IMMUNIZATION PROTOCOLS FOR PHARMACISTS

VARICELLA
Live Virus Vaccine

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 vaccine (0.5 ml) **subcutaneously**, to persons at least 12 months of age.
    a. Can administer varicella vaccine simultaneously with all routine adolescent 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, delay PPD for at least 4 weeks. (see Section V-C for details).

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

_____

Pharmacist signature Date

Electronic copy of this protocol available at
http://www.oregon.gov/DHS/ph/imm/provider/pharmpro.shtml
To request material in an alternate format (e.g. Braille), call (971) 673-0300.

Original provided courtesy of the Oregon Department of Human Services, Immunization Program
May 2006

II. 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

[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 vaccine is reconstituted.

III. RECOMMENDATIONS FOR USE:

A. Adolescents and Adults ≥ 18 years of age

- Susceptible due to no evidence of varicella immunity.
- Susceptible persons who have close contact with persons at high risk for serious complications should be immunized.
  - Healthcare workers
  - Family contacts of immunocompromised persons
- Susceptible persons who live or work in environments where transmission of varicella zoster virus is likely should be immunized.
  - 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
- Susceptible 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.

B. Outbreak Control

During an outbreak, persons who have received 1 dose of varicella vaccine should, resources permitting, receive a 2nd dose, provided 28 days have elapsed since the 1st dose.

IV. SCHEDULE FOR SINGLE-ANTIGEN VARICELLA VACCINE

Dose and Route: 0.5 ml SC

1. Varicella Vaccine for Susceptible Persons ≥18 years of age (2 doses)

Dose	Minimum Spacing[1,2]	Recommended Spacing
1		
2	28 days	4-8 weeks

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

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

[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] With the consultation and written order from the personal physician, persons with impaired humoral immunity may now be immunized.

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.

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]
- HIV infection or AIDS diagnosis
- Cellular immunodeficiency; except those with isolated humoral immunodeficiency (e.g., hypogammaglobulinemia and agammaglobulinemia) may be vaccinated.

---

[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.

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 VariZIG 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

V. SIDE EFFECTS AND ADVERSE EVENTS*

Persons ≥13 years of age receiving Varicella Vaccine

Event	**Frequency***
Soreness, pain, swelling, erythema, rash, pruritus,	24 % (dose 1)
Hematoma, induration and stiffness	33 % (dose 2)
Fever (≥100°F orally)	10 % (dose 1) 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 % (dose 1) 1 % (dose 2)
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).

E. Postexposure propohylaxis
   - 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 dose number one of varicella vaccine **upon completion or termination of pregnancy.**

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

I. Salicylates:
   - No adverse events following varicella vaccination related to the use of salicylates (e.g., aspirin) have been reported to date. However, the manufacturer recommends that vaccine recipients avoid the use of 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. Written documentation of age-appropriate vaccination:
      a) Children vaccinated from age 12 months to age 12 years: 1 dose
      b) Persons vaccinated at age 13 years or older: 2 doses 4-8 weeks apart;
   2. Born in the US before 1966;
   3. History of varicella disease based on healthcare provider diagnosis, or self or parental report of typical varicella disease for non-US born persons born before 1966, and all persons born during 1966-1997;
   4. History of herpes zoster based on healthcare provider diagnosis[1]; or
   5. Laboratory evidence of Immunity or lab confirmation of disease.

---

[1] For persons born during or after 1998, history of disease is no longer considered as evidence of immunity, unless the illness was laboratory confirmed.

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**. May modify or prevent disease if given within 96 hours after exposure.
- ACIP recommends that these high-risk individuals, exposed to varicella, receive VariZig:
  1. Immunocompromised persons
  2. Newborn of mothers with onset 5 days before to 48 hours after delivery
  3. Premature infants with postnatal exposure
  4. Susceptible adults and 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

1. Varicella. In*: Epidemiology and Prevention of Vaccine-Preventable Diseases* ("Pink Book"). Atkinson W, Hamborsky J, Wolfe S, eds. 9th ed. Washington, DC: Public Health Foundation, 2006:171-91. Available at: http://www.cdc.gov/nip/publications/pink/default.htm
2. 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
3. General Recommendations on Immunization. MMWR 2002; 51 (RR-2) Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5102.pdf.
4. Prevention of Varicella. MMWR 1996; 45 (RR-11). Available at:: http://www.cdc.gov/mmwr/PDF/rr/rr4511.pdf.
5. Prevention of Varicella; MMWR 1999; 48, (RR-6). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr4806.pdf.

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

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