Protocol for Varicella Containing Vaccines (ProQuad® and Varivax®)

1. What's New

A. Updated to allow intramuscular administration for Varivax® and ProQuad®.[1,2]

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM or SQ, of Varicella-containing vaccine to persons ≥7 years of age. MMRV may be used for persons 7-12 years of age.

B. May be given simultaneously with all routinely commended vaccines. Do not give simultaneously with immune globulin.

3. Vaccine Schedule

Varicella Vaccine[1] Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable age range**	**Minimum acceptable spacing**
1	≥ 7 years	
2		28 days*
MMRV Vaccine[2] Dose and Route – 0.5-mL, IM or SQ		
1	7-12 years	
2		3 months

* For children between the ages of 7-12 years of age, the minimal acceptable spacing between doses is 3 months. A dose inadvertently administered after at least 4 weeks may be counted as valid. At least 3 months should elapse between a dose of varicella-containing vaccine and MMRV.[2]

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
Varivax®[1]	Varicella	0.5-mL single-dose vaccine vials and 0.5-mL single-dose diluent vials	≥ 7 years	No
ProQuad®[2]	MMRV		7 years-12 years	

5. Recommendations for Use[3]

A. Catch-up Vaccination: All healthy children should be routinely vaccinated with varicella-containing vaccine. A second dose of varicella-containing vaccines is recommended ≥ 3 months after dose 1.

B. Persons with immunodeficiency: Persons with impaired humoral immunity may be vaccinated. Persons receiving inhaled, nasal, or topical steroids may be vaccinated. Persons receiving systemic steroids who are not otherwise immunocompromised may receive varicella vaccine if they are receiving.

C. Children with HIV Infection: Because children infected with HIV are at increased risk for morbidity from varicella and herpes zoster compared with healthy children, ACIP recommends that, after weighing potential risks and benefits, single-antigen varicella vaccine should be considered for HIV infected children with CD4+ T-lymphocyte percentages >15%.

D. Household Contacts of Immunocompromised Persons: Children living with immunocompromised persons should be vaccinated routinely. Adults living with

immunocompromised persons should have their immunity assessed and be offered vaccination, if indicated.

E. Persons Aged ≥ 13 Years: Persons ≥ 13 years without acceptable evidence of varicella immunity should receive two doses of single-antigen varicella vaccine, 4-8 weeks apart.

F. Other Healthy Adults: All healthy adults should be assessed for varicella immunity, and those who do not have evidence of immunity should receive two doses of single-antigen varicella vaccine, 4–8 weeks apart.
Persons at increased risk of exposure, including students in post-secondary education, healthcare workers, people at occupational risk (e.g., teachers, daycare workers, corrections officers), non-pregnant women of childbearing age, international travelers, and household contacts of young children should receive special consideration for vaccination.

6. Contraindications[4]

A. Allergy: Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.

Vaccine	Contains[3]
Varivax®	sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, MRC-5 human diploid cells including DNA & protein, sodium phosphate monobasic, EDTA, neomycin, fetal bovine serum
ProQuad®	MRC-5 cells including DNA and protein, sucrose, hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, recombinant human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride, potassium phosphate dibasic, neomycin, bovine calf serum, other buffer and media ingredients

B. Pregnancy: Do not vaccinate pregnant persons with varicella or MMRV. Persons should be told to avoid pregnancy for one month after each vaccine dose. Nursing is not a contraindication to vaccination.

C. Immunodeficiency: Varicella and MMRV should not be administered to persons who have cancer, blood dyscrasias, or other malignant neoplasms affecting the blood marrow or lymphatic systems.
    a. MMRV should not be administered to persons with primary or acquired immunodeficiency, including persons with AIDS or other clinical manifestations of HIV infections.
    b. Persons with HIV who are not currently severely immunosuppressed may receive varicella vaccine. MMRV is contraindicated in persons with HIV.
    c. Persons who have a family history of congenital or hereditary immunodeficiency in first-degree relatives (e.g., parents and siblings), should not receive varicella or MMRV unless the immune competence of the potential vaccine recipient has been substantiated clinically or verified by a laboratory.
    d. Persons receiving systemic immunosuppressive therapy, including corticosteroids ≥2 mg/kg of body weight or ≥20 mg/day of prednisone (or equivalent) for persons who weigh >10 kg, when administered for ≥2 weeks, should not receive varicella or MMRV.

D. Immune Globulin (IG): Do not administer varicella or MMRV simultaneously with immune globulin.

Protocol for Varicella Containing Vaccines (ProQuad® and Varivax®)

7. Warnings and Precautions

A. Moderate or severe illness, with or without fever.[5]

B. Antibody-containing blood products: Receipt of antibody-containing blood products (e.g., IG, whole blood, or packed red blood cells) might interfere with the serologic response to varicella vaccine for variable periods, depending on the dose of IG administered. Varicella vaccine should be administered to persons who have received an IG preparation only after the recommended intervals have elapsed.[4] See Appendix for guidance.

C. Tuberculosis testing: TB skin tests may be administered simultaneously with varicella or MMRV vaccine. If not administered simultaneously, wait 4-6 weeks after vaccination to place the TB test.[5]

D. Personal or Family History of Seizures: A personal or family (i.e., sibling or parent) history of seizures of any etiology is a precaution for the first dose of MMRV vaccine but not single-antigen varicella vaccine.[4]

A. History of thrombocytopenia or thrombocytopenic purpura: Thrombocytopenia is not a contraindication for single-antigen varicella vaccine.[4] Persons who have a history of thrombocytopenia or thrombocytopenic purpura might be at increased risk for developing clinically significant thrombocytopenia after MMRV vaccination.[4]

E. Simultaneous and non-simultaneous vaccination with live vaccines: Two or more live vaccines may be administered on the same clinic day. Live vaccines not administered simultaneously need to be separated by 28 days. If not separated by at least 28 days, the vaccine administered second needs to be repeated at least 28 days later.[4]

F. Salicylate Therapy: Avoid the use of salicylates (aspirin) or salicylate containing products in children aged 7 years to 12 years for six weeks following vaccination wit MMRV due to the association of Reye Syndrome with salicylate therapy and wild-type varicella infection.[4]

8. Other Considerations

A. Post-Exposure Prophylaxis: Single-antigen varicella vaccine may be effective in preventing illness or modifying varicella severity if administered to children within 3 days, and possibly up to 5 days, of exposure to rash.[4]

B. Evidence of Immunity:

Evidence of Immunity to Varicella[4]

• Documentation of vaccination with a live varicella-virus containing vaccine:
  o PreK: 1 dose
  o K-12: 2 doses
  o Adults: 2 doses
• Laboratory evidence of immunity;
• Laboratory confirmation of disease;
• Birth in the United States before 1980;
• Diagnosis or verification of a history of varicella disease by a health care provider;
• Diagnosis or verification of a history of herpes zoster by a health care provider.

9. Side Effects and Adverse Reactions

Adverse Event	Frequency
Varivax®[1]	
Children 7-12 years of age	
Fever ≥102˚	Up to 15%
Local reactions: pain, swelling, redness, rash, itching	Up to 20%
Generalized varicella-like rash	Up to 4%
Children ≥13 years of age and adults	
Fever ≥100˚	Up to 11%
Local reactions: pain, swelling, redness, rash, itching	Up to 33%
Generalized varicella-like rash	Up to 6%
ProQuad®[2]	
Children up to 3 years of age	
Fever	Up to 21%
Other systemic reactions: irritability, rash, diarrhea	Up to 6%
Injection site pain	Up to 22%
Other local reactions: swelling, redness, bruising	Up to 15%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
Varivax®[1] and ProQuad®[2]	-50° to -15°C (-58° to 5°F)	Store frozen to maintain potency. Vaccine may be stored in the refrigerator for up to 72 hours before reconstitution.	Reconstituted vaccine may be stored at room temperature, protected from light, for up to 30 minutes. Do not freeze reconstituted vaccine.
Varivax®[1] and ProQuad® (diluent)[2]	2° to 25°C (36° to 77°F)	Diluent may be stored refrigerated or at room temperature.	Do not freeze.

11. References

1. Varivax® package insert. March 2020. Merck and Co. Available at: https://www.fda.gov/media/76008/download. Accessed on 5 June 2023.
2. ProQuad® package insert. Current as of April 2021. Merck and Co. Available at: https://www.fda.gov/media/147563/download. Accessed on 5 June 2023.
3. CDC. Vaccine Excipient Summary. February 2020. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. Accessed 5 June 2023.
4. CDC. Prevention of Varicella: Recommendations of the ACIP. MMWR 2007; 56(4);1-48. Available at: https://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf. Accessed CDC. Accessed 5 June 2023.

5. Kroger AT, Duchin J, Vázquez M. General Best Practice Guidelines for Immunization. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html. Accessed 5 June 2023.

12. Appendix

A. Recommended intervals between administration of antibody-containing products and measles or varicella virus-containing vaccine, by product or indication for vaccination. Revised February 2021: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/recommended-intervals-between-administration.pdf