# COMMONWEALTH OF VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS BOARD OF NURSING

# ADULT IMMUNIZATION PROTOCOL(S) REVIEW FORM

Vaccine(s):	Name of Company:	
	Contact Person:	
	Position Title:	
	Telephone/Fax #	
EVALUATION CRITERIA	CRITERIA MET / PENDING	COMMENTS
Purpose/Objectives of Immunization Program		
Target Population		
Name/Address of Medical Director		
Medical Directive (Signed/Dated)		
Inclusion/Exclusion Screening Criteria		
Informed Consent Form		
Procedural Guidelines:		
Dosage		
Single or Multiple Dose Administration		
Injection Site		
<ul> <li>Vaccine Storage (Temp between 35°-46°)</li> <li>Biohazardous Waste Disposal</li> </ul>		
Universal Precautions		
Post-Immunization Instructions:		
Minor and Major Side Effects		
Waiting Time of Approximately 15 Minutes		
Follow-up Care with Primary Doctor		
Emergency Plan		
<ul> <li>Assessment → CPR →911 Rescue</li> </ul>		
Emergency Care Guidelines		
Medical Directive		
<ul> <li>Emergency Supplies/Medications</li> </ul>		
<ul> <li>Appropriate Drugs/Dosages</li> </ul>		
Providers		
VA Licensure/Level of Preparation		
CPR Certification		
Supervision of LPN Provider		
Resource Personnel/Supervision		
Documentation of Patient Record		
Date, Vaccine, Inj. Site, Expiration Date, Lot #,		
Administering Person's Signature		
RECOMMENDATIONS		
Approved:	Date:	
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## Model Protocol for Pharmacists in the State of Virginia

#### Administration of Immunizations

## I. Purpose

As one of health care's most accessible practitioners, the pharmacist uniquely advocates public health initiatives. Pharmacists working in community pharmacies utilize their unique access to patients and their knowledge and skills to administer immunizations when a practitioner with prescriptive authority is not present provided that the following requirements for staff, emergency procedures and physician prescriptive protocol are followed.

## **II. Target Population**

Statistics show people living in rural and inner city areas and families with multiple changes of residences are poorly immunized. This population and any person who wishes to reduce the likelihood of a preventable disease must be adults (18 years of age or older) to be immunized under this protocol. The community pharmacy presents less of a barrier for these patients to receive immunizations and the pharmacist actively surveys the community for needs.

III. Name, Address and protocol)	Phone Number of Medical D	virector (Pharmacy's physician who signed the
Name:		
Address:		
Phone number:		
IV. A Signed and Dated	d Medical Directive	
I,	, MD licensed, RPh and other certifie	in the state of Virginia do hereby authorize ed pharmacists licensed in Virginia employed by tions to patients in accordance with the laws and
regulations of the State of	Virginia. In exercising this au	thority, the pharmacists shall comply with the protocol tive also covers emergency care if it is necessary.
The participants must agree	ee to any significant changes in	the protocol.
Date		
Signatures:		
Physician	License #	
Pharmacist	License #	

## V. Screening Criteria:

(All vaccinations will be administered to those 18 years of age or older)

## **Hepatitis A**

Persons traveling or working in countries with high rates of hepatitis A Persons who live in communities with high rates of hepatitis A

- Sexually active homosexual and bisexual men
- ♦ Illicit drug users
- Persons with clotting-factor disorders (e.g. hemophilia)
- ♦ Persons with chronic liver disease
- Food handlers, in whom health authorities or private employers determine vaccination to be costeffective

Adults who share a household or have sexual contact with someone who is infected with Hepatitis A virus

♦ Adult travelers visiting countries where Hepatitis A is common and where clean water and proper sewage disposal are not available

#### Contraindications:

Persons allergic to alum or the preservative 2-phenoxyethanol

• Persons with an acute illness until they have stabilized

## **Special Considerations:**

• Pregnancy-Hepatitis A has not been evaluated in pregnancy and these individuals who seek a vaccine should receive it from their physician

### **Hepatitis B**

Persons with occupational risk of exposure to blood or bloodfluids (nurses, physicians, physician assistants, nurse practitioners, lab technicians, emergency room attendants, public safety personnel)

- ♦ Illicit drug users
- Sexually active homosexual and bisexual men
- ♦ Sexually active heterosexual men and women with multiple sex partners or recent episode of a sexually transmitted disease
- Adults living with others who are chronically infected with Hepatitis B
- ◆ Travelers to endemic countries if they stay in that area for greater than 6 months or if they have sexual contact with persons from these countries

#### Contraindications:

- Persons who have had a prior serious allergic reaction to hepatitis B vaccine or vaccine component common baker's yeast
- Persons with an acute illness until they have stabilized

#### Special Considerations:

• Pregnancy-Hepatitis B has not been evaluated in pregnancy and these individuals who seek a vaccine should receive it from their physician

## Measles, Mumps and Rubella

◆ Adults in high-risk population groups (colleges, health care workers with direct patient contact, military bases)

Adults born after 1956 without written documentation of immunization on or after the first birthday

◆ Travelers to foreign countries (particularly Africa and Asia)

## **Contraindications:**

Persons who are pregnant

- Persons allergic to eggs or neomycin or have had a severe reaction to MMR
- Persons taking immunosuppressive therapy or immunodeficiency (except HIV)
- Persons with an acute illness until they have stabilized
- Persons with a history of seizures
- Persons receiving immune globulin or other blood products during the past several months.

## Meningococcal

- ◆ Adults in high-risk groups, including persons with terminal complement component deficiencies and those with anatomic or functional asplenia (damaged spleen or spleen removal)
- ♦ Travelers to and U.S. citizens residing in hyperendemic or epidemic countries, such as West Africa
- Anyone who has terminal complement component deficiency (an immune system disorder).
- Microbiologists who are routinely exposed to meningococcal bacteria
- College students (particularly those residing in dormitories or residence halls)
- ♦ U.S. military recruits

#### Contraindications:

- Persons who have had a severe allergic reaction to a previous dose of the vaccine
- Persons who are moderately or severely ill at the time of the scheduled vaccination

## **Special Considerations:**

♦ Meningococcal vaccine may be given to pregnant women

## **Tetanus and Diphtheria**

All adults who have not had a Td booster shot in last 10 years but especially

- agricultural workers where contact with animal manure is likely
- firefighters and construction workers

campers and gardeners

#### Contraindications:

Persons who have had a severe allergic or hypersensitivity reaction to vaccine or vaccine component of Td

- Persons with moderate or severe febrile illness
- Persons with a history of seizures or previous neurologic reaction to Td
- Pregnancy in 1st trimester

## Special considerations:

Pregnant women in the 2nd or 3rd trimester who seek the vaccine should have it administered by their physician

#### Varicella

- ♦ Adults who have not had chickenpox or gotten the chickenpox vaccine
- ♦ All susceptible health care workers

• Susceptible persons in the following groups who are at high risk for exposure (teachers, day care employees, college, military, nonpregnant women of childbearing age, and international travelers)

#### Contraindications:

- ♦ Persons who have ever had a serious allergic reaction to chickenpox vaccine, neomycin, or gelatin Persons with an acute illness until they have stabilized
- Persons who are pregnant. Women should not get pregnant for 1 month after getting chickenpox vaccine.
- ◆ Persons taking immunosuppressive therapy (i.e. long term steroids) or who have immunodeficiency (AIDS/HIV, cancer, cancer treatment)
- Persons receiving immune globulin or other blood products during the past five months.

## **Influenza- Inactivated vaccine (flu shot)**

- Persons wishing to reduce the likelihood of becoming ill with influenza
- Persons 65 years of age and older
- Residents or employees of nursing homes or other LTC facilities housing anyone of any age with chronic medical conditions
- Persons capable of nosocomial transmission of influenza to high-risk persons
- Persons with chronic disorders of lung (COPD, asthma, emphysema, chronic bronchitis), heart (CHF), diabetes mellitus, renal dysfunction, hemoglobinopathies (sickle cell disease)
- Health care workers and others with contact with people of high risk groups
- Persons who are less able to fight infections due to hereditary disease, infection with HIV, treatment with drugs such as long term steroids; and /or treatment with cancer with x-rays or drugs

Persons who are less able to fight infections because of a disease they are born with, infection with HIV, treatment with drugs such as long term steroids; and/or treatment with cancer with x-rays or drugs

## Contraindications:

- ♦ Pregnant women in the first trimester
- Persons who are allergic to eggs
- Persons who have had a serious allergic reaction or other problems after getting influenza vaccine
- Persons with an acute illness until they have stabilized

## **Special Considerations:**

Pregnant women in the 2nd or 3rd trimester who seek the vaccine should have it administered by their physician

#### Influenza – Intranasal- Live attenuated vaccine

- Persons wishing to reduce the likelihood of becoming ill with influenza
- Healthy persons 18 to 49 years of age
- It takes about 2 weeks for protection to develop after vaccination, and protection can last up to a year.
- Influenza viruses are constantly changing. Therefore, influenza vaccines are updated every year, and annual vaccination is recommended

#### Contraindications:

- ♦ Persons who are allergic to eggs
- Persons who have had a serious allergic reaction or other problem after getting influenza vaccine

♦ Children and adolescents (5-17 years of age) receiving aspirin therapy or aspirin-containing therapy

- Persons who are immunocompromised or have an immune deficiency disease
- Patients with a history of Guillain Barre syndrome

## **Special Considerations:**

- Not indicated in patients with diabetes, renal dysfunction, or chronic disorders of the pulmonary and cardiovascular systems
- Not indicated for adults 50 years of age or older
- ♦ Not indicated in women who are pregnant

#### **Pneumococcal Disease**

- Persons aged 65 years and older and adults of all ages with long-term illnesses that are associated with a high risk (heart or lung diseases, diabetes, alcoholism, and cirrhosis)
- Adults with and without symptoms who are infected with the AIDS virus
- ♦ Other people with weak immune system due to illnesses such as chronic renal failure, organ transplantation, Hodgkin's disease, lymphoma, multiple myeloma, and those who have had their spleen removed

#### Contraindications:

Persons with an acute illness until they have stabilized

### Rabies - Pre-exposure

- ◆ Adults in high-risk groups (veterinarians, animal handlers, and laboratory workers in either research or production facilities)
- ◆ International travelers who are likely to come in contact with animals in parts of the world where rabies is common.

#### **Contraindications**

- Persons allergic to the vaccine components such as neomycin and polymixin B
- Persons on immunosuppressive therapy or who are immunosuppressed
- Persons with a severe acute illness until they have stabilized

#### **Special Considerations:**

- It does not eliminate the need of post exposure treatment but does simplify it by eliminating the need for the immunoglobulin
- ◆ No studies have been done in pregnancy and these individuals should have it administered by their physician

## **Herpes Zoster**

- ♦ Adults age 60 years of age and older
- ♦ There are is insufficient data from studies to determine the risks versus benefits of use in persons under the age of 60

## **Contraindications:**

 Persons who have experienced an allergic reaction such as anaphylaxis to neomycin or any other component of this vaccine

- Persons who have a weakened immune system due to drug therapy
- ♦ Women who are pregnant or may become pregnant
- Persons with a history of primary or acquired immunodeficiency
- Persons with active, untreated tuberculosis

## **Special Considerations:**

- Studies have not been conducted in individuals who previously had shingles and is not currently approved for prevention of repeated episodes in those individuals
- ♦ Not indicated for the treatment of herpes zoster

## Human Papillomavirus (Types 6, 11, 16, and 18)

♦ Women ages 18-26 for the prevention of disease associated with HPV 6, 11, 16, and 18

#### Contraindications:

- Persons who have a hypersensitivity to yeast or any of the vaccine components
- Persons who are moderate or severe illness at the time of the scheduled vaccination
- Women who are pregnant or breast-feeding

## **Special Considerations:**

- Not indicated for the treatment of genital warts, cervical cancer, CIN, VIN, or VaIN
- Can be administered to persons with minor illnesses

## VI. Informed Consent Form & Patient Record

Signature

Conse	ent for Administration of Vacci	ne	
	_ Hepatitis A	Meningococcal	Influenza - Intranasal
	Hepatitis B	Pneumococcal	Influenza
	_ Varicella	Tetanus, Diphtheria	Human Papillomavirus
	_ Measles, Mumps, Rubella	Rabies	Herpes Zoster
the op	pportunity to ask questions that	were answered to my satisfac	vaccine/vaccines marked above. I have had etion. I understand the benefits and risks of istration of the vaccine/vaccines marked above.
	Name (print)		

Guidance document: 90-16

Date of vaccination:

Dose of vaccination:

Site of vaccination:

Vaccine Manufacturer & Lot Number:

Expiration Date:

Signature of administrator of vaccine:

## **VII. Immunization Procedures:**

Vaccinations to be administered (only include those you will be administering)

**Hepatitis A** 

Dosage: Adult: 1.0 ml

Injection Site: IM, deltoid is preferred

Directions for use: Adult: inject at months 0 & 6-12

Storage: Refrigerate, 36-46\*F

Source of Vaccine: (i.e., 5ml multi dose vial or 1ml prefilled syringe)

Hepatitis B

Dosage Age 18-19 yrs: based on product

≥20 yrs: based on product

Injection Site: IM, deltoid is preferred

Directions for use: Adults: Inject at days 0, 30, and 150

Storage: Refrigerate, 36-46\*F

Source of Vaccine: (i.e., 5ml multi dose vial or 1ml prefilled syringe)

Measles, Mumps, Rubella

Dosage: 0.5ml

Injection Site: SC, outer aspect of upper arm is preferred

Directions for use: Inject one time

Storage: Keep in a cool place <50\*F and protect from light Source of Vaccine: (i.e., 5ml multi dose vial or 1ml prefilled syringe)

Meningococcal

Dosage: 0.5ml Injection Site: SC

Directions for use: Inject one time

Storage: Store between  $2^{\circ} - 8^{\circ} \text{ C } (35^{\circ} - 46^{\circ} \text{ F})$ ;

Discard multi-dose vials within 5 days of

reconstitution; use single dose vials within 24 hours

of reconstitution

Source of Vaccine: (i.e., 0.78 ml single dose vial or 6 ml multi-dose vial)

## Tetanus, Diphtheria

Dosage: 0.5ml

Injection Site IM, thigh or deltoid

Directions for use: Unvaccinated: Inject at weeks 0, 4-8 and 25-52

Vaccinated: Inject once every 10 years

Storage: Refrigerate, 36-46\*F

Source of Vaccine: (i.e., 5ml multi dose vial or 0.5ml prefilled syringe)

Varicella

Dosage: 0.5ml Injection Site: SC

Directions for use: >18yrs: inject at weeks 0 and 4-8

Storage: Keep Frozen at < 6\*F

Source of Vaccine: (i.e., 5ml multi dose vial or 1ml prefilled syringe)

Influenza

Dosage: 0.5ml Injection Site: IM, deltoid

Directions for use: Inject once yearly between October and November for best

efficacy.

Storage: Refrigerate, 36-46\*F

Source of Vaccine: (i.e., 5ml multi dose vial or 1ml prefilled syringe)

## Influenza – Intranasal

Dosage: 0.5ml Injection Site: Intranasal

Directions for use: Spray 0.25 ml in each nostril once yearly between October and November for best

efficacy

Storage: Keep frozen <5\*F

Source of Vaccine: (i.e., 0.5ml prefilled syringe)

Pneumococcal

Dosage: 0.5ml

Injection Site: IM or SC, deltoid or lateral mid-thigh

Directions for use: Inject once, a 5 year booster is recommended in some cases.

Storage: Refrigerate, 36-46\*F

Source of Vaccine: (i.e., 5ml multi dose vial or 1ml prefilled syringe)

## Rabies - Pre-exposure

Dosage: 1.0ml

Injection Site: IM, deltoid

Directions for use: Inject once on days 0, 7 and 21 or 28

Storage: Refrigerate, 35-46\*F Source of Vaccine: (i.e. single dose vial)

**Herpes Zoster** 

Dosage: 0.65 mL Injection Site: SC

Directions for use: Inject once as a single dose

Storage: keep frozen, -15\*C (+5\*F) or colder

Source of Vaccine: (i.e. single dose vial)

## **Human Papillomavirus**

Dosage: 0.5 mL

Injection Site: IM, deltoid or high anterolateral thigh Directions for use: Inject once at 0, 2, and 6 months

Storage: Refrigerate, 36-46\*F Source of Vaccine: (i.e. single dose vial)

## **Injection Procedure**

- 1. Review and provide emergency procedures for pharmacy based immunizations. In all cases follow standard precautions.
- 2. Review indication for injection. Make sure patient has read CDC information sheets for the specific vaccine to be administered if available. Obtain history regarding allergy and previous adverse reactions to administration of specific vaccine. Rule out any specific contraindication or precaution for specific vaccine.
- 3. Obtain consent for injection.
- 4. Record lot number and expiration date from vaccine vial. Double check dose, swab top of vial with alcohol; allow to dry.
- 5. If not using a prefilled syringe, inject an equal volume of air into the vaccine vial of the volume of vaccine to be removed; then withdraw that volume of vaccine. Draw up an additional 0.2-0.3 ml air into the syringe to clear needle of vaccine and preventing vaccine seepage from injection site.
- 6. Cleanse injection site thoroughly using friction with alcohol. Allow to dry. All procedures must be performed in compliance with standard precautions.
- 7. Establish anatomic landmarks. Have the needle and syringe completely ready prior to contact with the patient.
- 8. Carry out the procedure quickly and gently.
- 9. Following injection, massage site. Apply adhesive bandage.
- 10. Dispose of uncapped needle in an approved sharps container using universal precautions. All full sharps containers must be disposed of according to state regulations.
- 11. Record the injection site in the chart or profile, and update the patient's immunization record.

#### VIII. Post-Immunization Procedures

Following immunization, keep patients under observation for at least 20-30 minutes. Before leaving, patients should be advised to report any adverse event to you and their primary care provider.

## **IX. Emergency Procedures:**

- 1. Be prepared to call 911
- 2. Take a thorough history of allergies and adverse reactions prior to vaccine administration.
- 3. Allow adequate physical space for fainting without injury, and to lay patient flat on a hard surface in the event that CPR is needed.
- 4. Maintain a readily available emergency supply kit including epinephrine 1:1000, diphenhydramine injection, stethoscope, and blood pressure cuff.
- 5. Have all staff associated with the program certified in CPR and trained in use of first aid associated with anaphylactic reaction.

## Management Protocol for Moderate or Severe Anaphylaxis

- 1 Have someone call 911
- 2. Administer epinephrine 1:1000 injection:

Subcutaneous epinephrine 0.3 ml in the opposite arm and 0.3 ml at the site of injection. Intervals for repeat administration of epinephrine are 5-20 minutes based on patient response. (Epinephrine effect is blunted in patients on beta adrenergic blockers. Be prepared to repeat the dose at shorter intervals based on patient response in these patients on beta blockers)

3. Administer CPR as necessary.

Reference: Thibodeau JL. Office management of childhood vaccine related anaphylaxis. Canadian Family Physician 1994;40: 1602-161

## X. Qualification of Immunization providers.

- ♦ Current validated Virginia pharmacy license
- ◆ Current CPR certification

#### Insured

- ♦ Review:
  - 1. Vaccine administration literature and procedure
  - 2. Screening Criteria
  - 3. Procedural Guidelines
  - 4. Post-Immunization Instructions
  - 5. Emergency Plan
- Comply with physician's prescriptive protocol

## XI. Resource Personnel and Supervision.

In the event of an emergency contact (insert names/locations here) Include supervisor's name
All pharmacists and technicians involved.

## XII. Documentation

Each pharmacy documents all immunizations as required by statute. The pharmacist records the immunization on the individual's personal immunization card or an immunization record provided to the patient or the patient's guardian. The pharmacy maintains a patient record of administration by documenting immunizations on a standard form.

## **Patient History**

(Model Patient History Questionnaire also available fro	om Immunization Action Coalition 612-647-9009)
Patient Name: D	Date:
Please read the questions below. Indicate Yes	or No for the person receiving a vaccine today.
	Yes No
1. Has this person ever had a severe reaction to any vaccine, which required medical care?	
2. Is this person allergic to eggs, baker's yeast, streptomycin or neomycin?	
3. Does this person have fever, diarrhea or vomiting today?	
4. Is this person or anyone in the home being treated with chemotherapy, radiation for cancer; have HIV/AIDS, or any immune deficiency disease?	
5. Is this person receiving treatments for any disease or illness?	
6. Has this person been under a doctor's care in the past year?	
7. Has this person had immune globulin or a blood transfusion in the past year?	
If yes, when?	
8. Is this person pregnant, or planning pregnancy in the next three months?	
9. List all prescriptions or over the counter medications that this person is taking.	
XIII. Minor and Major Side Effects	
Hepatitis A  Mild/Moderate (will go away in 1-2 days) soreness or swelling at the injection site headache tiredness	te

## Severe

loss of appetite

serious allergic reaction, within a few minutes to a few hours of the shot (very rare).

## Hepatitis B

## Mild/Moderate

soreness at the injection site mild to moderate fever headache fatigue

#### Severe

serious allergic reaction is very rare

## Measles, Mumps, Rubella

## Mild/Moderate

soreness, redness, or swelling at the injection site rash fever swelling of the glands in the cheeks, neck, or under the jaw seizure usually caused by fever - rare pain, stiffness, or swelling in one or more joints lasting up to 3 days

#### Severe

serious allergic reaction-anaphylaxis, anaphylactic shock low number of platelets that can lead to bleeding problems -almost always temporary long seizures, decreased consciousness, or coma encephalopathy, encephalitis

## Meningococcal

#### Mild/Moderate

soreness and/or redness at the injection site mild fever

#### Severe

Serious allergic reaction- difficulty breathing, weakness, hives, dizziness, swelling of the throat high fever unusual behavior

## Tetanus, Diphtheria

#### Mild/Moderate

soreness, redness, or swelling at the injection site fever a seizure usually caused by fever - rare

#### Severe

serious allergic reaction-anaphylaxis, anaphylactic shock a long seizure encephalopathy, encephalitis

#### Varicella

#### Mild/Moderate

soreness, redness, or swelling at the injection site very mild rash or several small bumps fever over 102 degree

seizure usually caused by fever

#### Influenza

#### Mild/Moderate

soreness, redness, or swelling at the injection site fever, aches

#### Influenza – Intranasal

#### Mild/Moderate

nasal congestion, runny nose, cough, and sore throat

#### **Pneumococcal Disease**

#### Mild/Moderate

redness and pain at the injection site fever, muscle aches severe local reactions

#### Severe

severe allergic reactions

#### **Rabies**

#### Mild/Moderate

injection site redness, swelling, and pain rash headache fatigue fever

## **Herpes Zoster**

## Mild/Moderate

Redness, pain, and tenderness at the injection site Swelling, puritus, and warmth headache severe local reactions

## Severe

severe cardiovascular events that can lead to death, asthma exacerbation, and polymyalgia rheumatica

## **Human Papillomavirus**

## Mild/Moderate

Redness, pain, swelling, puritus at the injection site fever, nausea, and dizziness

## Severe

severe headache, gastroenteritis, appendicitis, and pelvic inflammatory disease

Protocol revised: October 2006, February 2013