OREGON HEALTH AUTHORITY
IMMUNIZATION PROTOCOL FOR PHARMACISTS
VARICELLA
LIVE VIRUS VACCINE

Revisions as of 7/2012:

- In May 2011, FDA approved extending the period for administering VariZIG™ prophylactically, after exposure to varicella virus, from 96 hours (4 days) to 10 days (Section VIII, p. 11). Reference available at: [www.cdc.gov/mmwr/preview/mmwrhtml/mm6112a4.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6112a4.htm).
- Added varicella vaccine as a choice for immunocompetent hematopoietic stem cell transplants (HSCT) ≥24 months after transplant (Section VIII-F, p. 12).
- Added storage and handling guidance for Varivax® before and after reconstitution based on 2012 package inserts. (Section II, footnote #5, p. 3)

Order next page.
I. **Order:**

1. Check the ALERT Immunization Information System to determine whether the patient needs this vaccine and any other vaccines.
2. Screen clients ≥11 years for contraindications.
3. Provide an Adolescent Well Visit Flyer to those 11—18 years of age.
4. Provide a current Vaccine Information Sheet (VIS) answering any questions.
5. Obtain a signed Vaccination Administration Record (VAR)
6. Give varicella vaccine (0.5 ml) **subcutaneously**.
   a. Can administer varicella vaccine simultaneously with all routine 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, p.4-5 for details).

**VACCINE MUST BE GIVEN WITHIN 30 MINUTES ONCE IT IS RECONSTITUTED.**

---

Immunizing Pharmacist Signature

Date

For multiple signatures see: [http://1.usa.gov/PharmacyImmunizationProtocols](http://1.usa.gov/PharmacyImmunizationProtocols)
## II. LICENSED SINGLE-ANTIGEN VARICELLA VACCINE

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>VACCINE COMPONENTS</th>
<th>ACCEPTABLE AGE RANGE</th>
<th>Thimerosal</th>
</tr>
</thead>
<tbody>
<tr>
<td>VARIVAX®¹,²,³,⁴,⁵ (Merck)</td>
<td>1350 PFU⁶ of Oka/Merck varicella virus</td>
<td>≥12 months</td>
<td>No</td>
</tr>
</tbody>
</table>

¹ Varivax is a lyophilized preparation containing sucrose, phosphate, glutamate (MSG), and processed gelatin as stabilizers.
² To maintain potency, **Frozen** vaccine must be kept frozen at an average temperature of -15°C (+5°F) or colder.
³ Must be given within 30 minutes of reconstitution. **Do not re-freeze.**
⁴ Diluent should be stored separately at room temperature or in the refrigerator.
⁵ Varivax® may be stored at refrigerator temperature (2–8°C or 36–46°F) for up to 72 hours prior to reconstitution and still retain potency. Vaccine stored at refrigerator temperature but not used within 72 hours of removal from -15°C (5°F) storage should be discarded. Protect these vaccines from light at all times. The reconstituted vaccine may be stored at room temperature for up to 30 minutes before it needs to be either administered or discarded.
⁶ Plaque forming units

Source: 2012 Varivax® package insert is available at:
### III. VACCINE SCHEDULE

| A. Varicella Vaccine for Susceptible persons 11—12 years of age (2 doses): 0.5ml SQ |  |
|---|---|---|
| **Dose** | **Minimum Spacing\(^1,2\)** | **Recommended Spacing** |
| 1 | | |
| 2 | (28 days\(^3\)) | 3 months |

| B. Varicella Vaccine for Susceptible Persons ≥13 years of age (2 doses) |  |
|---|---|---|
| **Dose and Route:** 0.5 ml Subcutaneously (SC) |  |
| **Dose** | **Minimum Spacing\(^1,2\)** | **Recommended Spacing** |
| 1 | | 13 years |
| 2 | 28 days | |

| C. Varicella Vaccine for Immunocompromised persons\(^4,5\) (2 doses): |  |
|---|---|---|
| **Dose and Route:** 0.5 ml Subcutaneously (SC) |  |
| **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.

\(^3\) While 15 months is the recommended minimum age for the 2\(^{nd}\) 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 (reference: CDC. General Recommendations on Immunizations: recommendations of the Advisory Committee on Immunization Practices. MMWR 2011; 60 (RR-2): 21).
IV. RECOMMENDATIONS FOR USE

A. **All children 12 months to 12\(^2\) years of age** without contraindications or evidence of varicella immunity (immunity criteria see Section VIII-L on p.13) 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 1\(^{st}\) dose of varicella vaccine before discharge from the healthcare facility. The 2\(^{nd}\) 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)

## 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 clients 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)\textsuperscript{1,2}
• Cellular immunodeficiency; except those with isolated humoral immunodeficiency (e.g., hypogammaglobulinemia and agammaglobulinemia) may be vaccinated.
• HIV infection or AIDS diagnosis\textsuperscript{3}

E. 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

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

\textsuperscript{2} Persons whose immunosuppressive therapy with steroids has been discontinued for 1 month (3 months for chemotherapy) may be vaccinated.

\textsuperscript{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.

F. 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 2 months after administering Varivax\textsuperscript{®} vaccine unless the benefits exceed those of vaccination.(2011 Varivax\textsuperscript{®} vaccine package insert).
VI. Suggested intervals between administration of immune globulin preparations and measles- or varicella-containing vaccine*
<table>
<thead>
<tr>
<th>Product/Indications</th>
<th>Dose (mg IgG/kg body weight)</th>
<th>Interval (months) before measles or varicella-containing(^1) vaccine administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSV monoclonal antibody (Synagis(\textsuperscript{TM}))(^2)</td>
<td>15 mg/kg intramuscularly (IM)</td>
<td>None</td>
</tr>
<tr>
<td>Tetanus IG (TIG)</td>
<td>250 units (10 mg IgG/kg) IM</td>
<td>3</td>
</tr>
</tbody>
</table>

**Hepatitis A IG**

| Contact prophylaxis          | 0.02 ml/kg (3.3 mg IgG/kg) IM | 3                                                                                 |
| International travel         | 0.06 ml/kg (10 mg IgG/kg) IM  | 3                                                                                 |

**Hepatitis B prophylaxis (HBIG)**

| 0.06 ml/kg (10 mg IgG/kg) IM | 3 |

| Rabies IG (RIG)              | 20 IU/kg (22 mg IgG/kg) IM   | 4                                                                                 |

| Varicella IG                 | 125 units/10 kg (60-200 mg IgG/kg), IM – maximum 625 units | 5                                                                                 |

**Measles prophylaxis (IG):**

| Standard (i.e., non-immunocompromised) contact | 0.50 ml/kg (40 mg IgG/kg) IM | 5 |

| Severely Immunocompromised contact | 400 mg/kg of IV (Intravenously) IVIG | 8 |

**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    |
| Packed RBCs (Hct 65%)$^3$ | 10 ml/kg (60 mg IgG/kg) IV | 6 |
| Whole blood (Hct 35%-50%)$^3$ | 10 ml/kg (80-100 mg IgG/kg) IV | 6 |
| Plasma/platelet products | 10 ml/kg (160 mg IgG/kg) IV | 7 |
| Cytomegalovirus intravenous immune globulin (IGIV) | 150 mg/kg maximum | 6 |
| Replacement therapy for immune deficiencies$^4$ | 300-400 mg/kg IV (as IGIV) | 8 |
| Immune thrombocytopenic purpura (ITP) | 400 mg/kg IV (as IGIV) | 8 |
| | 1000 mg/kg IV (as IGIV) | 10 |
| Postexposure varicella prophylaxis$^5$ | 400 mg/kg IV | 8 |
| Kawasaki disease | 2 g/kg IV (as IGIV) | 11 |

* 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 immune globulin or measles vaccine might be indicated after measles exposure. Concentrations of measles antibody in an immune globulin preparation can vary by manufacturer’s lot. The rate of antibody clearance after receipt of an immune globulin 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.

$^1$ Varicella-containing vaccine, as used here, does not include zoster vaccine. Zoster vaccine may be given with antibody-containing blood products.

$^2$ Contains antibody only to respiratory syncytial virus

$^3$ Assumes a serum IgG concentration of 16 mg/mL.

$^8$ Measles and varicella vaccinations are recommended for children with asymptomatic or mildly symptomatic human immunodeficiency virus (HIV) infection but are contraindicated for persons with severe immunosuppression from HIV or any other immunosuppressive disorder.
The investigational product VariZIG, similar to licensed VZIG is a purified human immune globulin preparation made from plasma containing high levels of anti-varicella antibodies (immunoglobulin class G ( lgG)). When indicated, health-care providers make every effort to obtain and administer VariZIG. In situations in which administration of VariZIG does not appear possible within 96 hours of exposure, administration of immune globulin intravenous (IGIV) should be considered as an alternative. IGIV also should be administered within 96 hours of exposure. The recommended IGIV dose for postexposure prophylaxis of varicella is 400 mg/kg, administered once. For a pregnant woman who cannot receive VariZIG within 96 hours of exposure, clinicians can choose either to administer IGIV or closely monitor the woman for signs and symptoms of varicella and institute treatment with acyclovir if illness occurs (CDC. A new product for postexposure prophylaxis available under an investigational new drug application expanded access protocol. MMWR 2006;55:209-10.


(04-2013)NOTE: ACIP updates for VariZIG and Measles IG are coming soon.
VII. SIDE EFFECTS AND ADVERSE REACTIONS

<table>
<thead>
<tr>
<th>Event</th>
<th>Frequency¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soreness, pain, swelling, erythema, rash, pruritus</td>
<td>24 % (dose 1)</td>
</tr>
<tr>
<td>Hematoma, induration and stiffness</td>
<td>33 % (dose 2)</td>
</tr>
<tr>
<td>Fever (≥100°F orally)</td>
<td>10 % (dose 1) 0 % (dose 2)</td>
</tr>
<tr>
<td>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.</td>
<td>4-6 % (dose 1) 1 % (dose 2)</td>
</tr>
<tr>
<td>A varicella-like rash at the injection site consisting of about 2 lesions in children and adolescents, and 5 lesions in adults, occurring about 6-20 days after vaccination with dose one, and 0-6 days following the second dose.</td>
<td>3 % (dose 1) 1 % (dose 2)</td>
</tr>
</tbody>
</table>

¹List is taken from ACIP and package insert 2009

VIII. OTHER CONSIDERATIONS

A. Herpes zoster following vaccination: The VAERS rate of herpes zoster after varicella 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 is available through the Oregon State Public Health Laboratory. To check their fees and procedure for submitting specimens, see http://public.health.oregon.gov/LaboratoryServices/Pages/test.aspx?TestID=20
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. Hematopoietic stem cell transplant (HSCT) recipients: If varicella vaccine is ordered for a HSCT recipient who is considered immunocompetent, vaccinate ≥24 months post transplant (General Recommendations on Immunization. MMWR 2011; 60 [RR-2]:22).

G. Exposure of immunocompromised persons:
   - 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 (VaraZIG) does not need to be administered. Please consult your health officer or medical provider for direction.

H. Pregnant women: Assess pregnant women for evidence of varicella immunity. Women without immunity should receive dose number one of varicella vaccine upon completion or termination of pregnancy.

I. 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.

J. 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.

K. Internationally adopted children:
   ACIP recommends age-appropriate vaccination of children who lack a reliable history of previous varicella disease.
VIII. Other Considerations cont.

L. Evidence of varicella immunity: Any of the following:

1. Documentation of age-appropriate vaccination:
   a) Preschool-aged children ≥12 months of age: one dose\(^1\)
   b) School-aged children, adolescents, and adults: two doses\(^2\)
2. Laboratory evidence of immunity\(^3\)
3. Born in the US before 1980\(^4\)
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.

\(^1\)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.

IX. STORAGE AND HANDLING

Varivax\(^\text{®}\) retains a potency level of 1500PFU or higher per dose for at least 24 months in a frost-free freezer when an average temperature of −15°C (+5°F) or colder.

Varivax\(^\text{®}\) has a minimum potency level of approximately 1350 PFU 30 minutes after reconstitution at room temperature (20–25°C, 68–77°F).

**VACCINE MUST BE GIVEN WITHIN 30 MINUTES ONCE IT IS RECONSTITUTED.**

1. Varivax\(^\text{®}\) may be stored at refrigerator temperature (2–8°C or 36–46°F) for up to 72 hours
prior to reconstitution and still retain potency. Vaccine stored at refrigerator temperature but not used within 72 hours of removal from -15°C (5°F) storage should be discarded. Protect these vaccines from light at all times. The reconstituted vaccine may be stored at room temperature for up to 30 minutes before it needs to be either administered or discarded. (2012 Varivax® package inserts). Varivax® package insert is available at: http://www.merck.com/product/usa/pi_circulars/v/varivax/varivax_pi.pdf

2. The diluent should be stored separately at room temperature (20–25°C, 68–77°F), or in the refrigerator.

3. For information regarding stability under conditions other than those recommended, call 1-800-827-4820

**X.ADVERSE EVENTS REPORTING**

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website: www.vaers.hhs.gov. In addition, a copy of the reporting form should be reported to the patient’s primary provider, per Oregon Revised Statute (ORS) 855-019-0280(4)

**REFERENCES**

1. CDC. FDA Approval of an extended period for administering VariZIG for postexposure prophylaxis of varicella. MMWR 2012; 61:212. Available at: www.cdc.gov/mmwr/preview/mmwrhtml/mm6112a4.htm.


5. Prevention of Varicella; MMWR 1999; 48(RR-6). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr4806.PDF


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 or 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: http://1.usa.gov/PharmacyImmunizationProtocols