Human Papillomavirus (HPV) Immunization Protocol

NAME AND STRENGTH OF VACCINE TO BE USED

Vaccine name	HPV Type	Age group	Dosage	Number of doses	Route of Admin.	Injection Site
Human Papillomavirus 9-valent (Gardasil 9®)	6, 11, 16, 18, 31, 33, 45, 52, 58	Children and adults aged 9 through 26 yrs Some adults aged 27 through 45 yrs	0.5 mL	2 or 3*	IM	Deltoid region of upper arm

*Number of recommended doses is based on age at administration of the first dose.

INTENDED AUDIENCE AND PATIENT POPULATION

Children and adults aged 9 through 26 years:

- Routine vaccination initiated at 11 or 12 years of age; vaccination series can be given starting at age 9 years
- Catch-up HPV vaccination is recommended for all persons through age 26 years who are not adequately vaccinated

Adults aged >26 years:

- Catch-up HPV vaccination is not recommended for all adults aged >26 years. Shared clinical decision-making regarding HPV vaccination is recommended for some adults aged 27 through 45 years who are not adequately vaccinated. Clinicians can consider discussing HPV vaccination with persons who are most likely to benefit, including men who have sex with men, transgender persons, and persons with immunocompromising conditions. *(Note: Although many adults ages 27–45 years have prior exposures to 1 or more HPV types, most have not been exposed to all 9 HPV types that are contained in the vaccine. Also, at any age, having a new sex partner is a risk factor for being exposed to a new HPV infection.)*
- HPV vaccines are not licensed for use in adults aged >45 years.

VACCINATION SCHEDULE

HPV vaccines are administered in a 2-dose or 3-dose series based on age at administration of the first dose. If the series is interrupted, the HPV series does not need to be restarted.

For persons initiating HPV vaccination at ages 9 through 14 years (except immunocompromised persons):

- Administer a 2-dose series at 0, 6-12 months

For persons initiating HPV vaccination on or after their 15th birthday:

- Administer a 3-dose series at 0, 1-2, 6 months

For persons with immunocompromising conditions, including HIV infection, through age 26 years (even for those who initiate vaccination at age 9 through 14 years):

- Administer a 3-dose series at 0, 1-2, 6 months

For men who have sex with men and transgender persons through age 26 years:

- Administer a 2- or 3-dose series depending on age at initial vaccination as above

Adults through age 26 years who **initiated the HPV vaccination series before age 15 years and received 2 doses at least 5 months apart are considered adequately vaccinated** and do not need an additional dose of HPV vaccine.

Adults through age 26 years who **initiated the HPV vaccination series before age 15 years and received only 1 dose, or 2 doses less than 5 months apart, are not considered adequately vaccinated** and should receive 1 additional dose of HPV vaccine.

CONTRAINDICATIONS AND PRECAUTIONS

(1) Hypersensitivity, including severe allergic reactions to yeast (a vaccine component), or after a previous dose of the HPV vaccine

(2) Because vaccines may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following vaccination with HPV vaccine. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position.

(3) HPV vaccination is not recommended during pregnancy. Pregnancy testing is not needed before HPV vaccination. If a woman is found to be pregnant after initiating the vaccine series, the remaining doses should be delayed until after the pregnancy. No intervention is needed if inadvertently vaccinated while pregnant.

SIDE EFFECTS AND ADVERSE REACTIONS

(A) General: headache (most common adverse reaction). Other common adverse reactions are fever, nausea, dizziness, arthralgia.

(B) Local: injection-site pain, swelling, erythema, pruritus, and bruising.

(C) Anaphylaxis has been reported following vaccination.

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 HPV vaccine.

(4) Gardasil 9 vaccine should be refrigerated at temperature between 2 and 8 degrees Celsius; never frozen. The vaccine can be kept out of the refrigerator for up to 72 hours. The vaccine should be protected from light.

(5) Shake well before use. Thorough agitation immediately before administration is necessary to maintain suspension of the vaccine. After thorough agitation, the vaccine is a white, cloudy suspension. HPV vaccine should not be diluted or mixed with other vaccines.

(6) HPV vaccine is for intramuscular use only. The 0.5 mL dose should be administered intramuscularly in the deltoid region of the upper arm.

(7) *Single-Dose Vial Use*: Withdraw the 0.5 mL dose of vaccine from the single-dose vial using a sterile needle and syringe and use promptly.

(8) *Prefilled Syringe Use*: This package does not contain a needle. Shake well before use. Attach the needle securely on the syringe and administer the entire dose.

(9) Needles and supplies should be disposed of properly.

(10) 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.

(11) Monitor patients in the general vicinity of the administering pharmacist or pharmacy intern for 10 to 15 minutes after giving the injection and treat accordingly.

(12) 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 (0.3 mg and 0.15 mg autoinjectors)*. 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 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 HPV vaccine, under the direction of the physician who signed below, may be performed by the following individuals:

_____ _____ _____

_____ _____ _____

Administration of the HPV 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.