Varicella Immunization Protocol

NAME AND STRENGTH OF VACCINE TO BE USED

Vaccine name	Age group	Dosage	Number of doses	Route of Admin.
Varicella virus vaccine live (VARIVAX®)	7 years of age and older	0.5 mL	2	SC
Measles, Mumps, Rubella and Varicella Virus vaccine live (ProQuad®)	7 years through 12 years of age	0.5 mL	2	SC

INTENDED AUDIENCE AND PATIENT POPULATION

Patients 7 years of age and older without evidence of immunity, defined as:

(1) written documentation of 2 doses of varicella vaccine;
(2) history of varicella disease or herpes zoster (shingles) based on healthcare-provider diagnosis;
(3) laboratory evidence of immunity or confirmation of disease; and/or birth in the U.S. before 1980, with the exceptions that follow:
    (a) Healthcare personnel born in the U.S. before 1980 who do not meet the criteria above should be tested or given the 2-dose vaccine series
    (b) Pregnant women born in the U.S. before 1980 who do not meet the criteria above should either 1) be tested for susceptibility during pregnancy and if susceptible, given the first dose of varicella vaccine postpartum prior to discharge or 2) not tested for susceptibility and given the first dose of varicella vaccine postpartum prior to discharge

SCHEDULE

(1) Give a second dose to all older children/teens with history of only 1 dose
(2) If younger than age 13 years, space dose #1 and #2 at least 3 months apart
(3) If age 13 years or older, space doses at least 4 weeks apart
(4) May use as postexposure prophylaxis if given within 5 days of exposure.

PRECAUTIONS AND CONTRAINDICATIONS

(1) History of severe allergy to gelatin, neomycin, egg (ingredient in ProQuad®) or any other component of the vaccine is a contraindication.

(2) Severe immunodeficiency is a contraindication. This includes:
- hematologic and solid tumors; receipt of chemotherapy; congenital immunodeficiency; long-term immunosuppressive therapy, including high-dose corticosteroids; patients with HIV infection who are severely immunocompromised (CD4 percentage <15% or CD4 count <200 cells/mm^3).

(3) Vaccination should be deferred in patients with active untreated tuberculosis. Deferral should be considered in acute illness, for example, in the presence of fever.

(4) Varicella vaccine should not be administered to a pregnant female and pregnancy should be avoided for four weeks after vaccination.

(5) Avoid vaccination for at least 5 months after blood or plasma transfusions, or administration of immunoglobulins. Avoid administering immunoglobulins for 2 months thereafter vaccination.

(6) Receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination, if possible; delay resumption of these antiviral drugs for 14 days after vaccination

(7) Avoid use of salicylate-containing products (eg., aspirin) in children and adolescents through 17 years of age for six weeks following vaccination.

(8) Use caution when administering ProQuad® to children with a history of cerebral injury or seizures or thrombocytopenia.

(9) Transmission of vaccine virus may occur rarely between vaccinees and susceptible contacts.

SIDE EFFECTS AND ADVERSE REACTIONS

VARIVAX®

(A) Local reactions: injection-site complaints (pain/soreness, swelling and/or erythema, rash, pruritus, varicella-like rash)

(B) General reactions: fever, varicella-like rash

ProQuad®

(A) Local reactions: injection-site complaints (pain/tenderness/soreness, swelling and/or erythema, rash, pruritus)

(B) General reactions: fever, irritability, measles-like rash, varicella-like rash

ADMINISTRATION

(A) Procedures

(1) Prescription is required for patients who are seven years of age or older but not more than 13 years of age. (per Ohio Revised Code 4729.41)

(2) Patient or parent/legal guardian must first sign a consent form before the vaccination is administered.

(3) Provide patient/parent/legal guardian with a copy of the most current federal Vaccine Information Statement (VIS) for varicella vaccine.

(4) Vaccine is stored frozen and can be stored at refrigerated temperature for up to 72 continuous hours prior to reconstitution. If not used within 72 hours of removal from freezer, vaccine should be discarded. The diluent should be stored separately at room temperature or in the refrigerator. Use separate sterile needles for reconstitution and administration of vaccine.

To reconstitute the vaccine: Use only the diluent supplied. Withdraw the entire contents of the diluent into a syringe. Inject all of the diluent in the syringe into the vial of lyophilized vaccine and gently agitate to mix thoroughly. VARIVAX® Vaccine, when reconstituted, is a clear, colorless to pale yellow liquid. ProQuad®, when reconstituted, is a clear pale yellow to light pink liquid.

(5) Inject the total volume (approximately 0.5 mL) of reconstituted vaccine subcutaneously into the fatty tissue over the triceps.

(6) Do not inject intravascularly or intramuscularly. Use only sterile syringes free of preservatives, antiseptics, and detergents for each injection and/or reconstitution. Preservatives, antiseptics and detergents may inactivate the vaccine virus.

(7) Vaccine should be administered immediately after reconstitution, to minimize loss of potency. Reconstituted ProQuad® must be protected from light.

(8) Discard reconstituted vaccine if it is not used within 30 minutes.

(9) Do not freeze reconstituted vaccine.

(10) Needles should be disposed of properly and should not be recapped.

(11) Record the date of administration, name/manufacturer/strength/dose of the immunization, lot number and expiration date of the immunization, route of administration, location of the injection site, and positive identification of the person administering the vaccine.

(12) Monitor patients in the general vicinity of the administering pharmacist or pharmacy intern for at least 10 minutes after giving the injection and treat accordingly.

(13) Advise patient to report any adverse reaction to their pharmacist or primary care physician.

(B) Monitoring parameters

(1) Patients who faint should be placed supine. Check their pulse and blood pressure immediately.

(2) Watch for rapidly falling blood pressure, difficulty breathing, and sustained unconsciousness. Observe for adequate airway and pulse; administer CPR if needed. Have another member of the pharmacy staff call 911. Follow procedures in next section for treatment of severe allergic/anaphylactic reactions.

(3) Treat externally for shock. Keep patient warm, head low and feet elevated.

(4) Contact protocol physician as soon as possible to report the condition of the patient.

PROTOCOL FOR MANAGEMENT OF SEVERE ALLERGIC/ANAPHYLACTIC REACTIONS

(A) Pre-Vaccination Procedures
- (1) Be prepared to call 911.
- (2) Take a thorough history for allergies and prior adverse events before any immunization.
- (3) Allow adequate physical space for fainting or collapse without injury and to lay patient flat on a hard surface in the event CPR is needed.
- (4) Maintain current competency in vaccine administration and in cardiopulmonary resuscitation; observe all vaccinees for at least 10 minutes after immunization; remind vaccinees to report any adverse events to you.

(B) Supplies to Stock
- (1) Epinephrine USP, 1 mg/ml (1:1000). May be in vials of solution, *Ana-Guard* syringes, or in an *Epi-Pen* (0.15 mg & 0.3 mg). At least three adult and children's doses of epinephrine will be available wherever immunizations are given.
- (2) Diphenhydramine liquid and injection.
- (3) Blood-pressure cuff, adult and child's size, with stethoscope.

(C) Recognition of Anaphylactic Reaction
- (1) Sudden onset of itching, redness, with or without hives, within several minutes of administering a medication. The symptoms may be localized or generalized.
- (2) Angioedema (swelling of the lips, face, throat)
- (3) Bronchospasm

(D) Emergency treatment
- (1) If itching and swelling are confined to the extremity where the immunization was given, observe patient closely for a suitable period of time, watching for generalized symptoms. If none occur, go to paragraph D (8).

- (2) If symptoms are generalized, activate the emergency medical system (EMS). Call 911 **and** the protocol physician for instruction. This should be done by a second person, while the immunizer treats and observes the patient.

- (3) Administer epinephrine IM (refer to dosing chart). Standard dose is 0.01mg/kg up to 0.5 mg maximum in adults. Site of administration can be the anterolateral thigh if using auto-injector, or deltoid muscle above the vaccine injection site.

(4) Administer diphenhydramine by IM injection (refer to dosing chart). DO NOT administer diphenhydramine or any other drug by mouth if the patient is not fully alert or if the patient has respiratory distress.

(5) Monitor the patient closely until EMS arrives. Perform CPR and maintain airway, if necessary. Keep patient in supine position unless they are having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. Monitor vital signs frequently.

(6) If EMS has not arrived and symptoms still persist, repeat dose of epinephrine every 10-20 minutes for up to 3 doses, depending on patient response.

(7) Record all vital signs, medications administered to the patient, including the time, dosage, response, and other relevant clinical information.

(8) Patient must be referred for medical evaluation, even if symptoms resolve completely. Symptoms may recur after epinephrine and diphenhydramine wear off, as much as 24 hours later. After the event is concluded, complete a VAERS form. Report forms may be obtained online at www.vaers.hhs.gov or by calling 1-800-822-7967.

Suggested Dosing of Epinephrine and Diphenhydramine

Age Group Dose	**Weight * in kg**	**Weight * in lbs**	**Epinephrine Dose** ** 1 mg/mL injectable (1:1000 dilution) intramuscular	**Diphenhydramine (Benadryl)** 12.5 mg/5 mL liquid 25 and 50 mg capsules or tablets 50 mg/mL injectable
1-6 mos	4-7 kg	9-15 lbs	0.05 mg (0.05 ml)	5 mg
7- 18 mos	7-11 kg	15-24 lbs	0.1 mg (0.1 ml)	10 mg
19-36 mos	11-14 kg	24-31 lbs	0.15 mg (0.15 ml)	15 mg
37-48 mos	14-17 kg	31-37 lbs	0.15 mg (0.15 ml)	20 mg
49-59 mos	17-19 kg	37-42 lbs	0.2 mg (0.2 ml)	
5-7 yrs	19-23 kg	42-51 lbs	0.2 mg (0.2 ml)	30 mg
8-10 yrs	23-35 kg	51-77 lbs	0.3 mg (0.3 ml)	
11-12 yrs	35-45 kg	77-99 lbs	0.4 mg (0.4 ml)	40 mg
13 yrs & older	45+ kg	99+ lbs	0.5 mg (0.5 ml)	50-100 mg

*Dosing by body weight is preferred

**Epinephrine can also be administered using an autoinjector available in 0.15 mg and 0.3 mg doses. Children weighing 15 to 30 kg should receive 0.15 mg if given by autoinjector.

ACCIDENTAL NEEDLE STICK

(A) Procedures

(1) Wash needle stick site with soap and water.

(2) Report the exposure to the physician on the protocol. Prompt reporting is essential because, in some cases, post-exposure treatment may be recommended and it should be started as soon as possible. **The National Clinicians' Post Exposure Prophylaxis Hotline (PEPline) has current recommendations (888.448.4911).**

(3) Discuss risks of acquiring HBV, HCV, HIV and the need for post-exposure treatment with the provider managing your exposure.

(4) Person giving the vaccination should already have received the Hepatitis B vaccine (extremely safe and effective).

(5) Follow-up testing should be available to all workers concerned about possible infection through occupational exposure.

(B) Treatment of Exposure

HCV – no treatment available.

HBV – Post-exposure treatment of HBV is highly effective in preventing infection. Treat exposure as soon as possible after exposure, preferably within 24 hours and no later than 7 days after exposure. Hepatitis B vaccine and hepatitis B immune globulin (HBIG) are both approved for treatment use. If any symptoms suggesting HBV infection develop, patient should contact a physician.

HIV - Start as soon as possible, ideally within 72 hours of exposure. Benefit of treatment delayed beyond 72 hours is not defined. No medications are FDA-approved for prevention. Pharmacist will follow current HIV prevention guidelines recommended by CDC. Truvada® (emtricitabine and tenofovir disoproxil fumarate) plus Isentress® (raltegravir) OR Truvada® plus Tivicay® (dolutegravir) are recommended for 28 days with repeated testing to confirm HIV negative status.

(C) Precautions During Follow-Up

HBV – no precaution recommended.

HCV – low risk, so no precautions are recommended.

HIV - 6-12 weeks is when most of the signs and symptoms of infection show. Do not donate blood, semen, or organs during this time. Do not have sexual intercourse during this time, or else use a condom consistently and correctly. Women should not breast feed. HIV is transmitted through breast milk.

(See page 7 for Physician Authorization)

Administration of the varicella vaccine, under the direction of the physician who signed below, may be performed by the following individuals:

_____ _____ _____

_____ _____ _____

Administration of the varicella vaccine, under the direction of the physician who signed below, may be performed at the following location(s) including street address(es):

_____

_____

As the authorizing physician, I will review, on a biennial basis, the activities of the health care providers administering the vaccine under this protocol.

Date: _____
*MUST BE RENEWED WITH PHYSICIAN ON A BIENNIAL BASIS

Physician Signature: _____

Physician Name: _____

Address: _____

City: _____ State: _____ Zip:_____

Medical License #: _____

Pharmacist in Charge Name_____

Pharmacist in Charge Signature_____

Date_____ Pharmacist in Charge License #_____

Pharmacy Name_____

Pharmacy Address_____

City_____State_____ Zip_____

PHYSICIAN/BOARD OF HEALTH NOTIFICATION
Notify the individual's primary care physician, or if the individual has no family physician, the County Board of Health of the district in which the individual lives, within 30 days after administering the immunization; document accordingly.