaccinating children who appear to be in good health.[13]

VII. F. Recommended intervals between administration of antibody–containing products and measles–containing or varicella–containing vaccine[14]

Product / Indication	Dose, including mg immunoglobulin G (IgG)/kg body weight	Recommended interval before measles or varicella-containing[1] vaccine administration
Blood transfusion		
- Red blood cells (RBCs), washed	10 mL/kg (negligible IgG/kg) IV	None
- RBCs, adenine-saline added	10 mL/kg (10 mg IgG/kg) IV	3 months
- Packed RBCs (hematocrit 65%)[2]	10 mL/kg (60 mg IgG/kg) IV	6 months
- Whole blood (hematocrit 35%-50%)[2]	10 mL/kg (80-100 mg IgG/kg) IV	6 months
- Plasma/platelet products	10 mL/kg (160 mg IgG/kg) IV	7 months
Botulinum Immune Globulin Intravenous (Human)	1.5 mL/kg (75 mg IgG/kg) IV	6 months
Cytomegalovirus IGIV	150 mg/kg maximum	6 months
Hepatitis A IG		
- Contact prophylaxis	0.02 mL/kg (3.3 mg IgG/kg) IM	3 months
- International travel	0.06 mL/kg (10 mg IgG/kg) IM	3 months
Hepatitis B IG (HBIG)	0.06 mL/kg (10 mg IgG/kg) IM	3 months
IGIV		
- Replacement therapy for immune deficiencies[3]	300-400 mg/kg IV	8 months
- Immune thrombocytopenic purpura treatment	400 mg/kg IV	8 months
- Measles IG, contact prophylaxis (immunocompromised contact)	400 mg/kg IV	8 months
- Postexposure varicella prophylaxis	400 mg/kg IV	8 months
- Immune thrombocytopenic purpura treatment	1,000 mg/kg IV	10 months
Measles IG, contact prophylaxis - Standard (i.e., nonimmunocompromised) contact	0.5 mL/kg (80 mg IgG/kg) IM	6 months
Monoclonal antibody to respiratory syncytial virus F protein (Synagis™)[4]	15 mg/kg (IM)	None
Rabies IG (RIG)	20 IU/kg (22 mg IgG/kg) IM	4 months
Tetanus IG (TIG)	250 units (10 mg IgG/kg) IM	3 months
Varicella IG[5]	125 units/10 kg (60-200 mg IgG/kg) IM, maximum 625 units	5 months
Kawasaki disease	2gm/kg IV	11 months[14]

Footnotes:

This table is not intended for determining the correct indications and dosages for using antibody-containing products. Unvaccinated persons might not be fully protected against measles during the entire recommended interval, and additional doses of IG or measles vaccine might be indicated after measles exposure. Concentrations of measles antibody in an IG preparation can vary by manufacturer's lot. Rates of antibody clearance after receipt of an IG preparation also might vary. Recommended intervals are extrapolated from an estimated half-life of 30 days for passively acquired antibody and an observed interference with the immune response to measles vaccine for 5 months after a dose of 80 mg IgG/kg.

1. Does not include zoster vaccine. Zoster vaccine may be given with antibody-containing blood products.
2. Assumes a serum IgG concentration of 16 mg/mL.
3. Measles vaccination is recommended for children with mild or moderate immunosuppression from human immunodeficiency virus (HIV) infection, and varicella vaccination may be considered for children with mild or moderate immunosuppression from HIV, but both are contraindicated for persons with severe immunosuppression from HIV or any other immunosuppressive disorder.
4. Contains antibody only to respiratory syncytial virus.
5. Licensed VariZIG is a purified human IG preparation made from plasma containing high levels of anti-varicella antibodies (IgG).

Adapted from Table 5, ACIP General Recommendations on Immunization[6]

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/mmr_ig.pdf

IX. A. SIDE EFFECTS AND ADVERSE EVENTS[1]: Fever, Local Reactions, and Rashes (%) in Children 1 to 12 Years of Age

0 to 42 Days After Receipt of a Single dose of VARIVAX[1].

Number followed for Safety Age in Years	Varivax® N =8827 Adverse Reaction % 1–12	Varivax® N=8916 Adverse Reaction % 1–12	Peak Occurrence During Postvaccination Days 0–42
Local Reaction, Injection site			
Pain Redness Swelling Rash Hematoma Itching Induration Stiffness		19.3	0–2
Systemic Complaints			
Fever ≥102.0°F (38.9°C) oral	14.7		0–42
Varicella –like rash (injection site)		3.4	8–19
Median number of lesions		2	
Varicella–like rash (generalized)		3.8	5–26
Median number of lesions		5	
Table 1, page 4 of Varivax® package insert			

IX. B. SIDE EFFECTS AND ADVERSE EVENTS[1]: Fever, Local Reactions, and Rashes (%) in Adolescents 13 Years of Age and Adults 0 to 42 Days After Receipt of 2 doses of VARIVAX[1].

Number followed for Safety Age in Years	Varivax® N =1584 Adverse Reaction % ≥13 years	N=1606 %	Peak Occurrence During Postvaccination Days 0–42	Varivax® N=956 Adverse Reaction % ≥13 years	N=955 %	Peak Occurrence During Postvaccination On Days 0–42
	Post Dose 1			Post Dose 2		
Local Reaction, Injection site						
Pain, Redness Swelling, Hematoma Rash, Itching Induration Stiffness		24.4	0–2		32.5	0–2
Systemic Complaints						
Fever ≥102.0°F (38.9°C) oral	10.2		14–27	9.5		0–42
Varicella –like rash (injection site)		3	6-20		1	0–6
Median number of lesions		2			2	
Varicella–like rash (generalized)		5.5	7–21		0.9	0–23
Median number of lesions		5			5.5	
Table 2, page 5 of Varivax® package insert						

IX. C. SIDE EFFECTS AND ADVERSE EVENTS[2]: Vaccine-related Injection-site and Systemic Adverse Reactions Reported in ≥1% of Children Who Received ProQuad[2] Dose 1 or MMRII and Varivax[1] at 12 to 23 months of age (0 to 42 Days Postvaccination)

	ProQuad®[2]	M-M-R II® and Varivax®[1]
	N =4497 n=4424	N=2013 n=1997
	Adverse Reaction %	Adverse Reaction %
Number followed for Safety Age in Months	12–23	12–23
Local Reaction, Injection site*		
Pain, Tenderness, Soreness◊	22.0	26.7
Erythema◊	14.4	15.8
Swelling◊	8.4	9.8
Ecchymosis	2.3	1.5
Rash	2.3	1.5
Systemic Complaints		
Fever◊ § ≥102.0°F (38.9°C) oral	21.5	14.9
Irritability	6.7	6.7
Measles–like rash◊	3.0	2.1
Varicella –like rash◊	2.1	2.2
Rash (not otherwise specified)	1.6	1.4
Upper Respiratory Infection	1.3	1.1
Viral exanthema	1.2	1.1
Diarrhea	1.2	1.3

* Injection-site adverse reactions for M-M-R II and VARIVAX are based on occurrence with either of the vaccines administered.

◊ Designates a solicited adverse reaction. Injection-site adverse reactions were solicited only from Days 0 to 4 postvaccination.

§ Temperature reported as elevated (≥102°F, oral equivalent) or abnormal.

N = number of subjects vaccinated.

n = number of subjects with safety follow-up.

ProQuad® package insert, table 1, page 5–6.

IX. D. SIDE EFFECTS AND ADVERSE EVENTS[3]: Fever, Local Reactions, and Rashes (%) in Adults ≥60 (59–99) years of age 0 to 42 Days After Receipt of a Single dose of ZOSTAVAX®

Number followed for Safety	Zostavax® N =3345 Adverse Reaction % Post Dose 1	Placebo N=3271 %
Age in Years	≥60 years	
Local Reaction, Injection site		
Pain – Tenderness	34.3	8.3
Redness	35.6	6.9
Swelling	26.1	4.5
Hematoma	1.6	1.4
Itching	6.9	1.0
Warmth	1.6	0.3
Headache	1.4	0.8
Fever ≥101.0°F (38.3°C) oral	0.8	0.9
Varicella–like rash	3	7
Table 3, page 6 of Zostavax® package insert		

X. OTHER CONSIDERATIONS

1. **Adverse Events**: epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.[4]
2. **Military Personnel:** If an adult has a record of military service and does not have records available, providers can assume that the person has received all vaccines recommended by the military at the time of service entry. Serologic testing might be helpful in clarifying immune status if questions remain because at different times and depending on military assignments, there might be interservice and individual differences.[4]
3. **Immunocompromised**: individuals with altered immunocompetence may have reduced immune responses.[1, 2, 3]
4. **Lactation:** Varicella vaccine virus has not been found in human milk.[4]
5. **Serologic Screening:** is available through the Oregon State Public Health Laboratory. To check their fees and procedure for submitting specimens, see www.healthoregon.org/labtests (12-2015)
6. **Pregnancy:** Assess pregnant women for evidence of varicella immunity. Women who don't have immunity should receive varicella vaccine **upon completion or termination of pregnancy.**[5]
7. **HIV–infected persons:** Because persons with impaired cellular immunity are potentially at greater risk for complications after vaccination with a live vaccine, these vaccine recipients should be encouraged to return for evaluation if they experience a postvaccination varicella-like rash.[13]
8. **Salicylates:** While no adverse events following varicella vaccination related to the use of salicylates (e.g., aspirin) have been reported to date, the manufacturer recommends that vaccine recipients avoid using salicylates for 6 weeks after receiving varicella vaccine because of the association between aspirin use and Reye syndrome following chickenpox.[5]
9. **Internationally adopted children:** ACIP recommends age-appropriate vaccination of children who lack a reliable history of previous varicella disease.[15] See Section V Page 7 for acceptable evidence of immunity.
10. **Postexposure Prophylaxis with Vaccine:**
    A. Should HIV-infected children be exposed to varicella, they may now be considered for post-exposure immunization. Their contacts should be referred to their physician for evaluation.

B. A 2-dose series of VAR should be administered 24 months after HSCT to varicella-seronegative patients with neither Graft-Versus-Host-Disease nor ongoing immunosuppression and 8–11 months after the last dose of IGIV.[7]

C. Exposure of immunocompromised persons:

1. Vaccinees in whom vaccine-related rash develops, particularly healthcare workers and household contacts of immunocompromised persons, should avoid contact with susceptible persons who are at high risk for severe complications.[9, 13]

2. If a susceptible, immunocompromised person is inadvertently exposed to a person who has a vaccine-related rash, consider use of VariZIG Immune Globulin. See #11 B. below.[16]

11. Postexposure Prophylaxis with VariZIG Immune Globulin:[16]

A. Varicella Immune Globulin, VariZIG® is now approved for administration as soon as possible following varicella-zoster virus exposure, ideally within 96 hours (4 days) for greatest effectiveness; and within 10 days of exposure.

B. Patients without evidence of immunity to varicella who are at high risk for severe varicella and complications, who have been exposed to varicella or herpes zoster, and for whom **varicella vaccine is contraindicated,** should receive VariZIG. Patient groups recommended by CDC to receive VariZIG include the following:

- Immunocompromised patients without evidence of immunity.
- Newborn infants whose mothers have signs and symptoms of varicella around the time of delivery (i.e., 5 days before to 2 days after).
- Hospitalized premature infants born at ≥28 weeks of gestation whose mothers do not have evidence of immunity to varicella.
- Hospitalized premature infants born at <28 weeks of gestation or who weigh ≤1,000 g at birth, regardless of their mothers' evidence of immunity to varicella.
- Pregnant women without evidence of immunity.

XI. STORAGE AND HANDLING

All clinics and pharmacies enrolled with the VFC program must immediately report any storage and handling deviations to their Oregon Immunization Program health educator. The health educator assignment map is located at: http://bit.ly/HE_Map

Vaccine	Temp	Storage Issues*	Notes
Varivax® 1	−58°F and +5°F (−50°C and −15°C).	Lyophilized powder must be stored in a freezer with a separate freezer door. Lyophilized powder may be stored at refrigerator temperature (36°F to 46°F, 2°C to 8°C) for up to 72 continuous hours prior to reconstitution. Store diluent separately at room temperature or in the refrigerator at (36°F to 46°F, 2°C to 8°C).	Vaccine stored at 2°C to 8°C which is not used within 72 hours of removal from +5°F (−15°C) storage should be discarded. Protect from light. Must be given within 30 minutes of reconstitution or discarded.
ProQuad® 2	Store at -50°C–-15°C (-58˚F–+5˚F)	Do not use dry ice. Diluent may be stored in refrigerator or at room temperature (do not freeze diluent). ProQuad® vaccine powder may be stored at refrigerator temperature for up to 72 hours prior to reconstitution. Discard any ProQuad® vaccine powder stored at 36˚F–46˚F which is not used in 72 hours of removal from 5°F (-15°C) storage.	**If not used immediately** may be stored at room temperature and protected from light for up to 30 minutes. **Discard vaccine if** not used within 30 minutes of reconstitution. **Do not freeze reconstituted vaccine**

*Use of dry ice may subject frozen–formula varicella–containing vaccines to temperatures colder than −58°F (−50°C).

Vaccine	Temp	Storage Issues*	Notes
Zostavax® [3]	−58°F and +5°F (−50°C and −15°C).	Lyophilized powder must be stored in a freezer with a separate freezer door. Lyophilized powder may be stored or transported at refrigerator temperature (36°F to 46°F, 2°C to 8°C) for up to 72 continuous hours prior to reconstitution. Store diluent separately at room temperature or in the refrigerator at (36°F to 46°F, 2°C to 8°C).	Vaccine stored at 2°C to 8°C which is not used within 72 hours of removal from +5°F (−15°C) storage should be discarded. Protect from light. Must be given within 30 minutes of reconstitution or discarded.

*Use of dry ice may subject frozen–formula varicella–containing vaccines to temperatures colder than −58°F (−50°C).

XII. ADVERSE EVENTS REPORTING (pharmacy protocols)

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS). The VAERS online report form is available at https://vaers.hhs.gov/esub/step1.

A pharmacist who administers any vaccine must report to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A pharmacist is not required to notify the primary health care provider. Oregon Administrative Rule 855-019-0290-(2)(3).[17, 18]

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971.673.0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this protocol available at:
1.usa.gov/PharmacyImmunizationProtocols

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