Pneumococcal PCV13, PCV15, PCV20, PPSV23 Immunization Protocol

NAME AND STRENGTH OF VACCINE TO BE USED

Vaccine name	Age group	Dosage	Number of doses	Route of Admin.
13-valent pneumococcal conjugate vaccine (PCV13, Prevnar 13®)	7 years and older	0.5 mL	1	IM only
15-valent pneumococcal conjugate vaccine (PCV15, Vaxneuvance™)	18 years and older	0.5 mL	1	IM only
20-valent pneumococcal conjugate vaccine (PCV20, Prevnar 20 ™)	18 years and older	0.5 mL	1	IM only
Pneumococcal polysaccharide vaccine (PPSV23, Pneumovax 23®)	7 years and older	25mcg (0.5 mL)	1*	IM or SC

**Selective revaccination based on age and chronic medical conditions*

INTENDED AUDIENCE AND PATIENT POPULATION

(A) All adults aged ≥ 65 years should receive one dose of PCV20, or one dose of PCV15 followed by a dose of PPSV23 ≥ 1 year later.

(B) Adults age 19 through 64 years who have certain medical conditions or who smoke should receive pneumococcal vaccinations depending on the comorbid medical conditions (see next section).

(C) Children age 7 through 18 years who have certain medical conditions should receive pneumococcal vaccinations depending on the comorbid medical conditions (see next section).

VACCINATION AND REVACCINATION SCHEDULE:

(A) For all immunocompetent adults ≥ 65 years, administer one dose of PCV20, or one dose of PCV15 followed by a dose of PPSV23 ≥ 1 year later. If patient previously received PCV13, administer PPSV23 ≥ 1 year after PCV13, following previous guidelines. If PPSV23 was administered prior to age 65 years, administer either one dose of PCV15 or PCV20 ≥ 1 year after the last PPSV23 dose.

(B) For adults ≥ 65 years with an immunocompromising condition, cochlear implant, or CSF leak, administer one dose of PCV20, or one dose of PCV15 followed by a dose of PPSV23 ≥ 1 year later (A minimum interval of 8 weeks can be considered for adults with an immunocompromising condition, cochlear implant or CSF leak to minimize the risk for invasive pneumococcal disease caused by serotypes unique to PPSV23 in these groups.)

(C) For adults age 19 through 64 years who have cochlear implant, CSF leak, sickle cell disease or other hemoglobinopathies, anatomic or functional asplenia, congenital or acquired immunodeficiency, HIV infection, chronic renal failure or nephrotic syndrome, leukemia or lymphoma, Hodgkin disease, generalized and metastatic malignancies, iatrogenic immunosuppression (including radiation therapy), or multiple myeloma and who have not previously received the recommended pneumococcal vaccines: administer one dose of PCV20, or one dose of PCV15 followed by a dose of PPSV23 ≥ 1 year later. (A minimum interval of 8 weeks can be considered for adults with an immunocompromising condition, cochlear implant or CSF leak to minimize the risk for invasive pneumococcal disease caused by serotypes unique to PPSV23 in these groups.)

(D) For adults age 19 through 64 years who have alcoholism, chronic heart disease (including CHF and cardiomyopathies), chronic liver disease, chronic lung disease (including COPD, emphysema, and asthma) or diabetes mellitus: administer one dose of PCV20, or one dose of PCV15 followed by a dose of PPSV23 ≥ 1 year later.

(E) For adults age 19 through 64 years who smoke and have not previously received the recommended pneumococcal vaccine: administer one dose of PCV20, or one dose of PCV15 followed by a dose of PPSV23 ≥ 1 year later.

(F) For children age 7 through 18 with cerebrospinal fluid leaks or cochlear implant(s): administer one dose of PCV13 if they have not received it previously. Administer one dose of PPSV23 at least eight weeks later if they have no history of PPSV23.

(G) For children age 7 through 18 who have sickle cell disease or other hemoglobinopathies, anatomic or functional asplenia, congenital or acquired immunodeficiency, HIV infection, chronic renal failure or nephrotic syndrome, iatrogenic immunosuppression, including radiation therapy, leukemia or lymphoma, Hodgkin disease, multiple myeloma, generalized and metastatic malignancies, or solid organ transplant: administer one dose of PCV13 if they have not received it previously. Then, administer one dose of PPSV23 at least eight weeks after PCV13 dose, and a second PPSV23 dose at least five years after the first PPSV23 dose.

(H) For children age 7 through 18 who have chronic heart disease, chronic lung disease (including asthma treated with high-dose, oral corticosteroids), diabetes mellitus, alcoholism, or chronic liver disease: if they have no history of PPSV23: administer one dose of PPSV23 at least 8 weeks after any prior PCV13 dose.

(I) PCV13, PCV15, PCV20 and PPSV23 should not be co-administered.

PRECAUTIONS AND CONTRAINDICATIONS

1. Severe allergy to any vaccine component or hypersensitivity following prior dose. PCV13, PCV15, PCV20 are contraindicated with a previous anaphylactic reaction to diphtheria-toxoid-containing vaccine.

2. Moderate or severe acute illness with or without fever (mild illness is usually not a contraindication)

3. Pregnancy: it is not known whether the vaccine can cause fetal harm when administered to a pregnant woman.

4. For planning cancer chemotherapy or other immunosuppressive therapy (e.g., for Hodgkin's Disease or organ/bone marrow transplantation patients), pneumococcal vaccination should be administered at least two weeks prior to the initiation of immunosuppressive therapy. Vaccination during chemotherapy or radiation therapy should be avoided.

5. Severely compromised cardiovascular or pulmonary disease in which systemic reaction would pose a significant risk

SIDE EFFECTS AND ADVERSE REACTIONS

(A) Local reactions: soreness, pain, tenderness, erythema, ecchymosis, and swelling at the injection site, usually of less than 48 hours duration, occurs commonly; local induration occurs less commonly.

(B) General reactions: rash, urticaria, arthritis, arthralgia, serum sickness, adenitis, have been reported. Low grade fever (<100.9 F) occurs occasionally and is usually confined to the 24-hour period following vaccination. Although rare, fever over 102 degrees has been reported. Malaise, myalgia, headache, and asthenia have also been reported.

Patients with otherwise stabilized idiopathic thrombocytopenia purpura have, on rare occasions, experienced a relapse in their thrombocytopenia, occurring 12-14 days after vaccination, and lasting up to 2 weeks.

Reactions of greater severity, duration, or extent are unusual. Neurological disorders such as paresthesias and acute radiculoneuropathy including Guillain-Barré syndrome have been rarely reported in temporal association with administration of pneumococcal vaccine. No cause and effect relationship has been established. Rarely, anaphylactic reactions have been reported.

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 legal guardian must first sign a consent form before the vaccination is administered.

(3) Provide patient/legal guardian with a copy of the most current federal Vaccine Information Statement (VIS) for pneumococcal polysaccharide or pneumococcal conjugate vaccine.

(4) Inject 0.5 mL of PCV13, PCV15, PCV20, or PPSV23 vaccine **intramuscularly** into the thickest point of a relaxed **deltoid** muscle. Most patients will receive 25 gauge, 1-inch needle. For patients weighing less than 130 lbs [60 kg], a 5/8-inch needle may be used for injection in the deltoid muscle only if the subcutaneous tissue is not bunched and the injection is made at a 90-degree angle. For obese patients, a 1½ - inch needle will be used. Alternatively, the 0.5 mL dose of PPSV23 may be given **subcutaneously** in the posterolateral fat of the upper arm using a 25 gauge, 5/8-inch needle.

(5) Give with caution to persons on anticoagulant therapy or with bleeding tendencies. After giving the injection, apply steady pressure to the injection area.

(6) Dispose of all supplies properly.

(7) Record the date of administration, name/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.

(8) 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.

(9) 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, 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, 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 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 8 for Physician Authorization

Administration of the pneumococcal (polysaccharide or conjugate) vaccine, under the direction of the physician who signed below, may be performed by the following individuals:

_____ _____ _____

_____ _____ _____

Administration of the pneumococcal (polysaccharide or conjugate) 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_____

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.