OREGON STATE PUBLIC HEALTH DIVISION, DHS
IMMUNIZATION PROGRAM

VARICELLA
Live Virus Vaccine
AND
MEASLES, MUMPS, RUBELLA and VARICELLA VACCINE (MMRV)

Revisions as of 4/07:

- Updated Recommendations For Use (Section III, p. 3) to include all children, adolescents, and adults to receive a two–dose varicella vaccine series unless they have contraindications to the vaccine or evidence of immunity to the disease.
- HIV infected children ≥12 months of age who meet the criteria for varicella vaccine (Section III-A) should only receive single antigen varicella vaccine.
- On page 4 the recommended minimum age for a 2nd varicella dose changed to 15 months, and the 1st Varicella dose is now recommended for 12-15 months of age.
- On page 4 the 1st dose of MMRV (ProQuad®) is recommended for 12-15 months.
- Updated definition for Evidence of Varicella Immunity (Section VII–K, p.10).

I. ORDER:

1. Screen for contraindications and evidence of immunity (Section VII–K.)
2. Provide a current Vaccine Information Statement (VIS), answering any questions.
3. Obtain a signed Vaccine Administration Record (VAR).
4. Give varicella-containing vaccine (0.5 ml) **subcutaneously**, to persons at least 12 months of age.
    a. Can administer varicella-containing vaccine simultaneously with all routine childhood and adult immunizations according to age and immunization status of recipient.
    b. If varicella is not given simultaneously with MMR, administer at least 28 days apart.
    c. A PPD tuberculin skin test can be given simultaneously with varicella. If not given simultaneously see Section V-C for directions.

VACCINE MUST BE GIVEN WITHIN 30 MINUTES ONCE IT IS RECONSTITUTED. IF VACCINE IS DISCARDED OR OTHERWISE WASTED, THE AGENCY WILL BE CHARGED.

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Signature Health Officer or Medical Provider Date

II. A. LICENSED SINGLE-ANTIGEN VARICELLA VACCINE			
Product Name	**Vaccine Components**	**Acceptable Age Range**	**Thimerosal**
VARIVAX®[1,2,3] (Merck)	Live, attenuated varicella virus	≥12 months	No
II. B. LICENSED COMBINATION MMR AND VARICELLA VACCINE			
ProQuad®[2,3,4] (Merck)	Live combination vaccine containing measles, mumps, rubella and varicella viruses	12 months –12 years	No

[1] Varivax is a lyophilized preparation containing sucrose, phosphate, glutamate (MSG), and processed gelatin as stabilizers.
[2] To maintain potency, vaccine must be kept frozen at an average temperature of -15°C (+5°F) or colder.
[3] Must be given within 30 minutes once either vaccine is reconstituted.
[4] Diluent should be stored separately at room temperature.

III. RECOMMENDATIONS FOR USE:

A. All children 12 months to 13 years of age without contraindications or evidence of varicella immunity (immunity criteria on p.10-Section VII-K) 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.)

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

- 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.,
  - Healthcare workers
  - Family contacts of immunocompromised persons
- Persons who live or work in environments where transmission of varicella zoster virus is likely, such as
  - Teachers of young children
  - Day care employees
  - Residents and staff of institutional settings
  - College students
  - Inmates and staff of correctional institutions
  - Military personnel
  - 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.
- 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).
- Susceptible international travelers.

C. Outbreak Control

During an outbreak, persons ≥13 years of age who have received 1 dose of varicella vaccine should receive a 2nd dose, provided 28 days have elapsed since the 1st dose. (3 months recommended between the two doses for people 12 months through 12 years of age).

IV. A. SCHEDULE FOR SINGLE-ANTIGEN VARICELLA VACCINE

Dose and Route: 0.5 ml SC

1. Varicella Vaccine for Persons ≤13 years of age (2 doses):

Dose	Recommended Minimum Age[1,2]	Recommended Age
1	12 months	12–15 months
2	15 months[3]	4–6 years

2. Varicella Vaccine for Persons ≥13 years of age (2 doses):

Dose	Minimum Spacing[1,2]	Recommended Age
1		13 years
2	28 days	

3 Varicella Vaccine for Immunocompromised persons[4] (2 doses):

Dose	Recommended Minimum Age[2]	Minimum Spacing[1,2]	Recommended Age
1	12 months		15 months
2	15 months[3]	3 months	

[1]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.

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

[3]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.

IV. B. SCHEDULE FOR COMBINATION VARICELLA, MEASLES, MUMPS, AND RUBELLA VACCINE (MMRV)[1,2]

Dose and Route: 0.5 ml SC			
Dose	**Recommended Minimum Age**	**Recommended Spacing**	**Recommended Age**
1	12 months		12–15 months
2[3]	15 months[4]	3 months from dose #1 to dose #2[4]	4–6 years

[1] This varicella-containing vaccine can be administered to children 12 months through 12 years of age as the first or second dose of the two dose varicella series recommended as part of the routine childhood immunization schedule. MMRV (ProQuad®) is not licensed for persons ≥13 years of age.

[2]MMRV is not recommended or approved for individuals with HIV infection.

[3] For those children who are 12 months of age or older for whom additional protection from varicella disease is desired in response to an outbreak, a second dose may be administered if 28 days have elapsed since first dose.

[4] While 15 months is the recommended minimum age for the 2nd dose (allowing for a 3 month recommended spacing 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.

V. CONTRAINDICATIONS AND PRECAUTIONS

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 a constituent of the vaccine, e.g., gelatin or neomycin. (Contact dermatitis reaction to neomycin is not a contraindication.)

B. 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.

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

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

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

- Leukemia
- Lymphoma
- Generalized malignancy
- Immune deficiency disease
- Immunosuppressive therapy (e.g., steroids)[1,2]
- Cellular immunodeficiency; except those with isolated humoral immunodeficiency (e.g., hypogammaglobulinemia and agammaglobulinemia) may be vaccinated.
- HIV infection or AIDS diagnosis[3]

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

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

[3] 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.

V. CONTRAINDICATIONS AND PRECAUTIONS, continued

E. Receipt of blood products:

- Delay the administration of a varicella-containing vaccine for 3–11 months following the receipt of blood products (e.g., immune globulin, whole blood or packed red blood cells, plasma transfusions, intravenous immune globulin or varicella zoster immune globulin).
- Immune Globulins such as IGIV and VZIG should not be administered for 3 weeks after vaccination unless the benefits exceed those of vaccination. In such cases, either re-vaccinate the individual; or test for immunity 3 months later, and re-vaccinate if seronegative.

F. Pregnancy:

- 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: Report vaccination to VARIVAX Pregnancy Registry at 1-800-986-8999

VI. SIDE EFFECTS AND ADVERSE EVENTS*

Table A: **Adverse events reported 0-42 days post-vaccination in 12-23 month old children receiving MMRII®, Varivax® or ProQuad®**

	MMRII® and VARIVAX®	ProQuad®
	N=2038	N= 4497
Adverse Events	%	%
Injection Site[1]		
Pain/tenderness	26.7	22.0
Erythema[2]	15.8	14.4
Swelling[2]	9.8	8.4
Ecchymosis	2.3	1.5
Rash	1.5	2.3
Systemic		
Fever ≥ 102°F (≥ 38.9°C)	14.9	21.5
Irritabililty	6.7	6.7
Measles-like rash	2.1	3.0
Varicella-like rash	2.2	2.1
Rash (not otherwise specified)	1.4	1.6
Upper respiratory infection	1.1	1.3
Diarrhea	1.3	1.2

[1]Injection-site adverse reactions for MMRII® and VARIVAX® are based on occurrence with either of the vaccines administered.
[2]Injection-site adverse events solicited only from Days 0-4 post-vaccination.

Source: ProQuad 2005 package insert, pg.8

Table B: **Persons ≥13 years of age receiving Varicella Vaccine**

Event	**Frequency***
Soreness, pain, swelling, erythema, rash, pruritus, Hematoma, induration and stiffness	24 % (dose 1) 33 % (dose 2)
Fever (≥100°F orally)	10 % (dose1) 0 % (dose 2)
Non-localized, varicella-like rash consisting of about 5 lesions, occurring about 7-21 days after vaccination with dose one, and 0-23 days following the second dose.	4-6% (dose1) 1 % (dose2)
A varicella-like rash at the injection site consisting of about 2 lesions, occurring about 6-20 days after vaccination with dose one, and 0-6 days following the second dose.	3 % (dose 1) 1 % (dose 2)

* List is from ACIP and package insert

VII. OTHER CONSIDERATIONS

A. Herpes zoster following vaccination: The VAERS rate of herpes zoster after vaccination in healthy children is approximately 2.6/100,000 vaccine doses distributed. Herpes zoster has been reported in adult vaccinees, resulting in an incidence of 12.8/100,000 person-years. All the vaccinees' illnesses were mild, and without complications.

B. For someone with a history of fainting with injections, a 15-minute observational period is recommended post immunization.

C. Breastfeeding is not a contraindication to receiving a varicella-containing vaccine.

D. Serologic screening of persons over 13 years of age who have a negative or unreliable history of varicella is likely to be cost-effective. Serologic screening is available through the Oregon State Public Health Laboratory with the following fee structure: Requests from county health departments are $10.00 each (fee subject to change), and from private providers are $20.30 each (fee subject to change). Check here for most up-to-date-charges. http://www.oregon.gov/DHS/ph/phl/docs/quikref.pdf

E. Postexposure prophylaxis
- Varicella-containing vaccine administered within 72 hours after exposure, and perhaps as long as 5 days following exposure, can be useful in preventing clinical varicella in susceptible healthy persons (at least 90% efficacy in preventing infection).
- 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.

F. Exposure of immunocompromised persons:
- Healthy persons in whom varicella-like rash develops following vaccination have a minimal risk for transmitting the vaccine virus to their close contacts (e.g., family members).
- 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.
- If a susceptible, immunocompromised person is inadvertently exposed to a person who has a vaccine-related rash, Varicella Zoster Immune Globulin (VZIG) does not need to be administered. Please consult your health officer or medical provider for direction.

Cont.

OTHER CONSIDERATIONS, continued

G. Pregnant women: Assess pregnant women for evidence of varicella immunity. Women who don't have immunity should receive varicella vaccine **upon completion or termination of pregnancy.**

H. Vaccinating HIV-infected persons
- When HIV-infected persons are immunized with varicella vaccine they should be encouraged to watch for a rash and to notify their healthcare provider if they develop one.

I. 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.

J. Internationally adopted children:
ACIP recommends age-appropriate vaccination of children who lack a reliable history of previous varicella disease.

K. Evidence of varicella immunity: Any of the following:
1. Documentation of age-appropriate vaccination:
   a) Preschool-aged children ≥12 months of age: one dose
   b) School aged children, adolescents, and adults: two doses[1]
2. Laboratory evidence of immunity[2]
3. Born in the US before 1980[3]
4. A healthcare provider diagnosis of varicella or healthcare provider verification of history of varicella disease[4]
5. History of herpes zoster based on healthcare provider diagnosis

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[1] 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.

[2]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)

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

[4]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.

VIII. POSTEXPOSURE PROPHYLAXIS OF VARICELLA

- **VariZIG,** similar to the recently discontinued VZIG, is a purified human immune globulin preparation made from plasma containing high levels of anti-varicella antibodies. **VariZIG is currently under an Investigational New Drug (IND) Protocol**.
- ACIP recommends that these high-risk individuals, exposed to varicella, receive VariZig:
  1. Immunocompromised patients
  2. Neonates whose mothers develop signs and symptoms of varicella around time of delivery (5 days before to 2 days after)
  3. Premature infants born at ≥ 28 weeks of gestation who are exposed during the neonatal period and whose mothers do not have evidence of immunity
  4. Premature infants born < 28 weeks of gestation or who weigh ≤ 1,000 g at birth and were exposed during the neonatal period, regardless of maternal history of varicella disease or vaccination
  5. Pregnant women

Further information about administration, dosage, and procedure for acquiring informed consent before receiving product is available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5508a5.htm.

IX. ADVERSE EVENT REPORTING

Adverse events following immunization should be reported by public providers to the State Public Health Immunization Program, using a Vaccine Adverse Events Reporting System form (VAERS), according to state guidelines. Private providers report all adverse events directly to VAERS. The VAERS phone number is: (800) 822-7967, and the website address is: http://vaers.hhs.gov

X. REFERENCES

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2. Varicella Zoster Infection. In: Pickering LK, ed. *Red Book: 2003 Report of the Committee on Infectious Diseases*. 26th ed. Elk Grove Village, IL: American Academy of Pediatrics: 2003: 672-86.
3. CDC. ACIP Provisional Recommendations for Prevention of Varicella. June 2006. Available at: http://www.cdc.gov/nip/vaccine/varicella/varicella_acip_recs_prov_june_2006.pdf
4. CDC. Prevention of Varicella-Provisional Updated ACIP Recommendations for Varicella Vaccine Use; 11/05. Available at: http://www.cdc.gov/nip/vaccine/varicella/varicella_acip_recs.pdf
5. CDC. Licensure of a Combined Live Attenuated Measles, Mumps, Rubella, and Varicella Vaccine. MMWR 2005; 54 (47): 1212-14.
6. General Recommendations on Immunization. MMWR 2002; 51 (RR-2) Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5102.pdf.
7. Prevention of Varicella; MMWR 1999; 48, (RR-6). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr4806.pdf.
8. ProQuad® package insert. 10/05

For more information or to clarify any part of the above order, consult with your health officer or contact the Oregon State Public Health Immunization Program at 971-673-0300.

To download this order visit our website at:
http://oregon.gov/dhs/ph/imm/provider/stdgordr.shtml
To request this material in an alternate format (e.g., braille), please call 971-673-0300.